Table of Contents

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

Form 10-K

(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**

Commission File Number: 000-29959

Pain Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

Remi Barbier
President and Chief Executive Officer
416 Browning Way
South San Francisco, CA 94080
(650) 624-8200
(Address, including zip code, or registrant's principal executive offices and telephone number, including area code)

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

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

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 ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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 $296,011,004 computed by reference to the last sales price of $6.75 as reported by the Nasdaq National Market System, as of the last business day of the Registrant's most recently completed second fiscal quarter, June 30, 2005.

The number of shares outstanding of the Registrant's common stock on February 1, 2006 was 43,957,869.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2006 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed with the Securities and Exchange Commission, are incorporated by reference to Part III of this Form 10-K Report.

PAIN THERAPEUTICS, INC.

FORM 10-K
INDEX

PART I

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

- payments we may receive from our strategic alliance;
- timing of commencement and completion of enrollment of patients for our clinical trials and the anticipated number of patients to be enrolled;
- expected dates of announcement of achievement of our clinical milestones and results of our clinical trials;
- potential sources of clinical and commercial supply of Remoxy and its components;
- expansion of our product pipeline, including the formulation of additional dosage forms of Remoxy;
- increases in our collaboration revenues and program fee revenue;
- expectations regarding recognition of collaboration and program fee revenue;
- future operating losses and anticipated operating and capital expenditures;
- uses of proceeds from our securities offerings;
- the potential benefits of our drug candidates;
- the sufficiency of materials required for the clinical development of our drug candidates;
- the size of the potential market for our products;
- the utility or protection of our intellectual property;
- expected future sources of revenue and capital or increasing cash needs;
- potential competitors or competitive products;
- future market acceptance of our drug candidates;
- expenses increasing substantially or fluctuations in our operating results;
- future expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;
- anticipated hiring and development of our internal systems and infrastructure;
- the sufficiency of our current resources to fund our operations over the next twelve months; and
- potential future dividends.

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

- the success of our collaboration agreements, including our strategic alliance with King Pharmaceuticals, Inc., or King;
- difficulties or delays in development, testing, clinical trials (including patient enrollment), regulatory approval, production and commercialization of our drug candidates;
- unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product approval (including the risk that current and past results of clinical trials are not indicative of future results of clinical trials);

- the uncertainty of patent protection for our intellectual property or trade secrets;
- potential infringement of the intellectual property rights or trade secrets of third parties;
- pursuing in-license and acquisition opportunities;
- hiring and retaining personnel; and
- our financial position and our ability to obtain additional financing if necessary.

In addition such statements are subject to the risks and uncertainties discussed in Item 1A "Risk Factors" and elsewhere in this document.

Item 1. *Business*

Overview

We are a biopharmaceutical company dedicated to the development of innovative drugs. We specialize in developing safer or more efficacious drugs for use in pain management, particularly in the area of opioid painkillers, which are sometimes referred to as narcotic painkillers. According to IMS Health, sales for opioid painkillers in the United States exceeded $6.0 billion in 2004. We incorporated in Delaware in May 1998.

Our clinical pipeline consists of proprietary drug candidates. We are currently developing two oral, small molecule drugs to treat patients who suffer from severe chronic pain, such as pain associated with advanced osteoarthritis and low-back pain. Both of our novel drug candidates are currently in Phase III clinical trial programs:

- Remoxy™, an abuse-resistant version of long-acting oxycodone, and
- Oxytrex™, a new oral opioid painkiller for the treatment of severe chronic pain.

In November 2005, we and King announced a strategic alliance to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. King made an upfront cash payment of $150 million to us at the closing of this strategic alliance in December 2005. King is also obligated to pay us up to $150 million in payments based on the achievement of milestones in the course of clinical development of Remoxy and other abuse-resistant opioid painkillers under the strategic alliance. In addition, subject to certain limitations, King is obligated to fund development expenses incurred by us related to Remoxy and other abuse-resistant opioid painkillers pursuant to the collaboration agreement. King is obligated to fund the commercialization expenses of, and has the exclusive right to market and sell, drugs developed in connection with the strategic alliance. King is obligated to pay us a 20% royalty on net sales of drugs developed in connection with the strategic alliance, except as to the first $1 billion in net sales of such drugs, for which the royalty is set at 15%.

Remoxy

Remoxy is being developed as an abuse-resistant version of long-acting oral oxycodone. Sales of long-acting oxycodone were nearly $2.0 billion for the twelve months ended August 2005.

The active drug ingredient in Remoxy is oxycodone. Oxycodone is a strong narcotic painkiller that was developed around 1920 as a substitute for morphine. When used as prescribed, oxycodone can relieve severe chronic pain. The U.S. Drug Enforcement Administration, or DEA, and the national media have linked illicit oxycodone use to widespread patterns of drug abuse, addiction, diversion and drug overdose. In the United States, drug related emergency room visits are reported by the Department of Health and Human Service's Drug Abuse Warning Network, or DAWN. DAWN reports 22,000 oxycodone mentions in emergency room visits in 2002, a 450% increase from 4,000 oxycodone mentions in emergency room visits in 1994.

Remoxy's novel formulation is specifically designed to foil abusers who attempt to tamper with the drug in order to induce a powerful euphoric high. Our clinical results to date demonstrate Remoxy is significantly less

abusable than Oxycontin®, a brand of long-acting oxycodone. During 2004, we announced data from clinical comparisons of the two drugs. In a variety of clinical comparisons of the abuse resistant characteristics of Remoxy and Oxycontin, Oxycontin released significantly more active ingredient than Remoxy during the time when abusers presumably expect to get high.

In September 2005 we announced top line data from our Phase III clinical trial of Remoxy. In this randomized, double-blinded clinical trial of 209 osteoarthritic patients with moderate to severe chronic pain, Remoxy demonstrated a statistically significant reduction in pain ($p<0.05$) when compared to placebo.

In February 2006, we completed a Special Protocol Assessment, or SPA, from the Food and Drug Administration, or FDA, for a Phase III clinical trial of Remoxy in patients with chronic pain. Under this procedure, a sponsor may seek the FDA's agreement on the design and analysis of a clinical trial intended to form the primary basis of an effectiveness claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins except in limited circumstances, such as the FDA determining that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the trial had begun. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on the SPA as the basis for approval with respect to effectiveness. While we have received the FDA's SPA agreement for this Phase III clinical trial assessing Remoxy, there can be no assurance that this clinical trial will have a successful outcome or that we will ultimately receive approval for this drug candidate.

We expect to conduct additional clinical trials and non-clinical studies of Remoxy in 2006, including additional abuse-resistance studies and other registration-enabling studies.

We believe the abuse-resistant technology used in Remoxy is applicable to different oral opioid painkillers. Pursuant to our agreement with King, we plan to develop abuse-resistant versions of additional opioid painkillers using this platform technology. We plan to formulate and scale-up a range of dosage forms of Remoxy.

We formulate Remoxy using, in part, proprietary technology licensed from Durect Corporation. Under the terms of this agreement, we have exclusive worldwide rights to develop and to commercialize Remoxy and certain other opioid drugs that use Durect's technology. We reimburse Durect for certain formulation and related work, and are responsible to make milestone payments based on the achievement of certain technical, clinical or regulatory milestones. We are responsible to pay Durect royalties on related drug sales. King is obligated to reimburse us for all costs we incur under the agreement with Durect, including royalties.

We believe we can produce sufficient clinical materials necessary to complete our Phase III program for Remoxy. We rely on Durect Corporation and other third-party manufacturers to formulate, manufacture, fill, label, ship or store Remoxy.

Oxytrex

Oxytrex is an oral opioid painkiller with a novel mechanism of action. We believe Oxytrex could be an effective substitute for oxycodone, a narcotic painkiller widely used today to treat severe chronic pain. Sales of oxycodone were nearly $2.0 billion for the twelve months ended August 2005. We have worldwide commercial rights to Oxytrex.

Our clinical results to date have shown that Oxytrex can reduce physical dependence and provides superior and prolonged pain relief compared to oxycodone. Published preclinical results also demonstrate that the technology used in Oxytrex results in a lack of opioid addiction or tolerance in animals.

In March 2005, we announced positive clinical results from a Phase III clinical trial for Oxytrex. In this variable dose clinical trial of 719 patients with severe low-back pain, Oxytrex showed minimal physical dependence, better overall safety, less drug use and similar pain relief to oxycodone. Specifically, Oxytrex

patients reported 50% less symptoms of physical dependence and withdrawal ($p<0.01$) after cessation of prolonged, high-dose opioid therapy and about 20% less overall opioid-related side-effects during treatment, including less somnolence ($p<0.05$), less itching ($p<0.05$) and less moderate to severe constipation ($p<0.05$).

In November 2005, we announced results of a Phase III clinical trial with Oxytrex. Over 775 patients with moderate-to-severe osteoarthritic pain were enrolled in this randomized, double-blind, multi-center clinical trial in the United States. The pre-defined primary endpoint was reduction of physical dependence and withdrawal effects in the first 24 hours following cessation of therapy, as measured on the Short Opioid Withdrawal Scale. Oxytrex patients reported 22% less clinical symptoms of physical dependence and withdrawal effects in the first 24 hours following cessation of therapy, compared to patients on oxycodone. However, this result did not reach statistical significance, which we believe was due to a higher than expected overall drop-out rate in the clinical trial.

We expect to continue clinical progress of Oxytrex in 2006. We plan to meet with the FDA in the first half of 2006 to discuss next steps in the clinical development of Oxytrex.

Oxytrex is formulated with two active drug ingredients: oxycodone and low-dose naltrexone. We rely on a limited number of third-party manufacturers to manufacture, fill, label, ship and store Oxytrex.

PTI-901

In December 2005, we announced results of a Phase III clinical trial with PTI-901, an investigational drug candidate for the treatment of irritable bowel syndrome, or IBS. The clinical trial compared a daily dose of PTI-901 against placebo in 609 women with documented IBS over a three-month treatment period. PTI-901 did not demonstrate a meaningful benefit in the third month of treatment, which was the primary endpoint. According to current regulatory standards, an experimental drug for chronic IBS needs to show efficacy at the end of a three-month treatment period.

The Company believes this clinical trial was well designed to detect any durable benefits of PTI-901 versus placebo in a large patient population with IBS. Based on the adequacy of the clinical trial itself, coupled with the clinical results, we are discontinuing all further clinical development activities with PTI-901.

Strategy

Our commercial goal is to build a drug franchise in pain management. Our clinical goal is to continue to develop novel drugs that are more effective or safer than drugs used in the clinic today. Our strategy includes the following elements:

Focus on Clinical Development Stage Products. We believe this focus will enable us to generate product revenues earlier than if we were focused on early-stage research and discovery activities.

Retain Significant Rights to Our Drugs. We currently retain worldwide commercialization rights to all of our technology and drug candidates in all markets and indications, except for Remoxy and certain other abuse-resistant drug candidates that are subject to our strategic alliance with King. In general, we intend to independently develop our drug candidates through late-stage clinical trials. In market segments that require large or specialized sales forces, we may seek sales and marketing alliances with third parties.

Outsource Key Functions. We intend to continue to outsource preclinical studies, clinical trials and formulation and manufacturing activities. We believe outsourcing permits significant time savings and allows for more efficient deployment of our resources.

Pursue In-licensing or Acquisition Opportunities. We intend to evaluate promising drug candidates or technologies to further expand our product pipeline. Our in-licensing strategy consists of evaluating clinical or preclinical stage opportunities in therapeutic areas that can benefit from our core expertise in drug

development. Such in-licensing or acquisition opportunities may be in pain management or in other therapeutic areas outside of pain management. We believe this element of our corporate strategy could diversify some of the risks inherent in focusing on a single therapeutic area and could also increase our probability of commercial success.

We also conduct basic research in collaboration with academic and other partners. Company sponsored research and development expenditures were $18.9 million, $35.1 million, and $32.9 million in 2003, 2004 and 2005, respectively.

Oxytrex Science and Technology

Our science related to the use of opioid agonists combined with opioid antagonist and the use of opioid agonists alone was developed at Albert Einstein College of Medicine. It is well known that opioid painkillers produce their pain relieving effect by inhibiting the transmission of pain signals in certain nerve cells in the central nervous system. This inhibition of pain is achieved by inhibiting nerve cells that have opioid receptors on their membranes, via an inhibitory signaling pathway linked to the receptor. Scientists at Albert Einstein College of Medicine, however, have published results suggesting that opioid painkillers also activate an excitatory signaling pathway linked to opioid receptors, thereby stimulating the transmission of pain. This excitatory pathway counteracts pain inhibition and is believed to be a major cause of adverse side effects associated with opioid use, including the development of tolerance and addiction.

We believe that the excitatory pathway of opioid receptors contributes greatly to the adverse effects of chronic opioid use, such as tolerance, physical dependence and addiction. After repeated administration of morphine, oxycodone or other opioid painkillers, increasing doses of opioids are required in order to obtain the same level of pain relief, a process known as tolerance. If chronic opioid treatment is terminated abruptly, withdrawal symptoms rapidly appear. Continued administration of opioids prevents the appearance of withdrawal symptoms, at which point a patient is considered physically dependent. Published results in rodents also show that tolerance and physical dependence can be prevented by co-administration of low-dose naltrexone, an opioid antagonist. We believe low-dose naltrexone blocks the excitatory pathway, thus minimizing tolerance, physical dependence and addiction. In addition, preclinical work using animal models of addiction suggests that very low doses of opioid antagonists decrease the pleasurable effects and addictive potential of opioid drugs such as morphine or oxycodone.

Optimal dose ratios of low-dose opioid antagonist to opioid painkiller depend on their specific pharmacology and the mode of administration. Published preclinical and clinical dose response studies provide guidance in formulating optimal ratios of low-dose opioid antagonist to opioid painkiller for clinical development.

Oxytrex is a proprietary combination of two active drug ingredients. The first component is the opioid agonist oxycodone. The second component is an extremely low dose of the opioid antagonist naltrexone. Adding an antagonist to an agonist at usual clinical doses blocks the action of the agonist. This effect is clinically useful, for example, to reverse heroin overdose. At a very low dose, however, studies indicate that this effect is different: a very low-dose of an opioid antagonist can enhance pain relief and attenuate the development of tolerance or addiction. Oxytrex takes advantage of this effect by combining opioid agonists with low doses of opioid antagonists.

License from Albert Einstein College of Medicine

We have licensed certain technology from Albert Einstein College of Medicine. We have a worldwide exclusive license to the technology and all intellectual rights arising from the technology. Our license rights terminate upon the expiration of the patents used to protect the technology, which are scheduled to expire no earlier than September 2012. Pursuant to the agreement for the licensed technology, we are required to pay

Albert Einstein College of Medicine clinical milestone payments and royalties based on a percentage of net drug sales. If a product is combined with a drug or other substance for which we are paying an additional royalty, the royalty that we pay to Albert Einstein College of Medicine will be reduced by up to one-half of the amount of such additional royalty.

Albert Einstein College of Medicine originally received grants from the U.S. federal government to research some of the technology that we license. The terms of these grants provide the U.S. federal government with a non-exclusive, non-transferable paid-up license to practice inventions made with federal funds. Thus, our licenses are non-exclusive to the extent of the U.S. federal government's license. If the U.S. federal government exercises its rights under this license, it could make use of the same technology that we license and the size of our potential market could thereby be reduced.

Our Intellectual Property

We seek to protect our technology by, among other methods, filing and prosecuting U.S. and foreign patents and patent applications with respect to our technology and products and their uses. We plan to prosecute and defend our patent applications, issued patents and proprietary information. Our competitive position and potential future revenues will depend in large part upon our ability to protect our intellectual property from challenges and to enforce our patent rights against potential infringements. If our competitors are able to successfully challenge the validity or scope of our patent rights, based on the existence of prior art or otherwise, they might be able to market products that contain features and clinical benefits similar to those of our products, and demand for our products could decline as a result.

The focus of our patent strategy is to secure and maintain intellectual property rights to technology for the following categories of our business:

- the clinical use of a low-dose opioid antagonist, either alone or in combination with an opioid painkiller, for pain management and opioid and other addiction;
- the use of a low-dose opioid antagonist to render opioid-based products more effective; and
- the clinical use of a low-dose opioid antagonist, either alone or in combination with any opioid painkiller, for the treatment of other conditions.

In 2003, the U.S. Patent and Trademark Office, or PTO, disclosed that a law firm for an unidentified third-party filed requests for an Ex Parte Reexamination related to certain claims on patents we exclusively licensed from Albert Einstein College of Medicine. Between 2004 and 2006, Reexamination Certificates were issued resolving the proceedings.

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

Strategic Alliance with King Pharmaceuticals, Inc.

In November 2005, we entered into a collaboration agreement and a license agreement with King to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. King made an upfront cash payment of $150 million to us at the closing of this strategic alliance in December 2005. King is also obligated to pay us up to $150 million in payments based on the achievement of milestones in the course of clinical development of Remoxy and other abuse-resistant opioid painkillers under the strategic alliance. In addition, subject to certain limitations, King is obligated to fund development expenses incurred by us related to Remoxy and other abuse-resistant opioid painkillers pursuant to the collaboration agreement. King is obligated to fund the commercialization expenses of, and has the exclusive right to market and sell, drugs developed in connection with the strategic alliance.

We formed a joint operating committee, or JOC, with King to oversee drug development and commercialization strategies for the strategic alliance. Pursuant to the collaboration agreement in the strategic alliance, we retain sole control of drug development activities in the United States through Phase II clinical trials. We and King will jointly manage Phase III clinical trials and NDA submissions in the United States. King has responsibility for these development activities outside the United States. Upon regulatory approval, King will assume sole control and worldwide responsibility to exclusively commercialize Remoxy and other abuse-resistant opioid drugs developed pursuant to the strategic alliance. We retain all development and commercial rights in Australia and New Zealand.

Pursuant to the license agreement, King has the exclusive right to market and sell drugs developed pursuant to the strategic alliance and is obligated to pay us a 20% royalty on net sales, except as to the first $1 billion in cumulative net sales, for which the royalty is set at 15%. King is also obligated to reimburse us for our payment of third-party royalty obligations related to this strategic alliance.

The collaboration agreement continues until the later of the expiration of any patent rights licensed under the license agreement or developed under the collaboration agreement and the expiration of all periods of market exclusivity with respect to Remoxy and other abuse-resistant opioid drug candidates being developed under the strategic alliance. We and King can terminate the collaboration agreement under certain circumstances, including material breach and insolvency. King can terminate the collaboration agreement six months after the third anniversary of the effective date of the collaboration agreement, or sooner if the JOC determines that the development program under the collaboration agreement is unlikely to generate any marketable products. Our license agreement with King terminates at the time that the collaboration agreement terminates.

Formulation Agreement

We have an exclusive, worldwide licensing agreement with Durect Corporation to use a patented technology that forms the basis for a number of oral gel-cap drug candidates, including Remoxy. We have sub-licensed to King certain rights to develop and to commercialize Remoxy and certain other opioid drugs formulated in part with technology we licensed from Durect. Under the agreement with Durect, we control all of the preclinical, clinical, commercial manufacturing and sales/marketing activities for Remoxy and other abuse-resistant opioid painkillers. We reimburse Durect for formulation and related work, and will make milestone payments based on the achievement of certain technical, clinical or regulatory milestones. Durect will supply us with certain components of Remoxy and other abuse-resistant opioid painkillers on a cost-plus basis. We also are obligated to pay Durect royalties on any related drug sales.

King is obligated to reimburse us for costs we incur under the agreement with Durect, including royalties. Under our license agreement with King, we are obligated not to amend or terminate our agreement with Durect if an amendment or termination would alter the rights or obligations of King under the collaboration agreement or license agreement.

Manufacturing

We have no manufacturing facilities. We have entered into agreements with and rely upon qualified third parties for the formulation or manufacture of our clinical supplies. These supplies and the manufacturing facilities must comply with DEA regulations and current good manufacturing practices, or GMPs, enforced by the FDA and other government agencies. We plan to manufacture Remoxy with Mallinckrodt Pharmaceutical Outsourcing, a unit of Tyco Healthcare. Remoxy uses bulk oxycodone supplied by Noramco, Inc. We plan to continue to outsource formulation, manufacturing and related activities.

In 2006, we plan to continue to develop formulations of Remoxy and manufacture Remoxy to complete our Phase III clinical trial program. We also plan to develop abuse resistant formulations of other opioid drug candidates. We rely on a limited number of third-party manufacturers to formulate, manufacture, fill, label, ship or store all of our drug candidates.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. All of our products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical testing and clinical trials and other pre-marketing approval requirements by the FDA and regulatory authorities in other countries. In the United States, various federal, and in some cases state, statutes and regulations also govern or impact upon the manufacturing, safety, labeling, storage, record keeping and marketing of our products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require us to spend substantial resources. Regulatory approval, when and if obtained, may be limited in scope which may significantly limit the indicated uses for which our products may be marketed. Further, approved drugs, as well as their manufacturers, are subject to ongoing review and discovery of previously unknown problems with such products that may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

Applicable FDA regulations require the filing of an NDA and approval by the FDA prior to commercialization of Remoxy or Oxytrex in the United States.

The Drug Approval Process

We will be required to complete several activities before we can market any of our drug candidates for human use in the United States, including possibly:

- preclinical studies;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate;
- submission to the FDA of an NDA; and
- FDA approval of the NDA prior to any commercial sale or shipment of the drug.

Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety of the product. Preclinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practice. We submitted the results of preclinical tests to the FDA as part of our INDs prior to commencing clinical trials. We may be required to conduct additional toxicology studies concurrently with the clinical trials.

Based on preclinical testing, an IND is filed with the FDA to begin human testing of the drug in the United States. The IND becomes effective if not rejected by the FDA within 30 days. The IND must indicate the results of previous experiments, how, where and by whom the new clinical trials will be conducted, the chemical structure of the compound, the method by which it is believed to work in the human body, any toxic effects of the compound found in the animal studies and how the compound is manufactured. All clinical trials must be conducted in accordance with Good Clinical Practice. In addition, an Institutional Review Board, or IRB, generally comprised of physicians at the hospital or clinic where the proposed clinical trials will be conducted, must review and approve the IND. The IRB also continues to monitor the clinical trial. We must submit progress reports detailing the results of the clinical trials to the FDA at least annually. In addition, the FDA may, at any time during the 30-day period or at any time thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials under the IND cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. An FDA imposed clinical hold on an IND application can result in substantial delay and large, unforeseen expenses, and it may cancel the viability of developing a new drug candidate in the United States.

Clinical trials are typically conducted in three sequential phases that may overlap. Phase I clinical trials typically study a drug's safety profile, and may include the safe dosage range. Phase I clinical trials also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action. In addition, we may, to the extent feasible, assess early indicators of a drug's efficacy in our Phase I clinical trials. In Phase II clinical trials, controlled studies are conducted on volunteer patients with the targeted disease or condition. The primary purpose of these tests is to evaluate the effectiveness of the drug on the volunteer patients as well as to determine a drug's side effect profile. These clinical trials may be conducted concurrently with Phase I clinical trials. In addition, Phase I/II clinical trials may be conducted to evaluate not only the efficacy of the drug on the patient population, but also its safety. During Phase III clinical trials, the drug is studied in an expanded patient population and in multiple sites. Physicians monitor the patients to determine efficacy and to observe and report adverse events that may result from use of the drug.

Our clinical trials are designed to produce clinical information about how our drugs perform compared to placebo or compared to existing opioid drugs where appropriate. We have tested Oxytrex in several clinical settings of pain in order to support a broad approval by the FDA for use of the drug for the relief of moderate to severe pain. FDA guidelines recommend that we demonstrate Oxytrex's efficacy in more than one clinical presentation of pain, such as arthritis pain or generalized lower back pain. Because clinical models differ in their sensitivity to detect pain, we expect to complete clinical trials in multiple clinical models of pain.

We have designed most Phase II and Phase III clinical trials to date as randomized, double-blind, placebo- controlled, dose-ranging studies. A randomized clinical trial is one in which patients are randomly assigned to the various study treatment arms. A double-blind clinical trial is one in which the patient, the physician and our trial monitor are unaware if the patient is receiving placebo or study drug in order to preserve the integrity of the clinical trial and reduce bias. A placebo-controlled clinical trial is one in which a subset of patients is purposefully given inactive medication.

The FDA publishes industry guidelines specifically for the clinical evaluation of painkillers. We rely in part on these guidelines to design a clinical strategy for the approval of each of our drug candidates. In particular, FDA guidelines recommend that we demonstrate efficacy of our new painkillers in more than one clinical model of pain. Acceptable clinical models of pain include low-back pain or arthritis pain. Upon a clear demonstration of the safety and efficacy of painkillers in multiple clinical models of pain, the FDA has historically approved painkillers with broad indications. Such general purpose labeling often takes the form of "for the management of moderate to severe pain."

We may not successfully complete Phase I, Phase II or Phase III clinical trials within any specified time period, or at all, with respect to any of our drug candidates. Furthermore, we or the FDA may suspend clinical trials at any time in response to concerns that participants are exposed to an unacceptable health risk.

After the completion of clinical trials, if there is substantial evidence that the drug is safe and effective, an NDA is filed with the FDA. The NDA must contain all of the information on the drug gathered to that date, including data from the clinical trials. NDAs are often over 100,000 pages in length.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting a NDA for filing. In such an event, the NDA must be resubmitted with the additional information and, again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Federal Food, Drug and Cosmetic Act, the FDA has 365 days in which to review the NDA and respond to the applicant. The review process is typically extended for significant amounts of time by the FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. If the FDA's evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter, or an

approvable letter which usually contains a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter.

If the FDA approves the NDA, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported. The FDA may request additional post marketing studies, or Phase IV clinical trials, to evaluate long-term effects of the approved drug.

Other Regulatory Requirements

The FDA mandates that drugs be manufactured in conformity with current GMPs. If the FDA approves any of our drug candidates we will be subject to requirements for labeling, advertising, record keeping and adverse experience reporting. Failure to comply with these requirements could result, among other things, in suspension of regulatory approval, recalls, injunctions or civil or criminal sanctions. We may also be subject to regulations under other federal, state, and local laws, including the Occupational Safety and Health Act, the Environmental Protection Act, the Clean Air Act, national restrictions on technology transfer, and import, export, and customs regulations. In addition, any of our products that contain narcotics will be subject to DEA regulations relating to manufacturing, storage, distribution and physician prescribing procedures. It is possible that any portion of the regulatory framework under which we operate may change and that such change could have a negative impact on our current and anticipated operations.

The Controlled Substances Act imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products. A principal factor in determining the particular requirements, if any, applicable to a product is its actual or potential abuse profile. The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Any of our drug candidates that contain a scheduled substance will be subject to regulation by the DEA.

Competition

Our success will depend, in part, upon our ability to achieve market share at the expense of existing and established and future products in the relevant target markets. Existing and future products, therapies, technological approaches or delivery systems will compete directly with our products. Competing products may provide greater therapeutic benefits for a specific indication, or may offer comparable performance at a lower cost. Companies that currently sell generic or proprietary opioid formulations include but are not limited to Roxane Laboratories, Purdue Pharma, Janssen Pharmaceutica, Abbott Laboratories, Cephalon, Endo Pharmaceuticals, Teva Pharmaceuticals, Elkins-Sinn, Watson Laboratories, Ortho-McNeil Pharmaceutical and Forest Pharmaceuticals. Alternative technologies are being developed to increase opioid potency, as well as alternatives to opioid therapy for pain management, several of which are in clinical trials or are awaiting approval from the FDA.

We compete with fully integrated pharmaceutical companies, smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have opioid drugs already approved by the FDA or in development and operate larger research and development programs in these fields than we do. In addition, many of these competitors, either alone or together with their collaborative partners, have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;

- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing, distributing and selling drugs.

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

Employees

As of December 31, 2005, we had approximately 37 employees. We engage consultants from time to time to perform services on a per diem or hourly basis.

Available Information

We file electronically with the Securities and Exchange Commission, or SEC, our Annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on our website on the World Wide Web at http://www.paintrials.com, by contacting the Investor Relations Department at our corporate offices by calling 650-624-8200 or by sending an e-mail message to cwaarich@paintrials.com.

Item 1A. ***Risk Factors***

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

Risks Relating to our Financial Position and Need for Financing

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

We were founded in May 1998. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology and undertaking preclinical studies and clinical trials of our drug candidates. We have not yet demonstrated our ability to obtain regulatory approval, formulate and manufacture our drug candidates on a commercial scale or conduct sales and marketing activities. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

We have incurred net losses each year since our inception. As a result of ongoing operating losses, we had an accumulated deficit of $142.7 million as of December 31, 2005. Even if we succeed in developing and

commercializing one or more of our drug candidates, we expect to continue to use significant cash resources in our operations for the foreseeable future. We recognized positive cash flow from operations in 2005 as a result of the upfront payment from King. We anticipate that our expenses will increase substantially in the foreseeable future as we:

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

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

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

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

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

Clinical and Regulatory Risks

If we fail to obtain the necessary regulatory approvals, we will not be allowed to commercialize our drug candidates, and we will not generate product revenues.

Satisfaction of all regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the drug candidate, and requires the expenditure of substantial resources for research and development and testing. Our research and clinical approaches may not lead to drugs that the FDA considers safe for humans and effective for indicated uses we are studying. The FDA may require us to conduct additional clinical testing, in which case we would have to expend additional time and resources and would likely delay the date of potentially receiving regulatory approval. In particular, the FDA may require additional toxicology studies for certain excipients used in Remoxy or any of our other drug candidates. The approval process may also

be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals will:

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

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

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

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

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

Our Phase III clinical trials may not demonstrate the safety or efficacy of our drug candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. FDA guidelines recommend that the efficacy of new painkillers be demonstrated in more than one clinical model of pain. This means that even if one of our Phase III clinical trials demonstrates positive results for our drug candidates, we are likely to have to demonstrate positive results in one or more additional Phase III clinical trials prior to receiving broad label FDA approval for treatment of severe chronic pain. Even if the results of our Phase III clinical trials are positive, we may have to commit substantial time and additional resources to conducting further preclinical studies and clinical trials before we can submit NDAs or obtain FDA approvals for our drug candidates.

Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous requirements. The clinical trial process is also time consuming. Furthermore, if participating patients in clinical trials suffer drug-related adverse reactions during the course of such clinical trials, or if we or the FDA believe that participating patients are being exposed to unacceptable health risks, we will have to suspend or terminate our clinical trials. Failure can occur at any stage of the clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials.

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

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

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

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

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

We discuss with and obtain guidance from regulatory authorities on certain of our clinical development activities. These discussions are not binding obligations on the part of regulatory authorities. Regulatory authorities may revise previous guidance or decide to ignore previous guidance at any time during the course of our clinical activities or after the completion of our clinical trials. Even with successful clinical safety and efficacy data, we may be required to conduct additional, expensive clinical trials to obtain regulatory approval.

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

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

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

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

Government agencies may establish and promulgate usage guidelines that directly apply to our drug candidates.

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

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

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

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

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

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

Risks Relating to our Collaboration Agreements

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

Pursuant to our strategic alliance, we will jointly manage Phase III clinical trials and NDA submissions in the United States for Remoxy and other abuse resistant drug candidates with King. We rely on King to devote time and resources to the development and commercialization of Remoxy and other abuse resistant drug candidates. If King limits their time and resources attributable to the strategic alliance, or otherwise fails to perform as we expect, we may not achieve clinical and regulatory milestones and regulatory submissions and related product introductions may be delayed or prevented, and revenues that we would receive from these activities will be less than expected.

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

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

If we fail to maintain our strategic alliance for Remoxy and other abuse resistant drugs, we may have to reduce or delay our drug candidate development.

Our plan for developing, manufacturing and commercializing Remoxy and other abuse resistant drugs currently requires us to successfully maintain our strategic alliance with King to advance our programs and provide funding to support our expenditures on Remoxy and other drug candidates. If we are not able to maintain our existing strategic alliance with King, we may have to limit the size or scope of, or delay or abandon the development of Remoxy and other abuse resistant drug candidates or undertake and fund development of these drug candidates ourselves. If we elect to fund drug development efforts with respect to Remoxy and other abuse resistant drug candidates on our own, we may need to obtain additional capital, which may not be available on acceptable terms, or at all.

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

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

Our collaborative agreements may not succeed or may give rise to disputes over intellectual property or other issues.

Our strategy to focus on development of novel drug candidates discovered by third parties requires us to enter into license agreements with such third parties. In addition, we may enter into collaborative agreements to commercialize our products, such as our strategic alliance with King. Such agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property under collaborations. Such disputes can delay or prevent the development of potential new drug products, or can lead to lengthy, expensive litigation or arbitration. Other factors relating to collaborative agreements may adversely affect the success of our drug candidates, including:

- the development of parallel products by our collaborators or by a competitor;
- arrangements with collaborative partners that limit or preclude us from developing certain products or technologies;
- premature termination of a collaborative agreement; or
- failure by a collaborative partner to devote sufficient resources to the development of our potential products.

Risks Relating to Commercialization

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

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

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

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

If King is not successful in commercializing Remoxy and other abuse resistant drugs, our revenues and our business will suffer.

Our ability to commercialize Remoxy and other abuse resistant drugs and generate royalties from product sales of such drugs will depend on King's abilities in assisting us in developing such drugs and in maintaining regulatory approval and achieving market acceptance of such drugs once commercialized. King may elect to independently develop drugs that could compete with ours or fail to commit sufficient resources to the development, marketing and distribution of Remoxy and other abuse resistant drugs developed under our strategic alliance. King may not proceed with the commercialization of Remoxy and other abuse resistant drugs developed under our strategic alliance with the same degree of urgency as we would because of other priorities they face. If King is not successful in commercializing Remoxy for a variety of reasons, including but not limited to competition from other pharmaceutical companies, or if King fails to perform as we expect, our potential for revenue from drugs developed in connection with our strategic alliance with King, if any, could be dramatically reduced and our business would suffer.

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

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

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

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

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

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

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

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

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

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

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

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

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, health maintenance organizations and managed care organizations, are challenging the prices charged for medical products and services and/or are seeking pharmacoeconomic data to justify formulary acceptance and reimbursement practices. We currently have not generated pharmacoeconomic

data on any of our products. Government and other healthcare payers increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs, and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has or has not granted labeling approval. Adequate third-party insurance coverage may not be available to patients for any products we discover and develop, alone or with collaborators. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our products, market acceptance of our product candidates could be limited.

Risks Relating to our Intellectual Property

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

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

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

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

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

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

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

Risks Relating to our Business and Strategy

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

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

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

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

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

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

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

of our drug candidates. Successful defense against such claims can be expensive and might distract us from executing our strategies.

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

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

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

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

Business interruptions could limit our ability to operate our business.

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

Risks Relating to Manufacturing

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

Approved third-party commercial drug manufacturers may subsequently be stopped from producing, storing, shipping or testing our drug products due to their non-compliance with federal, state or local regulations. Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA, and corresponding state and foreign government agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

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

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

If we cannot formulate and scale-up a wide range of dosage forms of Remoxy and other abuse resistant product candidates, we and King might determine that the commercial opportunity for Remoxy is too limited to warrant further investment in clinical testing and development.

We plan to formulate and scale-up a wide range of dosage forms of Remoxy and other abuse resistant drug candidates. We may not be able to successfully complete our formulation or scale-up activities or we may determine that the commercial opportunity for Remoxy and other abuse resistant drug candidates in certain dosage forms is too limited to warrant further investment. If we are unsuccessful in our formulation or scale-up activities with Remoxy and other abuse resistant drug candidates, our future revenue from milestones and royalties under our strategic alliance with King may be less than expected and our operations may suffer.

We rely on Durect, our sole source provider of certain components of Remoxy and other abuse resistant drug candidates, to produce Remoxy and other abuse resistant drug candidates for clinical supplies and will rely on Durect to produce commercial supplies of these components.

We rely on Durect as our sole source provider of certain components of Remoxy and other abuse resistant drug candidates, and will rely solely on Durect to produce commercial supplies of these components. Durect's failure to achieve and maintain satisfactory manufacturing standards could result in product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could materially harm our business. Durect may encounter manufacturing difficulties involving production yields, quality control and quality assurance. Durect is subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We cannot control Durect's compliance with these regulations and standards.

To date, Durect has not produced commercial-scale supply of these components. If we and King receive marketing approval for and commercially launch Remoxy or other abuse resistant candidates, we anticipate that Durect will need to expand its manufacturing capacity, possibly materially. Durect may not be able to increase its manufacturing capacity for Remoxy and other abuse resistant drug candidates in a timely or economic manner, or at all. Moreover, significant scale up of manufacturing may require additional validation studies, which the FDA must review and approve. If Durect is unable to successfully increase the manufacturing capacity for such components of Remoxy and other abuse resistant drugs, at an acceptable cost or otherwise, and we are unable to establish alternative manufacturing capabilities, the commercial launch or continued commercialization after a commercial launch of Remoxy and other abuse resistant drugs may be delayed, prevented or impaired or there may be a shortage in supply, which would harm our revenues and cause our business to suffer.

Risks Relating to an Investment in our Common Stock

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

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

- the success of our collaboration agreements;
- results of or delays in our preclinical and clinical trials;
- publicity regarding actual or potential medical results relating to products under development by us or others;
- announcements of technological innovations or new commercial products by us or others;
- developments in patent or other proprietary rights by us or others;

- comments or opinions by securities analysts or major stockholders;
- future sales of our common stock by existing stockholders;
- regulatory developments or changes in regulatory guidance;
- litigation or threats of litigation;
- economic and other external factors or other disaster or crises;
- the departure of any of our officers, directors or key employees;
- period-to-period fluctuations in financial results; and
- limited daily trading volume.

The National Association of Securities Dealers, Inc., or NASD, and the Securities and Exchange Commission, or SEC, have adopted certain new rules. If we were unable to continue to comply with the new rules, we could be delisted from trading on the NASDAQ National Market, or Nasdaq, and thereafter trading in our common stock, if any, would be conducted through the over-the-counter market or on the Electronic Bulletin Board of the NASD. As a consequence of such delisting, an investor would likely find it more difficult to dispose of, or to obtain quotations as to the price of, our common stock. Delisting of our common stock could also result in lower prices per share of our common stock than would otherwise prevail.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

We currently lease approximately 10,500 square feet of space in South San Francisco, California, which is used as general office space. We believe that this facility is adequate and suitable for our current needs.

Item 3. ***Legal Proceedings***

We are not a party to any legal proceedings.

Item 4. ***Submission of Matters to a Vote of Security Holders***

There were no matters submitted to a vote of the security holders during the fourth quarter of 2005.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Our common stock is quoted on the Nasdaq National Market under the symbol "PTIE." The following table sets forth the high and low sales prices per share of our common stock as reported on the Nasdaq National Market for the periods indicated.

	Sale Price	
	High	**Low**
Fiscal 2005:		
First Quarter	$7.48	$4.99
Second Quarter	$7.24	$4.78
Third Quarter	$7.22	$5.79
Fourth Quarter	$9.45	$5.46
Fiscal 2004:		
First Quarter	$9.86	$5.77
Second Quarter	$9.34	$6.54
Third Quarter	$8.39	$6.22
Fourth Quarter	$8.13	$6.82

We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and have not paid and do not anticipate paying any cash dividends in the foreseeable future. As of February 1, 2006, there were approximately 75 holders of record of our common stock.

The following table summarizes the securities authorized for issuance under our equity compensation plans as of December 31, 2005.

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	**Weighted Average Exercise Price of Outstanding Options, Warrants and Rights**	**Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans**
Equity compensation plans approved by stockholders	6,993,492	$ 6.74	1,420,802
Equity compensation plans not approved by stockholders	—	—	—
Total	6,993,492	$ 6.74	1,420,802

Item 6. ***Selected Financial Data (in thousands except per share data)***

	Years ended December 31,				
	2005	2004	2003	2002	2001
Statement of operations data:					
Program fee revenue	$ 3,712	$ —	$ —	$ —	$ —
Collaboration revenue	1,368	—	—	—	—
Total revenues	5,080	—	—	—	—
Research and development expense	32,938	35,093	18,913	11,396	11,668
General and administrative expense	4,859	3,868	3,338	5,523	5,647
Total operating expenses	37,797	38,961	22,251	16,919	17,315
Operating loss	(32,717)	(38,961)	(22,251)	(16,919)	(17,315)
Interest and other income	2,047	1,185	634	994	2,978
Net loss	$ (30,670)	$ (37,776)	$ (21,617)	$ (15,925)	$ (14,337)
Basic and diluted loss per share	$ (0.70)	$ (1.01)	$ (0.73)	$ (0.59)	$ (0.57)
Weighted average shares used in computing basic and diluted loss per share	43,795	37,267	29,483	27,039	25,332

	December 31,				
	2005	2004	2003	2002	2001
Balance sheet data:					
Cash and cash equivalents	$ 95,651	$ 1,379	$ 12,027	$ 50,091	$ 65,274
Marketable securities	117,001	98,018	65,402	55	—
Working capital	181,817	91,860	74,799	48,146	63,195
Total assets	215,795	101,192	80,513	53,325	68,136
Deferred program fee revenue	146,288	—	—	—	—
Total liabilities	152,435	7,796	3,951	3,101	2,519
Total Stockholders' equity	63,360	93,396	76,562	50,224	65,616

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

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

Overview

We are a biopharmaceutical company dedicated to the development of innovative drugs. We specialize in developing safer or more efficacious drugs for use in pain management, particularly in the area of opioid painkillers, which are sometimes referred to as narcotic painkillers. According to IMS Health, sales for opioid painkillers in the United States exceeded $6.0 billion in 2004. We incorporated in Delaware in May 1998.

Our clinical pipeline consists of proprietary drug candidates. We are currently developing two oral, small molecule drugs to treat patients who suffer from severe chronic pain, such as pain associated with advanced osteoarthritis and low-back pain.

Both of our novel drug candidates are currently in Phase III clinical trial programs:

- Remoxy™, an abuse-resistant version of long-acting oxycodone, and
- Oxytrex™, a new oral opioid painkiller for the treatment of severe chronic pain.

In November 2005, we and King announced a strategic alliance to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. King made an upfront cash payment of $150 million to us at the closing of this strategic alliance in December 2005. We could also receive from King up to $150 million in milestone payments in the course of clinical development of Remoxy and other abuse-resistant opioid painkillers under the strategic alliance. In addition, subject to certain limitations, King is also obligated to pay us up to $150 million in payments based on the achievement of milestones in the course of clinical development of Remoxy and other abuse-resistant opioid painkillers under the strategic alliance. King is obligated to fund the commercialization expenses of, and has the exclusive right to market and sell, drugs developed in connection with the strategic alliance. King is obligated to pay us a 20% royalty on net sales of drugs developed in connection with the strategic alliance, except as to the first $1 billion in net sales of such drugs, for which the royalty is set at 15%.

We have yet to generate any revenues from product sales. We have not been profitable and through December 31, 2005, we have recorded an accumulated deficit of approximately $142.7 million. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of preclinical and clinical trials as well as clinical supplies associated with our drug candidates. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options granted to employees and non-employees. Our operating results may fluctuate substantially from period to period as a result of the timing and enrollment rates of clinical trials for our drug candidates and our need for clinical supplies.

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

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

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

We focus all our research and development efforts on the research and development of opioid drugs for the treatment of pain. The following table summarizes expenses by category for research and development efforts (in thousands):

	Years Ended December 31,		
	2005	2004	2003
Compensation	$ 4,717	$ 3,769	$ 3,690
Contractor fees [1]	23,642	26,605	10,049
Supplies [2]	2,351	2,575	3,262
Other [3]	2,228	2,144	1,912
	$32,938	$35,093	$18,913

(1) Contractor fees generally include expenses for preclinical studies and clinical trials.
(2) Supplies generally include costs for formulation and manufacturing activities.
(3) Other generally includes the allocation of common costs such as facilities.

Our technology has been applied across our portfolio of drug candidates. Data, know-how, personnel, clinical results, research results and other matters related to the research and development of any one of our drug candidates also relate to, and further the development of, our other drug candidates. As a result, costs allocated to a specific drug candidate may not necessarily reflect the actual costs surrounding research and development of that drug candidate due to cross application of the foregoing.

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

Critical Accounting Policies

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

- *Expenses for clinical trials.* Expenses for clinical trials are incurred from planning through patient enrollment to reporting of the underlying data. We estimate expenses incurred for clinical trials that are in process based on patient enrollment and based on clinical data collection and management. Costs that

are associated with patient enrollment are recognized as each patient in the clinical trial completes enrollment. Costs that are based on clinical data collection and management are recognized based on estimates of unbilled goods and services received. In the event of early termination of a clinical trial, we would accrue an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial.

- *Stock based compensation.* The preparation of the financial statement footnotes requires us to estimate the fair value of stock options granted to employees. While fair value may be readily determinable for awards of stock, market quotes are not available for long-term, nontransferable stock options because these instruments are not traded. We currently use the Black-Scholes option-pricing model, or Black-Scholes to estimate the fair value of employee stock options. However, Black-Scholes was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions, including but not limited to stock price volatility. Because our stock options have characteristics significantly different from those of traded options, changes to the assumptions used in Black-Scholes may materially affect the fair value estimate. After evaluating our option valuation policies and assumptions in light of current accounting standards related to employee stock options, we expect to continue to use the Black-Scholes option-pricing model for determining the fair value of our options.
- *Revenue recognition.* In connection with our strategic alliance with King, we recognize program fee revenue and collaboration revenue. Program fee revenue is derived from the upfront payment from King and is recognized ratably over our estimate of the development period under the strategic alliance with King. Collaboration revenues from reimbursement of development expenses are recognized as costs are incurred that relate to the strategic alliance with King.
- *Taxes*. We make estimates and judgments in determining income tax expense. We have accumulated significant deferred tax assets. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of deferred tax assets is dependent upon future earnings, if any. We are uncertain of the timing and amount of any future earnings. Accordingly, we fully offset the total deferred tax assets by a valuation allowance. We may in the future determine that some, or all, of our deferred tax assets will likely be realized, in which case we will reduce our valuation allowance in the quarter in which such determination is made. If the valuation allowance is reduced, we may recognize a benefit from income taxes in our statement of operations in that period.

Results of Operations

Years Ended December 31, 2005 and 2004

Revenues—Program fee revenue

King paid us a $150.0 million upfront fee in connection with the closing of our strategic alliance with King in December 2005. Revenues recognized from amortization of the upfront fee were $3.7 million in the fourth quarter of 2005 for recognition of the revenue for the period from the execution of the agreement in November 2005 to the end of 2005. We expect to recognize the remainder of the program fee ratably over our estimate of the development period under the strategic alliance with King.

Revenues—Collaboration revenue

Collaboration revenues were $1.4 million in the fourth quarter of 2005, related to reimbursement of our development expenses incurred pursuant to the King strategic alliance from the execution of the agreement in November 2005 to the end of 2005. We did not have any corresponding collaboration revenue in 2004.

We expect collaboration revenues to increase significantly in 2006 and beyond as compared to revenue recognized in 2005 in connection with future increases in our research and development activities for Remoxy and other abuse-resistant drug candidates and reimbursement of these expenses pursuant to the King Agreement.

Research and Development Expense

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

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

Research and development expense decreased to $32.9 million from $35.1 million in the years ended December 31, 2005 and 2004, respectively. The decrease was primarily due to lower clinical trial activity in 2005 as compared to 2004. This decrease was offset in part by increased formulation and development activities for Remoxy and other preclinical activities as well as increased compensation related expenses.

We expect research and development expenses to increase over the next several years as we expand our development efforts. We expect our development efforts to result in our drug candidates progressing through various stages of clinical trials, including our Phase III clinical trials of Oxytrex, Remoxy, and other abuse resistant drug candidates. King is obligated to reimburse development expenses for Remoxy and other abuse resistant drug candidates pursuant to our agreement. Also, we expect to continue other development efforts on our drug candidates. The increase in research and development expenses may fluctuate from period to period due to the timing and scope of our development activities and the results of clinical trials and preclinical studies.

General and Administrative Expense

General and administrative expense consists primarily of compensation and other general corporate expenses. General and administrative expense increased to $4.9 million from $3.9 million in the years ended December 31, 2005 and 2004, respectively, primarily due to increases in headcount and general corporate activities, offset in part by decreased non-cash stock-based compensation expense in 2005 as compared to 2004. We expect general and administrative expenses to increase over the next several years in connection with precommercialization and commercialization activities for our product candidates. The increase may fluctuate from period to period due to the timing and scope of these activities and the results of clinical trials and preclinical studies.

Interest and Other Income

Interest and other income increased to $2.0 million from $1.2 million in the years ended December 31, 2005 and 2004, respectively, primarily due to increases in yields on our investments in marketable securities and, to a lesser extent, in average balances of marketable securities. We expect our interest income to increase during 2006 because we expect our average balance of our marketable securities to be higher in 2006 as compared to 2005 and we expect the yield on our marketable securities to be higher in 2006 as compared to 2005.

Years Ended December 31, 2004 and 2003

Research and Development Expense

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

- preclinical testing,

- clinical trials,
- clinical supplies and related formulation and design costs, and
- salaries and other personnel-related expenses.

Research and development expense increased to $35.1 million from $18.9 million in the years ended December 31, 2004 and 2003, respectively. The increase was primarily due to the increase in Phase III clinical trials activities for Oxytrex, PTI-901 and Remoxy as well as continued development activities for Remoxy.

General and Administrative Expense

General and administrative expense consists primarily of compensation and other general corporate expenses. General and administrative expense increased to $3.9 million from $3.3 million in the years ended December 31, 2004 and 2003, respectively, primarily due to an increase in non-cash stock-based compensation expense.

Interest Income

Interest income increased to $1.2 million from $0.6 million in the years ended December 31, 2004 and 2003, respectively, primarily due to increases in average balances of marketable securities.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through public and private securities offerings. Additionally, in December 2005, we received a $150.0 million program fee under our strategic alliance with King. We intend to continue to use the proceeds from these offerings and from this program fee to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes. As of December 31, 2005, cash, cash equivalents and marketable securities were $212.7 million.

Net cash provided by operating activities was $113.2 million for the year ended December 31, 2005 compared to net cash used in operating activities of $32.6 million for the year ended December 31, 2004. The increase in cash provided by operating activities was primarily attributable to the December 2005 program fee received from King. Cash used in operating activities in both years related primarily to the funding of operating losses.

We may use cash in 2007 to pay certain alternative minimum taxes related to using either net operating loss carryforwards or tax credits to offset revenue stemming from the upfront payment from King.

Our investing activities to purchase property, equipment and leasehold improvements used cash of $0.5 million for the year ended December 31, 2005 and $0.2 million for the year ended December 31, 2004. Other investing activities for both years consisted primarily of the purchase and sale of marketable securities. We expect to continue to invest in our infrastructure to support our operations.

Net cash provided by financing was $0.3 million in 2005 compared to $54.8 million in 2004. In 2004, we issued 8,000,000 shares of common stock at $7.25 per share in a follow-on public offering and received approximately $54.5 million in net proceeds after deducting underwriting discounts and related expenses. In 2005, we filed with the Securities and Exchange Commission a registration statement on Form S-3, using a shelf registration process under which we may offer to sell any combination of securities described in such registration statement in one or more offerings, up to a total dollar amount of $150.0 million. We have not sold any securities under this shelf registration statement.

We lease approximately 10,500 square feet of general office space. In addition to office space, we also lease equipment pursuant to operating leases. Our leases expire at various dates through 2010. Under the terms of our real property and equipment leases, annual minimum lease payments are as follows as of December 31, 2005 (in thousands):

	2006	2007	2008	2009	2010	Total
Future minimum lease payments	$191	$187	$196	$206	$160	$940

We have license agreements that require us to make milestone payments upon the successful achievement of defined milestones, including clinical milestones. Our license agreements also require us to pay certain royalties to our licensors if we succeed in fully commercializing products under these license agreements. All of these potential future payments are cancelable as of December 31, 2005. Our formulation agreement with Durect Corporation obligates us to make certain milestone payments upon achieving clinical milestones and regulatory milestones. King is obligated to reimburse us for any of our milestone payments and royalty payments to Durect Corporation.

We have an accumulated deficit of approximately $142.7 million. While our cash requirements to fund our operations may be lower in the future than in the year ended December 31, 2005 due to the obligation of King under the strategic alliance to reimburse us for certain expenses, we expect our cash requirements to be significant in the future. The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our drug candidates and the resources we devote to researching and developing, formulating, manufacturing, commercializing and supporting our products. We believe that our current resources should be sufficient to fund our operations for at least the next twelve months. We may seek additional future funding through public or private financing within this timeframe, if such funding is available and on terms acceptable to us.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, the principal amount of our investment will probably decline. A hypothetical 50 basis point increase in interest rates reduces the fair value of our available-for-sale securities at December 31, 2005 by approximately $0.6 million. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents and marketable securities in a variety of securities, including commercial paper, government and non-government debt securities and/or money market funds that invest in such securities. We have no holdings of derivative financial or commodity instruments. As of December 31, 2005, our investments consisted of short-term investments in corporate and government notes and obligations or in money market accounts and checking funds with variable, market rates of interest.

Item 8. ***Financial Statements and Supplementary Data***

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Pain Therapeutics, Inc.

We have audited the accompanying balance sheets of Pain Therapeutics, Inc. as of December 31, 2005 and 2004, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Pain Therapeutics, Inc. at December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Pain Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 21, 2006 expressed an unqualified opinion thereon.

ERNST & YOUNG LLP

Palo Alto, California
February 21, 2006

PAIN THERAPEUTICS, INC.

BALANCE SHEETS
(in thousands except share and per share data)

	December 31, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 95,651	$ 1,379
Marketable securities	117,001	98,018
Collaboration revenue receivable	889	—
Prepaid expenses	623	259
Total current assets	214,164	99,656
Property and equipment, net	1,556	1,461
Other assets	75	75
Total assets	$ 215,795	$ 101,192
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 998	$ 877
Accrued development expense	4,461	6,358
Deferred program fee revenue—current portion	26,200	—
Accrued compensation and benefits	501	415
Other accrued liabilities	187	146
Total current liabilities	32,347	7,796
Non-current liabilities		
Deferred program fee revenue—noncurrent portion	120,088	—
Total liabilities	152,435	7,796
Commitments and contingencies		
Stockholders' equity		
Preferred stock; $.001 par value; 10,000,000 shares authorized, none issued and outstanding	—	—
Common stock, $.001 par value; 120,000,000 shares authorized; 43,936,088 and 43,652,116 shares issued and outstanding in 2005 and 2004, respectively	44	44
Additional paid-in-capital	206,489	205,920
Accumulated other comprehensive loss	(479)	(544)
Accumulated deficit	(142,694)	(112,024)
Total stockholders' equity	63,360	93,396
Total liabilities and stockholders' equity	$ 215,795	$ 101,192

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS
(in thousands except per share data)

	Years ended December 31,		
	2005	2004	2003
Revenues:			
Program fee revenue	$ 3,712	$ —	$ —
Collaboration revenue	1,368	—	—
Total revenues	5,080	—	—
Operating expenses:			
Research and development	32,938	35,093	18,913
General and administrative	4,859	3,868	3,338
Total operating expenses	37,797	38,961	22,251
Operating loss	(32,717)	(38,961)	(22,251)
Other income:			
Interest and other income	2,047	1,185	634
Net loss	$(30,670)	$(37,776)	$(21,617)
Basic and diluted loss per share	$ (0.70)	$ (1.01)	$ (0.73)
Weighted-average shares used in computing basic and diluted loss per share	43,795	37,267	29,483

Included in research and development and general and administrative expenses are stock-based compensation expenses of $248, $401, and $139 for the years ended December 31, 2005, 2004 and 2003, respectively.

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.

STATEMENT OF STOCKHOLDERS' EQUITY
(in thousands except share data)

	Common and Preferred stock		Additional paid-in capital	Deferred compensation	Notes receivable for stock	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Par value						
Balance at December 31, 2002	27,200,508	$ 27	$ 103,254	$ (304)	$ (122)	$ —	$ (52,631)	$ 50,224
Issuance of common stock pursuant to exercise of stock options	272,150	—	227	—	—	—	—	227
Issuance of common stock pursuant to follow-on offering, net of expenses	7,730,500	8	46,650	—	—	—	—	46,658
Issuance of common stock pursuant to exercise of warrants	120,000	—	600	—	—	—	—	600
Amortization of employee deferred compensation, net of reversals	—	—	(406)	297	—	—	—	(109)
Compensation with respect to non-employee option grants	—	—	248	—	—	—	—	248
Issuance of common stock related to employee stock purchase plan	58,151	—	159	—	—	—	—	159
Receipt of payment of stockholder notes receivable	—	—	—	—	122	—	—	122
Unrealized gains on investment in marketable securities	—	—	—	—	—	50	—	50
Net loss	—	—	—	—	—	—	(21,617)	(21,617)
Comprehensive loss								(21,567)
Balance at December 31, 2003	35,381,309	35	150,732	(7)	—	50	(74,248)	76,562
Issuance of common stock pursuant to exercise of stock options	184,257	1	473	—	—	—	—	474
Issuance of common stock pursuant to follow-on offering, net of expenses	8,000,000	8	54,074	—	—	—	—	54,082
Amortization of employee deferred compensation, net of reversals	—	—	—	7	—	—	—	7
Compensation with respect to non-employee option grants	—	—	394	—	—	—	—	394
Issuance of common stock related to employee stock purchase plan	86,550	—	247	—	—	—	—	247
Net unrealized losses on investment in marketable securities	—	—	—	—	—	(594)	—	(594)
Net loss	—	—	—	—	—	—	(37,776)	(37,776)
Comprehensive loss								(38,370)
Balance at December 31, 2004	43,652,116	44	205,920	—	—	(544)	(112,024)	93,396
Issuance of common stock pursuant to exercise of stock options	148,136	—	159	—	—	—	—	159
Issuance of common stock pursuant to exercise of warrants	60,450	—	6	—	—	—	—	6
Expenses pursuant to filing registration statements	—	—	(116)	—	—	—	—	(116)
Compensation with respect to non-employee option grants	—	—	248	—	—	—	—	248
Issuance of common stock related to employee stock purchase plan	75,386	—	272	—	—	—	—	272
Net unrealized gains on investment in marketable securities	—	—	—	—	—	65	—	65
Net loss	—	—	—	—	—	—	(30,670)	(30,670)
Comprehensive loss								(30,605)
Balance at December 31, 2005	43,936,088	$ 44	$ 206,489	$ —	$ —	$ (479)	$ (142,694)	$ 63,360

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended December 31,		
	2005	2004	2003
Cash flows used in operating activities:			
Net loss	$ (30,670)	$ (37,776)	$ (21,617)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	368	383	341
Non-cash net interest income	(100)	(484)	(27)
Non-cash stock based compensation	248	401	139
Changes in operating assets and liabilities:			
Collaboration revenue receivable	(889)	—	—
Prepaid expenses	(364)	1,062	(220)
Accounts payable	121	(1,354)	960
Accrued development expense	(1,897)	5,148	(167)
Deferred program fee revenue	146,288	—	—
Accrued compensation and benefits	86	46	96
Other accrued liabilities	41	5	(39)
Net cash provided by (used in) operating activities	113,232	(32,569)	(20,534)
Cash flows used in investing activities:			
Purchase of property and equipment	(463)	(156)	(26)
Purchase of marketable securities	(93,591)	(114,067)	(68,829)
Sales of marketable securities	74,773	81,341	3,559
Net cash used in investing activities	(19,281)	(32,882)	(65,296)
Cash flows from financing activities:			
Stock subscription note payments received	—	—	122
Proceeds from issuance of common stock, net	321	54,803	47,644
Net cash provided by financing activities	321	54,803	47,766
Net increase (decrease) in cash and cash equivalents	94,272	(10,648)	(38,064)
Cash and cash equivalents at beginning of period	1,379	12,027	50,091
Cash and cash equivalents at end of period	$ 95,651	$ 1,379	$ 12,027

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

1. Business

Pain Therapeutics, Inc. is a biopharmaceutical company dedicated to the development of innovative drugs. We specialize in developing safer or more efficacious drugs for use in pain management, particularly in the area of opioid painkillers, which are sometimes referred to as narcotic painkillers.

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

Our development activities involve inherent risks. These risks include, among others, dependence on our collaboration partners, key personnel and determination of patentability and protection of our products and processes. In addition, we have drug candidates that have not yet obtained FDA approval. Successful future operations depend on our ability to obtain approval for and commercialize these products.

Prior to 2005 we were a development stage company.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Revenue Recognition and Deferred Program Fee Revenue

In November 2005, we and King Pharmaceuticals, Inc., or King, announced that we have entered into a strategic alliance to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. In connection with this strategic alliance, we recognize program fee revenue and collaboration revenue. Program fee revenue is derived from the upfront payment from King and is recognized ratably over our estimate of the development period under the strategic alliance with King. Collaboration revenues from reimbursement of development expenses are recognized as costs are incurred that relate to the strategic alliance with King.

Collaboration Revenue Receivable from King

We accrue a receivable for yet-to-be reimbursed development expenses incurred in connection with the strategic alliance with King. We expect to receive payment for the receivable within 90 days of the balance sheet date and classify the receivable as a current asset.

Cash, Cash Equivalents and Concentration of Cash Risk

We consider all highly liquid financial instruments with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist of cash maintained at two financial institutions and money market funds.

Marketable Securities

In accordance with Statement of Financial Accounting Standards No. 115, “Accounting for Certain Investments in Debt and Equity Securities,” we consider our investments to be held as “available-for-sale.” We

classify these investments as current assets and carry them at fair value. Unrealized gains and losses are recorded as a separate component of stockholders' equity as accumulated other comprehensive income (loss). All realized gains and losses on our available-for-sale securities are recognized in results of operations. Our investments are maintained at one financial institution and are governed by our investment policy as approved by our Board of Directors. To date we have not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value. We would recognize an impairment charge when the decline in the estimated fair value of a marketable security below the amortized cost is determined to be other-than-temporary. We consider various factors in determining whether to recognize an impairment charge, including the duration of time and the severity to which the fair value has been less than our amortized cost, any adverse changes in the investees' financial condition and our intent and ability to hold the marketable security for a period of time sufficient to allow for any anticipated recovery in market value.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets (generally two to five years). Leasehold improvements are amortized over the shorter of the estimated useful life of the assets or the lease term.

Impairment of Long-Lived Assets

We regularly perform reviews to determine if the carrying value of our long-lived assets is impaired. We consider facts or circumstances, either internal or external, that indicate that we may not recover the carrying value of the asset.

We measure impairment loss related to long-lived assets based on the amount by which the carrying amounts of such assets exceed their fair values. Our measurement of fair value is generally based on an analysis of the present value of estimated future discounted cash flows. We use available information and reasonable and supportable assumptions and projections. We consider the likelihood of possible outcomes and our best estimates of projected future cash flows. If necessary, we perform subsequent calculations to measure the amount of the impairment loss based on the excess of the carrying value over the measurement of fair value of the impaired asset. No events or changes in circumstances have occurred with respect to our long-lived assets that would indicate that an impairment analysis should have been performed.

Business Segments

Statement of Financial Accounting Standards No. 131, *Disclosures about Segments of an Enterprise and Related Information*, requires an enterprise to report segment information based on how management internally evaluates the operating performance of its business units (segments). Our operations are confined to one business segment: the clinical development and commercialization of novel painkillers.

Expenses for Clinical Trials

Research and development expense includes the cost of clinical trials. Expenses for clinical trials are incurred from planning through patient enrollment to reporting of the underlying data. We estimate expenses incurred for clinical trials that are in process based on patient enrollment and treatment as well as on clinical data collection and management. Costs that are associated with patient enrollment are recognized as each patient in the clinical trial completes enrollment. Costs that are based on clinical data collection and management are recognized based on estimates of unbilled goods and services received. In the event of early termination of a clinical trial, we accrue an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Stock Based Compensation

We use the intrinsic-value method of accounting for stock based awards granted to employees and directors in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. Accordingly, we would recognize compensation expense in our financial statements in connection with stock options granted to employees and directors with exercise prices less than fair value at the time the stock option is granted. We record stock based compensation expense for non-employees at the fair value of the options granted in accordance with Statement of Financial Accounting Standards No. 123, or SFAS 123 and Emerging Issues Task Force No. 96-18, or EITF 96-18. The fair value of options granted to non-employees is estimated using a Black-Scholes option valuation model, or Black Scholes. The model considers a number of factors, including the market price and volatility of our common stock at the date of measurement. We periodically re-measure the compensation expense for options granted to non-employees as the underlying options vest. The compensation expense related to all grants is amortized using the graded vesting method, in accordance with SFAS 123, EITF 96-18 and FASB Interpretation No. 28, over the vesting period of each respective stock option, generally four years. Assuming no change in the fair value of the award, the graded vesting method results in expensing approximately 57% of the total award value in year one, 26% in year two, 13% in year three and 4% in year four.

If we had recorded compensation expense for our stock based plans in a manner consistent with the fair value approach of SFAS 123, our net loss and loss per share would have been increased as follows (in thousands, except per share data):

	Years Ended December 31,		
	2005	2004	2003
Net loss as reported	$(30,670)	$(37,776)	$(21,617)
Deduct: Total stock based employee and director compensation expense determined under the fair valued based method for all awards	(7,772)	(6,188)	(5,153)
Add (deduct): Total stock based employee and director compensation included in net loss	—	7	(109)
Adjusted net loss	$(38,442)	$(43,957)	$(26,879)
Net loss per share basic and diluted as reported	$ (0.70)	$ (1.01)	$ (0.73)
Adjusted net loss per share basic and diluted	$ (0.88)	$ (1.18)	$ (0.90)

The weighted average fair value of stock options granted to employees and directors was $4.47 in 2005, $6.25 in 2004, and $5.48 in 2003. The fair value of each option granted to both employees, directors and non-employees was estimated using Black-Scholes with an expected life of options of 5 years from vesting date for employees and directors, 10 years for non-employee options and no dividend yield. We assumed volatility was between 78% and 86% in 2005, 89% and 95% in 2004, and 91% and 100% in 2003. We used risk-free interest rates of between 4% and 5% in 2005, 3% and 4% in 2004, and 2% and 5% in 2003.

For the 2000 Employee Stock Purchase Plan, the weighted-average fair value of purchase rights granted was $2.14 per share in 2005, $2.85 per share in 2004 and $2.74 in 2003 calculated using Black-Scholes with an expected life of 1 year in 2005 and 2 years in 2004 and 2003, and no dividend yield. We assumed volatility was between 41% and 46% in 2005, 89% and 94% in 2004 and between 91% and 100% in 2003. We used risk-free interest rates of 3% to 4% in 2005, 3% in 2004, and between 1% and 2% in 2003.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Loss per Share

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

In all years presented we have reported a loss and therefore all potential common shares related to potentially dilutive securities have been excluded from the calculation of diluted loss per share because they are anti-dilutive. The following table sets forth the number of weighted-average potential shares of common stock that are in-the-money for the periods indicated but have not been included in the computation of diluted net loss per share because to do so would be anti-dilutive:

	Years Ended December 31,		
	2005	2004	2003
Options to purchase common shares	1,695,391	3,363,985	1,084,553
Warrants	150,000	220,000	220,000
	1,845,391	3,583,985	1,304,553

Comprehensive Loss

Comprehensive loss is comprised of net loss and unrealized holding gains and losses on available-for-sale securities as follows (in thousands):

	Years Ended December 31,		
	2005	2004	2003
Net loss	($30,670)	($37,776)	($21,617)
Other comprehensive income (loss)	65	(594)	50
Comprehensive loss	($30,605)	($38,370)	($21,567)

Income Taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some or all of the deferred tax assets may not be realized. Management performs assessments of the realization of deferred tax assets considering all available evidence, both positive and negative. These assessments require that management make significant judgments about many factors, including the amount and likelihood of future taxable income.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board, or FASB, issued a revision of Financial Accounting Standards No. 123, or SFAS 123R, which requires all share-based payments to employees and

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

directors, including grants of employee stock options, to be recognized in the income statement based on their values. We expect to calculate the value of share-based payments under SFAS 123R on a basis substantially consistent with the fair value approach of SFAS 123. We are required to adopt SFAS 123R in our fiscal quarter beginning January 1, 2006, using the modified prospective method. We expect the adoption of SFAS 123R will have a material impact on our results of operations in that fiscal quarter and in each subsequent quarter, although it will have no impact on our overall financial position. We cannot reasonably estimate the impact of adoption because it will depend on levels of share-based payments granted in the future as well as certain assumptions that can materially affect the calculation of the value share-based payments to employees and directors. However, had we adopted SFAS 123R in prior periods, the impact of the standard would have approximated the impact of SFAS 123 as described in the disclosure of pro-forma net loss and net loss per share in the Stock Based Compensation section above.

3. Collaboration Agreements

King Pharmaceuticals, Inc.

In November 2005, we and King announced a strategic alliance to develop and commercialize Remoxy and other abuse-resistant opioid painkillers. King made an upfront cash payment of $150 million to us at the closing of this strategic alliance in December 2005, of which $3.7 million was recorded as program fee revenue for the year ended December 31, 2005. King is also obligated to pay us up to $150 million in payments based on the achievement of milestones in the course of clinical development of Remoxy and other abuse-resistant opioid painkillers under the strategic alliance. In addition, subject to certain limitations, King is obligated to fund development expenses incurred by us related to Remoxy and other abuse-resistant opioid painkillers pursuant to the collaboration agreement, of which $1.4 million was recorded as collaboration revenue for the year ended December 31, 2005. King is obligated to fund the commercialization expenses of, and has the exclusive right to market and sell, drugs developed in connection with the strategic alliance. King is obligated to pay us a 20% royalty on net sales of drugs developed in connection with the strategic alliance, except as to the first $1 billion in net sales of such drugs, for which the royalty is set at 15%.

Durect Corporation

We have an exclusive, worldwide licensing agreement with Durect Corporation to use a patented technology that forms the basis for a number of oral gel-cap drug candidates, including Remoxy. We have sub-licensed to King certain rights to develop and to commercialize Remoxy and certain other opioid drugs formulated in part with technology we licensed from Durect. Under the agreement with Durect, we control all of the preclinical, clinical, commercial manufacturing and sales/marketing activities for Remoxy and other abuse-resistant opioid painkillers. We reimburse Durect for formulation and related work, and will make milestone payments based on the achievement of certain technical, clinical or regulatory milestones. Durect will supply us with certain components of Remoxy and other abuse-resistant opioid painkillers on a cost-plus basis. We also are responsible to pay Durect royalties on any related drug sales. King is obligated to reimburse us for costs we incur under the agreement with Durect, including royalties.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

4. Cash and Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities held as available-for-sale consisted of the following (in thousands):

	Cash, Cash Equivalents and Investments					
	Amortized Cost	Accrued Interest	Unrealized Gains	Unrealized Losses on Investments Held Under One Year	Unrealized Losses on Investments Held Over One Year	Estimated Fair Value
December 31, 2005						
Cash & cash equivalents:						
Money market securities	$ 95,599	$ 52	$ —	$ —	$ —	$ 95,651
Total	95,599	52	—	—	—	95,651
Marketable securities available-for-sale:						
U.S. government and agency obligation	40,785	255	—	(76)	(43)	40,921
Corporate obligation	65,644	854	7	(188)	(112)	66,205
Mortgage/asset-backed securities	9,928	14	—	(62)	(5)	9,875
	116,357	1,123	7	(326)	(160)	117,001
	$211,956	$1,175	$ 7	$ (326)	$ (160)	$212,652
December 31, 2004						
Cash & cash equivalents:						
Money market securities	$ 1,379	$ —	$ —	$ —	$ —	$ 1,379
Total	1,379	—	—	—	—	1,379
Marketable securities available-for-sale:						
U.S. government and agency obligation	41,676	228	—	(265)	—	41,639
Corporate obligation	44,574	648	—	(222)	(5)	44,995
Mortgage/asset-backed securities	11,424	12	—	(52)	—	11,384
	97,674	888	—	(539)	(5)	98,018
	$ 99,053	$ 888	$ —	$ (539)	$ (5)	$ 99,397

Of the $117.0 million of estimated fair value marketable securities at December 31, 2005, $107.6 million are in an unrealized loss position. This unrealized loss is primarily attributable to increases in prevailing interest rates subsequent to purchase of the underlying securities.

The gross realized losses and gains on the sale of available-for-sale securities during the years ended December 31, 2005, 2004 and 2003 were not material.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

The contractual maturities of our marketable securities at December 31, 2005, consisted of the following (in thousands):

Less than one year	$ 38,060
Greater than one year but less than three years	78,941
	$ 117,001

5. Property and Equipment

Property and equipment at December 31, consisted of the following (in thousands):

	2005	2004
Furniture and fixtures	$ 1,089	$ 630
Computers and software	128	224
Leasehold improvements	1,887	1,887
	3,104	2,741
Accumulated depreciation and amortization	(1,548)	(1,280)
	$ 1,556	$ 1,461

Depreciation expense was $368, $383 and $341 in 2005, 2004 and 2003, respectively.

6. Stockholders' Equity

Common Stock

In 2003, we issued 7,730,500 shares of common stock at $6.50 per share in a follow-on public offering and received net proceeds of approximately $46.7 million, after deducting underwriting discounts and related expenses.

In 2004, we file with the Securities and Exchange Commission a registration statement, using a shelf registration process, and reserved 15,000,000 shares of common stock to be offered via prospectus in amounts, at prices and at terms determined at the time of an offering and that may be sold directly by us to investors, through agents designated from time to time, or to or through underwriters or dealers. In 2004, we issued 8,000,000 shares of common stock at $7.25 per share in a follow-on public offering pursuant to this shelf registration statement and received net proceeds of approximately $54.5 million after deducting underwriting discounts and related expenses.

In 2005, we filed with the Securities and Exchange Commission a registration statement, using a shelf registration process under which we may offer to sell any combination of securities described in the registration statement in one or more offerings, up to a total dollar amount of $150 million. We have not sold any securities under this registration statement.

Preferred Stock

Our Board of Directors has the authority to issue preferred stock in one or more series and to fix the rights, preferences, privileges, restrictions and the number of shares constituting any series or the designation of the series.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

In 2005, our Board of Directors adopted a stockholder rights plan designed to guard against partial tender offers and other coercive tactics to gain control of the Company without offering a fair and adequate price and terms to all of Pain Therapeutics' stockholders. Pursuant to the stockholder rights plan, our Board of Directors declared and paid a dividend of one right to purchase one one-thousandth share of the Company's Series A Participating Preferred Stock for each outstanding share of our common stock. Each of these rights entitles the registered holder to purchase from us one one-thousandth of a share of Series A Preferred at an exercise price of $40.00, subject to adjustment at any time.

Warrants

As of December 31, 2005, we have outstanding warrants to purchase 150,000 shares of common stock at $1.00 per share. These warrants were issued in connection with corporate activities. The value of these warrants was immaterial. These warrants expire in 2010.

2000 Employee Stock Purchase Plan

Under the 2000 Employee Stock Purchase Plan, or the Purchase Plan, eligible employees may purchase common stock through payroll deductions of up to 15% of the employee's compensation. The purchase price of the stock is generally 85% of the lower of the fair market value of the common stock at the beginning of the offering period or at the end of the purchase period. A total of 500,000 shares of common stock have been reserved for issuance under the Purchase Plan. Shares reserved for issuance under the Purchase Plan may be automatically increased each year by the amount equal to the lesser of (i) 500,000 shares, (ii) 1% of the initially outstanding shares of common stock on such date, or (iii) an amount determined by our Board of Directors. We have issued 276,510 shares of common stock pursuant to the Purchase Plan through December 31, 2005, leaving 223,490 shares reserved for issuance.

1998 Stock Plan

Under the 1998 Stock Plan, our employees, directors and consultants may be granted options that allow for the purchase of shares of our common stock. Incentive stock options may only be granted to employees. Through December 31, 2005 a total of 10,600,000 shares of common stock were authorized for issuance under the 1998 Stock Plan. The 1998 Stock Plan allows for annual increases in the number of common shares authorized for issuance equal to the lesser of (i) 2,000,000 shares, (ii) 5% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (iii) an amount determined by our Board of Directors.

Our Board of Directors or a designated Committee of the Board is responsible for administration of the 1998 Stock Plan and determines the terms and conditions of each option granted, consistent with the terms of the plan. Incentive stock options may be granted under the 1998 Stock Plan at a price not less than 100% of the fair market value of the stock on the date of grant (not less than 110% of the fair market value on the date of grant in the case of holders of more than 10% of our voting stock). Options granted under the 1998 Stock Plan generally expire ten years from the date of grant (five years for incentive stock options granted to holders of more than 10% of our voting stock). Forfeited options become available for reissuance under the 1998 Stock Plan.

The 1998 Stock Plan also provides for the automatic grant of options to purchase shares of common stock to outside directors. On the date of each annual stockholders' meeting, each outside director is automatically granted an option to purchase 25,000 shares of common stock. The term of the option is ten years, the exercise price is 100% of the fair market value of the stock on the date of grant, and the option becomes exercisable as to 25% of the shares on the anniversary of its date of grant provided the optionee continues to serve as a director on such dates.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

The following table summarizes option activity under the 1998 Stock Plan:

	Number of options	Weighted-average exercise price
Options outstanding as of December 31, 2002	3,993,629	$ 6.15
Granted	1,146,300	6.70
Exercised	(272,150)	0.83
Forfeited	(499,270)	7.00
Options outstanding as of December 31, 2003	4,368,509	6.53
Granted	1,373,100	7.56
Exercised	(184,257)	2.57
Forfeited	(222,618)	6.28
Options outstanding as of December 31, 2004	5,334,734	6.94
Granted	1,880,300	5.75
Exercised	(148,136)	1.08
Forfeited	(73,406)	7.90
Options outstanding as of December 31, 2005	6,993,492	$ 6.74

Shares reserved for issuance and available for grant under the 1998 Stock Plan were 1,197,312 as of December 31, 2005.

The following table summarizes information about stock options outstanding as of December 31, 2005:

	Options outstanding			Options exercisable	
Range of exercise prices	Number of options	Weighted average remaining contractual life (years)	Weighted average exercise price	Number of vested options	Weighted average exercise price
$0.10—$ 4.99	700,200	6.43	$ 2.80	509,226	$ 2.33
5.25	995,000	9.41	5.25	145,101	5.25
5.34— 6.67	718,904	8.76	6.06	209,920	6.21
6.71— 6.85	786,000	6.72	6.75	616,166	6.72
6.90	700,000	6.45	6.90	685,416	6.90
6.92— 7.16	842,452	7.47	7.13	502,750	7.13
7.25— 7.75	745,512	8.52	7.50	237,397	7.50
7.78— 8.00	763,300	8.12	7.80	333,818	7.83
8.03— 14.13	667,124	5.92	9.72	585,244	9.88
18.63	75,000	4.71	18.63	75,000	18.63
$0.10—$18.63	6,993,492	7.59	$ 6.74	3,900,038	$ 7.00

7. Employee 401(k) Benefit Plan

We have a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all employees. Employees are eligible to participate in the plan the first day of the month after hire and may elect to contribute the lesser of 20% of their annual compensation or the current statutory limits under Internal Revenue Service regulations. The 401(k) plan permits us to make additional matching contributions on behalf of all employees. Through December 31, 2005, we have not made any matching contributions.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

8. Income Taxes

There is no provision for income taxes because we have incurred losses through December 31, 2005. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows (in thousands):

	December 31,		
	2005	2004	2003
Deferred tax assets:			
Net operating loss carryforwards	$ 51,300	$ 38,300	$ 25,300
Research and development credits	7,200	7,700	4,800
Stock related compensation	800	900	4,700
Other	2,400	3,000	800
Total deferred tax assets	61,700	49,900	35,600
Valuation allowance	(61,700)	(49,900)	(35,600)
Net deferred tax assets	$ —	$ —	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which we are uncertain. We have concluded that it was more likely than not that our deferred tax assets would not be realized. Accordingly, the total deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $11,800, $14,300, and $12,590, during 2005, 2004 and 2003, respectively.

As of December 31, 2005, we had net operating loss carryforwards for federal income tax purposes of approximately $126.2 million, which expire in the years 2018 through 2025 and federal research and developments tax credits of approximately $5.8 million, which expire in the years 2018 through 2025. As of December 31, 2005, we had net operating loss carryforwards for state income tax purposes of approximately $126.2 million, which expire in the years 2008 through 2015 and state research and development tax credits of approximately $1.3 million, which do not expire.

Utilization of our net operating loss and credit carryforwards may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss and credits before utilization.

9. Leases and Commitments

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

We currently lease office space and equipment pursuant to non-cancelable operating leases that will expire at various dates through 2010. Future minimum lease payments for these leases are as follows for the years ended December 31, (in thousands):

	2006	2007	2008	2009	2010	Total
Future minimum lease payments	$ 191	$ 187	$ 196	$ 206	$ 160	$ 940

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Rent expense was $178,000, $178,000, and $171,000 for the years ended December 31, 2005, 2004, and 2003 respectively.

10. Selected Quarterly Financial Data (Unaudited) (in thousands except per share data)

	Quarters Ended			
	March 31	June 30	September 30	December 31
2005				
Total revenues	—	—	—	$ 5,080
Net loss	$ (8,589)	$ (10,182)	$ (8,767)	$ (3,132)
Basic and diluted loss per common share	$ (0.20)	$ (0.23)	$ (0.20)	$ (0.07)
2004				
Net loss	$ (10,163)	$ (9,066)	$ (9,231)	$ (9,316)
Basic and diluted loss per common share	$ (0.29)	$ (0.26)	$ (0.26)	$ (0.22)

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

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

Management's annual report on internal control over financial reporting. We are responsible for establishing and maintaining adequate internal control over our financial reporting. We have assessed the effectiveness of internal control over financial reporting as of December 31, 2005. Our assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework.

Our internal control over financial reporting is a process designed 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. Our internal control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on using the COSO criteria, we believe our internal control over financial reporting as of December 31, 2005 was effective.

Changes in internal control over financial reporting. There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our independent registered public accounting firm, Ernst & Young LLP has audited the financial statements included in this Annual Report on Form 10-K and has issued a report on management's assessment of our internal control over financial reporting as well as on the effectiveness of our internal control over financial reporting. The attestation report of Ernst & Young LLP, the registered public accounting firm, on management's assessment of internal control over financial reporting is included below.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Pain Therapeutics, Inc.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting, that Pain Therapeutics, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Pain Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Pain Therapeutics, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Pain Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Pain Therapeutics, Inc. as of December 31, 2005 and 2004, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005 of Pain Therapeutics, Inc. and our report dated February 21, 2006 expressed an unqualified opinion thereon.

ERNST & YOUNG LLP

Palo Alto, California
February 21, 2006

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors and Officers of the Registrant***

The information regarding our directors, executive officers and the audit committee of our board of directors is incorporated by reference from "Directors and Executive Officers" in our Proxy Statement for our 2006 Annual Meeting of Stockholders.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended requires our executive officers and directors and persons who own more than ten percent (10%) of a registered class of our equity securities to file reports of ownership and changes in ownership with the Securities and Exchange Commission, or SEC, and the National Association of Securities Dealers, Inc. Executive officers, directors and greater than ten percent (10%) stockholders are required by Commission regulation to furnish us with copies of all Section 16(a) forms they file. We believe all of our executive officers and directors complied with all applicable filing requirements during the fiscal year ended December 31, 2005.

Code of Ethics

We have adopted a Code of Ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. We publicize the Code of Ethics through posting the policy on our website, http://www.paintrials.com. We will disclose on our website any waivers of, or amendments to, our Code of Ethics.

Item 11. ***Executive Compensation***

The information required by this Item is incorporated by reference from our definitive Proxy Statement referred to in Item 10 above where it appears under the heading "Executive Compensation and Other Matters."

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this Item regarding security ownership of certain beneficial owners and management is incorporated by reference from our definitive Proxy Statement referred to in Item 10 above where it appears under the heading "Security Ownership of Certain Beneficial Owners and Management." The table required by this Item regarding equity compensation plans is incorporated by reference from Item 5 above of this Annual Report on Form 10-K.

Item 13. ***Certain Relationships and Related Transactions***

The information required by this Item is incorporated by reference from our definitive Proxy Statement referred to in Item 10 above where it appears under the heading "Certain Relationships and Related Transactions."

Item 14. ***Principal Accountant Fees and Services***

The information required by this Item is incorporated by reference from our definitive Proxy Statement referred to in Item 10 above where it appears under the heading "Principal Accounting Fees and Services."

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.

Exhibit Number	Description of Document
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).
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.

(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 requested 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 report to be signed on its behalf by the undersigned, thereunto duly authorized.

PAIN THERAPEUTICS, INC.

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

Dated: February 23, 2006

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Remi Barbier and Peter S. Roddy, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report 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)	February 23, 2006
/s/ PETER S. RODDY **Peter S. Roddy**	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 23, 2006
/s/ NADAV FRIEDMANN, PH.D., M.D., **Nadav Friedmann, PH.D., M.D.,**	Chief Operating and Medical Officer and Director	February 23, 2006
/s/ ROBERT Z. GUSSIN, PH.D. **Robert Z. Gussin, Ph.D.**	Director	February 23, 2006
/s/ VERNON R. LOUCKS, JR. **Vernon R. Loucks, Jr.**	Director	February 23, 2006
/s/ MICHAEL J. O'DONNELL, ESQ. **Michael J. O'Donnell, Esq.**	Director and Secretary	February 23, 2006
/s/ SANFORD R. ROBERTSON **Sanford R. Robertson**	Director	February 23, 2006

EXHIBIT INDEX

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\+ Confidential treatment has been requested for certain portions of this agreement. The omitted portions have been filed separately with the Securities and Exchange Commission.

Exhibit 10.8

Execution Copy

COLLABORATION AGREEMENT

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

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 **Establishment and Function of JOC**. 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 "Co-Chairman" and together the "Co-Chairmen"). 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.

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

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 [***] U.S. dollars ($[***]) 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;

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(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 [***] percent ([***]%) of the [***] 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 "AAA"), 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 arbitral 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 procedure 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

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

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 **Committees**. 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 **Schedule of Meetings**. 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 **Agenda and Minutes**. 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 [***] as its opioid API, and the third such Product shall be a product within the Field containing [***] 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 [***] different Products under the Collaboration at all times; provided that beginning on [***], such minimum number of different Products shall increase to [***]. In order to satisfy the foregoing requirement that King is Marketing or funding the Development of at least [***] different Products under the Collaboration by [***], King further agrees that it will designate a [***] Product to be Developed and Marketed hereunder no later than [***]. King further agrees that in the event King (i) does not designate a [***] Product by [***] 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 on King's behalf. For purposes of this Section 3.1.3, King shall be deemed to be "funding the Development" of a Product if King has (A) designated 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 [***] different Products under the Collaboration at all times; provided that beginning on [***], such minimum number of different Products shall increase to [***].

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3.1.4 **Product Termination**. King shall have the right to terminate Development and Marketing of a Product (the "Terminated Product") hereunder by providing written notice to PTI [***] 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 **Durect License Agreement**. 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 [***], which updated budgets shall specify the funding which PTI projects to be required during the following [***] to perform its obligations under such Development Plans and Manufacturing/CMC Plans. Each

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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 [***] 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 [***] shall be at least [***]. 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 [***] a year in any of the first [***] 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 [***], (ii) costs of [***], including costs incurred in [***], (iii) all costs and expenses related to [***], and (iv) costs incurred in connection with [***], it being understood that the [***]. 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 any dosage form 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

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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 [***] 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

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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 [***]% of such funds, which additional expenditures shall be paid by King. If the actual costs under a particular Development Plan will likely exceed [***]% 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 [***] 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 [***] 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

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that are within the Field (including Products) outside the Territory, (c) to develop [***] pursuant to the terms of this Agreement and the License Agreement, (d) to develop products outside the Field, including [***], 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 of access or reference to Third Parties who are not engaged in a research, development, manufacturing, or marketing relationship with PTI.

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: [***]; 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 [***] 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 agonist as its API as such [***], King shall not be obligated to conduct Product Development, seek Regulatory Approval, or Market such Product in such country.

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

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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 [***] 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 [***]; and provided further that [***]. 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

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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 [***].

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 [***], or (b) there is an [***], or (c) [***]. 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

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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 [***] 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 by the FDA; provided that King will be entitled to suspend such spending in the event the JOC decides to cease pursuing 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

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particular Development Plan will likely exceed [***] 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 ("Discretionary Funding") 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 "Non-Defaulting Party") to proceed with the Development Program notwithstanding certain conduct of the other Party (the "Defaulting Party") 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 ("Third Party Agreements") 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

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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 **Remedy**. 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 **Records**.

4.1.1 **Record Keeping**. 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 6.4.3 hereof, 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 **Adverse Event Reports**. In addition to the reports described in Section 4.1.2 above, 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 **Confidential Information**. 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 **Sales Report**. 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 ("Claims"), 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 $[***]) 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 $[***] 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.

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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 **Mutual Financial Reporting**. 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) Reasonable Efforts. 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) Filings. 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 Exhibit B, 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 "Program Fee"). 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.

Milestone	Payment	
	Remoxy	All Other Products
Acceptance by a Regulatory Authority of the first IND filing for a Product in the Territory	N/A	$ [***]
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	$ 15 Million	$ [***]
Total Development Milestones for Each Product	**$30 Million**	**$ [***]**

6.3.2 **Termination of Milestones**. 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 [***] following the end of the [***] 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 [***], which King shall pay to PTI pursuant to Section 3.7 above. All such payments shall be made within [***] following the end of the second month of the applicable Calendar Quarter.

6.4.2 **Currency Conversion**. 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

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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 [***] percent ([***]%) 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 **Overdue Payments.** All overdue payments, not subject to a bona fide dispute, due and payable pursuant to this Agreement shall bear interest at a rate of [***] per month from the due date until paid in full.

6.4.5 **Withholding Taxes.** 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 [***], 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.

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

8.1 **Confidentiality**.

8.1.1 **Confidentiality Obligations**. 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 **Employees and Consultants**. 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 relief to prevent or curtail any breach of Article 7 or 8 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 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 (or in the case of a disclosure in connection with a scientific conference, at least fifteen (15) days prior to such disclosure). Within fifteen (15) days of receipt of the prepublication materials (or as soon as practicable in connection with an outline 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 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 all such Confidential Information contained therein).

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 "Term").

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

9.2.1 **Mutual Termination**. 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) Product Specific Termination. 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 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.

(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) Termination of the Agreement in its Entirety. 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, "Scientific Failure" 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 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.

(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 9.2.3, 9.2.4 or 9.4.3; the obligations of the Parties set forth in the first two sentences of 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 "Non-Debtor Party") 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 **Tax Treatment**. 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.

10. **REPRESENTATIONS AND WARRANTIES**

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

(a) Organization. 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) Authorization and Right to Grant Licenses. 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) Binding Agreement. 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) No Inconsistent Obligation. 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) Absence of Actions. To its Knowledge, it is not a party to or object of any litigation, suit, legal claim, action, proceeding, judgment, settlement, or investigation (an "Action") 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) Applicable Law. 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) Debarment. 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 **By PTI.** PTI further represents and warrants to King as of the Effective Date as follows:

(a) Clinical Trials. 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) Disclosure. 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 "Saber Infringement"), 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) No Omissions. 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 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 **Indemnification of King by PTI**. PTI shall indemnify, defend, and hold harmless King, its Affiliates, and their respective directors, officers, employees, and agents (the "King Indemnitees"), against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses of litigation) (collectively, "Losses") 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 10 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 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 "PTI Indemnitees"), 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 10 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 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 "Indemnified Party") shall give prompt notice of the claim to the other Party (the "Indemnifying Party") 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 11. The Indemnifying Party shall not 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 11 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 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 **Warranty Disclaimer**. 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. 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.

13. MISCELLANEOUS

13.1 **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:	If to PTI:
King Pharmaceuticals, Inc. 501 Fifth Street Bristol, Tennessee 37620 Tel.: (423) 989-8000 Fax: (423) 990-2566 Attention: General Counsel	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:	With a copy to:
King Pharmaceuticals, Inc. 501 Fifth Street Bristol, Tennessee 37620 Tel.: (423) 989-8000 Fax: (423) 274-2602 Attention: Business Development	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

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 **Binding Effect**. 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 **Performance by Affiliates**. 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 **Assignment and Successors**. 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 **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.

[Remainder of page intentionally left blank]

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. "**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.

4. "**Agreement**" 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. "**Applicable Law**" 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. "**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.

9. "**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.

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

11. "**Closing**" 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. "**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 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. "**Collaboration**" 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. "**Collaboration Costs**" 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:

(a) 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 [***] and provided further that King shall have title to any such capital equipment which it funds);

(b) 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

(c) 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

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

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. "**Completion of Phase II**" 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. "**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 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 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 this Agreement or the License Agreement.

19. "**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.

20. "**Consultation**" 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. "**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.

22. "**[***]**" 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 [***], and King shall consider such request in good faith. Notwithstanding the foregoing, with respect to United States Application Serial Nos. [***], 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 [***], 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. "**[***]**" means any dosage form of a [***] that (a) contains [***] as the only opioid agonist API and (b) is covered by the rights granted to PTI under the DLA.

24. "**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.

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

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

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, 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. "**Designated Product**" 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 [***] as the opioid API, and one (1) Product having [***] as the opioid API); and "**Designated Products**" 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.

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

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

33. "**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 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 [***] percent ([***]%) 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.

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. "**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.

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 [***] U.S. dollars ($[***]) per [***] 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.

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42. "**Good Clinical Practices**" 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. "**Good Laboratory Practices**" 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. "**Good Manufacturing Practices**" 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 [***] 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. "**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.

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.

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

52. "**Joint Oversight Committee**" or "**JOC**" means the committee of PTI and King representatives established pursuant to Section 2.1 of this Agreement to 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. "**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.

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. "**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 this Agreement, and a separate Manufacturing/CMC Plan will be generated and approved with respect to each Product.

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. "**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).

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. "**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.

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.

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. "**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.

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. "**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.

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. "**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.

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.

89. "**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.

90. "**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.

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. "**SABER Technology**" 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. "**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 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. "**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 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

Schedule 10.2 (d)

[***]

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

Schedule 22

[***]

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

Schedule 53

[***]

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

Schedule 58

[***]

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

Schedule 85

[***]

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

Exhibit 10.9

LICENSE AGREEMENT

This License Agreement (the "Agreement") is made effective this 29th day of December, 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 ("PTI") and KING PHARMACEUTICALS, INC., a Tennessee corporation with a principal place of business at 501 Fifth Street, Bristol, TN 37620 ("King"). Each of King and PTI is sometimes referred to individually herein as a "Party" and collectively as the "Parties."

RECITALS

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

WHEREAS, PTI and King have entered into that certain Collaboration Agreement, dated November 9, 2005 ("Collaboration Agreement"), 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 ("Products," 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.

*** Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission. ***

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:

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 **Rights of the Parties to Make Products**. 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 **Further Rights with Respect to Australia and New Zealand**. 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:

2.2.1 **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 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 **Outside the Territory**. 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 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 **[***]**. Beginning on the Closing Date and during the Term hereof and, 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, 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) [***] that do not incorporate the SABER Technology, and (ii) [***], 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 [***], 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) [***] that do not incorporate the SABER Technology, and (ii) [***], 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 [***]. 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 [***] that do not incorporate the SABER Technology or that are [***].

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 [***] 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.

*** Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission. ***

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 provisions of the DLA to the extent same are applicable to sublicensees, and to 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. [***]. [***]. 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

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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 [***], PTI shall immediately notify King, [***]. 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 **No Other Rights**. 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 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 **[***]**. The Parties acknowledge and agree that PTI retains the exclusive right to develop, make, use, offer for sale, sell, import and otherwise commercialize [***]. Notwithstanding the foregoing, PTI agrees that it shall not make, use, offer for sale, sell import or otherwise commercialize any [***] which

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incorporate the SABER Technology, other than [***]. [***]. If any [***] 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 [***] of their original amount (as specified in Sections 6.1.1 and 6.1.4 of this Agreement, respectively). If any [***] 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 [***] 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 [***] in the relevant country or region and continue for so long as such [***] 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 [***], and PTI shall be solely responsible and liable to Durect with respect to the diligence obligations pertaining to the relevant [***]. 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).

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3.2 **Ownership**. 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:

3.2.1 **PTI Intellectual Property Rights**. 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 **Patent Coordinators**. PTI and King shall each appoint a patent coordinator (each, a "Patent Coordinator" and, collectively, the "Patent Coordinators"), 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 **DLA**. 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.

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 **Information and Cooperation in Prosecution**. Each Party responsible for the preparation, filing, prosecution and maintenance of Patent Rights as described in Section 4.2 (the "Filing Party") 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 **Abandonment**. 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, what the rights of the Parties shall be with respect to the relevant Patent Rights, and how to allocate responsibility for any costs incurred in connection with same.

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 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 "Infringement"), that Party shall notify the JOC and other Party within thirty (30) days and shall provide each with full details (an "Infringement Notice"). 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 **Allocation of Costs and Damages Award**. 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 [***] to the Party initiating the suit and [***] to the other Party.

4.6 **Defense of Claims**.

4.6.1 **Notice and Conduct of Action**. 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 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 **Consequences of Action**. 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 [***]

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[***] 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 [***] 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 reduced by [***] of such milestone payments to such Third Party; provided that if and when King's outstanding milestone obligations to PTI are insufficient to permit full offset of the creditable Third Party milestone amounts, then King shall be entitled to offset [***] 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 by PTI hereunder be reduced by more than [***] of their original amount (as specified in Sections 6.1.1 and 6.1.4 of this Agreement).

4.7 **Cooperation in Litigation**. 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 **Trademark Prosecution**. 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.

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.

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6. CONSIDERATION

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 exceeds $1 billion, then King shall thereafter, for the Term 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 [***] of the royalty rate that would otherwise be owed with respect to such Net Sales under Section 6.1.1 above.

6.1.3 **Amounts Payable Under the DLA**. 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.

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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 [***] 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 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

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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 **Accounting Reports**. 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.

6.5 **Withholding Taxes.** 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

"Term"), 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 **Accrued Obligations**. 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 "Non-Debtor Party") 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 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 **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, 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 **Survival**. 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 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 "King Indemnitees"), against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses of litigation) (collectively, "Losses") 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 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 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 "PTI Indemnitees"), 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 **Conditions to Indemnification**. A Party seeking indemnification under this Article 9 (the "Indemnified Party") shall give prompt notice of the claim to the other Party (the "Indemnifying Party") 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 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 **Limited Liability**. 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 **Confidentiality Obligations**. 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 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 **Employees and Consultants**. 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 **Equitable Relief**. 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, 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.

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 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 (or in the case of a disclosure in connection with a scientific conference, at least fifteen (15) days prior to such disclosure). Within fifteen (15) days of receipt of the prepublication materials (or as soon as practicable in connection with an outline 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 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 all such Confidential Information contained therein).

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:	If to PTI:
King Pharmaceuticals, Inc. 501 Fifth Street Bristol, Tennessee 37620 Tel.: (423) 989-8000 Fax: (423) 990-2566 Attention: General Counsel	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:	With a copy to:
King Pharmaceuticals, Inc. 501 Fifth Street Bristol, Tennessee 37620 Tel.: (423) 989-8000 Fax: (423) 274-2602 Attention: Business Development	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

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 **Binding Effect**. 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 **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.

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 **Performance by Affiliates**. 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 **Assignment and Successors**. 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]

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.

By: /s/ Brian A. Markison
(Signature)

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

Date: December 29, 2005

PAIN THERAPEUTICS, INC.

By: /s/ Remi Barbier
(Signature)

Name: Remi Barbier
Title: President & CEO

Date: December 29, 2005

ANNEX A

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. "**[***]**" 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 [***], and King shall consider such request in good faith. Notwithstanding the foregoing, with respect to United States Application Serial Nos. [***], 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 [***], 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. "**[***]**" means any dosage form of a [***] that (a) contains [***] 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

*** Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission. ***

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 4th. 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. — Nov. 3, 2005

Jim Brown, D.V.M.
President & CEO

Date

CONFIDENTIAL

Exhibit 10.10

DEVELOPMENT AND LICENSE AGREEMENT

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

RECITALS

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

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

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

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

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

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

ARTICLE I

DEFINITIONS

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

1.1 "Accounting Period" means a calendar quarter commencing on the first day of an Accounting Period, respectively January 1, April 1, July 1 and October 1, each being the first day,

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

and finishing on the last day of an Accounting Period, respectively March 31, June 30, September 30 and December 31, each being the last day.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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and/or other formulants from such Active Ingredient(s). **[* * *]**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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ARTICLE II

DEVELOPMENT OF LICENSED PRODUCTS

2.1 Initiation of Development of Licensed Products.

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

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

2.2 Pre-Clinical Program.

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

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

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

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

2.3 Pre-Clinical Program Expenses.

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

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

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

2.4 Other Development Activities.

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

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

ARTICLE III

CLINICAL PROGRAM

3.1 Clinical Program.

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

3.2 Clinical Program Milestones.

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

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

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

3.3 DURECT's Cooperation.

(a) DURECT shall reasonably cooperate with PTI to obtain the Product Registration for each Licensed Product in the Territory by providing any information or other materials relating to the conduct of the Pre-Clinical Program or the SABER™ Delivery System in DURECT's possession or control as PTI shall reasonably request. Without limiting the generality of the

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foregoing, DURECT shall assist PTI or its designee in the completion of **[* * *]** as required in the Territory, for each Licensed Product.

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

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

ARTICLE IV

MINIMUM DEVELOPMENT REQUIREMENTS

4.1 Minimum Development Requirements.

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

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

4.2 Consequences.

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

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

4.3 Expiration of Development Diligence Requirements.

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

4.4 Addition or Deletion of Licensed Products.

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

ARTICLE V

DURECT MANUFACTURE AND SUPPLY

5.1 DURECT Manufacture and Supply During Clinical Phase.

(a) Subject to the terms and conditions set forth herein, DURECT shall manufacture and supply to PTI, and PTI shall purchase from DURECT: (i) **[* * *]** described in the written specifications designated by the JDT therefor in accordance with Section 5.1(b) (collectively,

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the "SABER™ Ingredients") for manufacture of Licensed Products used in the conduct of the Clinical Program and (ii) **[* * *]** as designated by the JDT (**[* * *]**, the "Bulk Dosage Form").

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

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

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

5.2 Supply of Opioid Drugs and Antagonists.

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

5.3 Terms and Conditions Applicable to Clinical Supply.

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

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

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

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

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

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

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Territory); and (vi) such SABER™ Ingredients or Bulk Dosage Form may be introduced into interstate commerce pursuant to the Act.

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

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

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

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

5.4 Failure to Supply.

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

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

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5.5 Supply Agreement for the Commercial Phase.

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

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

5.6 PTI Responsibilities.

Other than DURECT's foregoing supply obligations of SABER™ Ingredients and Bulk Dosage Form, as between the Parties, PTI shall be solely responsible for manufacturing, or having

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manufactured, the Licensed Products for use in the conduct of the Clinical Program and for Commercialization.

ARTICLE VI

PTI MANUFACTURE AND REGULATORY INTERACTIONS

6.1 PTI Manufacture and Supply.

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

6.2 Regulatory Authority Interactions.

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

6.3 DURECT Rights.

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

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ARTICLE VII

THE JOINT DEVELOPMENT TEAM

7.1 The Joint Development Team.

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

7.2 Meetings.

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

7.3 Responsibilities.

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

7.4 Decision Making and Authority.

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

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7.5 Termination of JDT.

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

ARTICLE VIII
GRANT OF LICENSE

8.1 License.

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

8.2 Term of License.

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

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

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

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

8.3 Sublicense.

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

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

8.4 Exclusivity.

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

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

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

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(i) [* * *]

(ii) [* * *]

(d) [* * *].

8.5 Commercial Diligence.

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

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

8.6 License to DURECT.

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

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ARTICLE IX

PAYMENTS

9.1 Upfront Payments.

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

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

9.2 Milestone Payments for Initial Licensed Product.

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

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

9.3 Milestone Payments for Each Subsequent Licensed Product.

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

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Event	Payment

(a) [* * *]

(b) [* * *]

(c) [* * *]

(d) [* * *]

9.4 Other.

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

9.5 Royalties.

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

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

(b) The obligation to pay royalties to DURECT under Section 9.5(a) above shall be imposed only once with respect to any sale of the Licensed Product, regardless of the number of DURECT Patent Rights covering or the DURECT Technology licensed by DURECT to PTI. There shall be no obligation to pay royalties to DURECT under Section 9.5(a) above on sales or transfer of

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the Licensed Product between or among PTI, its Affiliates and its Sublicensees (unless such Sublicensee or Affiliate is an end user of the Licensed Product).

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

9.6 Mode of Payment.

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

9.7 Tax Withholding.

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

9.8 Accounting and Audit.

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

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

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

ARTICLE X

REPRESENTATIONS AND WARRANTIES

10.1 Representations and Warranties of DURECT.

DURECT represents and warrants to PTI that:

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

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

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

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

10.2 Disclaimer of Warranties by DURECT.

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

10.3 Representations and Warranties of PTI.

PTI represents and warrants to DURECT that:

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

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

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

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

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

10.4 Disclaimer of Warranties by PTI.

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

ARTICLE XI
INDEMNIFICATION

11.1 Indemnification by PTI.

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

11.2 Indemnification by DURECT.

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

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

11.3 Obligations of the Party Seeking to Be Indemnified.

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

ARTICLE XII

OWNERSHIP OF INTELLECTUAL PROPERTY, PATENT PROSECUTION, ENFORCEMENT AND INFRINGEMENT

12.1 Patent Prosecution and Maintenance.

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

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

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

12.2 Notification of Infringement.

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

12.3 Patent Enforcement.

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

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

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

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

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

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

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

12.5 Ownership and Inventions.

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

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

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

12.6 Ownership of Data and Licensed Product Registrations.

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

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solely or jointly by the Parties during the Term of this Agreement shall be owned exclusively by PTI. [* * *]

12.7 Ownership of Information related to Intellectual Property.

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

ARTICLE XIII

CONFIDENTIALITY

13.1 Confidentiality.

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

13.2 Disclosure.

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

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

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

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

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

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

13.3 Publicity.

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

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

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

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

ARTICLE XIV

INSURANCE

14.1 Insurance.

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

(b) DURECT Corporation and SBS shall, in combination and at their sole cost and expense, procure and maintain comprehensive general liability insurance and products liability insurance policies from a qualified insurance company which has a superior rating from a recognized

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

rating service, with minimum limits of US **[* * *]** for combined bodily injury and property damage.

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

ARTICLE XV

TERM AND TERMINATION

15.1 Term.

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

15.2 Termination Without Cause.

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

15.3 Termination For Cause.

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

15.4 Termination for Insolvency

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

15.5 Effects of Termination.

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

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

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

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

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

15.6 Return of Records and Data.

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

15.7 Surviving Provisions.

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

ARTICLE XVI

DISPUTE RESOLUTION

16.1 Arbitration.

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

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

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

16.2 Pre-Arbitration Dispute Resolution.

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

16.3 Provisional Remedy.

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

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

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

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The Parties hereby consent to the exclusive venue and jurisdiction of such courts for such disputes, controversies or claims.

ARTICLE XVII
MISCELLANEOUS

17.1 Assignment.

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

17.2 Entire Agreement.

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

17.3 Severability.

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

17.4 Notices.

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

If to DURECT:

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

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

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

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

17.5 Choice of Law.

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

17.6 Waiver.

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

17.7 Force Majeure.

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

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

17.8 Bankruptcy

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

17.9 Headings.

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

17.10 Counterparts.

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

17.11 Relationship of Parties.

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

17.12 Limitation of Liability.

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

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

17.13 No Implied Licenses.

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

17.14 No Third Party Beneficiaries.

There are no third party beneficiaries under this Agreement.

[remainder of the page intentionally blank]

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

DURECT CORPORATION

By: /s/ James E. Brown

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

SOUTHERN BIOSYSTEMS, INC.

By: /s/ Arthur J. Tipton

Name: Arthur J. Tipton
Title: Vice President

PAIN THERAPEUTICS, INC.

By: /s/ Remi Barbier

Name: Remi Barbier
Title: President & Chief Executive Officer

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

Exhibit 3.2
CLINICAL PROGRAM MILESTONES

[* * *]

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

Exhibit 9.5
SCHEDULE OF ROYALTY PAYMENTS

For Licensed Products which do not include an Antagonist

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

For Licensed Products which include an Antagonist

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

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

Exhibit 5.1
TRANSFER PRICE

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

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

Exhibit 1.37
MANUFACTURING COSTS

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

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

Exhibit 1.19
DURECT PATENT RIGHTS

[* * *]

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

Exhibit 7.1
JDT MEMBERS

DURECT Members

[* * *]

PTI Members

[* * *]

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

Exhibit 10.11

EXECUTION COPY

December 21, 2005

Remi Barbier
President & CEO
Pain Therapeutics, Inc.
416 Browning Way
South San Francisco, CA 94080

Re: Amendment 1 to the Development and License Agreement

Dear Remi:

The following sets forth amendments to the Development and License Agreement entered into by Pain Therapeutics, Inc. and DURECT Corporation effective December 19, 2002 (the "Agreement"), as agreed to by the Parties. Unless otherwise defined in this letter, all terms shall have the meaning given to such terms in the License Agreement.

- PTI and DURECT agree that DURECT shall not be obligated to supply to PTI, and PTI shall not be obligated to purchase from DURECT, SABER™ Ingredients. Accordingly, Section 5.1(a) of the Agreement shall be amended to read as follows:

  "5.1(a) Subject to the terms and conditions set forth herein, DURECT shall supply to PTI, and PTI shall purchase from DURECT: (i) [***] (collectively, the 'Excipient Ingredients') for manufacture of Licensed Products used in the conduct of the Clinical Program and (ii) Licensed Products used in the Pre-Clinical Program and the initial pharmacokinetic studies in humans under the Clinical Program (the 'Bulk Dosage Form')."

- The terms and conditions of Article V of the Agreement shall govern the supply of [***] by DURECT to PTI under Section 5.1(a), with "Excipient Ingredients" substituted for "SABER™ Ingredients" throughout the Agreement except with respect to Sections 11.2(iv) and 12.4(b). For clarity, Excipient Ingredients shall be supplied by DURECT to PTI in their neat form according to specifications mutually agreed upon by PTI and DURECT.

- Exhibit 5.1 of the Agreement is amended to read as follows:

  "The Transfer Price for [***]

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

[***]

- Section 5.6 shall be amended to read as follows:

"(a) Subject to Section 5.1(a), PTI or its agents shall be solely responsible for all aspects of sourcing, supplying, formulating or manufacturing any excipient, additive, solvent or ingredient other than the Excipient Ingredients for manufacture of Licensed Products (each an 'Other Ingredient' and collectively 'Other Ingredients'); provided, however, notwithstanding the foregoing, in the event the Other Ingredient is [***], then PTI and DURECT shall determine, by mutual agreement in writing, which Party shall have the responsibility for sourcing and supplying such Other Ingredient, and the terms and conditions therefor, and neither Party may directly or indirectly (e.g., through agents or other Third Parties) source or supply such Other Ingredient absent such written agreement by the Parties. It is further understood that in the event the Parties disagree over who should have the right to source or to supply a particular Other Ingredient based on the interpretation of the above, then upon PTI's request, DURECT shall assume responsibility to insure continuous sourcing and supplying of such Other Ingredient on terms and conditions substantially similar to [***] until DURECT and PTI resolve such disagreement. [***]

(b) Subject to Sections 5.1 and 5.6(a), as between the Parties, PTI shall be solely responsible for manufacturing or having manufactured the Licensed Products for use in the Clinical Program and for Commercialization."

- The following shall be added as Section 5.7:

"5.7 [***] Related Costs.

(a) PTI shall reimburse DURECT [***] shall mean the DURECT Research Expenses incurred by DURECT to date and hereafter with respect to [***]. To effect this:

(i) PTI shall pay to DURECT the amount of [***], such amount equal to [***], within [***] after the execution of this Amendment No. 1.

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(ii) DURECT shall invoice PTI and PTI shall pay for [***] in accordance with the procedure for invoicing and payment of DURECT Research Expenses under the Pre-Clinical Program in Section 2.3(b), and PTI shall have the audit rights for [***] in accordance with Section 2.3(b).

(b) PTI shall reimburse DURECT [***] pursuant to that certain supply agreement entered into by DURECT and [***], a copy of pertinent financial terms thereof is attached hereto as Exhibit B, to enable long term production of [***] (including expenses for [***]. DURECT shall provide PTI with a copy of [***] as well as evidence of DURECT's payment of such CMO Expenses. PTI shall reimburse DURECT an amount equal to [***] made by DURECT for [***] within [***] after receipt of the documentation described above. In partial consideration of the above referenced payments, DURECT hereby grants to PTI [***].

For clarification purposes, [***] shall not include any expenses which relate exclusively to the manufacture of [***]."

- The following shall be added as Section 6.4:

"6.4 Data Use and Reference Rights.

[***], PTI agrees to use reasonable commercial efforts to [***]. PTI shall use commercially reasonable efforts to [***] that exist as of the effective date of this Amendment within 120 days of signing this Amendment.

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

[***]

PTI hereby grants to DURECT: (a) a right of reference and audit with respect to the [***], to the extent permissible under applicable laws and regulations, as well as the right to grant to third parties a sublicense to reference[***], provided that DURECT may only grant such a sublicense to the [***] to a third party that is [***] and (b) a non-exclusive, fully paid-up, perpetual license, with the right to sublicense, to use the [***], provided, however, that (i) DURECT may not use its right of reference or the [***] to develop or [***], and (ii) with respect to the [***], except as required to exercise the right of reference granted in subsection (a) above, DURECT and its sublicensees shall not disclose, either publicly or in their regulatory filings, such [***]. Furthermore, DURECT may not [***]. Notwithstanding the foregoing, in the event that [***] DURECT shall be free to use the [***] to obtain or maintain regulatory approval for such products. This Section 6.4 shall survive termination of the Agreement."

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

Unless otherwise specifically amended herein, all terms of the Agreement shall remain as set forth in the Agreement. Please sign below to indicate PTI's agreement with the foregoing.

Very truly yours,

/S/ JAMES E. BROWN

James E. Brown
President & CEO

AGREED TO BY PAIN THERAPEUTICS, INC.

By: /S/ REMI BARBIER

Remi Barbier, President & CEO

Date: 12/21/05

EXHIBIT A

[***]

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

[***]

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT B

[***]

*** Confidential treatment request pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement (Form S-3 No. 333-115362) of Pain Therapeutics, Inc. and in the related Prospectus, and in the Registration Statements (Form S-8 Nos. 333-115361, 333-105138, and 333-68118) pertaining to the 1998 Stock Plan of Pain Therapeutics, Inc. of our reports dated February 21, 2006, with respect to the financial statements of Pain Therapeutics, Inc., Pain Therapeutics, Inc.'s management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Pain Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2005.

Ernst & Young LLP

Palo Alto, California
February 21, 2006

EXHIBIT 31.1

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 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: February 23, 2006

EXHIBIT 31.2

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 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: February 23, 2006

EXHIBIT 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

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

1. The Company's 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: February 23, 2006

/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