# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 10-K/A

(Amendment No. 1)

## ANNUAL REPORT UNDER SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

## ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the Fiscal Year Ended December 31, 2005

or

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

to

For the transition period from

Commission File Number: 000-29959

# Pain Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of

incorporation or organization)

91-1911336 (I.R.S. Employer Identification Number)

7801 N. Capital of Texas Highway, Suite 260, Austin, TX 78731 (512) 501-2444

(Address, including zip code, or registrant's principal executive offices and telephone number, including area code) 416 Browning Way, South San Francisco, CA 94080

(former address)

Securities registered pursuant to Section 12(b) of the Act: Common Stock, \$0.001 par value

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 🗆 No 🗵

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(D) of the Act. Yes 🗆 No 🗵

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  $\boxtimes$  No  $\square$ 

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer		Accelerated filer	X	
Non-accelerated filer	□ (Do not check if a smaller reporting company)	Smaller reporting company		
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2). Yes 🗌 No 🗵				

The aggregate market value of the voting and non-voting common equity held by non-affiliates was \$144,131,648 computed by reference to the last sales price of \$3.87 as reported by the NASDAQ Global Select Market, as of the last business day of the Registrant's most recently completed second fiscal quarter, June 30, 2011.

The number of shares outstanding of the Registrant's common stock on April 17, 2012 was 44,732,017.

### DOCUMENTS INCORPORATED BY REFERENCE

None.

PART IV

Item 15. <u>Exhibits and Financial Statement Schedules</u>

#### EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A (this "Amendment") amends Pain Therapeutics, Inc.'s (the "Company") Annual Report on Form 10-K for the year ended December 31, 2005, originally filed on February 24, 2006 (the "Original Filing"). The Company is re-filing Item 15 of Part IV to reflect expiration of confidential treatment of certain terms excluded from exhibits 10.8 and 10.9 to the Original Filing, and to re-file such exhibits to include the originally omitted portions that were subject to the now expired order for confidential treatment. In addition, pursuant to the rules of the Securities and Exchange Commission, the Company is including with this Amendment certain currently dated certifications.

Except as described above, and other than changes to update the form of cover page to this filing to conform to the format of the current cover page on the Annual Report on Form 10-K, as promulgated by the Securities and Exchange Commission, and certain information in the cover page, no other changes have been made to the Original Filing. The filing of this Form 10-K/A is not a representation that any statements contained in items of Form 10-K other than Part IV, Item 15 are true or complete as of any date subsequent to the Original Filing.

#### PART IV

#### Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Form 10-K:

(1) Financial Statements (included in Part II of this report):

Reports of Independent Registered Public Accounting Firm Balance Sheets Statements of Operations Statement of Stockholders' Equity Statements of Cash Flows Notes to Financial Statements

(2) Financial Statement Schedules:

All financial statement schedules are omitted because the information is inapplicable or presented in the notes to the financial statements.

(3) Exhibits:

Exhibit Number	Description of Document
3.1 (1)	Amended and Restated Certificate of Incorporation.
3.2 (1)	Amended and Restated Bylaws.
4.1 (2)	Specimen Common Stock Certificate.
4.2 (3)	Preferred Stock Rights Agreement, dated as of April 28, 2005, between the 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 (4)	Form of Indemnification Agreement between the Registrant and each of its directors and officers.
10.2 (4)	1998 Stock Plan and form of agreements thereunder.
10.3 (4)	2000 Employee Stock Purchase Plan and form of agreements thereunder.
10.4 (5)	Employment Agreement dated August 29, 2000, between Registrant and Grant L. Schoenhard, Ph.D.
10.5 (5)	Employment Agreement dated October 23, 2001, between Registrant and Nadav Friedmann, M.D., Ph.D.
10.6 (4)	Second Amended and Restated Investors' Rights Agreement dated as of February 1, 2000 between Registrant and the holders of its series B and series C redeemable convertible preferred stock.
10.7 (6)	Lease Agreement dated July 21, 2000 between Registrant and Goss-Jewett Company of Northern California.
10.8 **	Collaboration Agreement dated November 9, 2005, between Registrant and King Pharmaceuticals, Inc.
10.9 **	License Agreement dated November 9, 2005, between Registrant and King Pharmaceuticals, Inc.
10.10 *+	Development and License Agreement dated December 19, 2002 between Registrant and DURECT Corporation and Southern Biosystems, Inc.
10.11 *+	Amendment dated December 15, 2005 to Development and License Agreement dated December 19, 2002 between Registrant and DURECT Corporation and Southern Biosystems, Inc.
23.1 *	Consent of Independent Registered Public Accounting Firm.
24.1 *	Power of Attorney (see page 55 of Original Filing).
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.

- \* Previously filed with the Original Filing.
- \*\* Filed herewith.
- (1) Incorporated by reference from exhibits to our report on Form 10-Q for the period ending June 30, 2005.
- (2) Incorporated by reference from exhibits to our report on Form 10-Q for the period ending March 31, 2005.
- (3) Incorporated by reference from exhibits to our report on Form 8-K as filed with the Securities and Exchange Commission on May 3, 2005.
- (4) Incorporated by reference from our registration statement on Form S-1, registration number 333-32370, declared effective by the Securities and Exchange Commission on July 13, 2000.

- (5) Incorporated by reference from exhibits to our report on Form 10-K for the period ending December 31, 2001.
- (6) Incorporated by reference from Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2000.
- + Confidential treatment has been granted for certain portions of this agreement. The omitted portions have been filed separately with the Securities and Exchange Commission.

#### (b) Exhibits

The exhibits listed under Item 14(a)(3) hereof are filed as part of this Form 10-K other than Exhibit 32.1, which shall be deemed, furnished.

#### (c) Financial Statement Schedules

All financial statement schedules are omitted because the information is inapplicable or presented in the notes to the financial statements.

#### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Form 10-K/A to be signed on its behalf by the undersigned, thereunto duly authorized.

PAIN THERAPEUTICS, INC.

Ву:

/s/ Remi Barbier Remi Barbier

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

Dated: May 9, 2012

Pursuant to the requirements of the Securities Exchange Act of 1934, this Form 10-K/A has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Remi Barbier Remi Barbier	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	May 9, 2012
Kelili Dai biei	Directors (r micipal Executive Officer)	May 9, 2012
/s/ Peter S. Roddy	Vice President and Chief Financial Officer (Principal Financial and	
Peter S. Roddy	Accounting Officer)	May 9, 2012
*/s/ Nadav Friedman, Ph.D., M.D.	Chief Operating and Medical Officer and Director	
Nadav Friedmann, Ph.D., M.D.		May 9, 2012
*/s/ Robert Z. Gussin, Ph.D.	Director	
Robert Z. Gussin, Ph.D.		May 9, 2012
*/s/ Michael J. O'Donnell, Esq.	Director and Secretary	
Michael J. O'Donnell, Esq.		May 9, 2012
*/s/ Sanford R. Robertson	Director	
Sanford R. Robertson		May 9, 2012
*/s/ Patrick Scannon, M.D., Ph.D.	Director	
Patrick Scannon, M.D., Ph.D.		May 9, 2012
*By: /s/ Peter S. Roddy		
Peter S. Roddy		
Attorney-in-Fact		

#### EXHIBIT INDEX

Exhibit <u>Number</u>	Description of Document
3.1 (1)	Amended and Restated Certificate of Incorporation.
3.2 (1)	Amended and Restated Bylaws.
4.1 (2)	Specimen Common Stock Certificate.
4.2 (3)	Preferred Stock Rights Agreement, dated as of April 28, 2005, between the 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 (4)	Form of Indemnification Agreement between the Registrant and each of its directors and officers.
10.2 (4)	1998 Stock Plan and form of agreements thereunder.
10.3 (4)	2000 Employee Stock Purchase Plan and form of agreements thereunder.
10.4 (5)	Employment Agreement dated August 29, 2000, between Registrant and Grant L. Schoenhard, Ph.D.
10.5 (5)	Employment Agreement dated October 23, 2001, between Registrant and Nadav Friedmann, M.D., Ph.D.
10.6 (4)	Second Amended and Restated Investors' Rights Agreement dated as of February 1, 2000 between Registrant and the holders of its series B and series C redeemable convertible preferred stock.
10.7 (6)	Lease Agreement dated July 21, 2000 between Registrant and Goss-Jewett Company of Northern California.
10.8 **	Collaboration Agreement dated November 9, 2005, between Registrant and King Pharmaceuticals, Inc.
10.9 **	License Agreement dated November 9, 2005, between Registrant and King Pharmaceuticals, Inc.
10.10 *+	Development and License Agreement dated December 19, 2002 between Registrant and DURECT Corporation and Southern Biosystems, Inc.
10.11*+	Amendment dated December 15, 2005 to Development and License Agreement dated December 19, 2002 between Registrant and DURECT Corporation and Southern Biosystems, Inc.
23.1 *	Consent of Independent Registered Public Accounting Firm.

- 24.1 \* Power of Attorney (see page 55 of Original Filing).
- 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.
- \* Previously filed with the Original Filing.
- \*\* Filed herewith.
- (1) Incorporated by reference from exhibits to our report on Form 10-Q for the period ending June 30, 2005.
- (2) Incorporated by reference from exhibits to our report on Form 10-Q for the period ending March 31, 2005.
- (3) Incorporated by reference from exhibits to our report on Form 8-K as filed with the Securities and Exchange Commission on May 3, 2005.
- (4) Incorporated by reference from our registration statement on Form S-1, registration number 333-32370, declared effective by the Securities and Exchange Commission on July 13, 2000.
- (5) Incorporated by reference from exhibits to our report on Form 10-K for the period ending December 31, 2001.
- (6) Incorporated by reference from Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter endedSeptember 30, 2000.
- + Confidential treatment has been granted for certain portions of this agreement. The omitted portions have been filed separately with the Securities and Exchange Commission.

#### **COLLABORATION AGREEMENT**

This COLLABORATION AGREEMENT is entered into as of November 9, 2005 (the "<u>Effective Date</u>"), by and between PAIN THERAPEUTICS, INC., a Delaware corporation having an address of 416 Browning Way, South San Francisco, California 94080 ("<u>PTI</u>"), and KING PHARMACEUTICALS, INC., a Tennessee corporation having an address of 501 Fifth Avenue, Bristol, Tennessee 37620 ("<u>King</u>"). Each of King and PTI is sometimes referred to individually herein as a "<u>Party</u>" and collectively as the "<u>Parties</u>."

WHEREAS, PTI owns or controls certain technology and intellectual property rights relating to the preparation of tamper-resistant opioid formulations;

WHEREAS, King is engaged in the development and marketing of human therapeutics;

WHEREAS, King is entering into this Agreement based on, among other things, PTI's specialized skill, knowledge, and expertise with respect to the technology and intellectual property relating to the preparation of tamper-resistant opioid formulations; and

WHEREAS, the Parties desire to enter into a collaboration for the purpose of Developing Remoxy and other Products and to give King the right to Market and manufacture Products, in each case, derived from PTI technology and intellectual property;

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration the receipt and sufficiency of which are acknowledged by the Parties, the Parties hereto, intending to be legally bound, agree as follows.

#### 1. **DEFINITIONS**

Capitalized words and phrases used in this Agreement have the meanings ascribed to such terms in Annex A attached hereto.

#### 2. ADMINISTRATION OF THE COLLABORATION

2.1 <u>Establishment and Function of JOC</u>. PTI and King shall establish the JOC within thirty (30) days of the Closing Date, which shall have the responsibilities set forth in this Agreement, including Section 2.2. Each Party shall appoint, in its sole discretion, three members to the JOC (which members shall be employees of such Party), with those members designated primarily to represent such Party with respect to clinical/regulatory, sales/marketing/finance and manufacturing matters. King and PTI each shall designate a co-chairman (each a "<u>Co-Chairman</u>" and together the "<u>Co-Chairmen</u>"). Upon the approval of both Co-Chairmen (or the remaining Co-Chairman in the event of a substitution in that position), which approval shall not be unreasonably withheld, each Party may substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JOC, by giving written notice thereof to the other Party. PTI and King shall each bear all out-of-pocket expenses of their respective JOC members related to their participation on the JOC and attendance at JOC meetings.

2.2 JOC Responsibilities. The JOC shall administer and monitor all matters with respect to the Collaboration, including the following matters:

2.2.1 oversight of the Development Plans and Manufacturing/CMC Plans, including all related strategy and objectives, timelines and activities thereunder, and changes with respect thereto on a quarterly basis; such oversight will confer to each Party, through its JOC representative, an ongoing right of Consultation;

2.2.2 review and approval of all budgets to support the Program Plans;

2.2.3 review of the management and allocation of resources of the Collaboration;

2.2.4 review of all Patent Rights and Technology used in connection with Product;

2.2.5 review and approval (prior to execution by either Party) of (a) all Third Party licenses (including all amendments thereto), and (b) all subcontracts, sublicenses, and other agreements (including all amendments thereto) that are required or to be entered into in connection with the Development Program and that either (i) require payments by a Party to a Third Party of greater than one hundred thousand U.S. dollars (\$100,000) over the life of the contract or (ii) are otherwise material, or reasonably likely to become material, to the Collaboration, such review in each case to include a determination, with respect to each such subcontract, sublicense, license, or agreement, regarding whether it is appropriate to require the inclusion of the protections set forth in Section 3.8 hereof; and

2.2.6 performance of such other functions as appropriate to further the purposes of this Agreement and the Collaboration as determined from time to time by the Parties.

#### 2.3 Dispute Resolution.

2.3.1 In the event that the JOC shall not be able, within 10 days, to reach a decision or take an action on any matter, then such unresolved matter shall first be referred for resolution to the Chief Executive Officer of each Party for attempted resolution by good faith negotiation. Such good faith negotiation may include the appointment by either Party, at its own expense, of an unaffiliated Consultant, who shall be an expert chosen based on such person's experience and expertise in the particular type of issue that is unresolved to advise such officers on the matter.

2.3.2 If such officers are unable to resolve the matter within 10 days, then, except as provided in Section 3.4.6 or 3.9, and subject to Section 3.3.2:

(a) the following matters shall be finally decided by PTI: (i) all matters related to the Development Plan in the U.S. Territory until immediately prior to the Phase II Meeting with respect to a Product (subject to Section 3.4.3); and (ii) all CMC matters relating to the Manufacturing/CMC Plan through the Regulatory Approval of an NDA for a Product;

(b) the following matters shall be finally decided by King: (i) all matters related to the Development Plan in the U.S. Territory after the Regulatory Approval of an NDA for a Product; (ii) all matters relating to the Development Plan in the ROW; (iii) all CMC matters relating to the Manufacturing/CMC Plan after the Regulatory Approval of an NDA for a Product; (iv) all non-CMC matters relating to the Manufacturing/CMC Plan that impact commercial supply (*i.e.*, matters relating to choice of secondary packaging, secondary labeling, logistics, and the like); and (v) all matters relating to the Yearly Brand Plan; and

(c) notwithstanding the foregoing provisions of this Section 2.3.2, neither Party shall have final decision-making authority with respect to the following: (i) all matters related to the Development Plan in the U.S. Territory during the period immediately prior to the Phase II Meeting until the Regulatory Approval of an NDA for a Product (subject to Section 3.4.3) and (ii) all other matters not otherwise described in Sections 2.3.2(a) and (b) above, including, subject to the parameters set forth in Sections 3.3.2 and 3.7, final decisions with respect to budgets and spending funds in excess of approved budgets (or in excess of one hundred ten percent (110%) of the funds allocated under the budget of a Development Plan, as provided in Section 3.7.2).

2.3.3 Disputes not subject to the final decision-making authority of either Party, as described in Section 2.3.2(c) above, will be resolved by binding arbitration in accordance with the rules of the American Arbitration Association (the "<u>AAA</u>"), unless another non-profit professional dispute resolution organization knowledgeable with respect to drug development is agreed to by the Parties within five (5) days, and the provisions of this Section 2.3.3.

(a) The Party desiring to initiate an arbitration proceeding will send a written notice to the other Party requesting the commencement of the arbitration proceeding and specifying the issue to be resolved. Following such notice, the JOC will work in good faith to select one neutral arbitrator, who will be an expert with respect to drug development and the pharmaceuticals industry so as to better understand the legal, business, and scientific issues addressed in the arbitration proceeding, In the event that, within 10 business days of such notice, the JOC is unable to agree upon an arbitrator, who is available to participate in the arbitration proceeding, then, each Party will designate one neutral arbitrator within 15 days thereafter. Within an additional 15 days thereafter, the first two arbitrators will designate a third. Each arbitrator will be a neutral arbitrator, who is an expert in drug development and the pharmaceuticals industry. If either Party fails to choose an arbitrator within the foregoing time period, the AAA (or equivalent organization) will choose an arbitrator on behalf of that Party. Disputes about arbitration proceedure will be resolved by the arbitrators or, failing agreement, by the AAA (or equivalent organization) in San Francisco, California. Unless otherwise agreed by the Parties, the arbitration proceedings will be conducted in San Francisco, California.

(b) Within 5 days of the selection of the final arbitrator, the Parties will deliver to the arbitrators a joint letter (i) stating each of the issues that is the subject of the dispute, (ii) setting forth each Party's final position with respect to each such issue, and (iii) directing the arbitrators to resolve the dispute by selecting the final position of one of the Parties; provided that, if the Parties cannot agree on a joint letter, each Party will submit a letter setting forth its position on each issue, and the failure of any Party to submit such a joint letter will not prevent the arbitration from proceeding. In addition, each Party may submit with the joint letter supporting documentation for such Party's final position or a request that the arbitrators permit the Parties to undertake limited discovery. In resolving the dispute, the arbitrators will have no authority to make a decision on any issue other than by selecting the final position of one of the Parties.

(c) An arbitration decision will be rendered in writing within 30 days of the submission of the letter described above, which award will be final and binding on the Parties and will be deemed enforceable in any court having concurrent jurisdiction of the subject matter hereof and the Parties. In selecting the final position of one of the Parties, the arbitrators will have the authority to grant specific performance and allocate costs between the Parties (excluding attorneys' fees, which each Party must bear itself); provided that the arbitrators will have no authority to award punitive damages or any damages in excess of the limitations contained in this Agreement.

2.4 <u>**Committees**</u>. The JOC shall have the right and power to appoint and delegate its responsibilities to committees, and the composition and eligibility requirements for the same shall be agreed upon by the members of the JOC. Except as otherwise mandated by the JOC, each committee established by the JOC shall be governed by the rules and guidelines applicable to the JOC set forth in this Agreement.

#### 2.5 Meetings.

2.5.1 <u>Schedule of Meetings</u>. The JOC shall establish a schedule of times for meetings, taking into account the planning needs of the Development Program and the need of the JOC to consult and render decisions. In no event shall the JOC meet less frequently than quarterly. Meetings shall alternate between the respective offices of the Parties in (i) Princeton, New Jersey or Cary, North Carolina and (ii) San Francisco, California, or another mutually agreed upon location; provided, however, that the Parties may mutually agree to meet by teleconference or video conference or may act by a written memorandum executed by the members of the JOC.

2.5.2 **Quorum; Voting; Decisions**. At each JOC meeting, the attendance of at least one member representing each Party shall constitute a quorum. All decisions of the JOC shall be made by unanimous vote. Representatives of each Party or of its Affiliates who are not members of the JOC may attend JOC meetings or committee meetings as non-voting observers at the invitation of either Party with the prior approval of the other Party, which approval shall not be unreasonably withheld.

2.5.3 **<u>Agenda and Minutes</u>**. An agenda for each JOC meeting shall be circulated no less than three days prior to the meeting, to the extent practicable. The JOC shall keep accurate minutes of its deliberations

that record all proposed decisions and all actions recommended or taken. Drafts of the minutes shall be delivered to the members of the JOC within a reasonable time, not to exceed 10 days after the meeting. The responsibility for the preparation and circulation of the draft minutes shall alternate between the Parties. Draft minutes then shall be edited by the Co-Chairmen and shall be issued in final form within a reasonable time not to exceed 14 days after the meeting.

#### 3. DEVELOPMENT PROGRAM

#### 3.1 Development of Products.

3.1.1 Initial Product Designations. The Parties shall Develop no less than four (4) Products under the Collaboration. The Parties agree that the first such Product shall be Remoxy, the second such Product shall be a product within the Field containing hydromorphone as its opioid API, and the third such Product shall be a product within the Field containing hydrocodone as its opioid API. The fourth Product, and all additional Products, shall be selected as set forth in Section 3.1.2 below.

3.1.2 Designation of Additional Products. In Consultation with PTI and review by the JOC and in accordance with the strategies of the Program Plans, King shall have the right to designate which products within the Field, in addition to the three (3) Products listed in Section 3.1.1 above, shall be selected for Development and Marketing under the Development Program. Upon King's designation of a product within the Field for inclusion in the Development Program, PTI shall inform Durect of such selection, and provided that such product is a product that may be developed under the DLA, PTI shall exercise its rights under Section 2.1 of the DLA to designate such product a "Licensed Product," and the Parties shall thereafter promptly generate the Program Plans for such Product, all as further described in this Article 3.

#### 3.1.3 Minimum Development and Marketing Obligations.

(a) King shall ensure that it is Marketing or funding the Development of a minimum of at least three (3) different Products under the Collaboration at all times; provided that beginning on October 1, 2006, such minimum number of different Products shall increase to four (4). In order to satisfy the foregoing requirement that King is Marketing or funding the Development of at least four (4) different Products under the Collaboration by October 1, 2006, King further agrees that it will designate a fourth Product to be Developed and Marketed hereunder no later than May 31, 2006. King further agrees that in the event King (i) does not designate a fourth Product by May 31, 2006 or (ii) notifies PTI of its intention to terminate Development and Marketing of a Product pursuant to Section 3.1.4, is required pursuant to Section 3.1.4 to designate a replacement Product, and fails to select such a replacement Product within the applicable time frame specified thereunder (and such failure would result in a default of King's obligations under this Section 3.1.3), PTI will be entitled to designate such Product for inclusion within the Collaboration pursuant to Section 3.1.2, (B) has used commercially reasonable efforts to have the JOC promptly approve a Development Plan and Manufacturing/CMC Plan for such Product, and (C) is meeting its material funding obligations under all existing Program Plans.

(b) Subject to King's satisfaction of its funding obligations pursuant to Section 3.1.3(a) above, PTI shall ensure that it is Developing, together with the Products King is Marketing, a minimum of at least three (3) different Products under the Collaboration at all times; provided that beginning on October 1, 2006, such minimum number of different Products shall increase to four (4).

3.1.4 **Product Termination**. King shall have the right to terminate Development and Marketing of a Product (the "<u>Terminated Product</u>") hereunder by providing written notice to PTI ninety (90) days prior to the effective date of such termination and, if necessary to comply with its obligations for maintaining a minimum number of Products, as provided in Section 3.1.3(a) above, designating a replacement Product in such notice, which shall be treated as a Product designation in accordance with Section 3.1.2 above, and the provisions of Section 9.2.2(a) shall apply to such Terminated Product in all respects. If a replacement Product is required to be designated, such notice of termination for such Terminated Product shall not be effective until a replacement Product has been selected and a Development Plan for such replacement Product has been approved by the JOC.

3.2 **<u>Durect License Agreement</u>**. Notwithstanding anything herein to the contrary, King acknowledges and agrees that PTI is subject to certain obligations under the Durect License Agreement as set forth in Section 2.4 of the License Agreement.

3.3 Program Plans. Disputes relating to the matters set forth in this Section 3.3 will be governed by Section 2.3.2.

3.3.1 **Generally**. In consultation with the JOC and in accordance with the strategy and objectives of the Program Plans, each Party shall be primarily responsible for those tasks assigned it as set forth in each Program Plan and such obligations set forth in this Agreement. The Parties will take such actions necessary to define, generate, and approve the Program Plans for each Product following the Effective Date. The Parties shall ensure that the Program Plans, including all timelines set forth therein, are consistent with each other, accurately reflect the objectives of the Development Program, and meet all of PTI's obligations to Durect under the DLA. Each Program Plan shall be in writing and shall set forth objectives and tasks to be performed by each of the Parties for the period covered by the Program Plan as agreed by such Party and as specifically set forth in this Agreement. Any Program Plan may be amended at any time in accordance with the same procedures applicable to the adoption thereof. Although not specifically a part of a Program Plan, all issues and activities relating to Patent Rights and Technology used in connection with a Product shall be subject to review of the JOC.

#### 3.3.2 Program Plan Budgets.

(a) Each Program Plan shall set forth an annual budget with respect to all material tasks required to be conducted by the Parties pursuant to such Program Plan. Each Party shall use commercially reasonable efforts to complete all tasks assigned to it pursuant to the Program Plans in accordance with the funding allocated to such tasks in the budget. All overruns and additional expenditures will be governed by Section 3.7.

(b) PTI will provide the JOC with updated budgets for each Development Plan and Manufacturing/CMC Plan on a semiannual basis, which updated budgets shall specify the funding which PTI projects to be required during the following six (6) months to perform its obligations under such Development Plans and Manufacturing/CMC Plans. Each such budget will be subject to review and approval of the JOC (such approval not to be unreasonably withheld); provided that it is understood that such budgets may include expenses for Third Party services extending beyond the six (6)-month period covered by such budget if incurring such expenses is contractually required in obtaining such services.

(c) Notwithstanding anything to the contrary herein, the Parties agree that the Collaboration Costs budgeted for PTI's activities under the Development Plan(s) and Manufacturing/CMC Plan(s) with respect to Remoxy between the Closing Date and December 31, 2006 shall be at least seventeen million U.S. dollars (\$17,000,000). The Parties further agree that King's financial commitment with respect to Products other than Remoxy shall be commensurate with the foregoing commitment to Remoxy, taking into account such factors as the stage of development and potential market of such Products relative to the stage of development and potential market of Remoxy and the regulatory strategy with respect to the Product; provided that the total Collaboration Costs budgeted for PTI's activities under the Development Plans and Manufacturing/CMC Plans for all Products shall not exceed twenty-five million U.S. dollars (\$25,000,000) a year in any of the first five (5) Calendar Years following the inception of this Agreement, or a cumulative total of one hundred million U.S. dollars (\$100,000,000). Notwithstanding the foregoing, the Parties agree that the JOC may (but the arbitrators may not) waive the preceding spending limits if, in its reasonable judgment, such increases in spending are warranted. For purposes of calculating the foregoing annual and cumulative spending limits, as well as the foregoing minimum financial commitment with respect to Remoxy, Collaboration Costs as used in this section shall exclude (i) any milestone, royalty or sublicensing revenue payments to PTI, Durect, or others, (ii) costs of preparing Product for commercial launch, including costs incurred in preparing to produce Product on a commercial scale, (iii) all costs and expenses related to filing, prosecution, enforcement, maintenance or defense of Patent Rights, and (iv) costs incurred in connection with establishing or expanding manufacturing capacity for Product, it being understood that the actual amounts budgeted

under the Program Plans in any given year must, in PTI's reasonable opinion, be sufficient to permit PTI to remain in full compliance with the terms and obligations of the DLA and achieve the prompt Development and Regulatory Approval of such Product in the U.S. Territory. The Parties further agree that with respect to Products subsequent to Remoxy, prompt Development and Regulatory Approval shall mean the speediest Development Plan needed to reach Development and Regulatory Approval of such Products in the U.S. Territory, consistent with patients' safety and all applicable regulatory rules and regulations. If the Program Plans need to be amended to maintain these annual and cumulative limits, King will propose those amendments it believes are required, subject to review and approval of PTI, which approval shall not be unreasonably withheld.

#### 3.4 Development Plans.

3.4.1 PTI, in Consultation with King, will prepare, and provide the JOC with a copy of, a Development Plan for each Product, which will include pre-clinical, clinical, and regulatory timelines and an annual budget, including a general overview of the expected schedule of meetings, discussions, and correspondence with Regulatory Authorities and the expected Regulatory Filings to be completed and maintained by the Collaboration. The Development Plan will be subject to review and approval of the JOC, including ongoing review as provided in Section 2.2.1, which approval not to be unreasonably withheld; provided that the JOC shall not withhold its approval or otherwise object to the budget in such Development Plan on any grounds that are inconsistent with the criteria and objectives set forth in Section 3.3.2(c) above.

3.4.2 Subject to Sections 3.4.5 and 3.4.6 below, the provisions of this Section 3.4.2 will apply to all matters relating to the Development Plan in the U.S. Territory. Until the Completion of Phase II for a Product (but immediately prior to the Phase II Meeting), PTI, in Consultation with King, will have sole control and responsibility for execution of all matters described in the Development Plan with respect to a Product. Following the Completion of Phase II for a Product but prior to the Regulatory Approval of an NDA for such Product, King and PTI will assume joint control and responsibility, through the JOC, for all matters described in the Development Plan with respect to such Product; provided that PTI, in Consultation with King, will continue to be responsible for execution of matters under such plan. Following such Regulatory Approval, King, in Consultation with PTI, will have sole control and responsibility for execution of all matters described in the Development Plan with respect to such Product. In addition, each Party will be given the opportunity to review and comment on draft and final development plans and all associated protocols, reports, and Regulatory Filings on an ongoing basis. Draft documents will be provided to a Party in electronic or written form in advance of finalization or submission to Regulatory Authorities.

3.4.3 In the event the FDA, during the Phase II Meeting for a Product, determines that the Development of such Product may not proceed to Phase III, or the Parties otherwise agree that additional Development should be performed before proceeding to Phase III, King and PTI will jointly develop a revised Development Plan for such Product, and PTI will then reassume sole control and responsibility for execution of such Development Plan until Completion of Phase II for a Product (immediately prior to the Phase II Meeting), as provided herein.

3.4.4 King, in Consultation with PTI, will have sole control and responsibility for execution of all Product Development and associated regulatory matters described in the Development Plan with respect to a Product in the ROW. King, or its Affiliates or Sublicensees, shall be responsible for all clinical and regulatory expenses incurred in seeking Regulatory Approval in markets in the ROW.

3.4.5 Upon the FDA's approval of an NDA for a Product in the U.S. Territory, PTI, in Consultation with King, shall continue to have sole control and responsibility for the execution of any post-approval commitments mandated by the FDA with respect to such Product and the first Regulatory Approval thereof, and King, in Consultation with PTI, shall assume sole control and responsibility for execution of further Product Development of the Product.

3.4.6 In the event an NDA for Remoxy has not been accepted for filing by the FDA within thirty (30) months of the Effective Date, King may elect to assume sole control and responsibility for execution of all matters under the Development Plan (and all CMC matters under the Manufacturing/CMC Plans) with respect to Remoxy in the U.S. Territory by providing PTI with written notice thereof. In such event, notwithstanding the

provisions of Section 2.3.2, PTI will not have final decision-making authority with respect to matters related to Remoxy under the Development Plan, but King will have the final decision-making authority with respect to all such matters. Both Parties agree that such transfer of control and responsibility from PTI to King described in this Section 3.4.6 shall in no way diminish PTI's or Durect's right to receive royalties or milestones, as provided in the License Agreement. King agrees to use commercially reasonable efforts to diligently proceed with execution of the Development Plan in good faith and consistent with PTI's obligations under the DLA and this Agreement and shall use commercially reasonable efforts and diligence in Developing and seeking Regulatory Approval of Remoxy in the U.S. Territory in accordance with its business, legal, medical, and scientific judgment and in undertaking investigations and actions required to obtain appropriate Regulatory Approvals necessary to market Remoxy in the U.S. Territory and to meet its obligations hereunder. In addition, following such transfer of control and responsibility, King will provide PTI with such plans, budgets, data, and other information as PTI had been obligated to provide to King prior to the assumption of control by King under this Section 3.4.6.

3.4.7 Upon transfer of control and responsibility of a Product, the Parties will cooperate with each other in effecting a Tech Transfer of such matters to King with respect to such Product.

3.4.8 PTI shall use commercially reasonable efforts to complete all tasks assigned to it pursuant to the Development Plans in accordance with the budget; provided, however, that PTI may spend the funds allocated to such task plus an additional 10% of such funds, which additional expenditures shall be paid by King. If the actual costs under a particular Development Plan will likely exceed 110% of the funds allocated to such task, the provisions of Section 3.7 shall govern.

3.4.9 During the period in which the Parties share joint control of matters under the Development Plan, both Parties agree that only PTI may initiate or respond to FDA communications (including e-mail) regarding a Product; provided, however, that PTI shall keep King informed regarding all important communications, whether written or oral, between PTI and the FDA and shall provide King with an opportunity to review and comment on all important written correspondence (including all e-mail correspondence) and participate in all planned meetings and telephone calls, between PTI and the FDA.

3.4.10 All INDs and NDAs for a Product in the U.S. Territory will be owned and maintained in the name of PTI; provided that, upon Regulatory Approval of a Product, ownership and maintenance of INDs and NDAs for such Product will be transferred to King. In connection with such transfer to King, PTI will transfer all underlying clinical data and regulatory filings in an electronic format, to the extent available, agreed upon by the Parties. PTI shall transfer the NDA for each approved Product to King within sixty (60) days of the receipt of Regulatory Approval of such Product. PTI further agrees to transfer the applicable INDs, clinical data, and other regulatory filings within one hundred twenty (120) days of the Regulatory Approval of the Product to which they relate. All INDs and NDAs for a Product in the ROW will be owned and maintained by King. PTI hereby grants King access to, and right of reference to, any INDs and NDAs for Products in the Territory owned and maintained in the name of PTI to the extent necessary for King to perform its obligations hereunder or conduct Product Development in the Territory. King hereby grants PTI access to, and right of reference to, any INDs and NDAs for Products in the Territory owned and maintained in the name of King to the extent necessary for PTI (a) to perform its obligations hereunder, (b) to develop products that are within the Field (including Products) outside the Territory, (c) to develop Crain/Shen SABER Drugs pursuant to the terms of this Agreement and the License Agreement, (d) to develop products outside the Field, including Crain/Shen Drugs, or (e) as otherwise reasonably requested by PTI. For purposes of clarity, the rights granted by King to PTI in the preceding sentence shall include the right to permit Third Parties to access or reference such Regulatory Filings, so long as such Third Parties have agreed to confidentiality obligations that are at least as stringent as those set forth herein; provided that PTI agrees that it will not provide such rights o

3.4.11 PTI will use commercially reasonable efforts and diligence in Developing and seeking Regulatory Approval of each Product in the U.S. Territory in accordance with its business, legal, medical, and scientific judgment and in undertaking investigations and actions required to obtain appropriate Regulatory Approvals necessary to market Products in the U.S. Territory and to meet its obligations hereunder.

3.4.12 Subject to Section 2.1.4 of the License Agreement, following the acceptance for review by a Regulatory Authority in the U.S. Territory of an NDA for a Product, King will use commercially reasonable efforts and diligence in conducting Product Development and seeking Regulatory Approval of such Product in the Major Market Countries in the ROW in accordance with its business, legal, medical, and scientific judgment and in undertaking investigations and actions required to obtain appropriate Regulatory Approvals necessary to market such Product in the Major Market Countries and to meet its obligations hereunder. In exercising its business, legal, medical, and scientific judgment, King may take the following factors, among other things, into consideration: (a) the existing and reasonable potential market for a Product in a country, (b) any unduly burdensome regulatory requirements related to the Product Development of or the filing, acquisition, or maintenance of a Regulatory Approval for a Product in a country, (c) unduly burdensome government restrictions or quotas on use of products containing opioids, (d) availability of and potential pricing or reimbursement for a Product in a country to allow a reasonable rate of return considering costs of Marketing such product in such country, and (e) reasonable risk of Products sold in a country becoming gray-market goods in other markets and countries in the Territory; provided that the level of efforts and diligence used by King in conducting Product Development and seeking Regulatory Approval of Products in the ROW shall at all times be at least a level of efforts sufficient to ensure that PTI's obligations to Durect under the DLA are satisfied. Notwithstanding anything herein or in the License Agreement to the contrary, in the event PTI obtains Regulatory Approval for a Crain/Shen SABER Drug in any country in the Territory, including a Major Market Country, before King obtains in such country Regulatory Approval for the Product that contains the same opioid agon

#### 3.5 Manufacturing/CMC Plans.

3.5.1 King and PTI will jointly prepare each Manufacturing/CMC Plan and provide a copy to the JOC for its review and approval. Notwithstanding the foregoing, the Parties agree that PTI shall be solely responsible for preparing a Manufacturing/CMC Plan for Remoxy, it being understood that King will be given an opportunity to review and offer recommendations regarding such plan during its preparation, which recommendations PTI will consider in good faith.

3.5.2 PTI, in Consultation with King, will have control and responsibility for execution and implementation of all CMC development of a Product throughout the Territory until the first Regulatory Approval for such Product in the applicable country, including responsibility for provision of CTM, CMC information for such Product in Regulatory Filings, and pre-market validation of such Product. Notwithstanding the foregoing, PTI, in Consultation with King, will continue to have control and responsibility for execution and implementation of all CMC development after the first Regulatory Approval of a Product for all changes in formulation, including changes in dosage strength, requiring a further pre-market clearance by the FDA or other Regulatory Authority. Such changes in formulation may include line extension developments or reformulations that are, in PTI's reasonable judgment, within the scope of the DLA. For purposes of clarity, with respect to novel Product formulations, PTI and Durect shall be responsible for determining the qualitative and quantitative composition of each novel formulation with respect to excipients and API and setting technical and regulatory specifications for each such excipient and API used in creating such novel formulation. King shall have the right to select the manufacturer of such excipients and API prior to the manufacture of Phase III CTM, so long as the excipients supplied by King's selected manufacturer comply with the technical and regulatory specifications set by PTI and Durect. King shall have the right to negotiate and enter into supply agreements for API and excipients and to be the assignee with respect to agreements that may be in place for such Product excipients and API as of the Effective Date, in each case to the extent permitted under such supply agreements, and in compliance with the DLA and Section 2.1.3 of the License Agreement.

3.5.3 Except as provided in Section 3.5.2 above, King, in Consultation with PTI, will have control and responsibility for execution and implementation of post-approval support of each Product immediately upon the Regulatory Approval of an NDA for such Product, including logistics planning relating to such Product. To the extent PTI is obligated to purchase any excipients, additives, solvents, API, bulk form of Product, or other ingredients or materials from Durect pursuant to the terms of the DLA and which ingredients or materials, under the terms of the DLA, would be required to be used by King in its manufacture of Products, PTI shall sell to King such ingredients or materials so purchased by PTI at PTI's actual cost, without any mark-up. In connection with the transfer of control and responsibility, upon filing of an NDA for a Product, the Parties will cooperate with each other

to develop a plan for the completion of the Tech Transfer of such matters; and, with respect to all information, files, and documentation available as of the date of such NDA filing, within sixty (60) days from the acceptance by a Regulatory Authority of the NDA filing for a Product, the Parties will complete the Tech Transfer of such matters, including transferring files necessary for chemistry and manufacturing, to King with respect to such Product. Thereafter, the Parties will continue to perform Tech Transfer in a timely manner with respect to all other information, files, and documentation relating to such matters, including permitting King to witness pre-market validation and manufacture and quality operations. PTI agrees to assist, as requested by King, in post-approval support (including providing technical assistance, troubleshooting, and provision of post-marketing clinical supplies) to maximize the market opportunity for the Products and to assure uninterrupted supply.

3.5.4 In Consultation with King, PTI may enter into such agreements covering the clinical supply and manufacture of Products as are reasonably necessary to accomplish the objectives and purposes of the Development Program; and King agrees to abide by the terms of any such agreements which King has approved or which has been unanimously approved by the JOC pursuant to its oversight and approval functions set forth in Section 2.2.5. King may enter into such agreements covering the commercial supply and manufacture of component materials and API following the Completion of Phase II as are reasonably necessary to accomplish the objectives and purposes of the Development Program. King may at any time enter into an agreement covering manufacture of commercial Product.

3.5.5 The Parties agree that PTI's existing plan for manufacturing and quality operations with respect to Remoxy will continue to be followed by the Collaboration, with a commercial supply agreement being entered into with Mallinckrodt-Hobart as the primary manufacturer. King acknowledges that PTI's current understanding with Mallinckrodt-Hobart contemplates a term for such supply agreement of at least five (5) Calendar Years, following the Calendar Year of commercial launch in the United States. PTI, in Consultation with King, may continue negotiating an agreement with Mallinckrodt-Hobart; provided that any such agreement will include a provision that the agreement may be assigned by PTI to a business partner or Affiliate, in PTI's sole discretion; and provided further that PTI will cooperate with King to achieve the most advantageous economic terms for manufacture of Remoxy, including exercising commercially reasonable efforts to incorporate a provision in the Mallinckrodt-Hobart supply agreement to allow PTI under certain circumstances to solicit competitive bids for manufacture of Product that may be used to obtain more favorable supply terms from Mallinckrodt-Hobart or, if Mallinckrodt-Hobart elects not to match such more favorable terms, then which would permit PTI to substantially reduce its obligation to purchase Product from Mallinckrodt-Hobart following the third commercial year. The Mallinckrodt-Hobart supply agreement, with respect to Remoxy, will be assigned by PTI to King at a time mutually agreed to by the Parties, but no later than upon FDA approval of an NDA for Remoxy. Except with King's consent, not to be unreasonably withheld, the Mallinckrodt-Hobart supply agreement will have provisions such that the supply of Remoxy is independent of the supply of any other products covered by the agreement (including provisions so that a breach by PTI of its obligations with respect to the other products will not affect the supply of Remoxy) and permit the assignment of the supply agreement with respect to Remoxy independent of any other products, it being understood that King shall not withhold its consent to PTI's entering into the Mallinckrodt-Hobart supply agreement if PTI agrees to indemnify King and hold King harmless with respect to damages which King may incur as a result of Mallinckrodt-Hobart's cross-termination of the supply agreement with respect to Remoxy as a result of a PTI's breach of its obligations thereunder with respect to a product other than Remoxy. PTI will use commercially reasonable efforts to have provisions of the type described in the preceding sentence included in the Mallinckrodt-Hobart supply agreement.

3.5.6 Except with respect to Remoxy, which is addressed by Section 3.5.5 above, King will have control and responsibility for the commercial supply of Products in the Territory. Except as provided for Remoxy in Sections 3.5.1, 3.5.2, and 3.5.5 above, King may, in its sole discretion, decide to include its own manufacturing facility as a primary manufacturing site in the initial Regulatory Filings for any Products. Upon PTI's request and with King's consent (such consent not to be unreasonably withheld), King agrees to enter into an agreement with respect to King's commercial supply of Products to PTI or its licensee in Australia and New Zealand, the terms of such agreement to be negotiated in good faith. In the event that King agrees to supply Product to PTI and PTI agrees to purchase Product from King for commercial supply in Australia and New Zealand, then such Product will be sold by King to PTI at King's fully allocated cost plus ten percent (10%).

3.5.7 Upon PTI's written request, a second manufacturing site will be qualified for each Product at such time as any of the following shall occur: (a) such Product reaches \$250 million in annual Net Sales, or (b) there is an interruption of commercial supply, or (c) marketing in the applicable country of the Territory so requires. With respect to Remoxy, such qualification will be obtained on a post-approval basis and may include, at King's discretion, a King facility or other contract manufacturer. With respect to all other Products, if the primary site for such Product is a King manufacturing site, PTI may require that the second manufacturing site not be a King manufacturing site.

#### 3.5.8 In connection with the Manufacturing/CMC Plans, each Party

(a) will, upon written request of the other Party, provide the other with the following documents to the extent that such documents being requested are available and in the possession or control of the Party to whom the request is made: for each Product, pharmaceutics development report and history, copies of CMC section submitted as part of any Regulatory Filings, and minutes from any meeting or correspondence with any Regulatory Authority regarding pharmaceutics development or CMC; and

(b) will allow the other Party to examine and copy, at the site where such records are normally stored and at a time that is mutually acceptable to the Parties, the following: (i) CMC development protocols and reports, (ii) for each batch of API and each batch of Product produced as CTM, batch records, analytical monograph (tests and specifications), certificate of analysis for Good Manufacturing Practices release, a table containing initial release and stability testing results (which table will be updated each time a stability pull point is analyzed), copies of any out of specification or laboratory investigation report events, and report of any failed batches and any corrective action; and (iii) for each batch of Product produced as CTM, packaging and labeling batch records.

The Manufacturing/CMC Plans will include a list and brief description of protocols to be developed thereunder. The reports described in clause (a) above and the protocols in the Manufacturing/CMC Plans that King notifies PTI that King would like to review will be developed in Consultation with the other Party and will be made available to the other Party in draft form with sufficient time for such Party to review and comment on the foregoing, as well as being provided to the other Party in final form when such materials are completed. In addition, each Party will make available to the other Party such additional documentation reasonably related to such other Party's performance of its obligations hereunder that is in the possession or control of the Party to whom the request is made as such documentation is reasonably requested by the other Party.

3.6 Yearly Brand Plans. King will prepare each Yearly Brand Plan for each Product and provide a copy to the JOC for its review and comment. King, in Consultation with PTI, will have control and responsibility for Marketing each Product and for all matters under the Yearly Brand Plan, including determining the packaging, trade dress, and labeling (to the extent not dictated by any applicable Regulatory Approval) for the distribution and sale of Product. Subject to Section 2.1.4 of the License Agreement, King shall use commercially reasonable efforts and diligence to Market the Product commensurate with industry standards; provided that in no event shall such level of efforts and diligence be less than King uses in marketing its own products of similar market potential and at a similar stage in development as the applicable Product, taking into account the competitiveness of the marketplace, the proprietary position of the Product, and the efforts and resources available to a company having a comparable market capitalization and taking into account then-current market conditions. King will spend at least \$10 million on Marketing for Remoxy in the U.S. Territory (excluding expenses related to a sales force) between the Closing Date and the date of Regulatory Approval of Remoxy in the U.S. Territory, such suspension to only remain in effect until such time as the JOC elects to resume pursuing Regulatory Approval of Remoxy in the U.S. Territory; provided further that King may propose changes in spending levels, with respect to which changes PTI will not unreasonably withhold its consent, in the event of (a) the FDA not accepting the NDA covering Remoxy for filing (or refusal to file), (b) a determination by the FDA that such NDA is not approvable, or (c) a failure by the FDA to approve such NDA within eighteen (18) months of the date of the FDA's acceptance of an NDA for Remoxy.

#### 3.7 Collaboration Costs, Overruns, and Additional Expenditures.

3.7.1 Subject to the terms and conditions of this Agreement, including Section 3.3.2, (a) all Collaboration Costs incurred by either Party on and after the Closing Date shall be paid by King; and (b) all Collaboration Costs incurred by either Party on or after the Effective Date but prior to the Closing Date will be paid by King, with such payment not to be paid prior to the Closing Date, so long as this Agreement is not terminated prior to Closing and such Collaboration Costs comply with the terms and conditions of this Agreement, as it will be in effect as of the Closing Date. Except as otherwise provided herein, PTI shall be entitled to reimbursement for the Collaboration Costs incurred by it in connection with the Collaboration; provided that all such Collaboration Costs must be included in the budget governing the activities for which such costs were incurred, subject to the provisions of this Section 3.7. All payments made by King hereunder shall be treated for all purposes, including all tax and accounting purposes, as the expenses of King and any applicable deductions shall be wholly allocable to King.

3.7.2 The Parties understand and agree that a Product may generate new data or may be the subject of new regulatory guidance at any time for any reason during a Calendar Year and that such changes may require substantial revisions to the clinical development activities associated with a Product or may cause PTI, in Consultation with King, or Durect to re-work a Product. In the event either Party anticipates or becomes aware that the actual costs of any given task assigned to it may or will likely exceed the funds allocated to such task in the applicable Program Plan budget, such Party shall promptly notify the JOC in writing. If the actual aggregate costs of conducting a particular Program Plan will likely exceed the aggregate annual funds budgeted for such Program Plan under the applicable Program Plan budget (or in the case of work conducted under a Development Plan, if the actual aggregate costs of conducting a particular Development Plan will likely exceed 110% of the aggregate annual funds budgeted for such Development Plan under the applicable Development Plan budget), the JOC shall work in good faith for up to thirty (30) days to approve a budget amendment that provides for the continued prompt clinical Development and Regulatory Approval of a Product. Such amendment may include increasing the budget, readjusting the budget to allocate additional funds to such task, revising the scope of such task to permit satisfactory completion at the then-budgeted funding level, or all three. In the event no decision is reached, the matter shall be subject to the arbitration provisions of Section 2.3.3 hereof. For purposes of clarity, neither Party shall be obligated to perform any additional services in connection with such task if the JOC does not approve increasing the budget to pay for such additional services.

3.7.3 Notwithstanding the foregoing, either Party may, in its discretion, spend additional amounts above and beyond those allocated in the applicable budget ("<u>Discretionary Funding</u>") on any task assigned to such Party pursuant to the Program Plans or on any other task the JOC has approved. In such event, the Party wishing to expend Discretionary Funding shall first inform the second Party of such first Party's intent to do so. If the second Party consents to the Discretionary Funding being deemed a Collaboration Cost, which consent shall not be unreasonably withheld, the Discretionary Funding shall constitute a Collaboration Cost. If the second Party does not consent, then the Discretionary Funding shall not constitute a Collaboration Cost, but shall be borne solely by the Party undertaking the Discretionary Funding.

3.7.4 Except to the extent this Agreement expressly provides for payments that do not require JOC approval, and except to the extent the JOC has approved any payment hereunder, neither Party shall (a) be obligated to incur any costs or expend any funds that have not been approved by such Party or (b) have the authority to cause the other Party to incur any costs or expend any funds that have not been approved by such other Party.

3.8 Third Party Licenses and Collaborations. Subject to the review and the approval of the JOC as provided in Section 2.2.5, King may enter into such other Third Party licenses and collaboration agreements as are reasonably necessary to accomplish the objectives and purposes of the Development Program; and subject to the review and the approval of the JOC as provided in Section 2.2.5, PTI may enter into such Third Party licenses and collaborations agreements as are reasonably necessary to accomplish the objectives and purposes of the Collaboration.Except with the other Party's consent, not to be unreasonably withheld, each such agreement shall (a) if only one Party is a party to the agreement, name the other Party as a third party beneficiary to such agreement, (b) include an assignment of all right, title, and interest in and to all work product and all inventions arising from the performance of such agreement, and all intellectual property rights attaching thereto to the contracting Party, and (c) bind the relevant Third Party by obligations of confidentiality and non-use with respect to all such work product, inventions, and intellectual property rights that are at least as stringent as those set forth herein. In order to ensure the ability of a Party (the "<u>Non-Defaulting Party</u>") to proceed with the Development Program notwithstanding certain conduct of the other Party (the "<u>Defaulting Party</u>") or the termination of this Agreement by the Non-

Defaulting Party pursuant to Section 9.2.3, the JOC may require the inclusion, in those subcontracts, licenses, and other agreements (including manufacturing and supply agreements) entered into in connection with the Development Program ("<u>Third Party Agreements</u>") that are or are likely to become material to the conduct of the Development Program, of (i) an enforceable provision granting to the Non-Defaulting Party hereto the same rights, benefits, and obligations as those granted to the Defaulting Party under that Third Party Agreement (whether by automatic assignment, a direct agreement, or otherwise), contingent upon a Default by the Defaulting Party of that Third Party Agreement or the termination of this Agreement by the Non-Defaulting Party pursuant to Section 9.2.3, and (ii) the applicable Third-Party's unconditional consent to such provision.

#### 3.9 Failure to Perform.

3.9.1 **General**. In the event that a Party does not perform a task or tasks assigned to it under a Program Plan, including due to a dispute as to the budget or scope of such task, or otherwise fails to perform its Development or Marketing obligations hereunder, including meeting timelines and budgets set forth in the Program Plans, PTI and King will negotiate in good faith with respect to remedying such failures. In the event such negotiations do not result in a resolution of such issues satisfactory to both Parties within thirty (30) days of the initiation of such negotiations, the matter shall be submitted to arbitration as set forth in Section 2.3.3.

3.9.2 **<u>Remedy</u>**. In the event the arbitrators determine that the failure to perform was intentional or willful (but not as a result of a failure to perform because of a disagreement about budget matters or regulatory strategy, which disagreement prevents the Parties from continuing to perform their obligations), the arbitrators may grant the non-breaching Party the right, but not the obligation, to perform the task or tasks of the breaching Party. In addition, in the event of any breach, including a failure to use commercially reasonable efforts to perform a Party's obligations, the arbitrators may award the non-breaching Party monetary damages.

3.9.3 No Waiver. In the event a Party is granted a right to perform the other Party's task, a Party's election to perform such task will not be deemed a waiver with respect to such electing Party's ability to exercise any other rights hereunder, including any rights under Section 9.2.2 or 9.2.3.

#### 4. **INFORMATION EXCHANGE**

#### 4.1 **<u>Records</u>**.

4.1.1 <u>Record Keeping</u>. Each of PTI and King shall maintain records in sufficient detail and in accordance with Good Laboratory Practice, Good Clinical Practice, and Good Manufacturing Practice, and as will properly reflect and document, in a manner appropriate for purposes of supporting the filing of potential patent applications and Regulatory Filings, all work done and results achieved in the performance of the Development Program (including all data in the form required under any Applicable Law); provided, however, that prior to King's election to assume control and responsibility of execution of all matters under the Development Plan with respect to a particular Product, PTI shall be responsible for maintaining master files in accordance with Good Clinical Practices, Good Laboratory Practices, and Good Manufacturing Practices, to the extent applicable; provided, further, that upon such election by King, PTI shall transfer such records to King with respect to such Product. Subject to Section 6.4.3hereof, PTI and King each hereby grants the other the right to inspect and copy such records to the extent reasonably required for the performance of its obligations or exercise of its rights under this Agreement, and neither Party shall use such records or information except to the extent otherwise permitted by this Agreement.

4.1.2 **Reports**. Each Party shall keep the JOC reasonably informed about the status of the Development Program, including furnishing the JOC with copies of all material reports that relate to the Development Program. In particular, without limitation, each Party shall (a) provide periodic reports in reasonable detail to the JOC, at least each Calendar Quarter and as requested from time to time by the JOC; (b) provide the other Party with access to all Technology and information employed in or arising out of the Development Program solely for the purpose of conducting their respective roles hereunder; (c) provide the other Party with the information and reports described in Section 3.5.8 at least each Calendar Quarter and as requested from time to time by the other Party; and (d) provide the other Party with information concerning the Development Program as such other Party shall reasonably request. For purposes hereof, "information" will include data, results, reports, records, and similar information.

#### 4.2 Updates; Adverse Event Information.

4.2.1 <u>Adverse Event Reports</u>. In addition to the reports described in Section 4.1.2above, each Party shall provide the JOC with all adverse event information and product complaint information required by such Party to be disclosed to any Regulatory Authority in connection with the Development, Marketing, or sale of any Product, within time frames consistent with reporting obligations under Applicable Law.

4.2.2 <u>Confidential Information</u>. Except as otherwise required in connection with disclosures to Regulatory Authorities required by Applicable Law, all reports, updates, adverse event, or product complaint and other information provided by a Party under this Agreement (including under this Section 4.2) shall be considered Confidential Information of both Parties, regardless of who provided the same, and shall be subject to the terms of Article 8.

4.3 <u>Sales Report</u>. Starting immediately following the First Commercial Sale of a Product and for the Term of this Agreement, King, at its own expense, shall provide PTI with such U.S. sales reports that King has obtained for itself from a third party vendor of King's choice (such as IMS or NDC). Such report shall be provided to PTI on a timely basis in electronic form, if available, each Calendar Quarter and shall include no less than the following data (provided that King has obtained or can obtain such data without undue burden): (a) Product sales by territory, by prescriber, and by strength, (b) Product sales by hospital, clinic, or mail-order services, independent pharmacies, chains, mass merchandisers, and food stores, (c) a comparison of actual Product sales versus King's forecast sales, (d) wholesale volume reports, (e) top 250 hospital report, and (f) a summary of managed care accounts by volume of Product. In addition, starting immediately following the First Commercial Sale of a Product and for eighteen (18) months thereafter, King, at its own expense, shall (i) provide PTI with a weekly Product sales report in electronic form and (ii) provide telephonic (or in-person) access to King's national sales manager for purposes of holding an accurate discussion of a Product's commercial sales trends, general market trends, and the like. PTI agrees that all information, data, and reports provided by King to PTI hereunder shall be considered Confidential Information of King, subject to the requirements of Article 8.

#### 5. CERTAIN OTHER PROVISIONS

5.1 **Product Liability Costs**. The Parties understand and agree that, because of the nature of the collaborative effort set forth in this Agreement, should any Third Party claims be asserted against either Party or both Parties or any of their Affiliates, agents, or representatives that are in the nature of product liability claims ("<u>Claims</u>"), the Parties will cooperate through the JOC to ensure that such claims are defended and settled or compromised in a manner that best protects the interests of the Parties. In addition, the Parties will procure and maintain product liability insurance with first-class carriers in coverages and amounts and with deductibles not less than those determined by the JOC; provided that:

(a) PTI shall obtain such insurance for a Product for Claims arising prior to the Completion of Phase II, at PTI's sole cost, which coverage shall continue until the earlier of (i) the initiation of Phase III for such Product and (ii) five years after the Completion of Phase II for such Product;

(b) If Phase III for a Product is initiated, PTI shall obtain such insurance for such Product for Claims arising following Completion of Phase II but prior to the First Commercial Sale of such Product, at PTI's and King's joint and equal cost, which coverage shall continue until the earlier of (i) the First Commercial Sale of such Product and (ii) five years after the first to occur of (A) the completion of Phase III, (B) the decision of the JOC not to proceed with the commercial sale of such Product, and (C) the termination of this Agreement in its entirety pursuant to Article 9 or with respect to such Product pursuant to Section 9.2.2(a), unless PTI or any of its Affiliates or its sublicensee continues to Develop the Product following such termination, in which case clause (d) below will apply;

(c) As of the First Commercial Sale of a Product, King shall, at its sole cost, have obtained such insurance for a Product for Claims arising following the First Commercial Sale of such Product, such insurance to be in an appropriate level (at a minimum of \$50 million) exclusive of self-insured amounts and shall be in amounts maintained by King for other products of King of similar market potential and at a similar stage in

development as the applicable Product, taking into account any particular risks related to such Product, which coverage shall continue until the earlier of (i) the termination of this Agreement in its entirety pursuant to Article 9 or with respect to such Product pursuant to Section 9.2.2(a), so long as PTI or any of its Affiliates or its sublicensee continues to sell the Product following such termination, and (ii) five years after the last commercial sale of the Product pursuant to this Agreement; and

(d) PTI shall, at its sole cost, obtain such insurance for a Product for Claims arising following the termination of this Agreement in its entirety or with respect to such Product, so long as PTI or any of its Affiliates or its sublicensee continues to Develop or sell the Product following such termination, such insurance to be in an appropriate level (at a minimum of \$50 million in the case of Marketed Products) exclusive of self-insured amounts and shall be in amounts maintained by PTI for other products of PTI of similar market potential and at a similar stage in development as the applicable Product, taking into account any particular risks related to such Product, which coverage shall continue until five years after (i) termination of the Development of such Product if PTI elects not to sell such Product commercially or (ii) the last commercial sale of the Product, as applicable.

The costs incurred to obtain the insurance described in this Section 5.1 shall not be deemed Collaboration Costs. The insurance described in this Section 5.1 shall name each Party as a co-insured.

5.2 **Product Packaging**. The Parties agree that packaging and package inserts for each finished Product sold to consumers will include King's and PTI's names and logos prominently displayed, subject to the approval of the applicable Regulatory Authorities. PTI agrees that it shall not use, and it will prohibit its Affiliates or sublicensees from using, trademarks, trade dress (including product intaglio), packaging, or marketing material with respect to the Marketing of products in the Field in Australia and New Zealand that is confusingly similar with the Product Trademarks and any Product trademarks, trade dress, packaging, or marketing material in the Territory, except with respect to the use of PTI's name or logo. For clarity, PTI has the right to develop and market for use in Australia and New Zealand the identical formula, including colorants and inks, and container-closure system, as is developed and marketed for each Product in the Territory; provided, however, that all secondary packaging components must be different.

5.3 <u>Mutual Financial Reporting</u>. Each Party covenants to provide the other Party written notice at such time as (a) such Party enters the "zone of insolvency," as defined in Applicable Law, including interpretations in applicable case law, (b) such Party's liabilities exceed its assets, (c) such Party is unable to pay its debts as they become due, (d) there is an occurrence of a Default by such Party with respect to any of its debt or payment obligations or any agreement material to the Development Program, or (e) such Party suspends, closes, or otherwise ceases to operate a majority of its business relating to this Agreement and the License Agreement. In addition, within 15 days of a written request of either Party (such request not to be made more than four times during any Calendar Year), the other Party covenants to provide the requesting Party with its most recent audited financial reports. Each Party will treat all notices and financial reports (and the information contained therein) as Confidential Information of the other Party, subject to the terms of Article 8.

#### 6. CLOSING; PAYMENTS

6.1 Closing.

#### 6.1.1 Covenants Pending Closing.

(a) <u>Reasonable Efforts</u>. Subject to the terms and conditions of this Agreement, each of the Parties agrees to use all reasonable efforts to do, or cause to be done, all things necessary and appropriate to satisfy all conditions of and to consummate the transactions contemplated by this Agreement, including the satisfaction of the applicable conditions set forth in Section 6.1.3 below.

(b) <u>Filings</u>. The Parties shall cooperate with one another in the preparation, execution, and filing of all documents that are required or permitted to be filed on or before the Closing, including filings pursuant to the HSR Act and will promptly file the same after the Effective Date. The related filing fees shall be borne by King, and the costs and expenses incurred by each Party shall be paid by such Party.

6.1.2 **Closing**. As promptly as practicable after the Effective Date and after the satisfaction by each Party or, if permissible, waiver of the conditions set forth in Sections 6.1.3(a) and (b), the Parties hereto shall cause the Closing to occur on the Closing Date. The Closing shall be held at the offices of Jones Day, 222 East 41st Street, New York, New York 10017, or such other place as the Parties shall agree, for the purpose of confirming the satisfaction or waiver, as the case may be, of the conditions set forth in Sections 6.1.3(a) and (b). If the Closing Date has not occurred prior to February 9, 2006, either Party may terminate this Agreement upon written notice to the other Party; provided, however, that, as of such date, the Party terminating this Agreement is not in default under this Agreement.

#### 6.1.3 Conditions to Closing.

(a) The obligation of PTI to close shall be subject to the satisfaction on or before the Closing Date of the following conditions, any or all of which may be waived in whole or in part by PTI:

(i) the expiration or termination of all applicable waiting periods under the HSR Act, unless a joint determination is made by PTI and King (by certification from PTI and King to each other) that notification under the HSR Act is not required;

(ii) the representations and warranties made by King in Article 10 shall be true and correct in all material respects as of the Effective Date and as of the Closing Date with the same force and effect as if they had been made as of the Closing Date, and King shall have performed all obligations and conditions herein required to be performed or observed by it on or prior to Closing;

(iii) the provision by King to PTI of an officer's certificate certifying that (i) and (ii) above are true and correct as of the Closing

Date;

(iv) the provision by King to PTI of an opinion of counsel, in form reasonably satisfactory to PTI, that the execution of this Agreement and the License Agreement and the transactions contemplated hereby and thereby are duly authorized by all corporate action on the part of King;

(v) the payment to PTI of the Program Fee by King;

(vi) the execution by King and delivery to PTI of the License Agreement; and

(vii) any agreement entered into by PTI with Mallinckrodt-Hobart pursuant to Section 3.5.5 shall be in form and substance

satisfactory to King.

(b) The obligation of King to close shall be subject to the satisfaction on or before the Closing Date of the following conditions any or all of which may be waived in whole or in part by King:

(i) the expiration or termination of all applicable waiting periods under the HSR Act, unless a joint determination is made by PTI and King (by certification from PTI and King to each other) that notification under the HSR Act is not required;

(ii) the representations and warranties made by PTI in Article 10 shall be true and correct in all material respects as of the Effective Date and as of the Closing Date with the same force and effect as if they had been made as of the Closing Date, and PTI shall have performed all obligations and conditions herein required to be performed or observed by it on or prior to Closing;

(iii) the provision by PTI to King of an officer's certificate certifying that (i) and (ii) above are true and correct as of the Closing

Date;

(iv) the provision by PTI to King of an opinion of counsel, in form reasonably satisfactory to King, that the execution of this Agreement and the License Agreement and the transactions contemplated hereby and thereby are duly authorized by all corporate action on the part of PTI;

(v) the execution by Durect and PTI of an agreement, in the form attached hereto as <u>Exhibit B</u>, granting Durect's consent to the transactions contemplated by this Agreement and the License Agreement; and

(vi) the execution by PTI and delivery to King of the License Agreement.

6.2 **Program Fee.** Simultaneous with the Closing, King shall pay to PTI a one-time collaboration fee in the amount of one hundred fifty million U.S. dollars (\$150,000,000) (the "<u>Program Fee</u>"). The Program Fee shall be paid by King in U.S. dollars by wire to an account designated by PTI.

#### 6.3 Milestone Payments.

6.3.1 **Development Milestones**. King will make the following payments to PTI within ten (10) days after the determination of the first achievement of each of the milestones set forth below. For purposes of clarity, it is understood and agreed that the following milestone payments shall (a) be non-refundable and non-creditable and (b) only be payable once with respect to each Product, such that that a payment will be due only once for (i) each Product with a given active opioid, but will not be payable with respect to line extensions, new indications, new dosages, or new Regulatory Filings that subsequently may be filed for a Product that contains the same active opioid, and (ii) the first filing of an IND or NDA or the first regulatory approvable letter for such Product in a country of the Territory, notwithstanding the subsequent filing or approval of other Regulatory Filings in other countries in the Territory for a Product with the same active opioid.

		Payment		
Milestone	Remoxy	All	Other Products	
Acceptance by a Regulatory Authority of the first IND filing for a Product in the Territory	N/A	\$	5 Million	
Acceptance by a Regulatory Authority of the first NDA filing for a Product in the Territory		\$	15 Million	
First regulatory approvable letter transmitted by a Regulatory Authority for NDA of a Product in the Territory		\$	20 Million	
Total Development Milestones for Each Product		\$	40 Million	

6.3.2 <u>Termination of Milestones</u>. In the event any suit, action, or proceeding results in the entry of an injunction pursuant to Section 4.6 of the License Agreement that prevents King from Marketing a Product, which injunction is unappealable or unappealed within the time allowed for appeal, King's obligation to make milestone payments with respect to future milestones for such Product pursuant to this Section 6.3 shall immediately terminate. It is understood and agreed that following the issuance of any such injunction, PTI's Development and manufacturing obligations with respect to such Product shall be waived, and the Parties shall promptly amend the Project Plans and, if required to meet the minimum obligations under Section 3.1.3, designate a replacement Product pursuant to Section 3.1.2. For purposes of clarity, it is understood that this Section 6.3.2 shall not relieve King of its obligation to pay any milestone payments for milestones that were achieved prior to the date such injunction is issued or to subsequently pay milestones in the event such injunction is lifted.

#### 6.4 Collaboration Costs.

6.4.1 **Determination of Collaboration Costs**. Within ten (10) days following the end of the second month of each Calendar Quarter, PTI shall submit to King a documented and reasonably detailed accounting of all Collaboration Costs, determined in accordance with GAAP, incurred by PTI with respect to all Products during the last month of the prior Calendar Quarter and the first two (2) months of the current Calendar Quarter, which King shall pay to PTI pursuant to Section 3.7 above. All such payments shall be made within thirty (30) days following the end of the second month of the applicable Calendar Quarter.

6.4.2 <u>Currency Conversion</u>. All Collaboration Costs incurred in currencies other than U.S. dollars shall be converted to U.S. dollars using the method agreed by the Parties and set forth in the budget of the applicable Program Plan.

6.4.3 Records. Each Party shall maintain its records in accordance with GAAP. PTI shall maintain, and shall require that its Affiliates, Sublicensees, and licensees maintain, for three years from the date of each quarterly reconciliation of Collaboration Costs, complete and accurate records of the same, in sufficient detail to allow calculation and verification of Collaboration Costs. King shall have the right for a period of three years after receiving any report or statement with respect to Collaboration Costs to appoint, at its expense, an independent certified public accountant reasonably acceptable to PTI to inspect the relevant records of PTI and its Affiliates and, if applicable, Sublicensees to verify such report or statement. PTI, its Affiliates, and, if applicable, Sublicensees shall each make its records available for inspection by such independent certified public accountant (who agrees to confidentiality provisions consistent with Article 8) during regular business hours at such place or places where such records are customarily kept, upon reasonable notice from King, solely to verify the accuracy of the reports and payments. PTI will use commercially reasonable efforts to ensure that King is granted the right to audit PTI's Sublicensees' financial records, as provided herein; provided that, to the extent that PTI does not obtain that right for King, PTI shall obtain for itself such right and, at the request of King, PTI shall exercise such audit right with respect to such Sublicensees and provide the results of such audit for inspection by King pursuant to this Section 6.4.3. Such inspection right shall not be exercised more than once in any Calendar Year. The results of each inspection, if any, shall be binding on both Parties. In the event that any such inspection shall conclude that Collaboration Costs were overstated by more than five percent (5%) in any given Calendar Year, PTI shall pay for all the reasonable costs of King in respect of the inspection, as well as make any payments required to remedy the overstatement. Any dispute regarding the results of any such inspection hereunder shall be subject to the dispute resolution provisions of Section 2.3 hereof; provided that if PTI is the Party with final decision-making authority over the subject matter in dispute, and the CEO's are unable to reach agreement even after good faith discussions in accordance with Section 2.3, then the dispute shall not be subject to the sole discretion of either Party but shall be subject to arbitration pursuant to the provisions of Section 2.3.3. All information and data reviewed in the inspection shall be used only for the purpose of verifying the accuracy of the reports and payments and shall be treated as PTI's Confidential Information subject to the obligations of this Agreement.

6.4.4 <u>Overdue Payments</u>. All overdue payments, not subject to a bona fide dispute, due and payable pursuant to this Agreement shall bear interest at a rate of 1% per month from the due date until paid in full.

6.4.5 <u>Withholding Taxes</u>. All payments made by a Party hereunder shall be made to the other Party free and clear of any Taxes. If a Party is required by law to deduct or withhold any Taxes from any payment made hereunder, then such Party shall (a) make such deductions and withholdings; (b) pay the full amount deducted or withheld to the relevant taxing authority or other applicable governmental authority; and (c) promptly provide the other Party with written documentation of any such payment that, if applicable, shall be in a form sufficient to satisfy the requirements of the United States Internal Revenue Code relating to a claim by such other Party for a foreign tax credit in respect of such Tax payment.

#### 7. LIMITATIONS

7.1 **For PTI**. Except as otherwise expressly permitted herein or in the License Agreement with respect to Crain/Shen SABER Drugs, during the Term, PTI agrees that it will not develop or market any products in the Field in the Territory on its own or with or through an Affiliate, Sublicensee, licensee, or other Third Party, or grant to any Affiliate, Sublicensee, licensee, or other Third Party any right, option, license, covenant not to sue, or any other agreement to forbear from enforcing PTI's rights to do so.

7.2 **For King**. Except as otherwise expressly permitted herein or in the License Agreement with respect to Products, during the Term, King agrees that it will not develop or market any products incorporating SABER Technology in the Territory with Durect or license from Durect or any licensee or other recipient of rights from Durect, any rights to develop or market any such products, except any rights for use in the Collaboration, in each case, either on its own or with or through an Affiliate, Sublicensee, licensee, or other Third Party.

#### 8. TREATMENT OF CONFIDENTIAL INFORMATION; PUBLICITY.

#### 8.1 Confidentiality.

8.1.1 <u>Confidentiality Obligations</u>. PTI and King each acknowledges and agrees that the other Party's Confidential Information constitutes highly valuable and proprietary confidential information and materials. PTI and King each agrees that during the Term of this Agreement and for an additional five years (or, in the case of any Confidential Information identified as a trade secret by the Disclosing Party at the time of disclosure, for so long as such trade secret Confidential Information is susceptible of remaining a trade secret), it will use commercially reasonable efforts to keep confidential, and will use commercially reasonable efforts to cause its employees, Consultants, Affiliates, agents, advisors, and Sublicensees to keep confidential. all Confidential Information of the other Party. Neither PTI nor King nor any of their respective employees, Consultants, Affiliates, or Sublicensees shall use Confidential Information of the other Party for any purpose whatsoever except as expressly permitted in this Agreement or the License Agreement.

8.1.2 Limited Disclosure. PTI and King each agree that any disclosure of the other Party's Confidential Information to any officer, employee, Consultant, agent, or Affiliate of PTI or King, as the case may be, shall be made only if and to the extent necessary to carry out its rights and responsibilities under this Agreement and the License Agreement, shall be limited to the maximum extent possible consistent with such rights and responsibilities, and shall only be made to persons who are bound by written confidentiality obligations to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement or the License Agreement. PTI and King each further agrees not to disclose or transfer the other Party's Confidential Information to any Third Parties under any circumstance without the prior written approval from the other Party (such approval not to be unreasonably withheld), except as otherwise required by law, and except as otherwise expressly permitted by this Agreement or the License Agreement. Each Party shall take such action, and shall cause its Affiliates and Sublicensees to take such action, to preserve the confidentiality of the Disclosing Party's Confidential Information as the Receiving Party would customarily take to preserve the confidentiality of its own Confidential Information, using a level of care that shall not under any circumstances be less than reasonable and prudent care. If a court or other government authority orders that the Receiving Party disclose Confidential Information, or proposes such an order, the Receiving Party must notify the Disclosing Party immediately after learning of the order, so as to provide the Disclosing Party an opportunity to protect the information, and the Receiving Party must limit the disclosure to the minimum that will comply with the order. Each Party, upon the request of the other Party, will return all the Confidential Information disclosed or transferred to it by the other Party pursuant to this Agreement, including all copies and extracts of documents and all manifestations in whatever form, within 60 days of the request or, if earlier, the termination or expiration of this Agreement; provided however, that a Party may retain Confidential Information of the other Party relating to any license or right to use Technology that survives such termination and one copy of all other Confidential Information may be retained in inactive archives solely for the purpose of establishing the contents thereof.

8.1.3 <u>Employees and Consultants</u>. PTI and King each hereby agrees that all of its employees, and all of the employees of its Affiliates, and any Consultants to such Party or its Affiliates, in any case that participate in the activities of the Development Program and who shall have access to Confidential Information of the other Party shall be bound by written obligations to maintain the same in confidence and not to use such information except as expressly permitted herein. Each Party agrees to enforce confidentiality obligations to which its employees and Consultants (and those of its Affiliates) are obligated. Each Party agrees to have each employee or Consultant that participates in the Development Program enter into a written agreement with such Party that includes an assignment to such Party of all right, title, and interest in and to all work product and all inventions arising during the course of his or her employment with or provision of services to such Party, and all intellectual property rights attaching thereto.

8.1.4 **Equitable Relief.** PTI and King each acknowledges that a breach by it of Article 7 or the provisions of this Article 8 cannot reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party may be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable remedy shall be construed as a waiver or prohibition against the pursuing of other legal or equitable remedies in the event of such a breach. Each Party agrees that the existence of any claim, demand, or cause of action of it against the other Party, whether predicated upon this Agreement, or otherwise, shall not constitute a defense to the enforcement by the other Party, or its successors or assigns, of the covenants contained in Articles 7 and 8.

8.2 **Publicity**. Neither Party may publicly disclose the existence or terms of this Agreement without the prior written consent of the other Party. Notwithstanding the foregoing, each Party shall have the right to disclose the existence or terms of this Agreement, or information relating to the Development Program, Remoxy, or other Products, without the consent of the other Party (a) to the extent the disclosure is required by law or by the requirements of any nationally recognized securities exchange, quotation system, or over-the-counter market on which such Party has its securities listed or traded, (b) to any investors, prospective investors, lenders, and other potential financing sources who are obligated to keep such information confidential, or (c) to any Third Party who is obligated by written confidentiality agreement to keep such information confidential; provided, in each case, that the Party making such disclosure shall use reasonable efforts to provide the other Party with as much notice beforehand as is reasonable under the circumstances with respect to any such disclosure. The Parties, upon the execution of this Agreement, will mutually agree to a press release with respect to the Development Program for publication. Once such press release or any other written statement is approved for disclosure by both Parties, either Party may make subsequent public disclosure of the contents of such statement without the further approval of the other Party. Additionally from time-to-time PTI may wish to issue press releases or make similar disclosures regarding the results or status of its research or Product activities, the achievement of a regulatory or development milestone, or any other material achievements under this Agreement or the DLA. Notwithstanding anything to the contrary in Section 8.3 or this Section 8.2, PTI shall be free to issue such press releases or make such disclosures, and shall have the right to choose the wording and timing of any such press releases and disclosures; provided that PTI agrees to provide King a draft copy of any such press release or disclosure at least twelve (12) hours prior to its publication or disclosure, which copy in any event must be provided during normal business hours, and provided further that such disclosure does not mention King without King's prior written consent. King shall have the right to inform PTI of any information contained therein that King believes is inaccurate.

8.3 **Publication**. It is expected that each Party may wish to publish the results of its research under this Agreement and the DLA in scientific journals or through scientific conferences, which disclosures will be subject to the obligations of this Section 8.3. At any time prior to the filing of an NDA for a particular Product, PTI may publish the results of its research for such Product in scientific journals or through scientific conferences; provided that PTI complies with the provisions of this Section 8.3; and provided further that such publication does not mention King without King's prior written consent. At any time following the filing of an NDA for a particular Product, King may publish the results of its research for such Product in scientific journals or through scientific conferences; provided that King complies with the provisions of this Section 8.3; and provided further that such publication does not mention PTI without PTI's prior written consent. In order to safeguard patent rights and other intellectual property, the Party wishing to publish in any scientific journal or at any scientific conference the results of any research being conducted by the Parties in the Development Program shall first submit a draft of each proposed technical publication or an outline of each proposed presentation for a scientific conference, with any related materials to be published or distributed in connection therewith, to the other Party for review, comment, and consideration of appropriate patent action at least thirty (30) days prior to any submission for publication as to whether a patent application shall delay submission until the first to occur of the filing of a patent application shall delay submission until the first to occur of the filing of a patent application and thirty (30) days from such notice provided by the JOC) or whether such publication must be revised to eliminate Confidential Information of a Party (in which case the Party seeking publication shall delete from any proposed publication al

#### 9. TERM AND TERMINATION

9.1 **Term**. This Agreement shall commence on the Closing Date and shall continue in full force and effect until the later of (a) the expiration of the last to expire of any Patent Rights licensed under the License Agreement or developed in the Collaboration and (b) the expiration of all periods of market exclusivity relating to any Products in the Territory, unless earlier terminated in accordance with the provisions of Section 6.1.2 or this Article 9(the "<u>Term</u>").

9.2 Termination. This Agreement may be terminated, with respect to a particular Product or in whole, as follows:

9.2.1 <u>Mutual Termination</u>. The Parties may agree in writing to mutually terminate this Agreement at any time. If a Party has given notice of termination of this Agreement pursuant to Section 9.2.2, 9.2.3, or 9.2.4 hereof, the other Party may not invoke this Section 9.2.1 by agreeing to such termination. In the event of termination pursuant to this Section 9.2.1, the Parties shall negotiate in good faith within thirty (30) days after the date of such termination the terms and conditions of such termination. In addition, King shall make payments due and payable for the Final Calendar Year as required by Sections 6.3 and 6.4, as well as pay any other amounts due and owing on the date of termination.

#### 9.2.2 Termination At Will.

(a) <u>Product Specific Termination</u>. King may terminate this Agreement with respect to a particular Product as set forth in Section 3.1.4 above. In connection with a termination pursuant to this Section 9.2.2(a), the following shall apply:

(i) King shall execute and deliver to PTI such documents, material, data, records, analyses, and information and do such things as reasonably requested by PTI to the extent reasonably related to the Development and Marketing of such Terminated Product in the Territory, including the following, in each case to the extent so related: (A) King shall use its commercially reasonable efforts to effect a reasonably smooth and orderly transition of any ongoing clinical studies, Regulatory Approval, or pre-marketing efforts to PTI (including all data and reports in the possession of King) with respect to the Terminated Product, including the assignment of any relevant Third Party contracts and Regulatory Filings and, unless otherwise requested by PTI, shall use commercially reasonable efforts to cancel all cancelable costs already incurred and mitigate all other costs incurred in connection with the Development Program for such Terminated Product; (B) King shall make its personnel and other resources reasonably available to PTI as reasonably necessary to effect a reasonably orderly transition of development responsibilities for such Terminated Product; (C) King shall pay all non-cancelable costs in connection with the Development Program for such Terminated Product; (D) King shall pay all costs of any of the ongoing clinical trials of such Terminated Product for a period of six (6) months from the effective date of termination, but only for such costs incurred for those patients already enrolled in the study at the time of giving the termination notice (it being understood that King shall continue to be liable beyond the end of such six (6)-month period for any non-cancelable costs associated with such clinical trials); (E) all rights and licenses granted herein to King with respect to the Terminated Product shall, for no additional consideration, immediately terminate; and (F) King shall, within ten (10) days after the termination date, provide and assign to PTI all clinical data, INDs, NDAs, Regulatory Approvals, Regulatory Filings, and all other documentation reasonably useful in respect of the Terminated Product in the Territory. Except as otherwise provided herein, all reasonable costs and expenses incurred with respect to the foregoing (except for noncancelable costs as described in clause (C) above) will be borne by King for a period of six (6) months after the effective date of termination, unless the Parties otherwise agree.

(ii) The Parties shall make payments due and payable for the Final Calendar Year with respect to the Terminated Product as required by Sections 6.3 and 6.4, as well as pay any other amounts due and owing on the date of termination.

(b) <u>Termination of the Agreement in its Entirety</u>. King may terminate this Agreement in its entirety upon six (6) months' prior written notice to PTI, which notice may be given (1) following the third anniversary of the Effective Date, or (2) in the event of Scientific Failure, with such termination to be effective at the end of such six (6)-month period. As used herein, "<u>Scientific Failure</u>" means a determination by the JOC that the Development Program is unlikely to be commercially viable, or is unlikely to generate any marketable Products, as determined in accordance with its business, legal, medical, and scientific judgment. In connection with a termination pursuant to this Section 9.2.2(b), the following shall apply:

(i) King shall execute and deliver to PTI such documents, material, data, records, analyses, and information and do such things as reasonably requested by PTI to the extent reasonably related to the Development and Marketing of all Products in the Territory, including the following, in each case only to the extent so related: (A) King shall use its commercially reasonable efforts to effect a reasonably smooth and orderly transition of any ongoing clinical studies, Regulatory Approval, or pre-marketing efforts to PTI (including all data and reports in the possession of King) with respect to the Products, including the assignment of any relevant Third Party contracts and Regulatory Filings and, unless otherwise requested by PTI, shall use commercially reasonable efforts to cancel all cancelable costs already incurred and mitigate all other costs incurred in connection with the Development Program for all Products; (B) King shall make its personnel and other resources reasonably available to PTI as reasonably necessary to effect a reasonably orderly transition of development responsibilities for such Products; (C) King shall pay all non-cancelable costs in connection with the Development Program for such Products; (D) King shall pay all costs of any of the ongoing clinical trials of such Products for a period of six (6) months from the effective date of termination, but only for such costs incurred for those patients already enrolled in the study at the time of giving the termination notice (it being understood that King shall continue to be liable beyond the end of such six (6)-month period for any non-cancelable costs associated with such clinical trials); (E) all rights and licenses granted herein to King with respect to the Products shall, for no additional consideration, immediately terminate; and (F) King shall, within ten (10) days after the termination date, provide and assign to PTI all clinical data, INDs, NDAs, Regulatory Approvals, Regulatory Filings, and all other documentation reasonably useful in respect of the Products in the Territory. All reasonable costs and expenses incurred with respect to the foregoing (except for non-cancelable costs as described in clause (C) above) will be borne by King for a period of six (6) months after the effective date of termination, unless the Parties otherwise agree. In addition, King shall continue to pay the labor costs of PTI personnel at the FTE Rate for the number of hours of service called for in the budget then in effect, whether or not such PTI employees are providing such services, for a period of six (6) months after the effective date of termination; provided that, if a budget is not in effect for a portion of such six (6)-month period, the labor costs for such unbudgeted period will be paid for the number of hours of service set forth in the final approved budget pro-rated to the length of such unbudgeted period. Notwithstanding the foregoing, King shall not be obligated to continue to pay such labor costs for such PTI personnel to the extent such PTI personnel are actually redeployed to other projects funded by a Third Party or are no longer employed by PTI.

(ii) The Parties shall make payments due and payable for the Final Calendar Year with respect to the Products as required by Sections 6.3 and 6.4, as well as pay any other amounts due and owing on the date of termination.

9.2.3 **Termination for Material Breach**. In the event that either Party breaches any material term of this Agreement that applies to it, the other Party shall have the right to terminate this Agreement by giving sixty (60) days' prior written notice to the breaching Party; provided, however, that in the case of a breach capable of being cured, if the breaching Party shall cure the breach within such notice period after notice shall have been given, then such notice shall not be effective. For purposes of this Section 9.2.3, (i) the failure to timely make any payment or fulfill any funding obligation under this Agreement that is not subject to a bona fide dispute and (ii) the commission of any act or the occurrence of any omission, in each case that constitutes a breach of any material term of this Agreement shall each constitute a material breach of this Agreement (but the list set forth in clauses (i) and (ii) shall not be deemed an exhaustive list of material breaches of this Agreement). In the event of a termination pursuant to this Section 9.2.3, the following shall apply (the "Termination Procedures"):

(a) In the event that PTI is the breaching Party, King shall execute and deliver to PTI such documents, material, data, records, analyses, and information and do such things as reasonably requested by PTI to the extent reasonably related to the Development and Marketing of the Products in the Territory, including the following, in each case to the extent so related: (i) King shall use its commercially reasonable efforts to effect a reasonably smooth and orderly transition of any ongoing clinical studies, Regulatory Approval, or pre-marketing efforts to PTI with respect to the Products (including all data and reports in the possession of King), including the assignment of any relevant Third Party contracts and Regulatory Filings and, unless otherwise requested by PTI, use commercially reasonable efforts to cancel all cancelable costs already incurred and mitigate all other costs incurred in connection with the Development Program; (ii) King shall make its personnel and other resources reasonably available to PTI as reasonably necessary to effect a reasonably orderly transition of development responsibilities for the Products; (iii) all rights and licenses granted herein to King with respect to the Products shall, for no additional consideration, immediately terminate; and (iv) King shall, within 10 days after the termination date, provide and assign to PTI all clinical data, INDs, NDAs, Regulatory Approvals, Regulatory Filings, and all other documentation reasonably useful in respect of the Products in the Territory. Except as otherwise provided herein, all reasonable costs and expenses incurred with respect to the foregoing will be borne by PTI, unless the Parties otherwise agree.

(b) In the event that King is the breaching Party, King shall execute and deliver to PTI such documents, material, data, records, analyses, and information and do such things as reasonably requested by PTI to the extent reasonably related to the Development and Marketing of the Products in the Territory, including the following, in each case to the extent so related: (i) King shall use its commercially reasonable efforts to effect a reasonably smooth and orderly transition of any ongoing clinical studies, Regulatory Approval, or pre-marketing efforts to PTI with respect to the Products (including all data and reports in the possession of King), including the assignment of any relevant Third Party contracts and Regulatory Filings and, unless otherwise requested by PTI, use commercially reasonable efforts to cancel all cancelable costs already incurred and mitigate all other costs incurred in connection with the Development Program; (ii) King shall make its personnel and other resources reasonably available to PTI as reasonably necessary to effect a reasonably orderly transition of development responsibilities for the Products; (iii) King shall pay all the costs for the completion of any of the ongoing clinical trials of Products, but only for such costs directly incurred for those patients already enrolled in the study at the time of giving the termination notice, as well as all other non-cancelable costs in connection with the Development Program for the Products; (iv) all rights and licenses granted herein to King with respect to the Products shall, for no additional consideration, immediately terminate; and (v) King shall, within 10 days after the termination date, provide and assign to PTI all clinical data, INDs, NDAs, Regulatory Approvals, Regulatory Filings, and all other documentation reasonably useful in respect of the Products in the Territory. Except as otherwise provided herein, all reasonable costs and expenses incurred with respect to the foregoing will be borne by King, unless the Parties otherwise agree. In addition, King shall continue to pay the labor costs of PTI personnel at the FTE Rate for the number of hours of service called for in the budget then in effect, whether or not such PTI employees are providing such services, for a period of six (6) months after the effective date of termination; provided that, if a budget is not in effect for a portion of such six (6)-month period, the labor costs for such unbudgeted period will be paid for the number of hours of service set forth in the final approved budget prorated to the length of such unbudgeted period. Notwithstanding the foregoing, King shall not be obligated to continue to pay such labor costs for such PTI personnel to the extent such PTI personnel are actually redeployed to other projects funded by a Third Party or are no longer employed by PTI.

(c) The Parties shall make payments due and payable for the Final Calendar Year as required by Sections 6.3 and 6.4, as well as pay any other amounts due and owing on the date of termination.

9.2.4 **Termination for Insolvency**. In the event that a Party (a) makes an assignment for the benefit of creditors, (b) appoints or suffers appointment of a receiver or trustee over its property, (c) is generally unable to pay its debts as they become due, (d) files a petition under, or invokes the protection of, any bankruptcy, insolvency, or similar laws, and consent is requested but not granted for an assignment of

the Agreement under Section 9.4.1(c) hereof, (e) has a petition or proceeding filed against it under any bankruptcy, insolvency, or similar laws, which is not dismissed within sixty (60) days, and consent is requested but not granted for an assignment of the Agreement under Section 9.4.1(c) hereof, or (f) suspends, closes, or otherwise ceases to operate a majority of its business relating to this Agreement and the License Agreement, then the other Party may terminate this Agreement effective immediately upon written notice to the first Party. In the event of a termination pursuant to this Section 9.2.4, the Termination Procedures shall apply, with the terminating Party treated as the non-breaching Party. Nothing in this Section 9.2.4 limits or affects any other rights, elections, or remedies that the terminating Party may have under the Bankruptcy Code, or other Applicable Law and all such rights, elections, and remedies are expressly reserved.

9.2.5 **Required Assignments**. If a Party is required by the terms of this Agreement to assign or transfer to the other Party any agreement, document, or right and such Party, after utilizing the level of efforts required hereunder, is unable to do so as the result of forces beyond its reasonable control, then the Party shall use its commercially reasonable efforts to make available to the other Party the material benefits of such agreement, document, or right in lieu of such assignment or transfer.

9.3 Surviving Provisions. Termination and expiration of this Agreement for any reason shall be without prejudice to:

(a) the following provisions, which shall survive termination or expiration of this Agreement for as long as necessary to permit their full discharge: Sections 5.1, 6.4.3, 8.1, 11.1, 11.2, 11.3, 11.5 and 11.6; Sections 9.2.2(b)(i) and 9.2.2(b)(ii) in the event of a termination by King pursuant to Section 9.2.2(b); Sections 9.2.3(b) and 9.2.3(c) in the event of a termination by PTI pursuant to Section 9.2.3, 9.2.4 or 9.4.3; Sections 9.2.3(a) and 9.2.3(c) in the event of a termination by King pursuant to Section 8.2; Articles 12 and 13; and the definitions set forth in Annex A; additionally, in the event of termination of this Agreement for any reason, King's reporting obligations under Section 4.2.1 with respect to adverse event information and product complaint information shall survive; provided that King shall provide such information directly to the PTI rather than to the JOC, and

(b) any other rights or remedies provided at law or equity that either Party may otherwise have against the other. Except as otherwise provided in this Section 9.3, all rights and obligations of the Parties under this Agreement shall terminate upon the expiration or termination of this Agreement; provided that it is expressly understood that nothing herein shall relieve any Party from liability from any breach of any covenant or agreement of such Party contained herein or any willful or intentional breach of any representation or warranty of such Party contained herein.

#### 9.4 Treatment Upon Bankruptcy.

#### 9.4.1 Assumption and Assignment of Agreement.

(a) Notwithstanding any other provision of this Agreement, the License Agreement, or any other related agreements, each Party hereby consents to the assumption of this Agreement by the other Party (the "Debtor Party") in any case commenced by or against the Debtor Party under the Bankruptcy Code to the extent that such consent is required under Section 365(c)(1) of the Bankruptcy Code, but only if the Debtor Party is otherwise entitled to assume this Agreement under the applicable requirements of the Bankruptcy Code. The sole purpose of the foregoing consent is to overcome any restriction potentially imposed by Section 365(c)(1) of the Bankruptcy Code on the Debtor Party's assumption of this Agreement in a bankruptcy case concerning the Debtor Party. It is not intended to limit any other rights of the other Party (the "<u>Non-Debtor Party</u>") under this Agreement or any provision of the Bankruptcy Code, including Section 365(c)(1). The foregoing consent applies only to the assumption of this Agreement by the Debtor Party and does not apply to the Debtor Party's assignment of this Agreement or any rights hereunder to a Third Party.

(b) Notwithstanding any other provision of this Agreement (including Sections 9.4.1(c) and 13.9), the License Agreement, or any other related agreements, the Non-Debtor Party hereby consents to the assignment of this Agreement by the Debtor Party to a Third Party solely in connection with a sale of all or substantially all of the Debtor Party's business or assets relating to this Agreement and the License Agreement to such Third Party, pursuant to an orderly sale process under Section 363 of the Bankruptcy Code or a confirmed plan

under Section 1129 of the Bankruptcy Code, that contemplates the continued operation of the purchased business or assets and, if PTI is the Debtor Party, the retention of the Existing Management Team, provided that such Third Party promptly agrees in writing to be bound by the terms and conditions of this Agreement and the Debtor Party is otherwise entitled to assign this Agreement under the applicable requirements of the Bankruptcy Code. The sole purpose of the foregoing consent is to overcome any restriction potentially imposed by Section 365(c)(1) of the Bankruptcy Code on the Debtor Party's assignment of this Agreement under the specific circumstances described in this Section 9.4.1(b). It is not intended to limit any other rights of the Non-Debtor Party under this Agreement or any provision of the Bankruptcy Code, including Section 365(c)(1), or to apply to the assignment of this Agreement in any other context.

(c) Notwithstanding any other provision of this Agreement (including Section 13.9), the License Agreement, or any other related agreements, but subject to Section 9.4.1(b) above, the Debtor Party may only assign this Agreement to a Third Party in any case commenced by or against it under the Bankruptcy Code with the prior written consent of the Non-Debtor Party.

9.4.2 Intellectual Property Rights. All rights related to and licenses of intellectual property granted under this Agreement and the License Agreement by one Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. In addition to any other rights, elections, and remedies under this Agreement, any related agreements, the Bankruptcy Code, or any other Applicable Law, upon a written request under Section 365(n) of the Bankruptcy Code, the Non-Debtor Party shall be entitled to complete access to any intellectual property of the Debtor Party pertaining to the rights granted in the licenses under the License Agreement, all embodiments of such intellectual property and all documents, material, data, records, analyses, and information related thereto (including all clinical data, INDs, NDAs, Regulatory Approvals, Regulatory Filings, and all other documentation reasonably useful in respect of Product in the Territory in the Field). This Agreement and any other related agreements (to the extent such agreements do not constitute licenses of intellectual property under the Bankruptcy Code) shall be considered agreements supplementary (as such term is used in Section 365(n) of the Bankruptcy Code) to the License Agreement and any other intellectual property licenses between the Parties.

9.4.3 **Rejection in Bankruptcy**. Any rejection of this Agreement by the Debtor Party pursuant to Section 365 of the Bankruptcy Code shall constitute a material breach of this Agreement not subject to notice or cure. Upon any such rejection, (a) all rights, elections, and remedies of the Non-Debtor Party to this Agreement (including under Section 365 of the Bankruptcy Code) are expressly reserved, and (b) in the event that this Agreement is deemed terminated upon or subsequent to such rejection, the Termination Procedures shall apply, with the Non-Debtor Party treated as the non-breaching Party. Further, upon any such rejection, the Parties intend and agree that the Non-Debtor Party may elect to retain its rights under this Agreement pursuant to Section 365(n) of the Bankruptcy Code and that such election shall, among other things, entitle the Non-Debtor Party to invoke and exercise all of its rights to any intellectual property under this Agreement, the License Agreement, and any other related agreements.

9.5 **Damages; Relief**. Termination of this Agreement shall not preclude any Party from claiming any other damages, compensation, or legal or equitable relief that it may be entitled to upon such termination.

9.6 <u>**Tax Treatment</u>**. The Parties intend that, for United States federal income tax purposes and all other applicable state, local, and foreign income or franchise taxes as may be permitted by law, the Collaboration shall be treated as a cost sharing arrangement between the Parties and shall not be treated as a partnership. The Parties agree that, to the extent permitted by law, they will report their participation in the Collaboration in accordance with the foregoing.</u>

#### 10. REPRESENTATIONS AND WARRANTIES

10.1 **<u>By Each Party</u>**. PTI and King each represents and warrants to the other as of the Effective Date as follows:

(a) <u>Organization</u>. It is a corporation duly organized, validly existing and is in good standing under the laws of the jurisdiction of its organization, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the performance of its obligations hereunder requires such qualification, and, except as would not have a material adverse effect on the ability of the Party to perform its obligations hereunder, has all requisite power and authority, corporate or otherwise, to conduct its business as now being conducted, to own, lease, and operate its properties and to execute, deliver, and perform this Agreement.

(b) <u>Authorization and Right to Grant Licenses</u>. The execution, delivery, and performance by it of this Agreement have been duly authorized by all necessary corporate action and do not and will not (i) require any consent or approval of its stockholders or (ii) violate any provision of any agreement, law, rule, regulation, order, writ, judgment, injunction, decree, determination, or award presently in effect having applicability to it or any provision of its charter documents. Each Party has the right, power, and authority to grant licenses granted by it hereunder.

(c) <u>Binding Agreement</u>. This Agreement is a legal, valid, and binding obligation of it, enforceable against it in accordance with its terms and conditions, except as enforceability may be limited by bankruptcy, insolvency, or other laws affecting the enforcement of creditors' rights generally, and except that the availability of the remedy of specific performance or other equitable relief is subject to the discretion of the court before which any proceeding therefor may be brought.

(d) <u>No Inconsistent Obligation</u>. It is not under any obligation to any person or entity, contractual or otherwise, that is conflicting or inconsistent in any respect with the terms of this Agreement, and it has all power and authority under all instruments or agreements to which it is a Party to enter into this Agreement and to perform its obligations hereunder.

(e) <u>Absence of Actions</u>. To its Knowledge, it is not a party to or object of any litigation, suit, legal claim, action, proceeding, judgment, settlement, or investigation (an "<u>Action</u>") pending or threatened against it, or any of its Affiliates, or any of its properties or assets, before any governmental authority or Regulatory Authority that might reasonably be expected to have a material adverse effect on its ability to diligently and completely fulfill its obligations hereunder. A material breach of or inaccuracy in this Section 10.1(e) with respect to a Party shall constitute a material breach of this Agreement by such Party pursuant to Section 9.2.3.

(f) <u>Applicable Law</u>. It has complied with and shall continue to comply with and shall perform all its duties and obligations hereunder in accordance with all Applicable Law.

(g) <u>Debarment</u>. As of the date hereof, neither it nor any of its respective employees or agents, in their capacity as such, have been disqualified or debarred by the FDA, pursuant to 21 U.S.C. § 335(a) or (b), or been charged with or convicted under any Applicable Law of the United States for conduct relating to the development or approval, or otherwise relating to the regulation of any Product under the Generic Drug Enforcement Act of 1992, or any other relevant law, rule, or regulation or been disbarred, disqualified, or convicted under or for any equivalent or similar applicable foreign law, rule, or regulation.

10.2 **<u>By PTI</u>**. PTI further represents and warrants to King as of the Effective Date as follows:

(a) <u>Clinical Trials</u>. All pre-clinical and clinical work, studies, and trials conducted, supervised, or monitored by PTI with respect to any Designated Product and that are intended to be used to support Regulatory Approval, have, to the Knowledge of PTI, been conducted and performed in substantial compliance with Applicable Laws, including Good Laboratory Practice, Good Clinical Practice, and Good Manufacturing Practice requirements and ICH Guidelines. PTI has, or, as applicable, any Third Parties with whom PTI has contracted to perform any clinical trials or modifications thereto with respect to any Designated Product has, to the Knowledge of PTI, obtained and maintained any necessary IRB approvals of clinical trials or modifications thereto sponsored by PTI. To the Knowledge of PTI, in no clinical trial sponsored, conducted, supervised, or monitored by PTI with respect to any Designated Product has any IRB, ethics committee, or European competent authority approval ever been suspended, terminated, put on clinical hold, or voluntarily withdrawn.

(b) <u>Disclosure</u>. To PTI's Knowledge, no employees or agents of PTI have made an untrue statement of material fact on behalf of PTI to any Regulatory Authority with respect to any product in the Field or failed to disclose a material fact required to be disclosed to any Regulatory Authority with respect to any product in the Field that at the time such disclosure was made, could reasonably be expected to (i) provide a basis for the FDA or any other Regulatory Authority to invoke its policy respecting Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities, set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy or (ii) otherwise materially adversely affect the prospect of, or materially delay the obtaining of, Regulatory Approval for such product.

(c) Intellectual Property. To the actual knowledge of Remi Barbier, Nadav Friedmann, Michael Zamloot, Grant Schoenhard, and Peter Roddy, the manufacture, use, offer for sale, sale, or importation of the Designated Products (provided that King acknowledges PTI has not conducted any patent search with regard to hydrocodone), in each case as such Designated Product is specifically formulated, will not infringe or misappropriate the intellectual property rights of any Third Party as of the Effective Date, specifically excluding from such representation and warranty the patents that have been identified by patent number to King prior to the Effective Date (it being acknowledged by King that PTI has not conducted, among other things, a comprehensive analysis of the other family members of the patent families to which such identified patents belong); provided, however, that with regard to infringement or misappropriation of the intellectual property rights of a Third Party arising from the utilization of the Saber Technology with regard to any such Designated Product (the "<u>Saber Infringement</u>"), King acknowledges and agrees that the foregoing representation by PTI with respect to the Saber Infringement is based solely on the representation and warranty received by PTI from Durect with regard to the infringement of Third Party intellectual property rights pursuant to the DLA, and PTI shall have no liability to King with regard to any Saber Infringement beyond the amount of damages or any other remedy that PTI shall receive from Durect as a result of such breach.

(d) <u>No Omissions</u>. No representation or warranty of PTI contained in this Agreement or the License Agreement, and no written information previously provided by PTI to King in connection with the transactions contemplated hereby, including any representation, warranty, or information relating to any pre-clinical, clinical, manufacturing, or regulatory issues concerning any Designated Product, contains any untrue statement of a Material Fact or omits to state a Material Fact actually known to PTI and which would be necessary in order to make the statements contained herein or therein not misleading in light of the circumstances under which they were made. For purposes of this representation and warranty, King shall be deemed to be on notice and to have received disclosures of the following information: (i) with respect to PTI, information publicly available through PTI's filings with the Securities and Exchange Commission and the publications listed on Schedule 10.2(d)(i) attached hereto, and, (ii) with respect to Durect, information publicly available through Durect's filings with the Securities and Exchange Commission and the publications listed on Schedule 10.2(d)(ii) attached hereto, Schedule 10.2(d)(ii) attached hereto as well as any peer-reviewed publications in English generally available to the public regarding the subject matter of this Agreement (including Remoxy and the SABER Technology) and written by the individuals set forth on Schedule 10.2(d)(ii). As used in this Section 10.2(d), a "Material Fact" means a fact that would have a materially adverse effect on the commercial prospects for products in the Field in the Territory taken as a whole.

#### 11. **INDEMNIFICATION**

11.1 <u>Indemnification of King by PTI</u>. PTI shall indemnify, defend, and hold harmless King, its Affiliates, and their respective directors, officers, employees, and agents (the "<u>King Indemnitees</u>"), against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses of litigation) (collectively, "<u>Losses</u>") incurred by or imposed upon the King Indemnitees, or any one of them, as a result of claims, causes of action, suits, actions, demands, or judgments made against such King Indemnitees by Third Parties, including claims for personal injury and claims of suppliers and PTI employees (except in cases where such claims, suits, actions, demands, or judgments result from a material breach by King of its representations or warranties under this Agreement, gross negligence, or willful misconduct on the part of King), in each case to the extent arising out of (a) the breach of any representation or warranty of PTI under Article 10hereof, (b) the gross negligence or willful misconduct of PTI, its Affiliates, or their respective employees or agents in the performance of any obligation under this Agreement, and (c) any government funding received by PTI prior to the Effective Date in connection with the research or development of any Products or any subject matter disclosed in any PTI Patent Rights, including

pursuant to any grants from the National Institutes of Health, and the failure of PTI to comply in all material respects with the terms and conditions of such funding agreements and grants, and with all Applicable Laws with respect thereto, including to obtain any necessary permits or waivers thereunder. For purposes of clarity, it is understood and agreed that, except as provided in this Section 11.1 or in Section 9.1 of the License Agreement, PTI provides no indemnification to King with respect to product liabilities claims relating to Products.

11.2 Indemnification of PTI by King. King shall indemnify, defend, and hold harmless PTI, its Affiliates, and their respective directors, officers, employees, and agents (the "<u>PTI Indemnitees</u>"), against any Losses incurred by or imposed upon the PTI Indemnitees, or any one of them, as a result of claims, causes of action, suits, actions, demands, or judgments made against such PTI Indemnitees by Third Parties, including personal injury and claims of suppliers and King employees (except in cases where such claims, suits, actions, demands, or judgments result from a material breach by PTI of its representations or warranties under this Agreement, gross negligence, or willful misconduct on the part of PTI), in each case to the extent arising out of (a) the breach of any representation or warranty of King under Article 10hereof and (b) the gross negligence or willful misconduct of King, its Affiliates, or their respective employees or agents in the performance of any obligation under this Agreement. For purposes of clarity, it is understood and agreed that, except as provided in this Section 11.2 or in Section 9.2 of the License Agreement, King provides no indemnification to PTI with respect to product liabilities claims relating to Products.

11.3 **Conditions to Indemnification**. A Party seeking indemnification under this Article 11 (the "<u>Indemnified Party</u>") shall give prompt notice of the claim to the other Party (the "<u>Indemnifying Party</u>") and, provided that the Indemnifying Party is not contesting the indemnity obligation, shall permit the Indemnifying Party to control any litigation relating to such claim and disposition of any such claim. The Indemnifying Party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of any claim as the settlementor disposition relates to Parties being indemnified under this Article 11. The Indemnifying Party shall not settle or otherwise resolve any claim without prior notice to the Indemnified Party and the consent of the Indemnifying Party. The Indemnified Party shall reasonably cooperate with the Indemnifying Party in its defense of any claim for which indemnification is sought under this Article 11and shall have the right to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification. For purposes of clarity, it is understood that in the event that a claim is eligible for indemnification under both this Article 11 and under Article 9 of the License Agreement, the Indemnified Party shall be entitled to seek indemnification for such claim under either this Agreement or the License Agreement, but not both.

11.4 **Insurance**. In addition to the insurance coverages required by Section 5.1 hereof, each Party shall obtain other insurance coverage from first class insurers in types and amounts commensurate with industry standards for such Party's activities hereunder.

11.5 <u>Warranty Disclaimer</u>. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT OR THE LICENSE AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS, OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, NEITHER PARTY MAKES ANY GUARANTEES TO THE OTHER CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE ACTIVITIES CONTEMPLATED UNDER THIS AGREEMENT.

11.6 Limited Liability. EXCEPT WITH RESPECT TO A BREACH OF THE OBLIGATIONS IN ARTICLE 8 OR WITH RESPECT TO AMOUNTS PAID TO THIRD PARTIES UNDER THE INDEMNIFICATION OBLIGATIONS OF THIS ARTICLE 11, NEITHER PTI NOR KING WILL BE LIABLE WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY, OR OTHER LEGAL OR EQUITABLE THEORY FOR (I) ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES OR (II) COST OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY, OR SERVICES.

#### 12. **<u>REMEDIES</u>**

Subject to the terms of this Agreement, the Parties are not excluded from exercising or seeking any and all rights and remedies available, in law or in equity, under Applicable Law.

#### 13. MISCELLANEOUS

13.1 <u>Notices</u>. All notices or other communications that shall or may be given pursuant to this Agreement shall be in writing and shall be deemed to be effective (a) simultaneously with the transmission or delivery thereof, if sent by facsimile transmission (followed by hard copy by mail), (b) when delivered, if sent by United States registered or certified mail, return receipt requested, or (c) on the next business day, if sent by overnight courier, in each case to the Parties at the following addresses (or at such other addresses as shall be specified by like notice) with postage or delivery charges prepaid:

If to King:	If to PTI:
King Pharmaceuticals, Inc.	Pain Therapeutics, Inc.
501 Fifth Street	416 Browning Way
Bristol, Tennessee 37620	South San Francisco, California 94080
Tel.: (423) 989-8000	Tel.: (650) 825-3342
Fax: (423) 990-2566	Fax: (650) 624-8222
Attention: General Counsel	Attention: President & CEO
With a copy to:	With a copy to:
King Pharmaceuticals, Inc.	Wilson Sonsini Goodrich &Rosati
501 Fifth Street	650 Page Mill Road
Bristol, Tennessee 37620	Palo Alto, California 94304-1050
Tel.: (423) 989-8000	Tel.: (650) 493-9300
Fax: (423) 274-2602	Fax: (650) 493-6811
Attention: Business Development	Attention: Michael O'Donnell

13.2 **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the application of principles of conflicts of law.

13.3 **<u>Binding Effect</u>**. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors, and permitted assigns.

13.4 Counterparts. This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original.

13.5 **Amendment; Waiver**. This Agreement may be amended, modified, superseded, or canceled, and any of the terms may be waived, only by a written instrument executed by each Party or, in the case of waiver, by the Party or Parties waiving compliance. The delay or failure of any Party at any time or times to require performance of any provisions shall in no manner affect the rights at a later time to enforce the same. No waiver by any Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

13.6 No Third Party Beneficiaries. No Third Party, including any employee of any Party to this Agreement, shall have or acquire any rights by reason of this Agreement.

13.7 **Purposes and Scope**. The Parties hereto understand and agree that this Development Program is limited solely to the Field in the Territory, and to the activities, rights, and obligations as set forth in this Agreement. Nothing in this Agreement shall be construed (a) to create or imply a general partnership between the Parties, (b) to make either Party the agent of the other for any purpose, (c) to alter, amend, supersede, or vitiate any other arrangements between the Parties with respect to any subject matters not covered hereunder, (d) to give either Party the right to bind the other, (e) to create any duties or obligations between the Parties except as expressly set forth herein, or (f) to grant any direct or implied licenses or any other right other than as expressly set forth herein.

13.8 <u>Performance by Affiliates</u>. Each Party shall have the right to direct its wholly-owned Affiliates to act in satisfaction of such Party's or Affiliate's obligations hereunder or make an assignment to an Affiliate in accordance with Section 13.9; provided that such Party shall remain liable and fully responsible for the performance of such Affiliate hereunder.

13.9 <u>Assignment and Successors</u>. Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the consent of the other, except that, subject to Section 9.4.1, each Party may assign this Agreement and the rights, obligations, and interests of such Party, in whole or in part, to any of its Affiliates (subject to Section 13.8) or to any Third Party that succeeds to all or substantially all of a Party's business or assets relating to this Agreement and the License Agreement, whether by sale, merger, operation of law, or otherwise; provided that such assignee or transferee promptly agrees in writing to be bound by the terms and conditions of this Agreement. Any attempted assignment in violation of this Section 13.9 shall be null, void, and of no effect. This Agreement shall be binding upon and inure to the benefit of all permitted successors-in-interest and assigns.

13.10 **Force Majeure**. In the event of the occurrence of a Force Majeure Event, the Parties shall not be deemed in breach of their obligations to the extent of the Force Majeure Event. The Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

#### 13.11 Interpretation.

(a) The Parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

(b) The headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement. Whenever the words "include," "includes," or "including" are used in this Agreement, they will be deemed to be followed by the words "without limitation." Unless the context otherwise requires, (i) "or" is disjunctive but not necessarily exclusive, (ii) words in the singular include the plural and vice versa, and (iii) the use in this Agreement of a pronoun in reference to a Party hereto includes the masculine, feminine, or neuter, as the context may require. The Annex, Schedules, and Exhibits hereto will be deemed part of this Agreement and included in any reference to this Agreement.

13.12 **Integration**; **Severability**. This Agreement and the License Agreement, when executed, are the sole agreements with respect to the subject matter hereof and supersede all other agreements and understandings between the Parties with respect to same. If any provision of this Agreement (including the temporal and substantive scope of the restrictions set forth in Article 7) is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, such provision or portion thereof will be modified or deleted in such a manner so as to make this Agreement, as modified, legal and enforceable to the fullest extent permitted under Applicable Law, and it is the intention of the Parties that the remainder of the Agreement shall not be affected.

13.13 <u>Further Assurances</u>. Each of PTI and King agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such additional assignments, agreements, documents, and instruments, that may be necessary or as the other Party hereto may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

#### [Remainder of page intentionally left blank]

30

**IN WITNESS WHEREOF**, the Parties have caused this Collaboration Agreement to be executed by their duly authorized representatives as of the Effective Date.

# PAIN THERAPEUTICS, INC.

By: /s/ Remi Barbier

Name: Remi Barbier Title: President & CEO

# KING PHARMACEUTICALS, INC.

By: /s/ Brian A. Markison

Name: Brian A. Markison Title: President and Chief Executive Officer

## ANNEX A

#### **DEFINITIONS TO COLLABORATION AGREEMENT**

1 "AAA" has the meaning set forth in Section 2.3.3 of this Agreement.

2 "Action" has the meaning set forth in Section 10.1(e) of this Agreement.

3 "<u>Affiliate</u>" means any corporation, firm, partnership, or other entity that directly or indirectly controls or is controlled by or is under common control with a Party to this Agreement. For purposes of this definition, "control" means ownership, directly or through one or more Affiliates, of (a) 50% or more of the shares or voting rights in the case of a corporation or limited company, (b) 50% or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, (c) 50% or more of the equity or controlling interests in the case of any other type of legal entity (including joint ventures) or status as a general partner in any partnership, or (d) any other arrangement whereby a Party controls or has the right to control the Board of Directors or equivalent governing body of an entity.

4 "<u>Agreement</u>" means this Collaboration Agreement, including all attached exhibits, schedules and annexes, as well as all amendments, supplements, and restatements thereof.

5 "API" means, with respect to a Product, the active pharmaceutical ingredient used in the Product.

6 "<u>Applicable Law</u>" means applicable U.S. and foreign laws, rules, regulations, guidelines, and standards, including those of the FDA and comparable foreign Regulatory Authorities.

7 "Bankruptcy Code," means the U.S. Bankruptcy Code, 11 U.S.C. §§ 101 et seq.

8 "<u>Calendar Quarter</u>" means, with respect to the first such Calendar Quarter, the period beginning on the Closing Date and ending on the last day of the calendar quarter within which the Closing Date falls and, thereafter, each successive period of three consecutive calendar months ending on March 31, June 30, September 30, or December 31. In the event that the termination of this Agreement does not fall on the last day of a Calendar Quarter, the "<u>Final Calendar Quarter</u>" shall mean the period from the last day of the most recent Calendar Quarter through the applicable date of termination of this Agreement.

9 "<u>Calendar Year</u>" means each successive twelve (12)-month period commencing on January 1 and ending on December 31; provided that the first such Calendar Year shall begin on the Closing Date and end on December 31, 2005. In the event that the termination of this Agreement does not fall on the last day of a Calendar Year, the "<u>Final Calendar Year</u>" shall mean the period from the last day of the most recent Calendar Year through the applicable date of termination of this Agreement.

10 "Claims" has the meaning set forth in Section 5.1 of this Agreement.

11 "<u>Closing</u>" shall mean, subject to the satisfaction or waiver of the conditions set forth in Section 6.1.3 of this Agreement, the closing of the transactions contemplated by this Agreement.

12 "<u>Closing Date</u>" shall mean the earlier of: (a) the third day, unless the first day falls on a weekend or holiday, in which case it shall be the next business day, after the expiration or termination of all applicable waiting periods under the HSR Act and the satisfaction of all the other conditions set forth in Section 6.1.3 of this Agreement or (b) the third day, unless the first day falls on a weekend or holiday, in which case it shall be the next business day, after the joint determination (by certification from each Party to the other) that notification under the HSR Act is not required and the satisfaction of all the other conditions set forth in Section 6.1.3 of this Agreement.

13 "CMC" means, with respect to a Product, the chemistry, manufacturing, and controls information that would typically be, or is, included in an IND or NDA for such Product.

14 "Co-Chairman" has the meaning set forth in Section 2.1 of this Agreement.

15 "<u>Collaboration</u>" means the association of PTI and King established pursuant to this Agreement for the purpose of conducting the Development of Products so as to accomplish the Development objectives of the Development Program.

16 "<u>Collaboration Costs</u>" means the sum of each of the following costs incurred by or on behalf of a Party in fulfilling its responsibilities under the Development Program in accordance with the Program Plans for such Product, which costs must be documented and supported, calculated in accordance with Sections 3.3.2 and 3.7 of this Agreement, and included in the budget of a Program Plan or otherwise approved by King:

16.1 all out-of-pocket costs, including amounts paid to Durect for materials and services PTI is obligated to obtain from Durect under the DLA and any capital expenses for equipment purchased for purposes of fulfilling PTI's obligations under the Agreement (provided that the cumulative costs for such capital equipment shall not exceed two million U.S. dollars (\$2,000,000) and provided further that King shall have title to any such capital equipment which it funds);

16.2 all internal labor costs incurred by a Party in connection with its research employees dedicated to providing services relating to a Product, such costs to be calculated by multiplying the Hourly FTE Rate by the total number of hours expended by such Party's personnel in performance of such services; provided that no time of PTI's Chief Executive Officer, Chief Financial Officer, or any administrative personnel of PTI will be billed to the Collaboration; and

16.3 any other costs expressly provided for in this Agreement or a Project Plan.

Except to the extent this Agreement expressly provides for payments that do not require such approval, and except to the extent King has approved any payment hereunder, neither Party shall (i) be obligated to incur any costs or expend any funds that have not been approved by such Party or (ii) have the authority to cause the other Party to incur any costs or expend any funds that have not been approved by such other Party. Notwithstanding anything to the contrary contained herein, Collaboration Costs shall not include (A) except to the extent included in the FTE Rate, indirect costs, overhead, general, and administrative costs and other similar costs of a Party, or (B) any costs that relate to the business of a Party as a whole without specifically relating to a Product. In calculating the Collaboration Costs, the following principles shall apply: (1) there shall be no double counting of any costs or expenses or of any revenues; (2) when allocating costs and expenses under this Agreement, each Party shall utilize the same policies and principles as it utilizes consistently within its group and business units when making internal cost allocations; and (3) all costs and expenses shall be determined, and all calculations shall be made, in accordance with GAAP.

17 "<u>Completion of Phase II</u>" means completion of the final statistical results of clinical trials that collectively evaluate the safety and efficacy of a Product's specific dosage strength in an indication the Product is intended to treat, which data enables the Parties to proceed with pivotal registration Phase III studies, without any objection from the FDA, as documented by FDA contact reports. For the avoidance of doubt, the "Completion of Phase II" for each Product in the Collaboration shall be independent events.

18 "<u>Confidential Information</u>" means all information, Technology, and Proprietary Materials that are disclosed to a Party (the "<u>Receiving Party</u>") by or on behalf of the other Party (the "<u>Disclosing Party</u>") hereunder or under the License Agreement or disclosed to any of the Receiving Party's employees, Consultants, Affiliates, or Sublicensees, except to the extent that any such information (a) as of the date of disclosure is known to the Receiving Party or its Affiliates, as demonstrated by credible written documentation; (b) as of the date of disclosure is in, or subsequently enters, the public domain, through no fault or omission of the Receiving Party; (c) is obtained from a Third Party having a lawful right to make such disclosure free from any obligation of confidentiality to the Disclosing Party; or (d) is independently developed by or for the Receiving Party without reference to or reliance upon any Confidential Information of the Disclosing Party as demonstrated by credible written documentation. It is further agreed that PTI Technology shall be deemed the Confidential Information of PTI, King Technology shall be deemed the Confidential Information of King, and Joint Technology shall be deemed the Confidential Information of both Parties. During the Term hereof, neither Party shall discloseany of its own Confidential Information in such

- 2 -

a manner that would reasonably be expected to adversely impact any intellectual property rights or commercial interests of the Development Program or the Products, unless such disclosure is subject to confidentiality obligations as strict as those contained in this Agreement or the License Agreement.

19 "<u>Consultant</u>" means a Third Party who has entered into or hereafter enters into a written agreement with PTI or King or both to provide consulting services that are material or are reasonably likely, in the judgment of the JOC, to become material to the Development Program, which written agreement shall (a) include an assignment of all right, title, and interest in and to all work product and all inventions arising from the performance of such agreement, and all intellectual property rights attaching thereto, to PTI or King, as applicable, and (b) bind the relevant Third Party by obligations of confidentiality and non-use with respect to all such work product, inventions, Confidential Information, and intellectual property rights that are at least as stringent as those set forth herein.

20 "<u>Consultation</u>" means providing a Party with an opportunity to review and comment on the development of strategies and the implementation of Program Plans, permitting a Party to participate in, where practical, either by telephone or in person, and to examine formal minutes of, all meetings and telephone calls with respect to a matter under consideration, keeping a Party informed regarding the progress of all matters, and giving due consideration to the input and comments of a Party with respect to the matters under consideration.

21 "<u>Control</u>" or "<u>Controlled</u>" means, (a) with respect to Technology (other than Proprietary Materials) or Patent Rights, the possession by a Party of the ability to grant a license or sublicense of such Technology or Patent Rights as provided herein without the payment of additional consideration (other than any additional consideration to be paid pursuant to the DLA) and without violating the terms of any agreement or arrangement between such Party and any Third Party and, (b) with respect to Proprietary Materials, the possession by a Party of the ability to supply such Proprietary Materials to the other Party as provided herein without the payment of additional consideration and without violating the terms of any agreement or arrangement between such Party and any Third Party.

22 "<u>Crain/Shen Drug</u>" means any dosage form that is covered by any patent or patent application set forth on Schedule 22 hereto (the "Existing Patents"), as well as any continuations, divisionals, continuations-in-part (to the extent any claims thereof are entitled to claim priority to the filing date of any of the Existing Patents), patents of addition, and substitutions of the Existing Patents, together with all registrations, reissues, reexaminations or extensions of any kind with respect to any of the foregoing patents, in each case to the extent same are owned or controlled by PTI. In the event PTI reasonably believes that any claims of a continuation-in-part application of any of the Existing Patents, which claims are not entitled to claim priority to the filings date of any of the Existing Patents, cover only an incremental improvement to the subject matter described and claimed in the Existing Patents, PTI shall have the right to request that King permit such additional claims to be included within the definition of Crain/Shen Drugs, and King shall consider such request in good faith. Notwithstanding the foregoing, with respect to United States Application Serial Nos. 10/119,615 and 10/742,672, and any applications or patents that claim priority to either of same, to the extent that any claims cover a dosage form of an opioid agonist alone or a method or process of using or making such a dosage form, such claims shall not be within the definition of Crain/Shen Drug, but shall be considered PTI Technology and PTI Patent Rights (and such applications and issued patents will be included on the schedule of PTI Patent Rights solely to such extent).

23 "<u>Crain/Shen SABER Drug</u>" means any dosage form of a Crain/Shen Drug that (a) contains oxycodone, hydromorphone, oxymorphone or hydrocodone as the only opioid agonist API and (b) is covered by the rights granted to PTI under the DLA.

24 "<u>CTM</u>" or "<u>Clinical Trial Materials</u>" means any Product manufactured, packaged, and labeled as required by Applicable Law to be used as an investigational drug or placebo for use in the conduct of clinical trials in humans.

25 "Debtor Party" has the meaning set forth in Section 9.4.1(a) of this Agreement.

26 "Default" means (a) a material breach, default, or violation, (b) for purposes of Section 5.3 of this Agreement only, the occurrence of an event that with or without the passage of time or the giving of notice, or both,

- 3 -

would constitute a material breach, default, or violation or cause any material mortgages, liens, security interests, charges, covenants, options, claims, restrictions, and encumbrances of any kind to arise, or (c) for purposes of Section 3.8 of this Agreement only, the occurrence of an event that with or without the passage of time or the giving of notice, or both, would give rise to a right of termination, renegotiation, or acceleration or a material right to receive damages or a payment of material monies or penalties of or under such contract by a party other than a Party.

27 "Defaulting Party" has the meaning set forth in Section 3.8 of this Agreement.

28 "<u>Designated Product</u>" means a Product being developed by PTI as of the Effective Date (*i.e.*, the first three (3) products specified in Section 3.1.1 of this Agreement, namely one (1) Product having oxycodone as the opioid API (Remoxy), one (1) Product having hydromorphone as the opioid API, and one (1) Product having hydrocodone as the opioid API); and "<u>Designated Products</u>" means, collectively, all of the foregoing Products.

29 "**Development**" or "**Develop**" means, with respect to a Product, all research, pre-clinical, pharmaceutical, clinical, and regulatory activities and all other activities undertaken in order to obtain Regulatory Approval of such Product in accordance with this Agreement prior to Regulatory Approval of such Product. These activities shall include, among other things: test method development, CMC methods and reports (including formulation, process development, development-stage manufacturing, manufacturing scale-up, technical transfer, quality assurance, and quality control), pre-clinical pharmacology and toxicology studies and associated reports, planning and conduct of clinical studies, protocols, clinical study reports, statistical analysis plans, and clinical quality assurance prior to obtaining Regulatory Approvals, obtaining Regulatory Approvals, and regulatory affairs related to the foregoing.

30 "Development Plans" means the written plans (which shall include detailed strategy, budget, and proposed timelines) describing the pre-clinical and clinical Development activities and the regulatory activities, including a general overview of the expected schedule of meetings, discussions, and correspondence with Regulatory Authorities to be carried out for each Product during each Calendar Year pursuant to this Agreement, which plans shall include the expected Regulatory Filings to be completed and maintained by the Collaboration for each Product. The Development Plans will be amended from time to time to include statistical analysis plans, protocols, case report forms, clinical study reports, audit reports, and similar matters, as such matters are developed during the Collaboration. Without limiting the foregoing, such plans shall include, at a minimum, the activities required to remain in compliance with the terms and obligations applicable to PTI under the DLA. Each Development Plan will be set forth in a written document prepared by the Parties pursuant to Section 3.4 of this Agreement, and a separate Development Plan will be generated and approved with respect to each Product.

31 "Development Program" means, collectively, (a) the collaborative development program in the Field conducted by PTI and King and (b) the marketing program in the Field conducted by King, in each case, commencing on the date hereof and conducted pursuant to this Agreement and the Program Plans.

32 "Discretionary Funding" has the meaning set forth in Section 3.7.3 of this Agreement.

33 "<u>Durect License Agreement</u>" or "<u>DLA</u>" means the Development and License Agreement, dated as of December 19, 2002, by and among PTI, DURECT Corporation ("<u>Durect</u>"), and Southern BioSystems, Inc., a copy of which has been provided to King, as it may be amended from time to time hereafter in accordance with Section 2.4 of the License Agreement.

34 "Effective Date" has the meaning set forth in the first paragraph of this Agreement.

35 "Existing Management Team" means not less than fifty percent (50%) of the individuals who, as of the date that is one year prior to the commencement of any case by or against PTI under the Bankruptcy Code, are designated as "Officers" of PTI under Rule 16a-1(f) promulgated pursuant to the Securities Exchange Act of 1934, as amended.

36 "FDA" means the United States Food and Drug Administration or any successor agency.

- 4 -

37 "Field" means pharmaceutical formulations for use in humans that contain no more than one opioid API formulated using the SABER Technology, in accordance with the DLA.

38 "<u>First Commercial Sale</u>" means, with respect to any product, the first arm's-length sale by King, its Affiliates, or Sublicensees to a Third Party for enduse or consumption, including any sale to a wholesaler or distributor, of such product in a country after the applicable Regulatory Authority has granted Regulatory Approval. For purposes of this definition, any sale to an Affiliate or Sublicensee will not constitute a First Commercial Sale.

39 "Force Majeure Event" means an event beyond the reasonable control of a Party that prevents the performance, in whole or in part, by the Party of any of its obligations hereunder, including by reason of any act of God, flood or other inclement weather patterns, fire, explosion, earthquake, or war, terrorist act, revolution, civil commotion, acts of public enemies, blockage or embargo, or the like, or any injunction, law, order, ordinance, or requirement of any government or of any subdivision, authority, or representative of any such government, if, and only if, the Party affected shall have used commercially reasonable efforts to avoid the effects of such occurrence and to remedy it promptly if it has occurred.

40 "FTE Rate" means a rate of two hundred fifty thousand U.S. dollars (\$250,000) per 1,635 hours of work performed by personnel during Calendar Years 2005 and 2006, said rate to be increased as of January 1, 2007, and annually thereafter to reflect actual increases in the applicable Party's expenses.

41 "GAAP" means United States generally accepted accounting principles of the Party performing the applicable work, consistently applied.

42 "<u>Good Clinical Practices</u>" means the international ethical and scientific quality standards for designing, conducting, recording, and reporting trials that involve the participation of human subjects. In the U.S. Territory, Good Clinical Practices are established through FDA guidances (including ICH E6).

43 "<u>Good Laboratory Practices</u>" means the minimum standards for conducting non-clinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the FDA or equivalent foreign Regulatory Authority, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. In the U.S. Territory, Good Laboratory Practices are established through FDA regulations (including 21 CFR Part 58), FDA guidances, FDA current review and inspection standards, and current industry standards.

44 "<u>Good Manufacturing Practices</u>" means the minimum standards for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the Federal Food, Drug and Cosmetic Act of 1938, or its foreign equivalent, as amended, as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess. In the U.S. Territory, Good Manufacturing Practices are established through FDA regulations (including 21 CFR Parts 210-211), FDA guidances, FDA current review and inspection standards, and current industry standards.

45 "Hourly FTE Rate" means the hourly rate obtained by dividing the FTE Rate by 1,635 hours.

46 "HSR Act" means the Hart-Scott-Rodino Act of 1976, as amended.

47 "IND" means (a) an Investigational New Drug Application (as defined in 21 CFR § 312.3) that is required to be filed with the FDA before beginning clinical testing of a Product in human subjects, or any successor application or procedure, or (b) any counterpart of a U.S. Investigational New Drug Application that is required in any other country or region in the Territory before beginning clinical testing of a Product in human subjects in such country or region.

48 "Indemnified Party" has the meaning set forth in Section 11.3 of this Agreement.

49 "Indemnifying Party" has the meaning set forth in Section 11.3 of this Agreement.

50 "Invented" means (a) with respect to patentable Technology, to invent or discover, as such terms are used in 35 U.S.C. § 101 and (b) with respect to non-patentable Technology, to discover, make or otherwise develop.

51 "**IRB**" means an Institutional Review Board or any constituted group that has been formally designated by a clinical site to review and monitor biomedical research involving human subjects.

52 "Joint Oversight Committee" or "JOC" means the committee of PTI and King representatives established pursuant to Section 2.1 of this Agreementto administer the affairs of the Development Program.

53 "Joint Patent Rights" means Patent Rights claiming Joint Technology, as set forth on Schedule 53 hereto, which may be amended from time to time as necessary to accurately reflect the foregoing.

54 "Joint Technology" means any Technology jointly Invented by employees of King and PTI, or Consultants to King and PTI, during and in the conduct of the Development Program.

55 "King" has the meaning set forth in the first paragraph of this Agreement.

56 "King Background Technology" means any Technology that is useful in the Field or that is actually used in the Development, making or Marketing of Products and that is Controlled by King on the Closing Date.

57 "King Indemnitees" has the meaning set forth in Section 11.1 of this Agreement.

58 "King Patent Rights" means all Patent Rights that are Controlled by King and that claim King Technology, as set forth on Schedule 58 hereto, which may be amended from time to time as necessary to accurately reflect the foregoing.

59 "<u>King Program Technology</u>" means any Technology that is (a) Invented by employees of, or Consultants to, King, alone or jointly with Third Parties (other than Consultants of PTI), in the conduct of the Development Program or (b) useful in the Field or that is actually used in the Development, manufacturing or Marketing of Products and that are acquired by King after the Closing Date pursuant to a Third Party Agreement.

60 "King Technology" means, collectively, King Background Technology and King Program Technology.

61 "Knowledge" means the actual knowledge of a Party having taken reasonable steps to be informed of applicable actions and activities in the normal course of business.

62 "License Agreement" means that certain License Agreement to be executed by the Parties in the form attached hereto as Exhibit A.

63 "Losses" has the meaning set forth in Section 11.1 of this Agreement.

64 "Major Market Country" means one of Canada, Germany, the United Kingdom, France, Spain, Italy, or Japan; and "Major Market Countries" means, collectively, all of the foregoing countries.

65 "<u>Manufacturing/CMC Plans</u>" means the written CMC and manufacturing plans (which shall include a detailed strategy, budget, and proposed timelines) describing the API, synthesis, choice of manufactures and Third Party suppliers, expected manufacturing scale-up, manufacture, formulation, process development, development-stage manufacture, clinical supplies manufacturing, quality assurance/quality control development, stability, filling, packaging and labeling, and shipping requirements for each Product (in accordance with customary standards for a product of comparable market potential), including all CMC, and the activities to be carried out by each Party during the applicable Calendar Year. Each Manufacturing/CMC Plan will be set forth in a written document prepared by the Parties pursuant to Section 3.5 of this Agreement, and a separate Manufacturing/CMC Plan will be generated and approved with respect to each Product.

- 6 -

66 "Market" or "Marketing" means any and all activities directed to the marketing, detailing, and promotion of a Product for commercial sale and shall include pre-launch and post-launch marketing, mandated and non-mandated risk-management policies and procedures, market surveillance activities, promoting, detailing, distributing (including the cost and distribution of Product samples), offering to sell, and selling a Product, importing a Product for sale, and any and all Product Development conducted after obtaining marketing approval for any Product that is not performed as a condition to the first Regulatory Approval for a Product. If a Phase IV trial is performed as a condition to fulfill an obligation for Regulatory Approval for a Product, such trial shall be considered a Development activity (but not Product Development).

67 "**NDA**" means a New Drug Application (or an abbreviated New Drug Application) to market the Product in the Territory or similar application submitted to the FDA, or its foreign equivalent submitted to any Regulatory Authority in the Territory, and all supplements and amendments thereto.

68 "<u>Net Sales</u>" means the gross amount invoiced by King its Affiliates or Sublicensees, to Third Parties for sale of Products, less, to the extent deducted from such amount or on such invoice consistent with GAAP, the following items: (a) quantity, trade or cash discounts, chargebacks, returns, allowances, rebates (including any and all federal, state or local government rebates, such as Medicaid rebates) and price adjustments, to the extent actually allowed; (b) sales and other excise taxes and duties or similar governmental charges levied on such sale, to the extent such items are included in the gross invoice price; (c) amounts actually refunded due to rejected, spoiled, damaged, outdated or returned Product; and (d) freight, shipment and insurance costs actually incurred in transporting Product to a Third Party purchaser. If any Products are sold to Third Parties in transactions that are not at arm's length between the buyer and seller, or for consideration other than cash, then the gross amount to be included in the calculation of Net Sales for such sales shall be the amount that would have been invoiced had the transaction been conducted at arm's length, which amount shall be determined, whenever possible, by reference to the average selling price of the relevant Product in arm's-length transactions in the country of sale at the time of sale. Net Sales shall not include amounts invoiced for the supply, disposal of Product for, or use of Product, in clinical or pre-clinical trials or as free samples (such samples to be in quantities common in the industry for this sort of Product).

69 "Non-Debtor Party" has the meaning set forth in Section 9.4.1(a) of this Agreement.

70 "Non-Defaulting Party" has the meaning set forth in Section 3.8 of this Agreement.

71 "Party" or "Parties" has the meaning set forth in the first paragraph of this Agreement.

72 "<u>Patent Rights</u>" means the rights and interests in and to issued patents and pending patent applications (which for purposes of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention and priority rights) in any country, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, and renewals, all letters patent granted thereon, and all reissues, reexaminations and extensions thereof.

73 "Phase II" means a human clinical trial or trial program in any country that is intended to evaluate the safety and efficacy of a Product's dose and dose regimen in a specific indication the Product is intended to treat.

74 "Phase II Meeting" means, with respect to a Product, the meeting with the FDA held at the end of Phase II, it being agreed that King shall have the right to participate in the preparations and planning conducted in anticipation of or in connection with such meeting.

75 "Phase III" means a human clinical trial in any country that would otherwise meet the definition of 21 CFR 312.21(c), or its foreign equivalent.

- 7 -

76 "**Product**" means (a) any dosage form of Remoxy, and (b) any other product in the Field (i) that incorporates the SABER Technology and is covered by the rights licensed to PTI under the DLA, and (ii) that is Developed or Marketed pursuant to this Agreement. For purposes of clarity, "Product" includes those products within the Field that the Parties have agreed to Develop and Market as of the Effective Date, as well as any and all other products in the Field that King actually designates to be Developed or Marketed under this Agreement during the Term thereof.

77 "**Product Development**" means (a) with respect to the U.S. Territory, the conduct by King and its Affiliates of additional clinical studies of a Product that has previously received Regulatory Approval from the FDA, which additional clinical studies are conducted using CTM that is in the same formulation and dosage form as the Product for which Regulatory Approval was previously obtained, and (b) with respect to the ROW, the conduct by King, its Affiliates, or its Sublicensees of clinical studies of a Product, which additional clinical studies are conducted using CTM that is in the same formulation and dosage form as the Product for which Regulatory Approval was previously obtained in the U.S. Territory (or if Regulatory Approval has not yet been obtained in the U.S. Territory, then using CTM in the same formulation(s) and dosage form(s) then being utilized by PTI under the Development Plan for such Product in the U.S. Territory). For purposes of clarity, Product Development shall include the right (i) to use the clinical data generated in such clinical studies to seek additional Regulatory Approvals for a Product and engage in associated regulatory activities and (ii) to develop new indications for a Product with the same formulation and dosage form and to develop additional support for the Product generally.

78 "<u>Product Trademark(s)</u>" means any trademarks and trade names, whether or not registered, and any trademark applications, renewals, extensions or modifications thereto in the Territory together with all goodwill associated therewith, trade dress and packaging which are applied to or used with Products, and any promotional materials relating thereto.

79 "Program Fee" has the meaning set forth in Section 6.2 of this Agreement.

80 "Program Plans" means the Development Plans, the Manufacturing/CMC Plans, and the Yearly Brand Plans.

81 "Proprietary Materials" means any tangible chemical, biological or physical research materials.

82 "PTI" has the meaning set forth in the first paragraph of this Agreement.

83 "<u>**PTI Background Technology**</u>" means any Technology that is useful in the Field or that is actually used in the Development, manufacturing or Marketing of Products and that is Controlled by PTI on the Closing Date, expressly including all rights licensed to PTI pursuant to the DLA.

84 "PTI Indemnitees" has the meaning set forth in Section 11.2 of this Agreement.

85 "**PTI Patent Rights**" means all Patent Rights that are Controlled by PTI and that claim PTI Technology, expressly including all rights licensed to PTI pursuant to the DLA, all as set forth on Schedule 85 hereto, which may be amended from time to time as necessary to accurately reflect the foregoing.

86 "<u>PTI Program Technology</u>" means any Technology that is (a) Invented by employees of, or Consultants to, PTI, alone or jointly with Third Parties (other than Consultants of King), in the conduct of the Development Program or (b) useful in the Field or that is actually used in the Development, manufacturing or Marketing of Products and that are acquired by PTI after the Closing Date pursuant to a Third Party Agreement.

87 "PTI Technology" means, collectively, PTI Background Technology and PTI Program Technology.

88 "Regulatory Approval" means approval by the FDA or other Regulatory Authority to market a product in a regulatory jurisdiction.

- 8 -

89 "<u>**Regulatory Authority**</u>" means the FDA, the Drug Enforcement Administration, or any counterpart of such agencies outside the United States, or other national, supra-national, regional, state, or local regulatory agency, department, bureau, commission, council, or other governmental entity with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, or clinical testing, pricing, or sale of a Product, including any device incorporating the Product.

90 "**<u>Regulatory Filings</u>**" means, collectively, any and all INDs and drug master files, NDAs, applications for any device incorporating the Product, applications for designation of a Product as an "Orphan Product(s)" under the Orphan Drug Act or any other similar filings (including any foreign equivalents and further including any related correspondence and discussions), and all data contained therein, as may be required by or submitted to any Regulatory Authority for the Regulatory Approval.

91 "Remoxy" means a drug product in the Field that contains oxycodone as its opioid API and that is formulated using the SABER Technology.

92 "ROW" means all countries and jurisdictions in the Territory, other than the U.S. Territory.

93 "Saber Infringement" has the meaning set forth in Section 10.2(c) of this Agreement.

94 "<u>SABER Technology</u>" means the pharmaceutical formulation technology and methods of use that are covered by the rights granted to PTI pursuant to the DLA.

95 "Scientific Failure" has the meaning set forth in Section 9.2.2(b) of this Agreement.

96 "<u>Sublicensee</u>" means any Third Party to which a Party or both Parties grant a sublicense of some or all of the rights granted to such Party under this Agreement or the License Agreement, as permitted by this Agreement or the License Agreement.

97 "Taxes" means, collectively, taxes, deductions, duties, levies, fees, or charges (including any interest or penalties imposed thereon or related thereto.

98 "Technology" means and includes all inventions, discoveries, improvements, trade secrets and proprietary methods and materials, including Proprietary Materials, whether or not patentable, relating to the Field, including (a) samples of, methods of production or use of, and structural and functional information pertaining to, chemical compounds, proteins or other biological substances and (b) data, formulations, techniques and know-how (including any negative results).

99 "Tech Transfer" means cooperation between the Parties in effecting an orderly transition of the matters in question with respect to a Product, including transferring all information and files, and disclosing all necessary Technology, to the transferee. To the extent Applicable Law requires the transferee to control original documents, such original documents will be provided to the transferee as part of the Tech Transfer. Unless otherwise provided, all costs associated with Tech Transfers will be deemed Collaboration Costs.

100 "Term" means the term of this Agreement as set forth in Section 9.1 of this Agreement.

101 "Termination Procedures" has the meaning set forth in Section 9.2.3 of this Agreement.

102 "Territory," means worldwide, including the U.S. Territory, but excluding Australia and New Zealand.

103 "Terminated Product" has the meaning set forth in Section 3.1.4 of this Agreement.

104 "Third Party" means any person or entity other than King and PTI and their respective Affiliates.

105 "Third Party Agreements" has the meaning set forth in Section 3.8 of this Agreement.

106 "U.S. Territory" means the United States, including Puerto Rico, and any other U.S. protectorates, territories, and possessions.

107 "Valid Claim" means a claim of a pending patent application or an issued unexpired patent which, in each case, shall not have been withdrawn, canceled or disclaimed, or held unpatentable, invalid or unenforceable by a court or other tribunal of competent jurisdiction in an unappealed or unappealable decision.

108 "<u>Yearly Brand Plans</u>" means the written Marketing plans (which shall include a detailed strategy and proposed timelines to be undertaken) describing the activities to be carried out by King during each applicable Calendar Year pursuant to this Agreement. Each Yearly Brand Plan will be set forth in a written document prepared by King and reviewed by the JOC pursuant to Section 3.6 of this Agreement, and a separate Yearly Brand Plan will be generated and approved with respect to each Product.

EXHIBIT A

## LICENSE AGREEMENT

- 10 -

#### Schedule 10.2(d)

#### (i) LIST OF PTI PUBLICATIONS

AAPM Poster – February 2005: Remoxy<sup>TM</sup>, A Novel Drug Candidate Deters Oxycodone Abuse In Humans

World Pain Congress Poster – September 2004: Clinical Pharmacokinetics of Oxycodone After Single and Multiple Doses of Remoxy™, A Novel, Abuse-Resistant Long-Acting Oxycodone Formulation

World Pain Congress Poster – September 2004: Remoxy™, A Novel Drug Candidate, Deters Oxycodone Abuse In Humans

Wall Street Journal Story – June 29, 2004: As Abuse of Painkillers Climbs, OxyContin Gets Reformulated, By David P. Hamilton To Thwart Improper Use, Pain Therapeutics' Version Can't Be Dissolved, Crushed, By David P. Hamilton

Analyst Day Presentation in New York – November 5, 2003: Remoxy™: A New Drug Candidate

New York Times Story – November 5, 2003: Company Said to Develop Substitute for Painkiller, By Andrew Pollack

#### Press Release - September 9,2005

Pain Therapeutics Announces Positive Phase III Results

- Remoxy<sup>TM</sup> Meets Primary and Secondary Endpoints In Chronic Pain Study –

#### Press Release - June 8, 2005

Pain Therapeutics Completes Patient Enrollment In A Phase III Study of Remoxy<sup>™</sup> - Top-Line Results Expected In Third Quarter, Ahead of Schedule -

#### Press Release - December 23,2004

Pain Therapeutics Meets All Milestones In 2004 – Pipeline Now Includes Three Novel Drug Candidates In Phase III –

#### Press Release - December 6, 2004

Study Results Confirm Remoxy<sup>™</sup> Is Significantly Less Abusable Than OxyContin<sup>®</sup> - Goal Is To Prevent Drug Abuse, Patient Misuse and Accidental Overdose -

#### Press Release - September 2, 2004

Pain Therapeutics' Remoxy Cleared For U.S. Clinical Trials

#### Press Release - June 29, 2004

Pain Therapeutics Demonstrates Remoxy<sup>™</sup> Is Significantly Less Abusable Than OxyContin<sup>®</sup> – Remoxy and OxyContin Are Expected to Provide Equal Pain Relief–

#### Press Release - January 15, 2004

Pain Therapeutics' New Drug Now In Clinical Testing - Remoxy™ Designed to Deter Oxycodone Abuse -

### Press Release – November 5, 2003

Pain Therapeutics Announces Remoxy<sup>™</sup> A New Drug To Deter Oxycodone Abuse

(11091)

- 11 -

## (ii) LIST OF DURECT AUTHORS AND PUBLICATIONS

(1) List of Durect Authors

J.W. Gibson F.W. Okumu F. Theeuwes A.J. Tipton S. Yum J. C. Middleton

## (2) List of Durect Publications

DUROS® Osmotic Pharmaceutical Systems for Parenteral & Site-Directed Therapy. J. Wright, S. Yum, RM. Johnson Drug Delivery Technology Magazine 2003 Vol 3 No 1: 64-73.

*Pharmacokinetic Advantage of Intrapericardially Applied Substances in the Rat.* J. Hermans, H. Van Essen, H. Struijker-Boudier, R. Johnson, F. Theeuwes, J. Smits. *The Journal of Pharmacology and Experimental Therapeutics*. 2002; 301: 672-678.

Applications of Continuous Site-Directed Drug Delivery. R. Johnson, A. Verity. Proceedings of the Western Pharmacology Society. 2002; 45: 219-222.

*Evaluation of the SABER™ Delivery System for Sustained Release of Growth Hormone – Formulation Design and In Vivo Assessment.* F. Okumu, A. Daugherty, L. Dao, P. Felder, D. Brooks, S. Sane, S.A. Sullivan, A.J. Tipton, J. Cleland. Presented at the 28<sup>th</sup> International Symposium of The Controlled Release Society, 2001, June 23-27, San Diego, California.

*Gels.* A.J. Tipton. Presented at the American Association of Pharmaceutical Scientists Workshop: Assuring Quality and Performance of Sustained and Controlled Release Parenterals, 2001, April 19-20, Washington, D.C.

Drug Delivery from a Controlled Release Aerosol: Effects of Formulation Variables. K.M. Carraway, S.K. Meador, S.A. Sullivan, J.W. Gibson, A.J. Tipton. Presented at the AAPS Annual Meeting and Exposition, 2000, October 29 - November 2, Indianapolis, Indiana.

In Situ Gelling Systems to Deliver Peptides and Proteins. A.J. Tipton, Presented at the 5<sup>th</sup> International Drug Delivery Technologies & Deal-Making Summit and Exposition, 2000, July 26-28, Princeton, New Jersey.

*Evaluation of SABER™ as a Local Delivery System for rh VEGF-Formulation Design and in vitro Assessment.* F.W. Okumu, A. Daugberty, S.A. Sullivan, A.J. Tipton, J.L. Cleland. Presented at the 27<sup>th</sup> International Meeting of The Controlled Release Society, 2000, July 7-13, Paris, France.

Incorporation of Polymer Microparticles into Sucrose Acetate Isobutyrate Reduces Burst and Extends Release. S.A. Sullivan, S.K. Meador, K.M. Carraway, A.J. Tipton, J. W. Gibson. Presented at the 27<sup>th</sup> International Meeting of The Controlled Release Society, 2000, July 7-13, Paris, France.

Drug Release from a Novel Controlled Release Aerosol Based on Sucrose Acetate Isobutyrate. K. Michelle Carraway, Stacey A. Sullivan, Stacey K. Meador, Julie C Williams, John W. Gibson, and Arthur J. Tipton. Presented at the AAPS Midwest Regional Meeting. 2000, May 22, Chicago, Illinois.

- 12 -

(11091)

Schedule 10.2(d)

Local Delivery from a Novel Biodegradable In Situ Delivery System. Arthur J. Tipton, Stacey A. Sullivan, K. Michelle Carraway, Dawn A. Smith, and John W. Gibson. Presented at the Sixth World Biomaterials Congress, 2000, May 15-20, Kamuela, Hawaii.

SABER<sup>TM</sup> Provides Burst Free Release of Growth Hormone from PLGA Microspheres. F.W. Okumu, S. Darling, L.N. Dao, P. J. Fielder, S.A. Sullivan, A.J. Tipton, and J.L. Cleland. Presented at the Millennial World Congress of Pharmaceutical Sciences, 2000, April 16-20, San Francisco, California.

*Extended Release of Human Growth Hormone Suspended in SABER™ Formulation Design and In Vitro Assessment.* S. Darling, F.W. Okumu, S.A. Sullivan, A.J. Tipton, and J.L. Cleland. Presented at the Millennial World Congress of Pharmaceutical Sciences, 2000, April 16-20, San Francisco, California.

Depot Delivery of Proteins in the New Millennium: From Microspheres to injectable Gels. Jeffrey L, Cleland, OluFumni L. Johnson, Susan Darling, Arthur J. Tipton, Gaylen M. Zentner, Stacey Sullivan, John Gibson, and Franklin W. Okumu. Presented at the 6th European Symposium on Controlled Drug Delivery, 2000, April 12, Noordwijk Aan Zee, The Netherlands.

*In Situ Gelling Formulations*. Arthur J. Tipton and Richard L. Dunn. In: *Sustained Release Injectable Products*, edited by Judy Senior and Michael Radomsky, Interpharm Press, Inc., Buffalo Grove, Illinois, 2000.

Peptide Delivery from an In Situ Gelling System Based on Sucrose Acetate Isobutyrate. A. J. Tipton. Invited lecture at the AAPS Annual Meeting and Exposition, 1999, November 14-18, New Orleans, Louisiana.

*Sustained Release of Lysozyme from the SABER Delivery System*. S.A. Sullivan, S.K. Meador, K.M. Carraway, J.C. Williams, J.W. Gibson, and A.J. Tipton. Presented at the AAPS Annual Meeting and Exposition, 1999, November 14-18, New Orleans, Louisiana.

*Oral Controlled Release of Antiretrovirals using the SABER Delivery System Incorporated into Soft Gelatin Capsules.* K.M. Carraway, S.A. Sullivan, J.W. Gibson, and A.J. Tipton. Presented at the AAPS Annual Meeting and Exposition, 1999, November 14-18, New Orleans, Louisiana.

Effects of Formulation Variables on Controlled Release of Paclitaxel and other Chemotherapeutic Agents from a Novel Delivery System. J.W. Gibson, S.A. Sullivan, K.M. Carraway, and A.J. Tipton. Presented at the AAPS Annual Meeting and Exposition, 1999, November 14-18, New Orleans, Louisiana.

Biodegradable Delivery Systems for Estradiol: Comparison Between Poly(DL-lactide) Microspheres and the SABER Delivery System. C.A. Johnson, D.L. Thompson, Jr., S.A. Sullivan, J.W. Gibson, A.J. Tipton, B.W. Simon, and P.J. Burns. Presented at the 26<sup>th</sup> International Meeting of The Controlled Release Society, 1999, June 20-25, Boston, Massachusetts.

*Evaluation of the SABER Delivery System for the Controlled Release of Deslorelin; Effect of Dose in Estrogen Primed Ovarectomized Gilts.* R. Barb, R. Kreaeling, G. Rampacek, D. Thompson, Jr., J. Gibson, S. Sullivan, B. Simon, and P.J. Burns. Presented at the 26<sup>th</sup> International International Meeting of The Controlled Release Society, 1999, June 20-25, Boston, Massachusetts.

Induction of Mucosal IgA Specific for SeMF3 of Streptococcus equi with Intranasal Vaccination Using a Sucrose Acetate Isobutyrate Based Delivery System. J. Nally, S. Artiushin, A. Sheoran, J. Timoney, J. Gibson, S. Sullivan, R. Gilley, B. Simon, and P.J. Burns. Presented at the 26<sup>th</sup> International Meeting of The Controlled Release Society, 1999, June 20-25, Boston, Massachusetts.

(11091)

- 13 -

Schedule 10.2(d)

*New Delivery – Extension of Existing Products*. A.J. Tipton. Invited Lecture at the AAPS Eastern Regional Meeting, 1999, June 10-11, Paisippany, New Jersey.

Long-term Stability of Biodegradable Polymers. C.T. Williams, C.S. Martin, P.P. Kines, R.P. Swaim, D.R. Whitfield, and J.Y.Williams. Presented at the 18<sup>th</sup> Annual Southern Biomedical Engineering Conference, 1999, May 21-23, Clemson University, South Carolina.

*In Vitro and In Vivo Evaluation of a Novel In Situ-Forming Parenteral Delivery System.* J.W. Gibson, S.A. Sullivan, P.J. Burns, and A.J. Tipton. Poster presented at the meeting of Recent Advances in Drug Delivery Systems, 1999, February 22-25, Salt Lake City, Utah.

Sustained Release of Bupivacaine from the SABER Delivery System. S.A. Sullivan, J. W. Gibson, and A.J. Tipton. Presented at the AAPS Annual Meeting and Exposition, 1998, November 15-19, San Francisco, California.

Sustained Release of Orally Administered Active Using SABER<sup>™</sup> Delivery System Incorporated into Soft Gelatin Capsules. S.A. Sullivan, J.C. Yarbrough, R.W. Fengl, A.J. Tipton, and J.W. Gibson. Presented at the 25<sup>th</sup> International Meeting of The Controlled Release Society, 1998, June 21-26, Las Vegas, Nevada.

Pharmacodynamic Evaluation of Biodegradable Estradiol-17b Microspheres and Prostaglandin F2a for the control of Estrus and Ovulation in Gilts, R. Cushman, J.H. Britt, P. Davis, U. Boonyaprakob, V. Hedgpeth, J, Gibson, B. Hudson, and P.J. Burns. Presented at the 25<sup>th</sup> International Meeting of The Controlled Release Society, 1998, June 21-26, Las Vegas, Nevada.

Sustained Release of Progesterone and Estradiol From the SABER <sup>TM</sup> Delivery System: In Vitro and In Vivo Release Rates. S.A. Sullivan, J.W. Gibson, P.J. Burns, L. Franz, E.L. Squires, D.L. Thompson, and A.J. Tipton. Presented at the 25<sup>th</sup> International Meeting of The Controlled Release Society, 1998, June 21-26, Las Vegas, Nevada.

Evaluation of the SABER<sup>™</sup> Delivery System for the Controlled Release of the GnRH Analog Deslorelin for Advancing Ovulation in Mares: Effect of Gamma Radiation. R. Betschart, J. Fleury, E.L. Squires, T. Nett, J. Gibson, S. Sullivan, A. Tipton, and P.J. Burns. Presented at the 25<sup>th</sup> International Meeting of The Controlled Release Society, 1998, June 21-26, Las Vegas, Nevada.

Evaluation of the SABER<sup>™</sup> Delivery System for the Controlled Release of Deslorelin for Advancing Ovulation in the Mare: Effects of Formulation & Dose. J. Fleury, E.L. Squires, R. Betschart, J. Gibson, S. Sullivan, A. Tipton, and P.J. Burns. Presented at the 25<sup>th</sup> International Meeting of The Controlled Release Society, 1998, June 21-26, Las Vegas, Nevada.

*Synthetic Biodegradable Polymers as Medical Devices.* John C. Middleton and Arthur J. Tipton. *Medical Plastics and Biomaterials*, 1998, March/April, 31-38. To view this paper, please click here.

Long-Term Stability of Biodegradable Polymers. C.T. Williams, J.C. Middleton, K.R. Sims, R.P. Swaim, D.R. Whitfield, and J.C. Yarbrough. Presented at the 17<sup>th</sup> Southern Biomedical Engineering Conference, 1998, February 6-8, San Antonio, Texas.

*Drug Delivery from In Situ Formed Depot Systems*. A.J. Tipton, Invited Lecture at the 33<sup>rd</sup> Annual AAPS Pharmaceutical Technologies Section Arden House Conference, 1998, January 18-23, Harriman, New York.

(11091)

Schedule 10.2(d)

- 14 -

Delivery of Taxolâ and Other Antineoplastic Agents from a Novel System Based on Sucrose Acetate Isobutyrate. S.A. Sullivan, R.M. Gilley, J.W. Gibson and A.J. Tipton. Pharm. Res., 1997, 14 (11), 291.

Pharmacodynamic Evaluation of the SABER<sup>™</sup> Delivery System for the Controlled Release of the GnRH Analogue Deslorelin Acetate for Advancing Ovulation in Cyclic Mares. P.Burns, D. Thompson, F. Donadue, L. Kincald, B. Leise, J. Gibson, R. Swaim, and A. Tipton. Presented at the 24<sup>th</sup> International Meeting of The Controlled Release Society, 1997, June 16-19, Stockholm.

*Evaluation of the Saber Delivery System for the Release of GnRH Analog Deslorelin Acetate for Advancing Ovulation in the Mare.* F.J. Donadue, D.L. Thompson, P.J. Burns, A.J. Tipton, J.W. Gibson, R.P. Swaim, L.A. Kincald, and B.S. Leise. Presented at the 15<sup>th</sup> Annual Meeting of The Equine Nutrition and Physiology Society Meeting, 1997, May 29-31, Fort Worth, Texas.

A Novel Parenteral Delivery System. Dawn Alison Smith and Arthur J. Tipton. Pharm. Res. 1996, 13(9), 300.

*Evaluation of a New Continuous Process for Preparation of Progesterone and Estradiol Microspheres: An In Vivo Pharmacokinetics Study.* P.J. Burns, T.R. Tice, D. Mason, D. Love, T. Ferrell, J. Gibson, K. Dippert, and E. Squires. The Controlled Release Society, Advances in Controlled Delivery, 1996, August 21-22, Baltimore, Maryland.

Controlled Release of Diclofenac-Na from Cellulose Ester Microspheres. J. A. Nabors. W.K. Hopkins, M.E. Hudson, J. Gibson, D.M. Wyatt, and A.J. Tipton. Pharm. Res. 1994, 11(10). 295

(11091)

- 15 -

Schedule 10.2(d)

### Schedule 22 Crain Shen Existing Patents

1. Method of Simultaneously Enhancing Analgesic Potency and Attenuating Dependence Liability Caused by Morphine and Other Opioid Agonists

United States – Patent No. 5,472,943 Australia – Patent No. 691515 Canada – Application No. 2,168,262 Europe – Application No. 04017033.4 Japan – Application No. 505899

2. Method of Simultaneously Enhancing Analgesic Potency and Attenuating Dependence Liability Caused by Exogenous and Endogenous Opioid Agonists

United States – Patent No. RE 36,547 [Reexamination Certificate No. RE 36,547 Fl] Australia – Patent Acceptance No. 782475 Australia – Patent Acceptance No. 782665 Canada – Application No. 2,195,122 Europe – Application No. 05008904.4 Japan – Application No. 08-505298

3. Method of Simultaneously Enhancing Analgesic Potency and Attenuating Dependence Liability Caused by Morphine and Other Bimodally-Acting Opioid Agonists

United States – Patent No. 5,580,876 [Reexamination Certificate No. 5,580,876 Cl] United States – Patent No. 5,767,125 [Reexamination Certificate No. 5,767,125 Cl] United States – Patent No. 6,096,756 [Reexamination Certificate No. 6,096,756 Cl] United States – Patent No. 6,362,194 [Reexamination No. 90/006,475 (Certificate to be issued)] United States – Application No. 10/319,789 United States – Application No. 10/925,368

### 4. Method and Composition for Treating Irritable Bowel Syndrome Using Low Doses of Opioid Receptor Antagonists

United States – Patent No. 6,194,382 United States – Patent No. 6,395,705 United States – Patent No. 6,737,400 United States – Application No. 10/807,508 Australia – Patent No. 780013 Australia – Application No. 2005202245 Canada – Application No. 2,365,391 Europe – Application No. 00915994.8 Japan – Application No. 2000-602060

Schedule 22

- 16 -

5. Methods for Increasing Analgesic Potency and Attenuating Adverse Excitatory Effects of Bimodally-Acting Opioid Agonists by Inhibiting GMI-Ganglioside

United States – Application No. 10/459,418 Australia – Application No. 2002305066 Canada – Application No. 2,441,889 Europe – Application No. 02733865.6 Japan – Application No. 2002-574904

#### 6. Use of Excitatory Opioid Receptor Antagonists to Prevent Growth Factor-Induced Hyperalgesia

United States - Patent No. 5,585,348

## 7. Compositions and Methods for Enhancing Analgesic Potency of Tramadol and Attenuating its Adverse Side Effects

United States – Patent No. 6,765,010 United States – Application No. 10/894,349 Australia – Patent Acceptance No. 782533 Canada – Application No. 2,373,348 Europe – Application No. 00932162.1 Japan – Application No. 2000-616766

### 8. Novel Composition and Methods for Enhancing Potency or Reducing Adverse Side Effects of Opioid Agonists

United States – Application No. 10/228,835 Australia – Application No. 2001259560 Canada – Application No. 2,408,098 Europe – Application No. 01933110.7 Japan – Application No. 2001-581804

## 9. Opioid Antagonist Compositions and Dosage Forms

United States – Application No. 10,119,615 Australia – Application No. 2001259458 Canada – Application No. 2,408,106 Europe – Application No. 01932983.8 Japan – Application No. 2001-581910

## 10. Inhibitors of ABC Drug Transporters at the Blood-Brain Barrier

United States – Application No. 10/000,113 Australia – Application No. 2002239427 Canada – Application No. 2,427,330 Europe – Application No. 01987187.0 Japan – Application No. 2002-544063

Schedule 22

- 17 -

## 11. Inhibitors of ABC Drug Transporters in Cancer Cells

United States – Application No. 10/159,012

#### 12. Inhibitors of ABC Drug Transporters in Microbial Cells

United States – Application No. 10/000,107 United States – Application No. 10/159,212

## 13. Oral Dosage Forms with Therapeutically Active Agents in Controlled Release Cores And Immediate Release Gelatin Capsule Coats

United States – Patent Application No. 10/742,672 Australia – Application No. 2003301121 Canada – Application No. 2,510,465 Europe – Application No. 03813786.5

## 14. Methods and Materials for the Treatment of Pain Comprising Opioid Antagonists

United States – Application No. 10/825,257 Australia Canada Europe

## 15. Methods and Materials Useful for the Treatment of Arthritic Conditions, Inflammation Associated with a Chronic Condition or Chronic Pain

United States – Application No. 10/966,703 PCT – Application No. PCT/US2004/34184

# 16. Methods and Materials for the Treatment of Pain Comprising Opioid Antagonists

United States – Application No, 11/089,283 PCT – Application No. PCT/US2005/10043

Schedule 22

- 18 -

<u>Schedule 53</u> Joint Patent Rights

None

Schedule 53

- 19 -

<u>Schedule 58</u> <u>King Patent Rights</u>

None

Schedule 58

- 20 -

## Schedule 85 PTI Patent Rights

# 1. High Viscosity Liquid Controlled Delivery System

United States – Patent No. 5,747,058 Australia – Patent No. 698281 Brazil – Application No. PI9609033-2 Canada – Patent No. 2,222,567 China – Application No. 96195895.2 Hong Kong – Application No. 99100601.3 Europe – Patent No. 1006935 Europe – Application No. 05075143.7 (Divisional of EP 1006935) Japan – Application No. 09-502181 Mexico – Application No. 979606 New Zealand – Patent No. 311405 New Zealand – Application No. 536473 (Divisional of NZ 311405)

# 2. High Viscosity Liquid Controlled Delivery System as a Device

United States – Patent No. 5,968,542 Australia – Application No. 94750/98 Brazil – Application No. PI9812313-0 Canada – Application No. 2,303,442 China – Application No. 98810977.8 Europe – Application No. 98948113.0 Japan – Application No. 2000-511528 Mexico – Application No. 002545 New Zealand – Patent No. 503366

# 3. High Viscosity Liquid Controlled Delivery System and Medical or Surgical Device

United States – Patent No. 6,413,536 United States – Application No. 09/699,002 (Divisional of US 6,413,536) Australia – Application No. 73319/00 Canada – Application No. 2,382,540 Europe – Application No. 9613858.9 (to be granted as EP 1212092) Japan – Application No. 2001-520145

# 4. High Viscosity Liquid Controlled Delivery System and Medical or Surgical Device

United States – Application No. 10/316,441 (Continuation-in-part of 09/699,002)

- 21 -

# 5. Oral Drug Delivery System

United States – Application No. 60/433,116 United States – Application No. 60/517,464 United States – Application No. 10/737,144 Canada – Application No. 2,507,522 China Europe – Application No. 03799943.0 India Israel Japan – Application No. 2005-508335

Schedule 85

- 22 -

#### LICENSE AGREEMENT

This License Agreement (the "<u>Agreement</u>") is made effective this day of , 2005 by and between PAIN THERAPEUTICS, INC., a Delaware corporation with a principal place of business at 416 Browning Way, South San Francisco, CA 94080 ("<u>PTI</u>") and KING PHARMACEUTICALS, INC., a Tennessee corporation with a principal place of business at 501 Fifth Street, Bristol, TN 37620 ("<u>King</u>"). Each of King and PTI is sometimes referred to individually herein as a "<u>Party</u>" and collectively as the "<u>Parties</u>."

#### RECITALS

WHEREAS, PTI owns or controls certain intellectual property rights relating to the preparation of tamper-resistant opioid formulations ("<u>PTI Background</u> <u>Technology</u>," as further defined herein);

WHEREAS, PTI and King have entered into that certain Collaboration Agreement, dated November 9, 2005 ("<u>Collaboration Agreement</u>"), pursuant to which PTI and King have agreed to use the PTI Background Technology to develop one or more pharmaceutical formulations of tamper-resistant opioids for use in humans ("<u>Products</u>," as further defined herein);

WHEREAS, King desires to obtain, and PTI is willing to grant, a license under the PTI Background Technology to develop, manufacture and market Products upon the terms and conditions set forth herein and in the Collaboration Agreement;

WHEREAS, the Parties anticipate that, in the conduct of the Collaboration Agreement, certain intellectual property may be developed with applicability to products in the Field (as defined herein), including Products, which intellectual property may constitute King Program Technology, PTI Program Technology or Joint Technology (each as defined herein); and

WHEREAS, the Parties desire to include any such developed intellectual property in the rights licensed under this Agreement, such that PTI's right, title and interest in any PTI Program Technology or Joint Technology will be included within the license granted to King hereunder, and King's right, title and interest in any King Program Technology or Joint Technology will be included in the license granted to PTI hereunder.

NOW, THEREFORE, in consideration of the mutual promises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

#### 1. **DEFINITIONS**

Capitalized words and phrases used in this Agreement have the meanings ascribed to such terms in Annex A attached hereto.

### 2. LICENSES AND DLA

2.1 Licenses to King. Subject to the terms and conditions of this Agreement and further subject to the pre-existing non-exclusive license granted by PTI to Durect under the DLA, beginning on the Closing Date and thereafter during the Term, PTI hereby grants to King the following licenses under PTI Technology and PTI Patent Rights and under PTI's ownership interest in Joint Technology and Joint Patent Rights, which licenses shall be exercisable only as set forth in this Agreement or in the Collaboration Agreement and for the conduct of the activities required or permitted in the performance of King's obligations and exercise of its rights thereunder:

- 1 -

2.1.1 Development. An exclusive license (a) in the U.S. Territory, beginning immediately upon approval by the FDA of the NDA for each Product, to conduct Product Development with respect to such Product, (b) in the ROW, beginning immediately following the initiation of Phase II clinical trials for each Product by PTI in the U.S. Territory, to conduct Product Development with respect to such Product, (c) in the Territory, to conduct Development on Remoxy, exercisable only pursuant to Section 3.4.6 of the Collaboration Agreement, and (d) in the Territory, to conduct Development on Products, exercisable only in the event that: (i) PTI suspends, closes or otherwise ceases to operate a majority of its business relating to this Agreement and the Collaboration Agreement, or (ii) in any case commenced by or against PTI under the Bankruptcy Code (other than a case against PTI commenced with the participation, support, or encouragement of King), upon entry of an appropriate order or findings by the court presiding over such case, (A) PTI is in material breach of this Agreement or the Collaboration Agreement and such breach is not cured within sixty (60) days of the occurrence of the breach or (B) PTI rejects this Agreement or the Collaboration Agreement. For purposes of clarity, except in connection with the exercise of the licenses in clauses (c) and (d), King shall not have the right to make changes in the formulation or dosage form of Product without PTI's prior written consent, which consent shall be at PTI's sole discretion.

2.1.2 Commercialization. An exclusive license in the Territory to Market, use, offer for sale, sell and import Products.

2.1.3 **<u>Rights of the Parties to Make Products</u>**. An exclusive license in the Territory, subject to the rights retained by PTI pursuant to Sections 2.2.1 and 2.2.5 hereof, to make Products. For the avoidance of doubt, notwithstanding anything to the contrary in Sections 2.2.1 and 2.2.5 hereof and subject only to Durect's right, pursuant to Section 5.5 of the DLA, to make and supply GMP-qualified Excipient Ingredients (as defined in the DLA) in the making of Products, King shall have the exclusive right, in the Territory, to make Products for sale in the Territory and the exclusive right to sublicense Third Parties to do so.

2.1.4 King's Right to Sublicense. King's right to sublicense its rights to conduct Product Development, Market, use, offer for sale, sell, and import Products, and, with respect to Remoxy, to Develop pursuant to Section 3.4.6 of the Collaboration Agreement in the ROW shall be subject to PTI's consent, not to be unreasonably withheld; provided that such sublicense shall not diminish PTI's rights hereunder.

2.1.5 <u>Further Rights with Respect to Australia and New Zealand</u>. The Parties acknowledge and agree that PTI has not granted to King any licenses in Australia and New Zealand. In the event PTI intends to enter into an agreement granting a Third Party any rights to Develop and Market any products in the Field in Australia or New Zealand under PTI Technology, PTI Patent Rights or PTI's ownership interest in Joint Technology and Joint Patent Rights, which rights are, in the judgment of the JOC, material or reasonably likely to become material, to the Collaboration or to any Products, King shall have the right to review such proposed agreement prior to its execution and provide its comments to PTI, which comments PTI will consider in good faith. PTI will use commercially reasonable efforts to ensure that such agreements contain (a) terms and conditions prohibiting the export of Products from Australia or New Zealand, except as to import/export trade between these two countries, commensurate in scope with the obligations set forth in Section 2.6 hereof and (b) provisions granting to PTI the right to use, in the Territory, all Technology and Patent Rights developed by PTI or such Third Party, in whole or in part, through the use of the PTI Patent Rights, PTI Technology, Joint Patent Rights or Joint Technology, and the right to license or sublicense such rights to King, which PTI rights shall be included within the licenses granted to King hereunder so long as King agrees to assume those royalty, milestone and similar payment obligations (if any) due to such Third Party in connection with King's, its Affiliate's or Sublicensee's, use of such rights in the Territory.

2.2 Licenses to PTI. Subject to the terms and conditions of this Agreement, King hereby grants to PTI the following licenses, exercisable only as set forth in this Agreement or in the Collaboration Agreement and only for the conduct of the activities required or permitted in the performance of PTI's obligations and exercise of its rights thereunder:

- 2 -

2.2.1 In the Territory. Beginning on the Closing Date and thereafter during the Term, in the Territory, (a) a co-exclusive (with King only) license, with the right to grant sublicenses only as expressly set forth in the Collaboration Agreement, under King Technology and King Patent Rights to Develop Products, (b) a non-exclusive license to make products in the Field, including Products, in each case solely and exclusively for export to Australia and New Zealand, subject to the limitations set forth in Section 5.2 of the Collaboration Agreement, with the right to grant sublicenses subject to any applicable requirements set forth in this Agreement, under King Technology and King Patent Rights, solely to the extent any of the foregoing are Invented based on the use of PTI Technology or PTI Patent Rights or developed or acquired by King primarily for use in the Development, manufacture or Marketing of Products in the Collaboration, and (c) a right to negotiate in good faith with King to obtain a non-exclusive, royalty-bearing license, with other appropriate terms, to make products in the Field, including Products, in each case solely and exclusively for export to Australia and New Zealand, subject to the limitations set forth in Section 5.2 of the Collaboration Agreement, with the right to grant sublicenses subject to any applicable terms, to make products in the Field, including Products, in each case solely and exclusively for export to Australia and New Zealand, subject to the limitations set forth in Section 5.2 of the Collaboration Agreement, with the right to grant sublicenses subject to any applicable requirements set forth in Section 5.2 of the Collaboration Agreement, with the right to grant sublicenses subject to any applicable requirements set forth in this Agreement, under any other King Technology and King Patent Rights not set forth in subsection (b) hereof that are reasonably necessary to make products in the Field, including Products.

2.2.2 <u>Outside the Territory</u>. Beginning on the Closing Date and thereafter during the Term, outside the Territory (a) a non-exclusive, royalty-free license to Develop, make, use, sell, offer for sale, import and Market products in the Field, including Products, with the right to grant sublicenses subject to the terms set forth in Section 2.1.5 of this Agreement, under King Technology and King Patent Rights, solely to the extent any of the foregoing are Invented by King based on the use of PTI Technology or PTI Patent Rights or developed or acquired by King primarily for use in the Development, making, or Marketing of Products in the Collaboration, and (b) a right to obtain, on commercially reasonable terms, a non-exclusive, royalty-bearing license, with other appropriate terms, to Develop, make, use, sell, offer for sale, import and Market products in the Field, including Products, with the right to grant sublicenses subject to the terms set forth in Section 2.1.5 of this Agreement, under any other King Technology and King Patent Rights that are reasonably necessary to Develop, make, use, sell, offer for sale, import and Market products in the Field, including Products.

2.2.3 Post-Termination. In the event of the expiration of the Collaboration Agreement or a termination of the Collaboration Agreement pursuant to Section 9.2.2 thereof (by King at will) or by PTI pursuant to Section 9.2.3 thereof as a result of King's breach, beginning on the effective date of such termination or expiration, (a) a non-exclusive, world-wide, royalty-free license to Develop, make, use, offer for sale, sell, import and Market products in the Field, including Products, (or, in the case of termination under Section 9.2.2(a) of the Collaboration Agreement with respect to a particular Product, only to Develop, make, use, offer for sale, sell, import and Market the Terminated Product, as defined therein), including the right to grant sublicenses without restriction, under King Technology and King Patent Rights, solely to the extent any of the foregoing are Invented by King based on the use of PTI Technology or PTI Patent Rights, or are developed or acquired by King primarily for use in the Development, making or Marketing of Products in the Collaboration, and (b) a right to obtain, on commercially reasonably terms, a non-exclusive, world-wide, royalty-bearing license to Develop, make, use, offer for sale, sell, import and Market products in the Field, including Products, (or, in the case of termination under Section 9.2.2(a) of the Collaboration Agreement with respect to a particular Product, only to Develop, make, use, offer for sale, sell, import and Market the Terminated Product, as defined therein), with other appropriate terms, including the right to grant sublicenses without restriction, under any other King Technology and King Patent Rights that are reasonably necessary to Develop, make, use, offer for sale, sell, import and Market products in the Field, including Products, (or, in the case of termination under Section 9.2.2(a) of the Collaboration Agreement with respect to a particular Product, only to Develop, make, use, offer for sale, sell, import and Market the Terminated Product, as defined therein). In the event of a termination of the Collaboration Agreement by King pursuant to Section 9.2.3 thereof as a result of PTI's breach, PTI shall have the right to obtain, on commercially reasonable terms, a non-exclusive, world-wide, royalty-bearing license, with other appropriate terms, to Develop, make, use, offer for sale, sell, import and Market products in the Field, including Products, including the right to grant sublicenses without restriction, under King Technology and King Patent Rights, solely to the extent any of such King Technology and King Patent Rights are Invented by King based on the use of PTI Technology or PTI Patent Rights, or are developed or acquired by King primarily for use in the Development, making or Marketing of Products in

- 3 -

the Collaboration. Except as set forth in this Section 2.2.3, Section 2.2.1 (with respect to Development of Products in the U.S. Territory and making of Products for use outside the Territory) or Section 2.2.5 (with respect to CTM), PTI shall have no right to Develop, make, use, offer for sale, sell, import or Market Products in the Territory.

2.2.4 <u>Crain/Shen Drugs</u>. Beginning on the Closing Date and during the Term hereof and, in the event of the expiration of the Collaboration Agreement pursuant to Section 9.2.2 thereof (by King at will) or by PTI pursuant to Section 9.2.3 thereof as a result of King's breach, continuing after the effective date of such termination or expiration, (a) a non-exclusive, world-wide, royalty-free license to develop, make, use, offer for sale, sell, import and market (i) Crain/Shen Drugs that do not incorporate the SABER Technology, and (ii) Crain/Shen SABER Drugs, with the right to grant sublicenses without restriction, under King Technology and King Patent Rights that are reasonably necessary to develop, make, use, offer for sale, sell, import and market Crain/Shen Drugs, solely to the extent any of such King Technology or King Patent Rights are Invented by King based on the use of PTI Technology or PTI Patent Rights or are or are developed or acquired by King primarily for use in the Development, making or Marketing of Products in the Collaboration, and (b) a right to obtain, on commercially reasonable terms, a non-exclusive, world-wide, royalty-bearing license to develop, make, use, offer for sale, sell, import and market (i) Crain/Shen Drugs that do not incorporate the SABER Technology, and (ii) Crain/Shen SABER Drugs, with other appropriate terms, with the right to grant sublicenses without restriction, under any other King Technology and King Patent Rights that are reasonably necessary to develop, make, use, offer for sale, sell, import and market (i) Crain/Shen Drugs that do not incorporate the SABER Technology, and (ii) Crain/Shen Drugs. For the avoidance of doubt, the licenses and rights granted by King to PTI under this Section 2.2.4 shall be exercisable by PTI only with respect to Crain/Shen Drugs that do not incorporate the SABER Technology or that are Crain/Shen SABER Drugs.

2.2.5 To Make CTM.PTI shall have, and hereby retains under the PTI Technology, PTI Patent Rights and PTI's interest in the Joint Technology and Joint Patent Rights, (a) the exclusive right to make CTM, solely for use by King or its Affiliates or Sublicensees in novel formulations and dosage strengths for the conduct of Product Development in the Territory, and (b) the exclusive right to make CTM solely for use by PTI or its Sublicensees in the U.S. Territory in the Development of Products. King hereby grants to PTI a limited, exclusive license under the King Technology, King Patent Rights and King's interest in the Joint Technology and Joint Patent Rights, to manufacture such CTM for use by PTI, King and the Affiliates and permitted licensees and Sublicensees of each in the Territory. The rights granted to and retained by PTI pursuant to this Section 2.2.5 shall be exercisable by PTI only as set forth under the Collaboration Agreement and for the conduct of the activities required in the performance of its obligations or exercise of its rights thereunder. PTI may sublicense its rights to make CTM of Products for use in the Territory hereunder; provided that King shall have the right to review, prior to execution, any such agreement that either (x) requires payments by a Party to a Third Party of greater than one hundred thousand U.S. dollars (\$100,000) over the life of the contract or (y) is, in the judgment of the JOC, otherwise material, or reasonably likely to become material, to the Collaboration. King shall have the right to provide its comments to PTI on such agreements, which comments PTI will consider in good faith.

2.3 Joint Technology and Joint Patent Rights. Subject to the rights and licenses granted hereunder, each Party shall have the unrestricted right to use, license and otherwise exploit all Joint Technology and Joint Patent Rights, without accounting to the other Party or obtaining any approval of the other Party with respect thereto.

2.4 Fulfillment and Observance of Certain Obligations Under the DLA. Notwithstanding anything to the contrary herein, King acknowledges and agrees that PTI is subject to certain obligations under the DLA. In the event of any conflict between the terms of (a) this Agreement or the Collaboration Agreement and (b) the DLA, the terms of the DLA (to the extent valid and enforceable) shall govern PTI's rights and obligations, and the rights and obligations of King hereunder (and under the Collaboration Agreement) are, and shall be, in all respects subject to the limitations placed on the rights granted to PTI under the DLA. In furtherance of the grant of rights set forth in this Section 2, PTI acknowledges that it is responsible for the fulfillment of its obligations under the DLA, except to the extent King has agreed to assume any such obligations pursuant to Sections 5 and 6 hereof or under the Collaboration Agreement. King hereby agrees to use commercially reasonable efforts to abide by the

- 4 -

provisions of the DLA to the extent same are applicable to sublicensees, andto use commercially reasonable efforts to fulfill King's obligations hereunder, and under the Collaboration Agreement, to Market and conduct Product Development (and, in the case of King's exercise of its rights under Section 3.4.6 of the Collaboration Agreement, Development with respect to Remoxy). Additionally King agrees to use commercially reasonable efforts to fulfill King's obligations under this Agreement and the Collaboration Agreement in a manner so as to enable PTI to remain in full compliance with PTI's obligations under the DLA, to the extent King is obligated to do so under this Agreement or under the Collaboration Agreement. King shall not knowingly cause PTI to be in breach of or under the DLA. PTI shall not amend, terminate or cause to be terminated the DLA, if such amendment or termination would alter the rights or obligations of King under this Agreement or the Collaboration Agreement (it being expressly understood and agreed that any modification to any of the financial provisions of the DLA shall be deemed to alter the rights or obligations of King under this Agreement), without the prior written consent of King, not to be unreasonably withheld. PTI shall have the right to amend the DLA without the consent of King if, and only if, such amendment does not in any way alter the rights or obligations of King hereunder or under the Collaboration Agreement; provided, however, that if any such amendment of the DLA results in a financial benefit to PTI or a reduction in financial obligations of PTI to Durect, then PTI and King shall negotiate in good faith sharing such benefit or reduction with King. Similarly, PTI shall not exercise or fail to exercise any of PTI's material rights or obligations under the DLA to the extent such exercise or failure to exercise would alter the rights or obligations of King under this Agreement or the Collaboration Agreement, without the prior written consent of King, not to be unreasonably withheld. At the reasonable request of King, PTI shall exercise such rights and make such requests with respect to Products as are permitted under the DLA, and PTI hereby agrees to permit one designee of King to participate in all regularly scheduled meetings and, to the extent practicable, all unscheduled material meetings and telephone discussions, of the Joint Development Team (as such term is defined in the DLA). PTI will use commercially reasonable efforts to comply with all obligations and duties under the DLA including any provisions necessary to maintain in effect any rights sublicensed to King hereunder and the exclusive nature of such rights, including the preservation of King's rights hereunder in the event that PTI shall breach or default on its obligations under the DLA. If PTI should at any time breach or default on the DLA or become unable to timely perform its obligations thereunder, or receive notice that it may be, is or is deemed to be in breach or default of the DLA or has otherwise given rise to a right on Durect's part to terminate PTI's license in whole or in part, PTI shall immediately notify King, and King shall be permitted to cure such breach or default, in accordance with the terms and conditions of the DLA or otherwise resolve such breach or default directly with Durect; provided that such cure or resolution shall not diminish the rights of PTI under the DLA. If the DLA should terminate or expire for any reason other than termination as a consequence of King's breach or default of its obligations under this Agreement or the Collaboration Agreement, then King's sublicensed rights thereunder shall continue in full force and effect provided that King promptly agrees in writing to be bound by the applicable terms and conditions of the DLA, and PTI shall take whatever reasonable steps and perform whatever reasonable acts are reasonably necessary or helpful to ensure that King's sublicense continues, *mutatis mutandis*, in full force and effect.

2.5 <u>No Other Rights</u>. King hereby receives no rights to utilize PTI Technology or PTI Patent Rights except as expressly set forth herein. PTI hereby receives no rights to utilize King Technology or King Patent Rights except as expressly set forth herein.

2.6 **Reimportation**. PTI hereby acknowledges and agrees that it has granted to King hereunder exclusive rights to Market, distribute, offer for sale, sell, and import Products, and manufacture or have manufactured Products for sale in the Territory, in each case within the Territory, as set forth in Section 2.1 hereof. PTI acknowledges and agrees that PTI has no right to, and shall not, and shall not grant any right or license to any of its Affiliates, licensees, Sublicensees or other Third Parties, directly or indirectly, under the PTI Patent Rights, the PTI Technology, the Joint Patent Rights, the Joint Technology, the King Patent Rights or the King Technology in the Territory, to (a) sell, distribute, have distributed, offer for sale, have sold, import or have imported Products or (b) manufacture or have manufactured Products, except to the extent expressly permitted in Section 2.2.1 or 2.2.5 hereof, and shall not grant any such right to any Affiliate or Third Party outside the Territory if PTI knows or has reason to know that such Third Party intends to undertake any such activities in the Territory. PTI shall use commercially reasonable efforts to prevent, in the Territory, the making of any Products by PTI or any of its Affiliates, licensees, Sublicensees or other Third Parties (except to the extent permitted in Section 2.2 hereof) and the selling, distribution, offer for sale and importation of Products by PTI or any of its Affiliates, licensees, Sublicensees or other Third Parties. In the event PTI fails to use such commercially reasonably efforts, and any Products are sold, distributed, offered for sale, or imported by PTI or any of its Affiliates, licensees, Sublicensees or

- 5 -

other Third Parties in the Territory, King shall be entitled to adjust its royalty obligations payable pursuant to Sections 6.1.1 and 6.1.4 hereof in an amount adequate to compensate King for lost profits incurred as a result of such unauthorized sale, distribution, offer for sale or importation.

2.7 Crain/Shen SABER Drugs. The Parties acknowledge and agree that PTI retains the exclusive right to develop, make, use, offer for sale, sell, import and otherwise commercialize Crain/Shen Drugs. Notwithstanding the foregoing, PTI agrees that it shall not make, use, offer for sale, sell import or otherwise commercialize any Crain/Shen Drugs which incorporate the SABER Technology, other than Crain/Shen SABER Drugs. PTI agrees that it will not undertake, initiate or continue any development activities directed towards a Crain/Shen SABER Drug that contains oxycodone as the opioid agonist for a period of eighteen (18) months from the Closing Date. If any Crain/Shen SABER Drug is sold by PTI, its Affiliates or Sublicensees in any country in the Territory in which a corresponding Product that contains the same opioid agonist as its API has already received Regulatory Approval, then King's royalty obligations to PTI pursuant to Sections 6.1.1 and 6.1.4 hereof with respect to Net Sales of and sublicensing revenue derived from such Product in such country shall automatically and immediately be reduced by fifty (50%) of their original amount (as specified in Sections 6.1.1 and 6.1.4 of this Agreement, respectively). If any Crain/Shen SABER Drug receives Regulatory Approval in any country in the Territory in which the corresponding Product containing the same opioid agonist as its API has not already received Regulatory Approval, then, at King's sole discretion, King may elect either (a) not to conduct Product Development, seek Regulatory Approval, or Market such corresponding Product in the relevant country in the Territory, pursuant to Section 3.4.12 of the Collaboration Agreement, in which case, notwithstanding anything to the contrary in this Agreement or the Collaboration Agreement, King's diligence obligations hereunder and under the Collaboration Agreement with respect to such corresponding Product in such country in the Territory shall be waived and King shall have no obligation to designate a replacement Product to be Developed or Marketed instead of such corresponding Product in such country in the Territory or (b) to Market such corresponding Product, in which case King's royalty obligations to PTI pursuant to Sections 6.1.1 and 6.1.4 hereof with respect to Net Sales of and sublicensing revenue derived from such Product in such country or region shall automatically and immediately be reduced by fifty (50%) of their original amount (as specified in Section 6.1.1 and 6.1.4 of this Agreement, respectively). King's right to reduce payments otherwise due to PTI pursuant to this Section 2.7 shall be effective immediately upon the First Commercial Sale of the relevant Crain/Shen SABER Drug in the relevant country or region and continue for so long as such Crain/Shen SABER Drug is being sold in such country or region by PTI, its Affiliates, licensees or Sublicensees. Notwithstanding anything herein or in the Collaboration Agreement to the contrary, PTI shall at all times be and remain liable and responsible for any and all royalty, milestone and other payments due to Durect under the DLA with respect to any and all Crain/Shen SABER Drugs, and PTI shall be solely responsible and liable to Durect with respect to the diligence obligations pertaining to the relevant Crain/Shen SABER Product. In the event King elects not to launch a Product pursuant to Section 2.7(a) hereof, PTI shall be solely responsible and liable to Durect with respect to the diligence obligations pertaining to the relevant Product in the relevant country or region.

#### 3. INTELLECTUAL PROPERTY RIGHTS

3.1 **Disclosure**. Each Party shall, through its Patent Coordinator, keep the other Party reasonably informed regarding developed or acquired King Background Technology or PTI Background Technology, as applicable, as well as all Technology that is invented, made or developed in the course of carrying out the Development and Marketing Program (or the manufacture of Products) by employees or Consultants of such Party or its Affiliates, alone or jointly with employees or Consultants of the other Party or its Affiliates. The provisions of this Section 3 shall apply to rights in the Technology invented, made or developed by or on behalf of PTI or King, or both, during the course of carrying out the Development and Marketing Program (including the manufacture of Products in connection therewith).

3.2 **<u>Ownership</u>**. The terms and conditions of this Agreement, including this Section 3 are expressly subject to the applicable terms and conditions of (including restrictions and limitations and the pre-existing rights and obligations of Durect pursuant to) the DLA, and to the extent the DLA expressly requires the assignment of any of the PTI Technology, PTI Patent Rights, King Technology, King Patent Rights, Joint Technology or Joint Patent Rights to Durect, PTI and King hereby agree to assign same in accordance with the terms and conditions of the DLA. To the extent not inconsistent with the terms of the DLA, the ownership of Technology and Patent Rights shall be as follows:

- 6 -

3.2.1 **<u>PTI Intellectual Property Rights</u>**. PTI shall have sole and exclusive ownership of all right, title and interest on a world-wide basis in and to any and all PTI Technology and PTI Patent Rights, with full rights to license or sublicense, subject to the obligations to King as set forth herein.

3.2.2 King Intellectual Property Rights. King shall have sole and exclusive ownership of all right, title and interest on a world-wide basis in and to any and all King Technology and King Patent Rights, with full rights to license or sublicense, subject to the obligations to PTI as set forth herein.

3.2.3 Joint Technology Rights. King and PTI shall jointly own all Joint Technology and Joint Patent Rights, subject to the rights of, and the licenses granted to, each Party hereunder. Subject to the rights of, and the licenses granted to, each Party hereunder, the Parties hereby agree that as joint owners of such rights, each Party may use or license or sublicense to any Affiliate or Third Party or otherwise exploit all such rights for any or all purposes without restriction outside the Field and neither Party shall have any obligation to account to the other Party for profits or to obtain any approval of the other Party with respect thereto.

3.2.4 <u>Patent Coordinators</u>. PTI and King shall each appoint a patent coordinator (each, a "<u>Patent Coordinator</u>" and, collectively, the "<u>Patent</u> <u>Coordinators</u>"), reasonably acceptable to the other Party, who shall serve as such Party's primary liaison with the other Party on matters relating to patent filing, prosecution, maintenance and enforcement. Each Party may replace its Patent Coordinator at any time by notice in writing to the other Party.

3.2.5 Inventorship. The JOC, with the advice of the Patent Coordinators and, in the event of a dispute between the Parties, their legal counsel, shall determine the inventorship of any subject matter arising hereunder according to the principles set forth in this Section 3.2.5. Solely for purposes of determining ownership of any PTI Patent Rights, King Patent Rights and Joint Patent Rights and the rights and obligations of the Parties hereunder, the inventorship standards contained in United States patent law shall apply. For the avoidance of doubt, the inventorship set forth in any particular patent application or patent within the PTI Patent Right, King Patent Right or Joint Patent Right shall be made, as a legal matter, in accordance with the patent laws of the relevant jurisdiction. The JOC, with the advice of the Patent Coordinators, shall also, in the case of dispute, make the determination as to whether an invention is King Technology, PTI Technology or Joint Technology. If the JOC cannot resolve the dispute, it shall be resolved by independent patent counsel, not otherwise engaged by either Party, selected by the Patent Coordinators. The reasonable expenses of such independent patent counsel shall be shared equally by the Parties.

### 4. FILING, PROSECUTION AND ENFORCEMENT OF PATENT RIGHTS

4.1 <u>DLA</u>. The terms and conditions of this Section 4 are expressly subject to the pre-existing rights and obligations of Durect pursuant to the DLA. To the extent the DLA permits PTI or its Sublicensees (as such term is defined in the DLA) to prepare, file, prosecute, maintain or enforce intellectual property rights, or defend against a claim of infringement or misappropriation, PTI hereby grants such rights to King as follows.

4.2 Patent Prosecution. During the Term of this Agreement, with respect to any Patent Rights arising hereunder:

4.2.1 PTI, acting through patent attorneys or agents of its choice, shall be responsible for the preparation, filing, prosecution (including the application for and conduct of any re-examination, reissue, term extension or similar procedure) and maintenance of all patents and patent applications claiming the PTI Patent Rights and the conduct of any interferences, the defense of any oppositions or other similar procedures with respect thereto, and King shall reimburse PTI for half of all documented reasonable costs actually incurred directly in connection therewith in the Territory. At PTI's request, King shall reasonably cooperate with and assist PTI in connection with such activities. PTI agrees to consider in good faith any reasonable request King may make in connection with such activities related to the PTI Patent Rights that are (a) licensed by PTI from Durect pursuant to the DLA or (b) actually then being used in the Development Program or are, in the judgment of the JOC, reasonably likely to be used or useful in the Development, manufacture or Marketing of any Products hereunder or under the Collaboration Agreement, in accordance with the terms and conditions of Article XII of the DLA.

- 7 -

4.2.2 King, acting through patent attorneys or agents of its choice, shall be responsible for the preparation, filing, prosecution (including the application for and conduct of any re-examination, reissue, term extension or similar procedure) and maintenance of all patents and patent applications claiming the King Patent Rights and the Joint Patent Rights and the conduct of any interferences, the defense of any oppositions or other similar procedures with respect thereto, in each case at King's sole expense. At King's request, PTI shall reasonably cooperate with and assist King in connection with such activities.

4.2.3 Except as expressly provided in Section 8, neither Party makes any warranty with respect to the validity, perfection or dominance of any patent or other proprietary right or with respect to the absence of rights in Third Parties which may be infringed by the manufacture or sale of any Product. Each Party agrees to bring to the attention of the JOC any patent or patent application it discovers which relates to the rights of either Party under this Agreement.

4.3 <u>Information and Cooperation in Prosecution</u>. Each Party responsible for the preparation, filing, prosecution and maintenance of Patent Rights as described in Section 4.2 (the "<u>Filing Party</u>") shall keep the JOC regularly informed of the status of the Patent Rights for which it is responsible in accordance with Section 4.2, in each case to the extent such Patent Rights are (a) licensed by PTI from Durect pursuant to the DLA or (b) actually then being used in the Development Program or are, in the judgment of the JOC, reasonably likely to be used or useful in the Development, manufacture or Marketing of any Products hereunder or under the Collaboration Agreement. The Filing Party shall provide the Patent Coordinator of the other Party with copies of all filings and correspondence with the patent offices, administrative boards or courts which the Filing Party sends or receives in connection with the activities described in Section 4.2 with respect to such Patent Rights, within twenty (20) days of receipt and at least twenty (20) days prior to filing, respectively, including copies of each patent application, office action, response to office action, declaration, information disclosure statement, request for terminal disclaimer, request for patent term extension and request for reissue or reexamination. The Filing Party shall give good faith consideration to the other Party's comments. The Filing Party shall carefully follow the advice and direction of the JOC with respect to strategy for the Patent Rights for which it is responsible.

4.4 <u>Abandonment</u>. Subject to the pre-existing rights and obligations of Durect pursuant to the DLA, to the extent applicable to those PTI Patent Rights licensed by PTI from Durect thereunder or to DURECT Inventions (as such term is defined in the DLA) developed by or on behalf of either Party under the Collaboration, if a Filing Party decides to abandon or to allow to lapse any of its Patent Rights described in this Agreement, the Filing Party shall inform the other Party and the JOC at least forty-five (45) days prior to the effective date of such decision, and the JOC shall decide what actions should be taken with respect to such Patent Rights. If the JOC has not reached a decision fifteen (15) days prior to such effective date, then the non-Filing Party shall have the right, at the non-Filing Party's expense, to take any actions it deems reasonably necessary and appropriate to prevent the abandonment or lapse of the relevant Patent Rights, in the Filing Party's name, in order to maintain the status quo. The Filing Party hereby authorizes the non-Filing Party to make, constitute, and appoint any representative as the non-Filing Party may select, in its sole discretion, as the true and lawful attorney-in-fact for the Filing Party, with power to endorse the Filing Party's name on all applications, documents, papers, and instruments necessary or desirable for the non-Filing Party to give effect to the provisions of this Section 4.4 and the intent of the Parties hereto. This power of attorney is coupled with an interest and is supported by the consideration set forth in this Agreement. The Filing Party hereby ratifies all that such attorney-in-fact may lawfully do or cause to be done by virtue hereof. This power of attorney is irrevocable until the earlier of the expiration of the last to expire of the PTI Patent Rights, King Patent Rights and Joint Patent Rights and the termination of this Agreement. In rendering its determination, the JOC shall decide how to respond to the activities of such non-Filing Party,

#### 4.5 Actual or Threatened Infringement.

4.5.1 In the event either Party becomes aware of any probable infringement or unauthorized possession, knowledge or use of any Patent Right or Technology that is (a) licensed by PTI from Durect

- 8 -

pursuant to the DLA or (b) actually then being used in the Development Program or, in the reasonable judgment of such Party, reasonably likely to be used or useful in the Development, manufacture or Marketing of any Products hereunder or under the Collaboration Agreement (collectively, an "<u>Infringement</u>"), that Party shall notify the JOC and other Party within thirty (30) days and shall provide each with full details (an "<u>Infringement Notice</u>"). The JOC shall decide what actions are to be taken with respect to such matters, subject to the provisions of this Section 4.5.

4.5.2 As between the Parties, King shall have the first right and option, but not the obligation, to prosecute or prevent the Infringement in the Territory of or relating to (a) King Patent Rights, King Technology, Joint Patent Rights or Joint Technology, (b) PTI Patent Rights and PTI Technology (whether or not licensed from Durect pursuant to the DLA) that are actually then being used in the Development Program or, in the judgment of the JOC, reasonably likely to be used or useful in the Development, manufacture or Marketing of any Products hereunder or under the Collaboration Agreement or (c) any continuations, divisionals, continuations-in-part (to the extent any of the asserted claims are entitled to claim priority to the filing date of any of the PTI Patent Rights identified in subsection (b) of this Section 4.5.2), patents of addition, and substitutions of the PTI Patent Rights identified in subsection (b) of this Section 4.5.2, together with all registrations, reissues, reexaminations or extensions of any kind with respect to any of the foregoing PTI Patent Rights. If King does not commence a suit, action or proceeding to prosecute, or otherwise take steps to prevent or terminate such Infringement within one hundred eighty (180) days from any Infringement Notice or, in the case of a certification filed pursuant to 21 U.S.C. 355(j)(2)(A)(vii)(IV), twenty (20) days, then PTI shall have the right and option to take such action as PTI will consider appropriate to prosecute or prevent such Infringement, but only if, with respect to King Patent Rights and King Technology, such King Patent Rights and King Technology are actually then being used in the Development Program or are, in the judgment of the JOC, reasonably likely to be used or useful in the Development, manufacture or Marketing of any Products hereunder or under the Collaboration Agreement. If the Party prosecuting an Infringement in accordance with this Section 4.5 determines that it is necessary or desirable for the other Party to join any such suit, action or proceeding, the other Party shall, upon written notice from the prosecuting Party, referencing this Section 4.5, and at the prosecuting Party's expense, execute all papers and perform such other acts as may be reasonably required in the circumstances for the prosecuting Party to exercise its rights under this Section 4.5, including for purposes of maintenance of standing or to otherwise prosecute such Infringement.

4.5.3 At King's reasonable request, PTI agrees to consider in good faith any reasonable request in connection with any suit, action or proceeding brought by Durect and relating to those PTI Patent Rights and PTI Technology Rights that are (a) licensed by PTI from Durect pursuant to the DLA or (b) actually then being used in the Development Program or, in the judgment of the JOC, reasonably likely to be used or useful in the Development, manufacture or Marketing of any Products hereunder or under the Collaboration Agreement, in accordance with the terms and conditions of Article XII of the DLA.

4.5.4 <u>Allocation of Costs and Damages Award</u>. Each Party shall have the right, at its sole expense, to be represented by counsel of its own selection in any suit, action or proceeding instituted in accordance with this Section 4.5 by the other Party for Infringement. The Party initiating a suit, action or proceeding pursuant to this Section 4.5 shall bear all other costs incurred by the Parties in connection therewith, and all damages, costs or other monetary awards shall first be used to reimburse such initiating Party, then to reimburse the other Party for all reasonable attorneys' fees incurred in connection with such Party's separate representation, and the remainder, if any, shall be shared 75% to the Party initiating the suit and 25% to the other Party.

#### 4.6 Defense of Claims.

4.6.1 <u>Notice and Conduct of Action</u>. In the event that any suit, action or proceeding is brought against PTI or King or any Affiliate or Sublicensee of either Party alleging the infringement of the Technology, Patent Rights or other intellectual property rights of a Third Party by reason of any Party's activities performed in accordance with this Agreement or by reason of the manufacture, use or sale of any Product in accordance herewith or with the Collaboration Agreement, then, subject to the pre-existing rights of Durect pursuant to the DLA, to the extent applicable to those PTI Patent Rights or PTI

- 9 -

Technology licensed by PTI from Durect thereunder or to DURECT Inventions (as such term is defined in the DLA) developed by or on behalf of either Party under the Collaboration, King shall assume control of the defense of any action, suit or proceeding at its expense. Each Party will give the other Party prompt written notice of the commencement of any such suit, action or proceeding or claim of infringement and will furnish the other Party a copy of each communication relating to the alleged infringement. King may join PTI as a party to the suit, action or proceeding and PTI shall execute all documents and take all other actions, including giving testimony, which may reasonably be required in connection with the conduct of such suit, action or proceeding. In the event PTI joins in any such action, suit or proceeding, PTI shall have the right to separate counsel in such action, suit or proceeding. All costs and expenses incurred in connection with any suit, proceeding or action under this Section 4.6 shall be borne solely and exclusively by King, including all attorneys fees; provided that if PTI elects to obtain separate counsel, PTI shall bear the costs of such separate representation unless in the reasonable opinion of PTI's counsel, either (a) one or more significant defenses are available to PTI that are not available to King or (b) a conflict or potential conflict exists between PTI and King that would make separate representation advisable.

4.6.2 <u>Consequences of Action</u>. The Parties shall examine and discuss in good faith the consequences of any actual or threatened suit, action or proceeding alleging infringement of the Technology, Patent Rights or other intellectual property rights of a Third Party with respect to activities under this Agreement or the Collaboration Agreement. In the event any such suit, action or proceeding, or threat thereof, results in an obligation on King to pay royalties, milestones, damages, costs, expenses or any other financial consideration to any Third Party, whether by court order, consent decree, settlement or license agreement or otherwise, King shall be entitled to deduct from such payments from the amounts owing to PTI hereunder, as follows: The corresponding royalty amounts otherwise owing to PTI hereunder shall be reduced by fifty percent (50%) of such royalty payments to such Third Party; provided that in no event will the royalty payments payable to PTI hereunder be reduced by more than fifty percent (50%) of their original amount (as specified in Sections 6.1.1 and 6.1.4 of this Agreement). The milestone amounts otherwise owing to PTI hereunder shall be entitled to offset 50% of the remaining Third Party milestone amounts against the royalty payments payable to PTI hereunder, until all of the creditable Third Party milestone payments have been offset; provided that at no time will the royalty payments payable to PTI hereunder third Party milestone payments have been offset; provided that at no time will the royalty payments payable by PTI hereunder be reduced by more than fifty percent (50%) of their original amount (as specified in Sections 6.1.1 and 6.1.4 of this Agreement).

4.7 <u>Cooperation in Litigation</u>. PTI and King shall each, and shall cause, to the extent it has the right to do so, each of its Affiliates to, require each past or present employee, consultant, representative, contractor, agent or other individual under the custody or control of such Party (including any such individual that is, or is identified as, an inventor of any of the PTI Patent Rights, the King Patent Rights or the Joint Patent Rights) to cooperate with the other Party, its attorneys, agents, successors and assigns, to litigate and to otherwise protect any and all of the King Patent Rights, the PTI Patent Rights and the Joint Patent Rights or to defend against any Third Party suit, in each case as such other Party may request, including to (a) execute such documents, sign all lawful papers, and make all rightful oaths as the party with primary responsibility hereunder for the relevant litigation deems reasonably necessary or appropriate in connection with same; (b) communicate any relevant facts known or reasonably available to such Party or its Affiliates; (c) provide testimony for and make available relevant documents, things, records, papers, information, samples and specimens within its possession, custody and control, as requested; and (d) generally do everything reasonably necessary to obtain and enforce proper protection for the King Patent Rights, the PTI Patent Rights and the Joint Patent Rights in accordance with this Agreement. No Party shall compromise, litigate, settle or otherwise dispose of any suit, action or proceeding under Section 4.5 or 4.6 without the advice and prior consent of the JOC.

4.8 <u>Trademark Prosecution</u>. King shall own all right, title and interest in and to the Product Trademark and PTI hereby assigns same to King and shall execute such assignment documents as King reasonably requests for purposes of recording the foregoing assignment. King shall have the right, at its own expense, and using mutually acceptable outside counsel, to file, prosecute, defend and maintain before all trademark offices the Product Trademarks.

- 10 -

## 5. DILIGENCE

5.1 **Reasonable Diligence By King**. King shall use commercially reasonable efforts and diligence to Market Products and shall allocate resources and personnel thereto consistent with contemporaneous reasonable scientific and business practices and judgments in the pharmaceutical industry for products with similar commercial value, market potential and profitability, in accordance with the terms and conditions of the Collaboration Agreement. King shall use commercially reasonable efforts to Commercialize (as such term is defined in the DLA) Products, in accordance with PTI's rights and obligations pursuant to Section 8.5 of the DLA as set forth herein and in the Collaboration Agreement.

## 6. <u>CONSIDERATION</u>

6.1 Payable by King. In consideration for the rights and licenses granted herein, King shall pay PTI the following:

6.1.1 **Royalties on King's Net Sales**. Beginning with the First Commercial Sale and except as provided in Section 6.1.2, King shall pay to PTI a running royalty equal to fifteen percent (15%) of Net Sales of Product by King or its Affiliates or Sublicensees in the Territory to the extent the sale of such Product, until the total aggregate Net Sales of all Products sold by King or its Affiliates or Sublicensees in the Territory equals \$1 billion, inclusive. When the total aggregate Net Sales of all Products sold by King or its Affiliates or Sublicensees in the Territory equals \$1 billion, inclusive. When the total aggregate Net Sales of all Products sold by King or its Affiliates or Sublicensees in the Territory exceeds \$1 billion, then King shall thereafter, for the Terr of this Agreement and except as provided in Section 6.1.2, pay to PTI a running royalty equal to twenty percent (20%) of Net Sales of Product by King or its Affiliates or Sublicensees in the Territory.

6.1.2 **No Patent Coverage**. In the event that the sale of any Product is not (i) covered by a Valid Claim of the PTI Patent Rights, or (ii) otherwise entitled to market exclusivity, in each case at the time and in the country of its sale, King and its Affiliates and Sublicensees shall be entitled to reduce the running royalties on Net Sales of such Products in such country at a rate equal to one-half of the royalty rate that would otherwise be owed with respect to such Net Sales under Section 6.1.1 above.

6.1.3 <u>Amounts Payable Under the DLA</u>. In accordance with the terms and conditions of the DLA, King shall pay to PTI, and PTI shall pay to Durect (or, at PTI's request, King shall pay directly to Durect), (a) those milestones owed by PTI to Durect under Sections 9.2 and 9.3 of the DLA, to the extent not accrued prior to the Closing Date, and (b) those royalties owed by PTI under Section 9.5 of the DLA solely to the extent attributable to Net Sales (as defined in the DLA) by King its Affiliates or Sublicensees of Licensed Product (as defined in the DLA) in the Territory (as defined in this Agreement). In no event shall King be liable to PTI for any royalty amounts owed by PTI to Durect on Net Sales (as defined in the DLA) of Licensed Product (as defined in the DLA) by or on behalf of PTI or an Affiliate, licensee or Sublicensee of PTI (other than King and King's Affiliates, licensees and Sublicensees), to the extent PTI is permitted to sell or have sold Licensed Product (as defined in the DLA) hereunder or under the Collaboration Agreement, nor for any other payments payable by PTI to Durect under the DLA. King's payment obligations pursuant to this Section 6.1.3 shall continue only for so long as King's sublicensed rights under the DLA remain in effect; provided that if any of King's sublicensed rights under the DLA become non-exclusive for reasons other than a breach by King of its obligations hereunder or under the Collaboration Agreement, then King and PTI shall negotiate in good faith an appropriate reduction in King's financial obligations hereunder and under the Collaboration Agreement.

6.1.4 **Sublicensing Revenue**. In the event King enters into an agreement sublicensing to a Third Party the rights and licenses granted to it pursuant to Section 2.1 hereof to Develop, Market, distribute, offer for sale, sell, import or otherwise commercialize Products in the ROW, King shall pay to PTI fifty percent (50%) of all up-front, milestones and other economic consideration received by King from such Third Party in exchange for the grant of such rights, which up-front, milestones and other payments shall be subject to Sections 6.2, 6.3 and 6.4 hereof.

6.2 **Records and Reporting**. King shall maintain, and shall require that its Affiliates, licensees and Sublicensees maintain, in accordance with GAAP, complete and accurate books of account containing all particulars

- 11 -

relevant to King's, its Affiliates' and Sublicensees' sales of Products in sufficient detail to allow calculation and verification of all royalties and other payments payable to PTI hereunder. Such books of account, as well as all reasonably necessary supporting data, shall be kept at the principal place of business of King for the five (5) years following the end of the Calendar Year to which each shall pertain, and shall be open for inspection by an independent certified public accountant reasonably acceptable to King, upon reasonable notice during normal business hours at PTI's expense, as the case may be, for the sole purpose of verifying quarterly payment statements or compliance with this Agreement. In the event the inspection determines that royalties due to PTI for any period have been underpaid by five percent (5%) or more in any given Calendar Year, then King shall pay for all costs of the inspection, as well as make any payments required to remedy the overstatement. King will use commercially reasonable efforts to ensure that PTI is granted the right to audit King's Sublicensees' financial records, as provided herein; provided that, to the extent that King does not obtain that right for PTI, King shall obtain for itself such right and, at the request of PTI, King shall exercise such audit right with respect to such Sublicensees and provide the results of such audit for inspection by PTI pursuant to this Section 6.2. All royalty payments set forth in this Agreement shall, if overdue, bear interest until payment at a per annum rate of two percent (2%) above the prime rate published in The Wall Street Journal, New York edition, on the due date. The payment of such interest shall not foreclose PTI from exercising any other rights it may have as a consequence of the lateness of any payment. All information and data reviewed in the inspection shall be used only for the purpose of verifying royalties and shall be treated as King's Confidential Information subject to the obligations of this Agreement. No audit shall be conducted hereunder more frequently than once during any twelve (12)-month period. The results of each audit, if any, shall be binding on both Parties. Any dispute regarding the results of any such inspection hereunder shall be subject to the dispute resolution provisions of Section 2.3 of the Collaboration Agreement; provided that if King is the Party with final decision-making authority over the subject matter in dispute, and the CEO's are unable to reach agreement even after good faith discussions in accordance with Section 2.3 of the Collaboration Agreement, then the dispute shall not be subject to the sole discretion of either Party but shall be subject to arbitration pursuant to the provisions of Section 2.3.3 of the Collaboration Agreement.

6.3 **Quarterly Payments and Reports**. In each year the amount of royalty due shall be calculated quarterly as of the end of each Calendar Quarter and shall be paid quarterly within the forty-five (45) days next following such date. Every such payment shall be supported by the accounting described herein. All royalties due hereunder are payable in United States dollars. When Products are sold for currency other than United States dollars, the earned royalties will first be determined in the foreign currency of the country in which such Products were sold and then converted into equivalent United States funds. The exchange rate will be that rate quoted in *The Wall Street Journal*, New York edition on the last business day of the Calendar Quarter in which such sales were made.

6.4 <u>Accounting Reports</u>. With each quarterly payment, King shall deliver to PTI a full and accurate accounting to include at least the following information:

6.4.1 Quantity of Product manufactured and sold, by country, by King, its Affiliates and Sublicensees, (including the quantity of Product subject to a royalty;

6.4.2 Total sales for each Product by King, its Affiliates and Sublicensees, by country and, to the extent used in any royalty calculations during such quarter, the exchange rate set forth herein;

6.4.3 Deductions applicable as provided herein or as otherwise agreed by the Parties and all Net Sales calculations;

6.4.4 Total up-front payments, milestone payments and other payments and compensation received by King from its Sublicensees in connection with the grant of a sublicense of the rights and licenses granted to it pursuant to Section 2.1; and

6.4.5 Total royalties and other payments and compensation payable to PTI.

If no royalties or other payment or compensation is due to PTI in such Calendar Quarter, King shall so report.

- 12 -

6.5 <u>Withholding Taxes</u>. All payments made by a Party hereunder shall be made to the other Party free and clear of any Taxes. If a Party is required by law to deduct or withhold any Taxes from any payment made hereunder, then such Party shall (a) make such deductions and withholdings; (b) pay the full amount deducted or withheld to the relevant taxing authority or other applicable governmental authority; and (c) promptly provide the other Party with written documentation of any such payment that, if applicable, shall be in a form sufficient to satisfy the requirements of the United States Internal Revenue Code relating to a claim by such other Party for a foreign tax credit in respect of such Tax payment. If by law, regulations or fiscal policy of a particular country in the Territory, remittance of royalty payments in United States dollars is restricted or forbidden, written notice thereof shall promptly be given by King to PTI, and such payment shall be made by the deposit thereof in local currency to the credit of PTI in a recognized banking institution designated by PTI. When in any country in the Territory, the law or regulations prohibit both the transmittal and the deposit of payments, such payments shall be suspended for as long as such prohibition is in effect and as soon as such prohibition ceases to be in effect, all payments that King would have been under an obligation to transmit or deposit but for the prohibition shall forthwith be deposited or transmitted, to the extent allowable.

### 7. TERM AND TERMINATION

7.1 **Term**. Unless otherwise terminated by operation of law or by acts of the Parties in accordance with the terms of this Agreement, this Agreement shall continue until the scheduled expiration (and not the earlier termination) of the Collaboration Agreement (the "<u>Term</u>"), except to the extent any of the rights licensed by PTI from Durect under the DLA and sublicensed to King hereunder expire or terminate earlier, pursuant to the terms and conditions of the DLA.

7.2 **Termination**. This Agreement shall be terminable only upon the conditions and in the manner specified in the Collaboration Agreement, in conjunction with a termination of the Collaboration Agreement, on a Product-by-Product basis or in its entirety. For the avoidance of doubt, termination of the Collaboration Agreement shall automatically terminate this Agreement.

7.3 <u>Accrued Obligations</u>. Any termination of this Agreement for any reason does not relieve either Party of any obligation or liability accrued prior to the termination or rescind anything done by either Party, and the termination does not affect in any manner any rights of either Party arising under this Agreement prior to the termination.

### 7.4 Treatment Upon Bankruptcy.

### 7.4.1 Assumption and Assignment of Agreement.

7.4.1.1 Notwithstanding any other provision of this Agreement, the Collaboration Agreement, or any other related agreements, each Party hereby consents to the assumption of this Agreement by the other Party (the "Debtor Party") in any case commenced by or against the Debtor Party under the Bankruptcy Code to the extent that such consent is required under Section 365(c)(1) of the Bankruptcy Code, but only if the Debtor Party is otherwise entitled to assume this Agreement under the applicable requirements of the Bankruptcy Code. The sole purpose of the foregoing consent is to overcome any restriction potentially imposed by Section 365(c)(1) of the Bankruptcy Code on the Debtor Party's assumption of this Agreement in a bankruptcy case concerning the Debtor Party. It is not intended to limit any other rights of the other Party (the "<u>Non-Debtor Party</u>") under this Agreement or any provision of the Bankruptcy Code, including Section 365(c)(1). The foregoing consent applies only to the assumption of this Agreement by the Debtor Party and does not apply to the Debtor Party's assignment of this Agreement or any rights hereunder to a Third Party.

7.4.1.2 Notwithstanding any other provision of this Agreement (including Sections 7.4.1.3 and 12.9), the Collaboration Agreement, or any other related agreements, the Non-Debtor Party hereby consents to the assignment of this Agreement by the Debtor Party to a Third Party solely in connection with a sale of all or substantially all of the Debtor Party's business or assets relating to this Agreement and the Collaboration Agreement to such Third Party, pursuant to an orderly sale process under

- 13 -

Section 363 of the Bankruptcy Code or a confirmed plan under Section 1129 of the Bankruptcy Code, that contemplates the continued operation of the purchased business or assets and, if PTI is the Debtor Party, the retention of the Existing Management Team, provided that such Third Party promptly agrees in writing to be bound by the terms and conditions of this Agreement and the Debtor Party is otherwise entitled to assign this Agreement under the applicable requirements of the Bankruptcy Code. The sole purpose of the foregoing consent is to overcome any restriction potentially imposed by Section 365(c)(1) of the Bankruptcy Code on the Debtor Party's assignment of this Agreement under the specific circumstances described in this Section 7.4.1.2. It is not intended to limit any other rights of the Non-Debtor Party under this Agreement or any provision of the Bankruptcy Code, including Section 365(c)(1), or to apply to the assignment of this Agreement in any other context.

7.4.1.3 Notwithstanding any other provision of this Agreement (including Section 12.9), the Collaboration Agreement, or any other related agreements, but subject to Section 7.4.1.2 above, the Debtor Party may only assign this Agreement to a Third Party in any case commenced by or against it under the Bankruptcy Code with the prior written consent of the Non-Debtor Party.

7.4.2 Intellectual Property Rights. This Agreement and all rights related to and licenses of intellectual property granted under this Agreement by one Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. In addition to any other rights, elections and remedies under this Agreement, any related agreements, the Bankruptcy Code, or any other Applicable Law, upon a written request under Section 365(n) of the Bankruptcy Code, the Non-Debtor Party shall be entitled to complete access to any intellectual property of the Debtor Party pertaining to the rights granted in the licenses under this Agreement, all embodiments of such intellectual property and all documents, material, data, records, analyses, and information related thereto (including all clinical data, INDs, NDAs, Regulatory Approvals, Regulatory Filings, and all other documentation reasonably useful in respect of Product in the Territory in the Field). This Agreement, the Collaboration Agreement and any other related agreements (to the extent such agreements do not constitute licenses of intellectual property under the Bankruptcy Code) shall be considered agreements supplementary (as such term is used in Section 365(n) of the Bankruptcy Code) to this Agreement.

7.4.3 **<u>Rejection in Bankruptcy</u>**. Any rejection of this Agreement by the Debtor Party pursuant to Section 365 of the Bankruptcy Code shall constitute a material breach of this Agreement not subject to notice or cure. Upon any such rejection, all rights, elections and remedies of the Non-Debtor Party to this Agreement (including under Section 365 of the Bankruptcy Code) are expressly reserved. Further, upon any such rejection, the Parties intend and agree that the Non-Debtor Party may elect to retain its rights under this Agreement pursuant to Section 365(n) of the Bankruptcy Code and that such election shall, among other things, entitle the Non-Debtor Party to invoke and exercise all of its rights to any intellectual property under this Agreement, the Collaboration Agreement, and any other related agreements.

7.5 <u>Survival</u>. The terms and conditions of the following provisions shall survive termination or expiration of this Agreement for as long as necessary to permit their full discharge: Articles 9, 11 and 12, the definitions set forth in Annex A, and Sections 2.2.3, 2.2.4, 3.2.1, 3.2.2, 3.2.3, 7.3, 7.5, 10.1, the obligations of the Parties set forth in the first two sentences of Section 10.2, and Sections 6.2, 6.3, 6.4 and 6.5 with respect to any final payments owing to PTI under Section 6.1. Additionally, in the event of expiration of this Agreement (but not the earlier termination), the licenses granted to King in Section 2.1 with respect to PTI Technology and Joint Technology will survive on a non-exclusive, royalty-free, fully-paid up basis. Except as otherwise provided in this Section 7.5, all rights and obligations of the Parties under this Agreement shall terminate upon the expiration or termination of this Agreement.

# 8. WARRANTIES

8.1 PTI represents and warrants to King that (a) to PTI's actual knowledge, PTI owns or Controls all right, title and interest in and to the PTI Patent Rights, free and clear of any encumbrances, liens, charges, adverse claims, pledges, assignments, licenses, and covenants by PTI not to sue any Third Party; (b) to PTI's actual

- 14 -

knowledge, all patent applications within the PTI Patent Rights have been duly prepared, filed, prosecuted and maintained in accordance with all applicable laws, rules and regulations; (c) to PTI's actual knowledge there is no litigation or proceeding pending or threatened concerning the validity or enforceability of any of the PTI Patent Rights, BUT PTI EXPRESSLY DISCLAIMS ANY WARRANTY THAT THE PTI PATENT RIGHTS ARE ACTUALLY VALID OR ENFORCEABLE; (d) PTI has the lawful right to enter into this Agreement and to grant the licenses granted hereunder without the consent or approval of another person or entity that has not been obtained; (e) neither PTI, nor to PTI's actual knowledge, Durect, is in material breach of the DLA and to PTI's actual knowledge the DLA is valid, binding, enforceable and in full force and effect; and (f) to the extent any government funding has been obtained or used in connection with the research and development of any Products or any subject matter disclosed in any of the PTI Patent Rights, including pursuant to any grants from the National Institutes of Health, the terms and conditions of such funding agreements and grants and all laws applicable thereto have been complied with in all material respects.

8.2 King represents and warrants to PTI that it has the lawful right and authority to enter into this Agreement without the consent or approval of another person or entity.

# 9. INDEMNIFICATION

9.1 Indemnification of King by PTI. PTI shall indemnify, defend, and hold harmless King, its Affiliates, and their respective directors, officers, employees, and agents (the "<u>King Indemnitees</u>"), against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses of litigation) (collectively, "<u>Losses</u>") incurred by or imposed upon the King Indemnitees, or any one of them, as a result of claims, causes of action, suits, actions, demands, or judgments made against such King Indemnitees by Third Parties, including claims for personal injury and claims of suppliers and PTI employees (except in cases where such claims, suits, actions, demands, or judgments result from a material breach by King of its representations or warranties under this Agreement, gross negligence, or willful misconduct on the part of King), in each case to the extent arising out of (a) the breach of any representation or warranty of PTI under Article 8 hereof, (b) the gross negligence or willful misconduct of PTI, its Affiliates, or their respective employees or agents in the performance of any obligation under this Agreement, and (c) any government funding received by PTI prior to the Effective Date of the Collaboration Agreement in connection with the research or development of any Products or any subject matter disclosed in any PTI Patent Rights, including agreements and grants, and with all Applicable Laws with respect thereto, including to obtain any necessary permits or waivers thereunder. For purposes of clarity, it is understood and agreed that, except as provided in this Section 9.1 or in Section 11.1 of the Collaboration Agreement, PTI provides no indemnification to King with respect to product liabilities claims relating to Products.

9.2 Indemnification of PTI by King. King shall indemnify, defend, and hold harmless PTI, its Affiliates, and their respective directors, officers, employees, and agents (the "<u>PTI Indemnitees</u>"), against any Losses incurred by or imposed upon the PTI Indemnitees, or any one of them, as a result of claims, causes of action, suits, actions, demands, or judgments made against such PTI Indemnitees by Third Parties, including personal injury and claims of suppliers and King employees (except in cases where such claims, suits, actions, demands, or judgments result from a material breach by PTI of its representations or warranties under this Agreement, gross negligence, or willful misconduct on the part of PTI), in each case to the extent arising out of (a) the breach of any representation or warranty of King under Article 8 hereof and (b) the gross negligence or willful misconduct of King, its Affiliates, or their respective employees or agents in the performance of any obligation under this Agreement. For purposes of clarity, it is understood and agreed that, except as provided in this Section 9.2 or the Section 11.2 of the Collaboration Agreement, King provides no indemnification to PTI with respect to product liabilities claims relating to Products.

9.3 <u>Conditions to Indemnification</u>. A Party seeking indemnification under this Article 9 (the "<u>Indemnified Party</u>") shall give prompt notice of the claim to the other Party (the "<u>Indemnifying Party</u>") and, provided that the Indemnifying Party is not contesting the indemnity obligation, shall permit the Indemnifying Party to control any litigation relating to such claim and disposition of any such claim. The Indemnifying Party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of any claim as the settlement or disposition relates to Parties being indemnified under this Article 9. The Indemnifying Party shall not

- 15 -

settle or otherwise resolve any claim without prior notice to the Indemnified Party and the consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned, or delayed) if such settlement involves anything other than the payment of money by the Indemnifying Party. The Indemnified Party shall reasonably cooperate with the Indemnifying Party in its defense of any claim for which indemnification is sought under this Article 9 and shall have the right to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification. For purposes of clarity, it is understood that in the event that a claim is eligible for indemnification under both this Article 9 and under Article 11 of the Collaboration Agreement, the Indemnified Party shall be entitled to seek indemnification for such claim under either this Agreement or the Collaboration Agreement, but not both.

9.4 Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT OR THE COLLABORATION AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS, OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, NEITHER PARTY MAKES ANY GUARANTEES TO THE OTHER CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE ACTIVITIES CONTEMPLATED UNDER THIS AGREEMENT.

9.5 <u>Limited Liability</u>. EXCEPT WITH RESPECT TO A BREACH OF THE OBLIGATIONS IN ARTICLE 10 OR WITH RESPECT TO AMOUNTS PAID TO THIRD PARTIES UNDER THE INDEMNIFICATION OBLIGATIONS OF THIS ARTICLE 9, NEITHER PTI NOR KING WILL BE LIABLE WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY, OR OTHER LEGAL OR EQUITABLE THEORY FOR (I) ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES OR (II) COST OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY, OR SERVICES.

# 10. CONFIDENTIALITY; PUBLICITY

### 10.1 Confidentiality.

10.1.1 <u>Confidentiality Obligations</u>. PTI and King each acknowledges and agrees that the other Party's Confidential Information constitutes highly valuable and proprietary confidential information and materials. PTI and King each agrees that during the Term of this Agreement and for an additional five years (or, in the case of any Confidential Information identified as a trade secret by the Disclosing Party at the time of disclosure, for so long as such trade secret Confidential Information is susceptible of remaining a trade secret), it will use commercially reasonable efforts to keep confidential, and will use commercially reasonable efforts to cause its employees, Consultants, Affiliates, agents, advisors, and Sublicensees to keep confidential, all Confidential Information of the other Party. Neither PTI nor King nor any of their respective employees, Consultants, Affiliates, or Sublicensees shall use Confidential Information of the other Party for any purpose whatsoever except as expressly permitted in this Agreement or the Collaboration Agreement.

10.1.2 Limited Disclosure. PTI and King each agree that any disclosure of the other Party's Confidential Information to any officer, employee, Consultant, agent, or Affiliate of PTI or King, as the case may be, shall be made only if and to the extent necessary to carry out its rights and responsibilities under this Agreement and the Collaboration Agreement, shall be limited to the maximum extent possible consistent with such rights and responsibilities, and shall only be made to persons who are bound by written confidentiality obligations to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement or the Collaboration Agreement. PTI and King each further agrees not to disclose or transfer the other Party's Confidential Information to any Third Parties under any circumstance without the prior written approval from the other Party (such approval not to be unreasonably withheld), except as otherwise required by law, and except as otherwise expressly permitted by this Agreement or the Collaboration Agreement. Each Party shall take such action, and shall cause its Affiliates and Sublicensees to take such action, to preserve the confidentiality of the Disclosing Party's Confidential Information as the Receiving Party would customarily take to preserve the

- 16 -

confidentiality of its own Confidential Information, using a level of care that shall not under any circumstances be less than reasonable and prudent care. If a court or other government authority orders that the Receiving Party disclose Confidential Information, or proposes such an order, the Receiving Party must notify the Disclosing Party immediately after learning of the order, so as to provide the Disclosing Party an opportunity to protect the information, and the Receiving Party must limit the disclosure to the minimum that will comply with the order. Each Party, upon the request of the other Party, will return all the Confidential Information disclosed or transferred to it by the other Party pursuant to this Agreement, including all copies and extracts of documents and all manifestations in whatever form, within 60 days of the request or, if earlier, the termination or expiration of this Agreement; provided however, that a Party may retain Confidential Information of the other Party relating to any license or right to use Technology that survives such termination and one copy of all other Confidential Information may be retained in inactive archives solely for the purpose of establishing the contents thereof.

10.1.3 <u>Employees and Consultants</u>. PTI and King each hereby agrees that all of its employees, and all of the employees of its Affiliates, and any Consultants to such Party or its Affiliates, in any case that participate in the activities of the Development Program and who shall have access to Confidential Information of the other Party shall be bound by written obligations to maintain the same in confidence and not to use such information except as expressly permitted herein. Each Party agrees to enforce confidentiality obligations to which its employees and Consultants (and those of its Affiliates) are obligated. Each Party agrees to have each employee or Consultant that participates in the Development Program enter into a written agreement with such Party that includes an assignment to such Party of all right, title, and interest in and to all work product and all inventions arising during the course of his or her employment with or provision of services to such Party, and all intellectual property rights attaching thereto.

10.1.4 <u>Equitable Relief</u>. PTI and King each acknowledges that a breach by it of this Article 10 cannot reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party may be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of Article 10 by the other Party; provided, however, that no specification in this Agreement of a specific legal or equitable remedy shall be construed as a waiver or prohibition against the pursuing of other legal or equitable remedies in the event of such a breach. Each Party agrees that the existence of any claim, demand, or cause of action of it against the other Party, whether predicated upon this Agreement, or otherwise, shall not constitute a defense to the enforcement by the other Party, or its successors or assigns, of the covenants contained in Article 10.

10.2 **Publicity**. Neither Party may publicly disclose the existence or terms of this Agreement without the prior written consent of the other Party. Notwithstanding the foregoing, each Party shall have the right to disclose the existence or terms of this Agreement, or information relating to the Development Program, Remoxy, or other Products, without the consent of the other Party (a) to the extent the disclosure is required by law or by the requirements of any nationally recognized securities exchange, quotation system, or over-the-counter market on which such Party has its securities listed or traded, (b) to any investors, prospective investors, lenders, and other potential financing sources who are obligated to keep such information confidential, or (c) to any Third Party who is obligated by written confidentiality agreement to keep such information confidential; provided, in each case, that the Party making such disclosure shall use reasonable efforts to provide the other Party with as much notice beforehand as is reasonable under the circumstances with respect to any such disclosure. The Parties, upon the execution of this Agreement, will mutually agree to a press release with respect to the Development Program for publication. Once such press release or any other written statement is approved for disclosure by both Parties, either Party may make subsequent public disclosure of the contents of such statement without the further approval of the other Party. Additionally from time-to-time PTI may wish to issue press releases or make similar disclosures regarding the results or status of its research or Product activities, the achievement of a regulatory or development milestone, or any other material achievements under this Agreement or the DLA. Notwithstanding anything to the contrary in Section 10.3 or this Section 10.2, PTI shall be free to issue such press releases or make such disclosures; provided that PTI agrees to provide King a draft copy of any such press release or disclosure at least twelve (12)

- 17 -

or disclosure, which copy in any event must be provided during normal business hours, and provided further that such disclosure does not mention King without King's prior written consent. King shall have the right to inform PTI of any information contained therein that King believes is inaccurate.

10.3 **Publication**. It is expected that each Party may wish to publish the results of its research under this Agreement and the DLA in scientific journals or through scientific conferences, which disclosures will be subject to the obligations of this Section 10.3. At any time prior to the filing of an NDA for a particular Product, PTI may publish the results of its research for such Product in scientific journals or through scientific conferences; provided that PTI complies with the provisions of this Section 10.3; and provided further that such publication does not mention King without King's prior written consent. At any time following the filing of an NDA for a particular Product, King may publish the results of its research for such Product in scientific journals or through scientific conferences; provided that King complies with the provisions of this Section 10.3; and provided further that such publication does not mention Ment to a scientific journal or at any scientific conferences; provided that King complex with the provisions of this Section 10.3; and provided further that such publication does not mention PTI without PTI's prior written consent. In order to safeguard patent rights and other intellectual property, the Party wishing to publish in any scientific journal or at any scientific conference the results of any research being conducted by the Parties in the Development Program shall first submit a draft of each proposed technical publication or an outline of each proposed presentation for a scientific conference, with any related materials to be published or distributed in connection therewith, to the other Party for review, comment, and consideration of an oral presentation), the other Party will notify the Party seeking publication as to whether a patent application shall be prepared and filed (in which case the Party seeking publication shall be prepared and filed (in which case the Party seeking publication must be revised to eliminate Confidential Information of a Party (in which case the

### 11. **REMEDIES**

Subject to the terms of this Agreement, the Parties are not excluded from exercising or seeking any and all rights and remedies available, in law or in equity, under Applicable Law.

### 12. MISCELLANEOUS

12.1 **Notices**. All notices or other communications that shall or may be given pursuant to this Agreement shall be in writing and shall be deemed to be effective (a) simultaneously with the transmission or delivery thereof, if sent by facsimile transmission (followed by hard copy by mail), (b) when delivered, if sent by United States registered or certified mail, return receipt requested, or (c) on the next business day, if sent by overnight courier, in each case to the Parties at the following addresses (or at such other addresses as shall be specified by like notice) with postage or delivery charges prepaid:

If to King: King Pharmaceuticals, Inc. 501 Fifth Street Bristol, Tennessee 37620 Tel.: (423) 989-8000 Fax: (423) 990-2566 Attention: General Counsel With a copy to: King Pharmaceuticals, Inc. 501 Fifth Street Bristol, Tennessee 37620 Tel.: (423) 989-8000 Fax: (423) 274-2602 Attention: Business Development If to PTI: Pain Therapeutics, Inc. 416 Browning Way South San Francisco, California 94080 Tel.: (650) 825-3342 Fax: (650) 624-8222 Attention: President & CEO With a copy to: Wilson Sonsini Goodrich & Rosati 650 Page Mill Road Palo Alto, California 94304-1050 Tel.: (650) 493-9300 Fax: (650) 493-6811 Attention: Michael O'Donnell

- 18 -

12.2 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the application of principles of conflicts of law.

12.3 **<u>Binding Effect</u>**. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors, and permitted assigns.

12.4 Counterparts. This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original.

12.5 <u>Amendment; Waiver</u>. This Agreement may be amended, modified, superseded, or canceled, and any of the terms may be waived, only by a written instrument executed by each Party or, in the case of waiver, by the Party or Parties waiving compliance. The delay or failure of any Party at any time or times to require performance of any provisions shall in no manner affect the rights at a later time to enforce the same. No waiver by any Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

12.6 No Third Party Beneficiaries. No Third Party, including any employee of any Party to this Agreement, shall have or acquire any rights by reason of this Agreement.

12.7 **Purposes and Scope**. The Parties hereto understand and agree that this Development Program is limited solely to the Field in the Territory, and to the activities, rights, and obligations as set forth in this Agreement. Nothing in this Agreement shall be construed (a) to create or imply a general partnership between the Parties, (b) to make either Party the agent of the other for any purpose, (c) to alter, amend, supersede, or vitiate any other arrangements between the Parties with respect to any subject matters not covered hereunder, (d) to give either Party the right to bind the other, (e) to create any duties or obligations between the Parties except as expressly set forth herein, or (f) to grant any direct or implied licenses or any other right other than as expressly set forth herein.

12.8 <u>Performance by Affiliates</u>. Each Party shall have the right to direct its wholly-owned Affiliates to act in satisfaction of such Party's or Affiliate's obligations hereunder or make an assignment to an Affiliate in accordance with Section 12.9; provided that such Party shall remain liable and fully responsible for the performance of such Affiliate hereunder.

12.9 <u>Assignment and Successors</u>. Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the consent of the other, except that, subject to Section 7.4.1, each Party may assign this Agreement and the rights, obligations, and interests of such Party, in whole or in part, to any of its Affiliates (subject to Section 12.8) or to any Third Party that succeeds to all or substantially all of a Party's business or assets relating to this Agreement and the Collaboration Agreement, whether by sale, merger, operation of law, or otherwise; provided that such assignee or transferee promptly agrees in writing to be bound by the terms and conditions of this Agreement. Any attempted assignment in violation of this Section 12.9 shall be null, void, and of no effect. This Agreement shall be binding upon and inure to the benefit of all permitted successors-in-interest and assigns.

12.10 **Force Majeure**. In the event of the occurrence of a Force Majeure Event, the Parties shall not be deemed in breach of their obligations to the extent of the Force Majeure Event. The Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

#### 12.11 Interpretation.

12.11.1 The Parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

12.11.2 The headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement. Whenever the words "include," "includes," or "including" are used in this Agreement, they will be deemed to be followed by the words "without limitation." Unless the context otherwise requires, (i) "or" is disjunctive but not necessarily exclusive, (ii) words in the singular include the plural and vice versa, and (iii) the use in this Agreement of a pronoun in reference to a Party hereto includes the masculine, feminine, or neuter, as the context may require. The Annex hereto will be deemed part of this Agreement and included in any reference to this Agreement.

12.12 **Integration; Severability**. This Agreement and the Collaboration Agreement are the sole agreements with respect to the subject matter hereof and supersede all other agreements and understandings between the Parties with respect to same. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, such provision or portion thereof will be modified or deleted in such a manner so as to make this Agreement, as modified, legal and enforceable to the fullest extent permitted under Applicable Law, and it is the intention of the Parties that the remainder of the Agreement shall not be affected.

12.13 **Further Assurances**. Each of PTI and King agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such additional assignments, agreements, documents, and instruments, that may be necessary or as the other Party hereto may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

# [SIGNATURE PAGE FOLLOWS]

- 20 -

IN WITNESS WHEREOF, both King and PTI have executed this Agreement, by their respective officers duly authorized, on the day and year written below.

KING PHARMACEUTICALS, INC.		PAIN THERAPEUTICS, INC.		
By:	(Signature)		By:	(Signature)
Name:	Brian A. Markison		Name: Remi Barbier	
Title:	President and Chief Executive Officer		Title: President & CEO	
Date:			Date:	
		- 21 -		

### DEFINITIONS TO LICENSE AGREEMENT

1. "Affiliate" means any corporation, firm, partnership, or other entity that directly or indirectly controls or is controlled by or is under common control with a Party to this Agreement. For purposes of this definition, "control" means ownership, directly or through one or more Affiliates, of (a) 50% or more of the shares or voting rights in the case of a corporation or limited company, (b) 50% or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, (c) 50% or more of the equity or controlling interests in the case of any other type of legal entity (including joint ventures) or status as a general partner in any partnership, or (d) any other arrangement whereby a Party controls or has the right to control the Board of Directors or equivalent governing body of an entity.

2. "Agreement" means this License Agreement, including all attached annexes, as well as all amendments, supplements, and restatements thereof.

3. "API" means, with respect to a Product, the active pharmaceutical ingredient used in the Product.

4. "Applicable Law" means applicable U.S. and foreign laws, rules, regulations, guidelines, and standards, including those of the FDA and comparable foreign Regulatory Authorities.

5. "Bankruptcy Code" means the U.S. Bankruptcy Code, 11 U.S.C. §§ 101 et seq.

6. "Calendar Quarter" means, with respect to the first such Calendar Quarter, the period beginning on the Closing Date and ending on the last day of the calendar quarter within which the Closing Date falls and, thereafter, each successive period of three consecutive calendar months ending on March 31, June 30, September 30, or December 31. In the event that the termination of this Agreement does not fall on the last day of a Calendar Quarter, the "Final Calendar Quarter" shall mean the period from the last day of the most recent Calendar Quarter through the applicable date of termination of this Agreement.

7. "Calendar Year" means each successive twelve (12)-month period commencing on January 1 and ending on December 31; provided that the first such Calendar Year shall begin on the Closing Date and end on December 31, 2005. In the event that the termination of this Agreement does not fall on the last day of a Calendar Year, the "Final Calendar Year" shall mean the period from the last day of the most recent Calendar Year through the applicable date of termination of this Agreement.

8. "Closing Date" shall mean the earlier of: (a) the third day, unless the first day falls on a weekend or holiday, in which case it shall be the next business day, after the expiration or termination of all applicable waiting periods under the HSR Act and the satisfaction of all the other conditions set forth in Section 6.1.3 of the Collaboration Agreement or (b) the third day, unless the first day falls on a weekend or holiday, in which case it shall be the next business day, after the joint determination (by certification from each Party to the other) that notification under the HSR Act is not required and the satisfaction of all the other conditions set forth in Section 6.1.3 of the Collaboration Agreement.

9. "CMC" means, with respect to a Product, the chemistry, manufacturing, and controls information that would typically be, or is, included in an IND or NDA for such Product.

10. "Collaboration" means the association of PTI and King established pursuant to the Collaboration Agreement for the purpose of conducting the Development of Products so as to accomplish the Development objectives of the Development Program.

11. "Collaboration Agreement" has the meaning set forth in the recitals hereof.

12. "Confidential Information" means all information, Technology, and Proprietary Materials that are disclosed to a Party (the "Receiving Party") by or on behalf of the other Party (the "Disclosing Party") hereunder or under this Agreement or disclosed to any of the Receiving Party's employees, Consultants, Affiliates, or Sublicensees, except

to the extent that any such information (a) as of the date of disclosure is known to the Receiving Party or its Affiliates, as demonstrated by credible written documentation; (b) as of the date of disclosure is in, or subsequently enters, the public domain, through no fault or omission of the Receiving Party; (c) is obtained from a Third Party having a lawful right to make such disclosure free from any obligation of confidentiality to the Disclosing Party; or (d) is independently developed by or for the Receiving Party without reference to or reliance upon any Confidential Information of the Disclosing Party as demonstrated by credible written documentation. It is further agreed that PTI Technology shall be deemed the Confidential Information of PTI, King Technology shall be deemed the Confidential Information of King, and Joint Technology shall be deemed the Confidential Information of both Parties. During the Term hereof, neither Party shall disclose any of its own Confidential Information in such a manner that would reasonably be expected to adversely impact any intellectual property rights or commercial interests of the Development Program or the Products, unless such disclosure is subject to confidentiality obligations as strict as those contained in the Collaboration Agreement or this Agreement.

13. "Consultant" means a Third Party who has entered into or hereafter enters into a written agreement with PTI or King or both to provide consulting services that are material or are reasonably likely, in the judgment of the JOC, to become material to the Development Program, which written agreement shall (a) include an assignment of all right, title, and interest in and to all work product and all inventions arising from the performance of such agreement, and all intellectual property rights attaching thereto, to PTI or King, as applicable, and (b) bind the relevant Third Party by obligations of confidentiality and non-use with respect to all such work product, inventions, Confidential Information, and intellectual property rights that are at least as stringent as those set forth herein.

14. "Control" or "Controlled" means, (a) with respect to Technology (other than Proprietary Materials) or Patent Rights, the possession by a Party of the ability to grant a license or sublicense of such Technology or Patent Rights as provided herein without the payment of additional consideration (other than any additional consideration to be paid pursuant to the DLA) and without violating the terms of any agreement or arrangement between such Party and any Third Party and, (b) with respect to Proprietary Materials, the possession by a Party of the ability to supply such Proprietary Materials to the other Party as provided herein without the payment of additional consideration and without violating the terms of any agreement or arrangement between such Party and any Third Party.

15. "Crain/Shen Drug" means any dosage form that is covered by any patent or patent application set forth on Schedule 22 to the Collaboration Agreement (the "Existing Patents"), as well as any continuations, divisionals, continuations-in-part (to the extent any claims thereof are entitled to claim priority to the filing date of any of the Existing Patents), patents of addition, and substitutions of the Existing Patents, together with all registrations, reissues, reexaminations or extensions of any kind with respect to any of the foregoing patents, in each case to the extent same are owned or controlled by PTI. In the event PTI reasonably believes that any claims of a continuation-in-part application of any of the Existing Patents, which claims are not entitled to claim priority to the filings date of any of the Existing Patents, cover only an incremental improvement to the subject matter described and claimed in the Existing Patents, PTI shall have the right to request that King permit such additional claims to be included within the definition of Crain/Shen Drugs, and King shall consider such request in good faith. Notwithstanding the foregoing, with respect to United States Application Serial Nos. 10/119,615 and 10/742,672, and any applications or patents that claim priority to either of same, to the extent that any claims cover a dosage form of an opioid agonist alone or a method or process of using or making such a dosage form, such claims shall not be within the definition of Crain/Shen Drug, but shall be considered PTI Technology and PTI Patent Rights (and such applications and issued patents will be included on the schedule of PTI Patent Rights solely to such extent).

16. "Crain/Shen SABER Drug" means any dosage form of a Crain/Shen Drug that (a) contains oxycodone, hydromorphone, oxymorphone or hydrocodone as the only opioid agonist API and (b) is covered by the rights granted to PTI under the DLA.

17. "CTM" or "Clinical Trial Materials" means any Product manufactured, packaged, and labeled as required by Applicable Law to be used as an investigational drug or placebo for use in the conduct of clinical trials in humans.

18. "Debtor Party" has the meaning set forth in Section 7.4.1.1 of this Agreement.

19. "Development" or "Develop" means, with respect to a Product, all research, pre-clinical, pharmaceutical, clinical, and regulatory activities and all other activities undertaken in order to obtain Regulatory Approval of such Product in accordance with the Collaboration Agreement prior to Regulatory Approval of such Product. These activities shall include, among other things: test method development, CMC methods and reports (including formulation, process development, development-stage manufacturing, manufacturing scale-up, technical transfer, quality assurance, and quality control), pre-clinical pharmacology and toxicology studies and associated reports, planning and conduct of clinical studies, protocols, clinical study reports, statistical analysis plans, and clinical quality assurance prior to obtaining Regulatory Approvals, obtaining Regulatory Approvals, and regulatory affairs related to the foregoing.

20. "Development Plans" means the written plans (which shall include detailed strategy, budget, and proposed timelines) describing the pre-clinical and clinical Development activities and the regulatory activities, including a general overview of the expected schedule of meetings, discussions, and correspondence with Regulatory Authorities to be carried out for each Product during each Calendar Year pursuant to the Collaboration Agreement, which plans shall include the expected Regulatory Filings to be completed and maintained by the Collaboration for each Product. The Development Plans will be amended from time to time to include statistical analysis plans, protocols, case report forms, clinical study reports, audit reports, and similar matters, as such matters are developed during the Collaboration. Without limiting the foregoing, such plans shall include, at a minimum, the activities required to remain in compliance with the terms and obligations applicable to PTI under the DLA. Each Development Plan will be set forth in a written document prepared by the Parties pursuant to Section 3.4 of the Collaboration Agreement, and a separate Development Plan will be generated and approved with respect to each Product.

21. "Development Program" means, collectively, (a) the collaborative development program in the Field conducted by PTI and King and (b) the marketing program in the Field conducted by King, in each case, commencing on the date hereof and conducted pursuant to the Collaboration Agreement and the Program Plans.

22. "Durect License Agreement" or "DLA" means the Development and License Agreement, dated as of December 19, 2002, by and among PTI, DURECT Corporation ("Durect"), and Southern BioSystems, Inc., a copy of which has been provided to King, as it may be amended from time to time hereafter in accordance with Section 2.4 of this Agreement.

23. "Effective Date" has the meaning set forth in the first paragraph of the Collaboration Agreement.

24. "Existing Management Team" means not less than fifty percent (50%) of the individuals who, as of the date that is one year prior to the commencement of any case by or against PTI under the Bankruptcy Code, are designated as "Officers" of PTI under Rule 16a-1(f) promulgated pursuant to the Securities Exchange Act of 1934, as amended.

25. "FDA" means the United States Food and Drug Administration or any successor agency.

26. "Field" means pharmaceutical formulations for use in humans that contain no more than one opioid API formulated using the SABER Technology, in accordance with the DLA.

27. "Filing Party" has the meaning set forth in Section 4.3 of this Agreement.

28. "First Commercial Sale" means, with respect to any product, the first arm's-length sale by King, its Affiliates, or Sublicensees to a Third Party for end-use or consumption, including any sale to a wholesaler or distributor, of such product in a country after the applicable Regulatory Authority has granted Regulatory Approval. For purposes of this definition, any sale to an Affiliate or Sublicensee will not constitute a First Commercial Sale.

29. "Force Majeure Event" means an event beyond the reasonable control of a Party that prevents the performance, in whole or in part, by the Party of any of its obligations hereunder, including by reason of any act of God, flood or other inclement weather patterns, fire, explosion, earthquake, or war, terrorist act, revolution, civil commotion, acts of public enemies, blockage or embargo, or the like, or any injunction, law, order, ordinance, or requirement of any government or of any subdivision, authority, or representative of any such government, if, and only if, the Party affected shall have used commercially reasonable efforts to avoid the effects of such occurrence and to remedy it promptly if it has occurred.

30. "GAAP" means United States generally accepted accounting principles of the Party performing the applicable work, consistently applied.

31. "GMP" means the minimum standards for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the Federal Food, Drug and Cosmetic Act of 1938, or its foreign equivalent, as amended, as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess. In the U.S. Territory, Good Manufacturing Practices are established through FDA regulations (including 21 CFR Parts 210-211), FDA guidances, FDA current review and inspection standards, and current industry standards.

32. "HSR Act" means the Hart-Scott-Rodino Act of 1976, as amended.

33. "IND" means (a) an Investigational New Drug Application (as defined in 21 CFR § 312.3) that is required to be filed with the FDA before beginning clinical testing of a Product in human subjects, or any successor application or procedure, or (b) any counterpart of a U.S. Investigational New Drug Application that is required in any other country or region in the Territory before beginning clinical testing of a Product in human subjects in such country or region.

34. "Indemnified Party" has the meaning set forth in Section 9.3 of this Agreement.

35. "Indemnifying Party" has the meaning set forth in Section 9.3 of this Agreement.

36. "Infringement Notice" has the meaning set forth in Section 4.5.1 of this Agreement.

37. "Invent" or "Invented" means (a) with respect to patentable Technology, to invent or discover, as such terms are used in 35 U.S.C. § 101 and (b) with respect to non-patentable Technology, to discover, make or otherwise develop.

38. "Joint Oversight Committee" or "JOC" means the committee of PTI and King representatives established pursuant to Section 2.1 of the Collaboration Agreement to administer the affairs of the Development Program.

39. "Joint Patent Rights" means Patent Rights claiming Joint Technology, as set forth on Schedule 53 to the Collaboration Agreement, which may be amended from time to time as necessary to accurately reflect the foregoing.

40. "Joint Technology" means any Technology jointly Invented by employees of King and PTI, or Consultants to King and PTI, during and in the conduct of the Development Program.

41. "King" has the meaning set forth in the first paragraph of this Agreement.

42. "King Background Technology" means any Technology that is useful in the Field or that is actually used in the Development, making or Marketing of Products and that is Controlled by King on the Closing Date.

43. "King Indemnitees" has the meaning set forth in Section 9.1 of this Agreement.

44. "King Patent Rights" means all Patent Rights that are Controlled by King and that claim King Technology, as set forth on Schedule 58 to the Collaboration Agreement, which may be amended from time to time as necessary to accurately reflect the foregoing.

45. "King Program Technology" means any Technology that is (a) Invented by employees of, or Consultants to, King, alone or jointly with Third Parties (other than Consultants of PTI), in the conduct of the Development Program or (b) useful in the Field or that is actually used in the Development, manufacturing or Marketing of Products and that are acquired by King after the Closing Date pursuant to a Third Party Agreement.

46. "King Technology" means, collectively, King Background Technology and King Program Technology.

47. "Losses" has the meaning set forth in Section 9.1 of this Agreement.

48. "Manufacturing/CMC Plans" means the written CMC and manufacturing plans (which shall include a detailed strategy, budget, and proposed timelines) describing the API, synthesis, choice of manufacturers and Third Party suppliers, expected manufacturing scale-up, manufacture, formulation, process development, development-stage manufacture, clinical supplies manufacturing, quality assurance/quality control development, stability, filling, packaging and labeling, and shipping requirements for each Product (in accordance with customary standards for a product of comparable market potential), including all CMC, and the activities to be carried out by each Party during the applicable Calendar Year. Each Manufacturing/CMC Plan will be set forth in a written document prepared by the Parties pursuant to Section 3.5 of the Collaboration Agreement, and a separate Manufacturing/CMC Plan will be generated and approved with respect to each Product.

49. "Market" or "Marketing" means any and all activities directed to the marketing, detailing, and promotion of a Product for commercial sale and shall include pre-launch and post-launch marketing, mandated and non-mandated risk-management policies and procedures, market surveillance activities, promoting, detailing, distributing (including the cost and distribution of Product samples), offering to sell, and selling a Product, importing a Product for sale, and any and all Product Development conducted after obtaining marketing approval for any Product that is not performed as a condition to the first Regulatory Approval for a Product. If a Phase IV trial is performed as a condition to fulfill an obligation for Regulatory Approval for a Product, such trial shall be considered a Development activity (but not Product Development).

50. "NDA" means a New Drug Application (or an abbreviated New Drug Application) to market the Product in the Territory or similar application submitted to the FDA, or its foreign equivalent submitted to any Regulatory Authority in the Territory, and all supplements and amendments thereto.

51. "Net Sales" means the gross amount invoiced by King its Affiliates or Sublicensees, to Third Parties for sale of Products, less, to the extent deducted from such amount or on such invoice consistent with GAAP, the following items: (a) quantity, trade or cash discounts, chargebacks, returns, allowances, rebates (including any and all federal, state or local government rebates, such as Medicaid rebates) and price adjustments, to the extent actually allowed; (b) sales and other excise taxes and duties or similar governmental charges levied on such sale, to the extent such items are included in the gross invoice price; (c) amounts actually refunded due to rejected, spoiled, damaged, outdated or returned Product; and (d) freight, shipment and insurance costs actually incurred in transporting Product to a Third Party purchaser. If any Products are sold to Third Parties in transactions that are not at arm's length between the buyer and seller, or for consideration other than cash, then the gross amount to be included in the calculation of Net Sales for such sales shall be the amount that would have been invoiced had the transaction been conducted at arm's length, which amount shall be determined, whenever possible, by reference to the average selling price of the relevant Product in arm's-length transactions in the country of sale at the time of sale. Net Sales shall not include amounts invoiced for the supply, disposal of Product for, or use of Product, in clinical or pre-clinical trials or as free samples (such samples to be in quantities common in the industry for this sort of Product).

52. "Non-Debtor Party" has the meaning set forth in Section 7.4.1.1 of this Agreement.

53. "Party" or "Parties" has the meaning set forth in the first paragraph of this Agreement.

54. "Patent Coordinator" has the meaning set forth in Section 3.2.4 of this Agreement.

55. "Patent Rights" means the rights and interests in and to issued patents and pending patent applications (which for purposes of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention and priority rights) in any country, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, and renewals, all letters patent granted thereon, and all reissues, reexaminations and extensions thereof.

56. "Phase II" means a human clinical trial or trial program in any country that is intended to evaluate the safety and efficacy of a Product's dose and dose regimen in a specific indication the Product is intended to treat.

57. "Product" means (a) any dosage form of Remoxy, and (b) any other product in the Field (i) that incorporates the SABER Technology and is covered by the rights licensed to PTI under the DLA, and (ii) that is Developed or Marketed pursuant to the Collaboration Agreement. For purposes of clarity, "Product" includes those products within the Field that the Parties have agreed to Develop and Market as of the Effective Date, as well as any and all other products in the Field that King actually designates to be Developed or Marketed under the Collaboration Agreement during the Term thereof.

58. "Product Development" means (a) with respect to the U.S. Territory, the conduct by King and its Affiliates of additional clinical studies of a Product that has previously received Regulatory Approval from the FDA, which additional clinical studies are conducted using CTM that is in the same formulation and dosage form as the Product for which Regulatory Approval was previously obtained, and (b) with respect to the ROW, the conduct by King, its Affiliates, or its Sublicensees of clinical studies of a Product, which additional clinical studies are conducted using CTM that is in the same formulation and dosage form as the Product for which Regulatory Approval was previously obtained in the U.S. Territory (or if Regulatory Approval has not yet been obtained in the U.S. Territory), then using CTM in the same formulation(s) and dosage form(s) then being utilized by PTI under the Development Plan for such Product in the U.S. Territory). For purposes of clarity, Product Development shall include the right (i) to use the clinical data generated in such clinical studies to seek additional Regulatory Approvals for a Product and engage in associated regulatory activities and (ii) to develop new indications for a Product with the same formulation and dosage form and to develop additional support for the Product generally.

59. "Product Trademark(s)" means any trademarks and trade names, whether or not registered, and any trademark applications, renewals, extensions or modifications thereto in the Territory together with all goodwill associated therewith, trade dress and packaging which are applied to or used with Products, and any promotional materials relating thereto.

60. "Program Plans" means the Development Plans, the Manufacturing/CMC Plans, and the Yearly Brand Plans.

61. "Proprietary Materials" means any tangible chemical, biological or physical research materials.

62. "PTI" has the meaning set forth in the first paragraph of this Agreement.

63. "PTI Background Technology" means any Technology that is useful in the Field or that is actually used in the Development, manufacturing or Marketing of Products and that is Controlled by PTI on the Closing Date, expressly including all rights licensed to PTI pursuant to the DLA.

64. "PTI Indemnitees" has the meaning set forth in Section 9.2 of this Agreement.

65. "PTI Patent Rights" means all Patent Rights that are Controlled by PTI and that claim PTI Technology, expressly including all rights licensed to PTI pursuant to the DLA, all as set forth on Schedule 85 to the Collaboration Agreement, which may be amended from time to time as necessary to accurately reflect the foregoing.

66. "PTI Program Technology" means any Technology that is (a) Invented by employees of, or Consultants to, PTI, alone or jointly with Third Parties (other than Consultants of King), in the conduct of the Development Program or (b) useful in the Field or that is actually used in the Development, manufacturing or Marketing of Products and that are acquired by PTI after the Closing Date pursuant to a Third Party Agreement.

67. "PTI Technology" means, collectively, PTI Background Technology and PTI Program Technology.

68. "Regulatory Approval" means approval by the FDA or other Regulatory Authority to market a product in a regulatory jurisdiction.

69. "Regulatory Authority" means the FDA, the Drug Enforcement Administration, or any counterpart of such agencies outside the United States, or other national, supra-national, regional, state, or local regulatory agency, department, bureau, commission, council, or other governmental entity with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, or clinical testing, pricing, or sale of a Product, including any device incorporating the Product.

70. "Regulatory Filings" means, collectively, any and all INDs and drug master files, NDAs, applications for any device incorporating the Product, applications for designation of a Product as an "Orphan Product(s)" under the Orphan Drug Act or any other similar filings (including any foreign equivalents and further including any related correspondence and discussions), and all data contained therein, as may be required by or submitted to any Regulatory Authority for the Regulatory Approval.

71. "Remoxy" means a drug product in the Field that contains oxycodone as its opioid API and that is formulated using the SABER Technology.

72. "ROW" means all countries and jurisdictions in the Territory, other than the U.S. Territory.

73. "SABER Technology" means the pharmaceutical formulation technology and methods of use that are covered by the rights granted to PTI pursuant to the DLA.

74. "Sublicensee" means any Third Party to which a Party or both Parties grant a sublicense of some or all of the rights granted to such Party under the Collaboration Agreement or this Agreement, as permitted by the Collaboration Agreement or this Agreement.

75. "Taxes" means, collectively, taxes, deductions, duties, levies, fees, or charges (including any interest or penalties imposed thereon or related thereto.

76. "Technology" means and includes all inventions, discoveries, improvements, trade secrets and proprietary methods and materials, including Proprietary Materials, whether or not patentable, relating to the Field, including (a) samples of, methods of production or use of, and structural and functional information pertaining to, chemical compounds, proteins or other biological substances and (b) data, formulations, techniques and know-how (including any negative results).

77. "Term" means the term of this Agreement as set forth in Section 7.1 of this Agreement.

78. "Territory" means worldwide, including the U.S. Territory, but excluding Australia and New Zealand.

79. "Terminated Product" has the meaning set forth in Section 3.1.4 of the Collaboration Agreement.

80. "Third Party" means any person or entity other than King and PTI and their respective Affiliates.

81. "Third Party Agreements" has the meaning set forth in Section 3.8 of the Collaboration Agreement.

82. "U.S. Territory" means the United States, including Puerto Rico, and any other U.S. protectorates, territories, and possessions.

83. "Valid Claim" means a claim of a pending patent application or an issued unexpired patent which, in each case, shall not have been withdrawn, canceled or disclaimed, or held unpatentable, invalid or unenforceable by a court or other tribunal of competent jurisdiction in an unappealed or unappealable decision.

84. "Yearly Brand Plans" means the written Marketing plans (which shall include a detailed strategy and proposed timelines to be undertaken) describing the activities to be carried out by King during each applicable Calendar Year pursuant to the Collaboration Agreement. Each Yearly Brand Plan will be set forth in a written document prepared by King and reviewed by the JOC pursuant to Section 3.6 of the Collaboration Agreement, and a separate Yearly Brand Plan will be generated and approved with respect to each Product.

EXHIBIT B

DURECT CONSENT



PAIN THERAPEUTICS, INC.

November 2, 2005

Jim Brown, D.V.M. President & CEO DURECT Corporation 10240 Bubb Road Cupertino, CA 95104

### **Re: Approval of Sublicensee**

Dear Jim:

Pursuant to Section 8.3 of the Development and License Agreement entered into by DURECT Corporation, Southern BioSystems, Inc., (collectively "Durect") and Pain Therapeutics, Inc. ("PTI") dated as of December 19, 2002 (the "Agreement"), I would like to inform you of PTI's intention to grant a sublicense to King Pharmaceuticals, Inc. ("King") to make and sell Licensed Products in the Territory (as such terms are defined in the Agreement).

Please sign below to indicate DURECT's approval of PTI's selection of King as a Sublicensee (as such term is defined in the Agreement) and return this letter to me by Friday, November 4 th . A duplicate original is enclosed for your records. Time is of the essence.

Best Regards,

/s/ Remi Barbier Remi Barbier

Agreed and accepted:

### **DURECT** Corporation

/s/ Jim Brown, D.V.M. Jim Brown, D.V.M. President & CEO Nov. 3, 2005 Date

CONFIDENTIAL

# PRINCIPAL EXECUTIVE OFFICER CERTIFICATION 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-K/A 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: May 9, 2012

# PRINCIPAL FINANCIAL OFFICER CERTIFICATION 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-K/A 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: May 9, 2012

# 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

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 Amendment No. 1 on Form 10-K/A to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2005, 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 this Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2012

/ 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