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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, 2011

or

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

Commission File Number: 000-29959

Pain Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

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

2211 Bridgepointe Parkway,
Suite 500,
San Mateo, California 94404
(Former Address)

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

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐
(Do not check if a smaller reporting company)	

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

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

The number of shares outstanding of the Registrant's common stock on January 12, 2012 was 44,732,017

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2011 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.

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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:

- timing expectations for potential regulatory approval of REMOXY® (oxycodone) Extended-Release Capsules CII by the U.S. Food and Drug Administration, or FDA;
- royalty, milestone or collaboration revenue we may receive from King Pharmaceutical, Inc., or King, a wholly-owned subsidiary of Pfizer, Inc., or Pfizer, pursuant to the collaboration agreement and license agreement between us and King, or the King Agreements;
- the duration of the development period for drug candidates being developed under our collaboration with King;
- expectations regarding REMOXY commercialization activities of Pfizer and Pfizer's acquisition of King potentially facilitating commercial success of REMOXY, if REMOXY is approved by the FDA;
- expansion of our potential product line, including the formulation of additional dosage forms of our drug candidates;
- 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 potential markets for our products;
- the utility of protection of our intellectual property;
- expected future sources of revenue and capital and increasing cash needs;
- potential competitors or competitive products;
- market acceptance of our drug candidates and potential drug candidates;
- expenses increasing or fluctuations in our operating results;
- 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;
- assumptions and estimates used for our disclosures regarding stock-based compensation; and
- estimates concerning the realization of deferred tax assets.

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

- the possibility of the FDA requesting additional data which would require an extended period of time to complete, significantly delaying or preventing the potential approval of REMOXY;
- the successful development and commercialization of REMOXY and other drug candidates pursuant to our collaboration agreement with King and development of other drug candidates pursuant to our other collaboration agreements, and the continuation of such agreements;

- physician reluctance to prescribe REMOXY, if approved, due to doubts about its ability to reduce unintended use or its cost-effectiveness;
- availability of reimbursement for REMOXY;
- difficulties or delays in development, testing, clinical trials (including patient enrollment), regulatory approval, production and commercialization of our drug candidates;
- unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product approval (including the risk that current and past results of clinical trials are not indicative of future results of clinical trials) or potential post-approval market acceptance;
- the uncertainty of protection of our intellectual property rights or trade secrets;
- potential infringement of the intellectual property rights of third parties;
- pursuing in-license and acquisition opportunities;
- maintenance or third party funding of our collaboration and license agreements;
- hiring and retaining personnel; and
- our financial position and our ability to obtain additional financing if necessary.

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

Item 1. *Business*

Overview

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

Pfizer acquired King in early 2011. We expect REMOXY will be commercialized within Pfizer’s primary care unit. We believe Pfizer’s acquisition of King may facilitate REMOXY’s commercial success if this drug is approved.

We and King jointly managed a Phase III clinical program and NDA submission for REMOXY. In mid-2008, the FDA accepted our NDA for REMOXY with Priority Review. In December 2008, we received from the FDA a Complete Response Letter for the NDA for REMOXY. In this Complete Response Letter, the FDA indicated additional non-clinical data was required to support the approval of REMOXY. Also, the FDA did not request or recommend additional clinical efficacy studies prior to approval. In 2009, King assumed sole responsibility for the regulatory approval of REMOXY. This shift of responsibility did not change any economic term of the King Agreements. In December 2010, King resubmitted the REMOXY NDA. In January 2011, we announced that the FDA had accepted the resubmission of the REMOXY NDA. In June 2011, we and Pfizer announced that King received a Complete Response Letter from the FDA in response to King’s resubmission of the REMOXY NDA. The FDA’s Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. Certain drug lots showed inconsistent release performance during *in vitro* testing. It is not known at this time whether this is an artifact of the testing method or a manufacturing deficiency. Sufficient information does not yet exist to accurately assess the time required to resolve the concerns raised in the FDA’s Complete Response Letter.

In January 2011, we announced that the FDA had accepted our IND for abuse-resistant oxymorphone and that we had received a $5.0 million milestone payment under the King Agreements for this milestone.

We are also conducting research and development on other pre-clinical novel drug candidates. We own all commercial rights to these pre-clinical drug candidates.

REMOXY

REMOXY is a novel controlled-release oral capsule form of oxycodone in a highly viscous liquid formulation matrix that includes novel excipients. It is specifically formulated to help address issues of abuse and misuse of time-release oxycodone tablets. Sales of time-release oxycodone were estimated to be over $3.0 billion in 2010.

The analgesic action of extracts of the opium poppy plant has been known for millennia. In more recent decades, semi-synthetic opium derivatives, such as oxycodone, a generic drug in clinical use since the 1930's, have become a standard of care for treating moderate-to-severe pain.

It is also well-known that medicinal opioids such as oxycodone can produce both analgesia and euphoria. The search for euphoric effects can lead to drug-seeking behavior, tolerance and dependence. In particular, rapid increases in plasma levels of oxycodone may lead to overdose, respiratory depression or death.

Opioid misuse and abuse are significant public health problems. The active drug ingredient in time-release oxycodone is oxycodone, an FDA approved substance for the relief of moderate to severe pain. Oxycodone is generally considered safe and effective when properly prescribed, dispensed and administered for legitimate medical purposes.

However, the U.S Drug Enforcement Administration, or DEA, has reported that time-release oxycodone tablet abuse has substantially increased since FDA approval of time-release oxycodone. Abusers can quickly and easily extract large amounts of oxycodone by simply breaking or crushing time-release oxycodone tablets. Doing so disrupts this time release mechanism and allows an abuser to immediately ingest, snort or inject a large dose of oxycodone that was originally intended to be slowly released over 12 hours. Patients may mistakenly cut or crush the time-release oxycodone tablets, which may also lead to accidental overdose.

The REMOXY formulation is designed to resist common methods of chemical or physical manipulation. REMOXY's capsule dosage form provides therapeutic drug levels of oxycodone on a twice-daily dosing schedule, while resisting the rapid increases in plasma levels of oxycodone associated with common methods of abuse and misuse. Its formulation also resists delivery by unapproved routes of administration, such as injection, snorting or inhalation.

REMOXY is an investigational drug candidate whose safety and efficacy have not yet been established by the FDA. REMOXY is intended to meet the needs of physicians who appropriately prescribe opioid painkillers and who seek to minimize the risks of drug diversion, abuse or accidental patient misuse as well as the needs of pharmacists and the managed care healthcare system in the United States.

Other product candidates

We believe the abuse-resistant technology used in REMOXY is applicable to different oral opioid painkillers. Our strategic alliance with King includes development of three other abuse-resistant opioid product candidates: hydromorphone, hydrocodone and oxymorphone. Our abuse-resistant formulations of hydromorphone and hydrocodone have completed Phase I clinical trials. These Phase I clinical trials were designed to investigate the safety, tolerability, pharmacokinetics and pharmacodynamic profile of a single, oral dose of the drug candidates in healthy volunteers. We believe results also indicate these product candidates are safe and well-tolerated and their release profile appears well-suited to use with a chronic pain population. In January 2011, we announced that the FDA had accepted our investigational new drug application, or IND, for abuse-resistant oxymorphone.

Our abuse-resistant product candidates are intended to meet the needs of physicians who appropriately prescribe opioid painkillers and who seek to minimize the risks of drug diversion, abuse or accidental patient misuse as well as the needs of pharmacists and the managed care healthcare system in the United States.

In July 2011, we terminated our license to certain technology from Albert Einstein College of Medicine, including technology we used in our monoclonal antibody program for the treatment of metastatic melanoma. We did not incur any expenses as a result of this termination.

Strategy

Our corporate strategy is to spend carefully but to keep innovation at the top of our agenda. Our clinical goal is to continue to develop novel drugs that are more effective or safer than drugs used in the clinic today. Elements of our strategy include:

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 drugs 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. Our research and development expenses were $21.1 million in 2009, $15.7 million in 2010 and $8.3 million in 2011. We recorded contract revenue related to customer-sponsored research activities under our collaboration with King of $6.2 million in 2009, $1.3 million in 2010 and $0.6 million in 2011.

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

- the technology that forms the basis of REMOXY and our other abuse resistant drug candidates;
- the clinical uses of a unique gene integration system intended to treat hemophilia or pain;
- the technologies or intellectual property related to our pre-clinical product candidates; and
- the manufacture and use of our drug candidates.

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.

We and our collaborators have filed patent applications with the U.S. Patent Office and outside the United States to further protect our technologies. Our material patents and the material patents we license from third parties include:

- For REMOXY and our other abuse resistant product candidates, we have licensed from Durect Corporation U.S. Patent 5,747,058 entitled “High Viscosity Liquid Controlled Delivery System” with estimated expiration of June 2015 and European Patent 1575569B1 entitled “Oral Drug Delivery System Comprising High Viscosity Liquid Carrier Materials” with estimated expiration of December 2023.

Certain U.S. patent applications have published and been allowed by the U.S. Patent Office but not yet issued. Other U.S. patent applications have published but not yet allowed or have not published but are pending. Certain patent applications outside the U.S. have been granted as patents. Other patent applications outside the U.S. have published or have not published but are pending. We believe that the published and allowed patent applications as well as issued and granted patents would protect certain of our technologies through at least 2023. If the patent applications do not result in issued or granted patents, the duration or scope of our patent rights may be limited and our future revenues could be lower as a result.

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 drug candidates, and demand for our drug candidates could decline as a result.

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

In 2005, we entered into collaboration agreement and a license agreement with King to develop and commercialize REMOXY and other abuse-resistant opioid painkillers. King made an upfront cash program fee payment of $150.0 million to us at the closing of this strategic alliance in 2005 and another upfront cash program fee payment of $5.0 million to us in June 2010 in connection with an amendment to the strategic alliance. Pfizer acquired King in early 2011. We believe Pfizer’s acquisition of King may facilitate REMOXY’s commercial success if REMOXY is approved.

We will receive a $15.0 million cash milestone payment from King upon regulatory approval of REMOXY in the United States. In January, 2011, we received $5.0 million for the acceptance by the FDA of the IND for abuse-resistant oxymorphone. In 2008, we received $15.0 million related to acceptance by the FDA of the NDA for REMOXY, and $5.0 million of acceptance by the FDA of the IND for abuse-resistant hydrocodone. In 2006, we received $5.0 million for the acceptance by the FDA of the IND for abuse-resistant hydromorphone. We could also receive from King up to $105.0 million in additional milestone payments in the course of clinical development of the other abuse-resistant opioid painkillers under the strategic alliance. In addition, subject to certain limitations, King is obligated to fund development expenses incurred by us pursuant to the collaboration agreement.

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

We and King have a joint oversight committee, or JOC, to oversee drug development and commercialization strategies for the strategic alliance. In March 2009, King assumed sole responsibility for the regulatory approval of REMOXY. Pursuant to the collaboration agreement in the strategic alliance, as amended, King retains sole

control of drug development and clinical activities, NDA submissions, and worldwide responsibility to commercialize abuse-resistant hydrocodone and we retain sole control of drug development activities in the United States through Phase II clinical trials for both abuse-resistant hydromorphone and oxymorphone. We and King will jointly manage Phase III clinical trials and NDA submissions in the United States for both abuse-resistant hydromorphone and oxymorphone. For both abuse-resistant hydromorphone and oxymorphone, upon regulatory approval, King will assume sole control and worldwide responsibility to exclusively commercialize abuse-resistant opioid drugs developed pursuant to the strategic alliance. King has responsibility for all development activities outside the United States. We retain all development and commercial rights in Australia and New Zealand.

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. Currently, the last to expire issued patent covered by such arrangement expires in December 2023; however, we expect such date may be extended by the issuance of any additional patents pursuant to pending patent applications. We and King can terminate the collaboration agreement under certain circumstances, including material breach and insolvency. Our license agreement with King terminates at the time that the collaboration agreement terminates.

Formulation Agreement with Durect Corporation

We have an exclusive, worldwide Development and License Agreement, or the Durect Agreement, with Durect Corporation, or Durect, to use a patented technology that forms the basis for certain drug candidates, including REMOXY. We reimburse Durect for formulation and related work, and make milestone payments based on the achievement of certain technical, clinical or regulatory milestones. Aggregate payments to Durect from the inception of the Durect Agreement in late 2002 to December 31, 2011 were approximately $35.9 million. We paid Durect $1.0 million in upfront payments under the Durect Agreement and $1.7 million for achievement of certain clinical and regulatory milestones. We could pay up to another $7.6 million of potential payments under the Durect Agreement following achievement of certain clinical and regulatory milestones. 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. King is obligated to reimburse us for all expenses for formulation and related work and for milestone payments we incur under our agreement with Durect.

We also are obligated to pay Durect royalties on any related drug sales. These royalties range from 6.0% to 11.5%, depending on the level of sales of licensed products in a given calendar year. In turn, King is obligated to reimburse us for all royalty expenses we incur under the agreement with Durect for product sales under our strategic alliance with King. Durect is obligated to supply King with certain components of REMOXY and other abuse-resistant opioid painkillers pursuant to a commercial supply agreement between King and Durect.

The Durect Agreement terminates on a country-by-country basis upon the later of the expiration of the last to expire of the patents licensed under such agreement or a certain number of years following first commercial sale in such country. Currently, the last to expire patent covered by such agreement expires in December 2023. However, we expect such date may be extended by the issuance of any additional patents pursuant to pending patent applications. We can terminate the Durect Agreement with notice to Durect and we and Durect can terminate such agreement under certain circumstances, including material breach and insolvency.

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 our collaboration agreement or license agreement with King.

Manufacturing

We do not own any manufacturing facilities. We plan to continue to outsource formulation, manufacturing and related activities.

We rely on a limited number of third-party manufacturers to formulate, manufacture, fill, label, ship or store all of our drug candidates. 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 and King rely on Durect and other third-party manufacturers to formulate, manufacture, fill, label, ship or store REMOXY and other abuse-resistant drug candidates and their components. King is responsible for all manufacturing and supply of REMOXY. REMOXY and other product candidates under our strategic alliance with King are formulated using, in part, proprietary technology licensed from Durect.

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 or a Biologic License Application, or BLA and approval by the FDA prior to commercialization of any of our drug candidates 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:

- preclinical studies;
- submission to the FDA of an 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.

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 drugs where appropriate. 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.

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 the equivalent of 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 an 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 reviews the NDA and responds to the applicant. The review process is typically extended for significant amounts of time by the FDA's 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 a Complete Response Letter indicating either an approval or may identify 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.

The process for FDA approval of a BLA is similar to the process for FDA approval of an NDA.

Other Regulatory Requirements

The FDA mandates that drugs be manufactured in conformity with current GMP. 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, Pfizer, Abbott Laboratories, Endo Pharmaceuticals, Teva Pharmaceuticals, Elkins-Sinn, Watson Laboratories, Ortho-McNeil Pharmaceutical and Forest Pharmaceuticals. Alternative technologies are being developed to address the issue of abuse or misuse of opioid painkillers or increase opioid potency, as well as alternatives to opioid therapy for pain management, and improved treatments for metastatic melanoma and hemophilia, 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. We also compete with these companies for qualified personnel and opportunities for product acquisitions, joint ventures or other strategic alliances.

REMOXY® is a trademark of Pain Therapeutics, Inc.

Incorporation

We were incorporated in Delaware in May 1998.

Employees

As of December 31, 2011, we had 10 employees. We engage consultants from time to time to perform services on retainer, 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 our corporate offices by calling 512-501-2444 or by sending an e-mail message to IR@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 in our common stock.

Clinical and Regulatory Risks

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

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

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

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

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

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

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

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

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

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

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

We have no history of developing drug candidates for other than REMOXY. We do not know whether any of our planned clinical trials will result in marketable drugs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. For example, we understand King is participating in a pharmaceutical Industry Working Group to propose a single class-wide Risk Evaluation and Mitigation Strategies, or REMS, system as announced by the FDA for all extended-release opioids. These proposals may result in changes to or additional government regulations with respect to our opioid drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could prevent us from marketing our drugs and our business could suffer.

Risks Relating to our Collaboration Agreements

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

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

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

We rely on Pfizer and its subsidiaries to devote time and resources to the development, manufacturing and commercialization of REMOXY and other drug candidates under the King Agreements. Pfizer and its subsidiaries and affiliates may commercialize, develop or acquire drugs or drug candidates that may compete directly or compete for resources with our drug candidates under the King Agreements. For instance, King is developing Oxycodone NT (an extended release abuse resistant formulation of oxycodone that would compete with REMOXY) and owns Embeda (an extended-release oral formulation of morphine sulfate) and Avinza (a once-daily morphine treatment for moderate to severe pain) and recently announced FDA approval of Oxecta, an

immediate release formulation of oxycodone designed to prevent drug tampering and misuse. There can be no assurance that these other drugs or drug candidates in the Pfizer corporate family will not become competitive with our drug candidates being developed under the King Agreements. If time and resources devoted are limited or there is a failure to fund the continued development of REMOXY or other opioid drug candidates as required by the King Agreements, or there is otherwise a failure to perform as we expect, we may not achieve clinical and regulatory milestones and regulatory submissions and related product introductions may be delayed or prevented, and revenues that we would receive from these activities will be less than expected. In addition, if King fails to perform as required under the King Agreements, their failure may jeopardize our rights under our license with Durect.

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

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

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

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

Our plan for developing, manufacturing and commercializing REMOXY and other drugs designed to reduce potential risks of unintended use currently requires us to successfully maintain the King Agreements to advance our programs and provide funding to support our expenditures on REMOXY and other drug candidates and to maintain our license from Durect. If we are not able to maintain the King Agreements or if King doesn't provide the required funding under the King Agreements and the funding required to meet our obligations to Durect, we may have to limit the size or scope of, or delay or abandon the development of other drug candidates or undertake and fund development of these drug candidates ourselves and if we are unable to meet the obligations necessary to maintain our license with Durect for one or more potential products we may lose the rights to utilize Durect's technology for such potential products. If we elect to fund drug development efforts with respect to REMOXY and other drug candidates on our own, we may need to obtain additional capital, which may not be available on acceptable terms, or at all.

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

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

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

Our strategy to focus on drug development requires us to enter into collaborative agreements with third parties, such as the King Agreements and our license agreement with Durect. Such agreements are generally

complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property under collaborations or disputes concerning the scope of collaboration activities. Such disputes can delay or prevent the development of potential new drug products, or can lead to lengthy, expensive litigation or arbitration. Other factors relating to collaborative agreements may adversely affect the success of our drug candidates, including:

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

Risks Relating to Commercialization

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

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

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our drugs, and, in particular, the effectiveness of REMOXY in reducing potential risks of unintended use;
- perceptions by physicians regarding the cost benefit of REMOXY in reducing potential risks of unintended use;
- published studies demonstrating the cost-effectiveness of our drugs relative to competing products;
- availability of reimbursement for our products from government or healthcare payers;
- our or our collaborators' ability to implement a risk management plan prior to the distribution of any Schedule II drug; and
- effectiveness of marketing and distribution efforts by King or Pfizer, us and other licensees and distributors.

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

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

Our ability to earn royalties from sales of REMOXY depends on King's, and the greater Pfizer corporate family's, ability to obtain regulatory approval for and commercialize REMOXY. Additionally, our ability to earn royalties from sales of REMOXY and other drugs subject to the King Agreements will depend on King's, and the greater Pfizer corporate family's, ability to maintain regulatory approval and achieve market acceptance of such drugs once commercialized. Pfizer or its subsidiaries (including King) may elect to independently develop drugs that could compete with ours or fail to commit sufficient resources to the development, marketing and distribution of REMOXY and other drugs developed under the King Agreements. King, along with its parent and affiliated entities, may not proceed with the commercialization of REMOXY and other drugs developed under the King Agreements with the same degree of urgency as we would because of other priorities they face. If King and its parent and affiliated entities are not successful in developing or commercializing REMOXY for a variety

of reasons, including but not limited to competition from other pharmaceutical companies, or if King and its parent and affiliated entities fail to perform as we expect, our potential for revenue from drugs developed the King Agreements, if any, could be dramatically reduced and our business would suffer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Relating to our Intellectual Property

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

Our ability to commercialize our drug candidates will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Intellectual property rights in the areas of controlled-release technology, pharmaceutical ingredients, antibodies, gene integration and more generally, in oncology, neurology, radiopharmaceutical technologies and gene therapy are complicated and are continuously evolving. Holders of patent rights in these areas may allege that the commercialization of REMOXY or our other drug candidates infringes such patent rights. While we believe that we would have valid defenses to any claim of infringement, there can be no assurance that these or other third party patents will not limit our ability to commercialize REMOXY or our other drug candidates.

In addition, because patent applications are published 18 months after their filing, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown

to us, which may later result in issued patents. If a third-party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

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

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

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

We and our collaborators have filed patent applications with the U.S. Patent and Trademark Office to further protect our technologies. If these patent applications do not result in issued patents, the duration or scope of our patent rights may be limited and our future revenues could be lower as a result.

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

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

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

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

Our technology could infringe upon claims of patents owned by others. If we were found to be infringing on a patent held by another, we might have to seek a license to use the patented technology. In that case, we might not be able to obtain such a license on terms acceptable to us, or at all. If a legal action were to be brought against

us or our licensors, we could incur substantial defense costs, and any such action might not be resolved in our favor. If such a dispute were to be resolved against us, we could have to pay the other party large sums of money and our use of our technology and the testing, manufacture, marketing or sale of one or more of our proposed products could be restricted or prohibited.

Risks Relating to our Business and Strategy

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

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

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

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

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

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

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

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

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

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

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

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

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

Business interruptions could limit our ability to operate our business.

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

Risks Relating to Manufacturing

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

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

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

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

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

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

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

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

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

If King receives marketing approval for and commercially launches REMOXY or other candidates under the King Agreements, Durect may need to materially expand its manufacturing capacity. Durect may not be able to increase its manufacturing capacity for REMOXY and these other drug candidates in a timely or economic manner, or at all. Moreover, significant scale up of manufacturing will require additional validation studies, which are subject to FDA review and approval. If Durect is unable to successfully increase the manufacturing capacity for such components of REMOXY and these other drugs, at an acceptable cost or otherwise, and King is unable to establish alternative manufacturing capabilities, commercialization of REMOXY and these other drugs may be delayed, prevented or impaired or there may be a shortage in supply, which would harm our future revenues and cause our business to suffer.

Risks Relating to our Financial Position and Need for Financing

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

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

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

Although we were profitable in some years in the past based on payments from King and interest income, we have yet to generate any revenues from product sales. We have an accumulated deficit of $132.2 million at December 31, 2011. Even if we succeed in developing and commercializing one or more of our drug candidates, we expect to continue to use significant cash resources in our operations for the foreseeable future. We anticipate that our expenses will increase substantially in the foreseeable future as we:

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

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

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

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

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

Risks Relating to an Investment in our Common Stock

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

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

- results of or delays in efforts to seek regulatory approval for REMOXY, and in preclinical studies and clinical trials for our other drug candidates;
- publicity regarding actual or potential medical results relating to products under development by us or others;
- the status of our collaboration agreements;
- announcements of technological innovations or new commercial products by us or others;
- developments in patent or other proprietary rights by us or others;
- comments or opinions by securities analysts or major stockholders;
- future sales of our common stock by existing stockholders;
- developments with respect to potential merger and acquisition activity of companies with whom we have strategic alliances or other agreements;
- regulatory developments or changes in regulatory guidance enacted by applicable governmental or other authorities;
- litigation, including with respect to the lawsuits currently filed against us, our officers and directors, or threats of litigation;
- economic and other external factors or other disaster or crises;
- the departure of any of our officers, directors or key employees;
- period-to-period fluctuations in financial results; and
- limited daily trading volume.

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

In the event of an adverse outcome the lawsuits filed against us, our officers and our directors, our business may be materially harmed, and defending against these lawsuits may be expensive and will divert the attention of our management.

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

On December 22, 2011, Anders Goldfarb filed a derivative action on behalf of Pain Therapeutics, Inc. against us and our directors in the U.S. District Court for the Western District of Texas. This action alleges, among other things, breach of fiduciary duties, waste of corporate assets and unjust enrichment by our directors in connection with allegedly untrue or misleading statements of material facts made by us regarding REMOXY's development and regulatory status from February 3, 2011 through June 23, 2011. The complaint states that monetary damages are being sought, but no amounts are specified. The complaint also seeks equitable relief on behalf of us against our directors as well as alterations to our corporate governance and internal procedures.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of these actions. We will have to incur expenses in connection with the defense of these lawsuits, and we may have to pay damages or settlement costs in connection with any resolution thereof. Any such expenses, damages or settlement costs may be substantial. Although we have insurance coverage against which we may claim recovery against some of these expenses and costs, the amount of coverage may not be adequate to cover the full amount or certain expenses and costs may be outside the scope the policies we maintain. In the event of an adverse outcome or outcomes, our business could be materially harmed from depletion of cash resources, negative impact on our reputation, or restrictions or changes to our governance or other processes that may result from any final disposition of the lawsuits. Moreover, responding to and defending pending litigation will result in a significant diversion of management's attention from our operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

None.

Item 2. ***Properties***

We currently lease approximately 36,400 square feet of office space pursuant to non-cancelable operating leases. Our lease in Austin, TX expires in 2014. Our lease in San Mateo, CA expires in 2012. In December 2011, we entered into a sublease for our entire facility in San Mateo. This sublease is conterminous with our lease in San Mateo. We believe that our facilities are adequate and suitable for our current needs.

Item 3. ***Legal Proceedings***

Charles Southey, Individually and On Behalf of All Others Similarly Situated v. Pain Therapeutics, Inc., Remi Barbier, Nadav Friedman, Grant L. Schoenhard and Peter S. Roddy.

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

Anders Goldfarb, derivatively on behalf of Pain Therapeutics, Inc. v. Remi Barbier, Nadav Friedmann, Michael J. O'Donnell, Patrick J. Scannon, Robert Z. Gussin, and Sanford R. Robinson.

On December 22, 2011, Anders Goldfarb filed a derivative action on behalf of Pain Therapeutics, Inc. against us and our directors listed above in the U.S. District Court for the Western District of Texas. This action alleges, among other things, breach of fiduciary duties, waste of corporate assets and unjust enrichment by our directors in connection with allegedly untrue or misleading statements of material facts made by us regarding REMOXY's development and regulatory status from February 3, 2011 through June 23, 2011. The complaint states that monetary damages are being sought, but no amounts are specified. The complaint also seeks equitable relief on behalf of us against our directors as well as alterations to our corporate governance and internal procedures.

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

We are required, if applicable, to provide a statement that the information concerning mine safety violations or other regulatory matters required by Section 1503(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act and Item 104 of Regulation S-K (17 CFR 229.104) is included in exhibit 95 to the annual report. This item is not applicable.

PART II

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

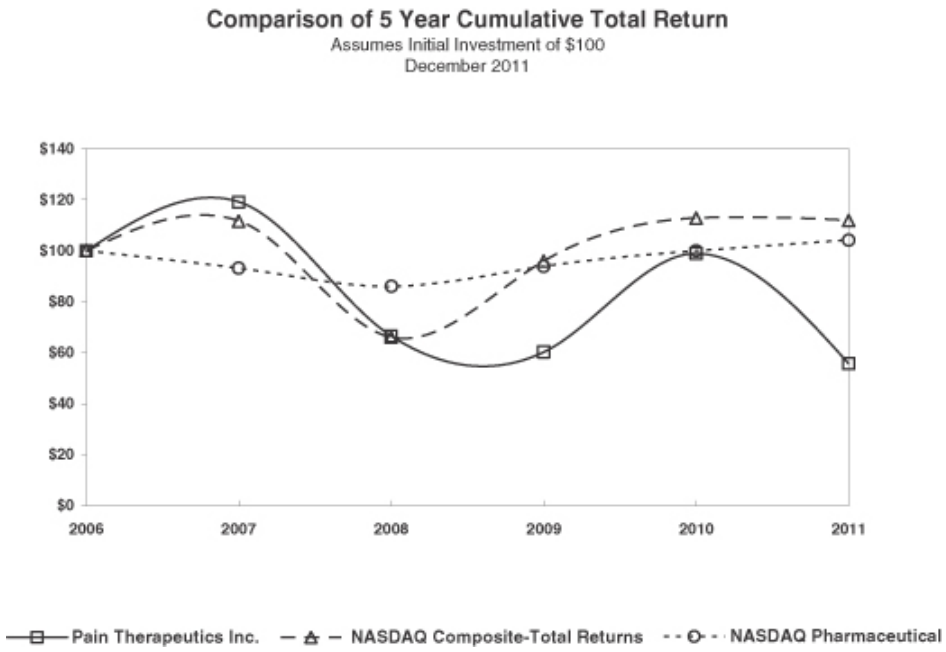
Our common stock is quoted on the NASDAQ Global Select Market, or Nasdaq, under the symbol "PTIE." The following table sets forth the high and low sales prices per share of our common stock as reported on the Nasdaq for the periods indicated.

	Sales Prices	
	High	Low
Fiscal 2010:		
First Quarter	$ 7.01	$4.24
Second Quarter	$ 6.66	$5.22
Third Quarter	$ 6.49	$5.22
Fourth Quarter	$ 8.83	$6.05
Fiscal 2011:		
First Quarter	$ 9.82	$5.95
Second Quarter	$10.45	$3.28
Third Quarter	$ 5.53	$3.85
Fourth Quarter	$ 5.07	$3.54

We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and, notwithstanding our December 2010 special, one-time nondividend distribution, we have not paid and do not anticipate paying any cash dividends in the foreseeable future. As of January 12, 2012, there were approximately 64 holders of record of our common stock.

Performance Graph

The following line graph compares the percentage change in the cumulative return to the stockholders of our common stock with the cumulative return of the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index for the period commencing December 31, 2006.



The graph assumes that $100 was invested on December 31, 2006 in our common stock or an index, and that all dividends were reinvested. Notwithstanding our special, one-time nondividend distribution completed in 2010, we have not declared or paid any dividends on our common stock. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

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

The following selected financial data should be read together with the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this report. The selected balance sheet data at December 31, 2011 and 2010 and the selected statement of operations data for 2011, 2010 and 2009 have been derived from our audited financial statements that are included elsewhere in this report. The selected balance sheet data at December 31, 2009, 2008 and 2007 and the statements of operations for 2008 and 2007 have been derived from our audited financial statements not included in this report. Historical results are not necessarily indicative of the results to be expected in the future.

	Years ended December 31,				
	2011	2010	2009	2008	2007
Statement of operations data:					
Program fee revenue	$ 10,897	$ 10,496	$ 14,348	$ 14,348	$ 23,238
Collaboration revenue	587	1,313	6,215	29,377	42,746
Milestone revenue	—	5,000	—	20,000	—
Total revenue	11,484	16,809	20,563	63,725	65,984
Research and development expense	8,300	15,746	21,059	45,817	47,730
General and administrative expense	6,698	14,766	6,258	9,196	8,085
Total operating expenses	14,998	30,512	27,317	55,013	55,815
Operating income (loss)	(3,514)	(13,703)	(6,754)	8,712	10,169
Interest and other income, net	901	1,680	1,777	6,018	10,136
Income (loss) before provision for (benefit from) income taxes	(2,613)	(12,023)	(4,977)	14,730	20,305
Provision for (benefit from) income taxes	—	—	(1,510)	(617)	—
Net income (loss)	$ (2,613)	$ (12,023)	$ (3,467)	$ 15,347	$ 20,305
Net income (loss) per share:					
Basic	$ (0.06)	$ (0.28)	$ (0.08)	$ 0.36	$ 0.46
Diluted	$ (0.06)	$ (0.28)	$ (0.08)	$ 0.35	$ 0.44
Weighted average shares used in computing net income (loss) per share:					
Basic	44,160	42,644	42,165	42,252	44,150
Diluted	44,160	42,644	42,165	43,857	45,676

	December 31,				
	2011	2010	2009	2008	2007
Balance sheet data:					
Cash and cash equivalents	$ 73,144	$ 4,798	$ 35,794	$ 153,158	$ 86,567
Marketable securities	24,986	86,428	139,965	36,937	118,504
Working capital	85,217	84,414	159,959	170,522	184,717
Total assets	98,963	99,195	182,005	193,436	207,625
Deferred program fee revenue	51,760	62,657	68,153	82,502	96,849
Total liabilities	54,570	66,262	73,753	89,150	103,711
Total stockholders' equity	44,393	32,933	108,252	104,286	103,914

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

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

We and King jointly managed a Phase III clinical program and NDA submission for REMOXY. In mid-2008, the FDA accepted our NDA for REMOXY with Priority Review. In December 2008, we received from the FDA a Complete Response Letter for the NDA for REMOXY. In this Complete Response Letter, the FDA indicated additional non-clinical data was required to support the approval of REMOXY. Also, the FDA did not request or recommend additional clinical efficacy studies prior to approval. In 2009, King assumed sole responsibility for the regulatory approval of REMOXY. This shift of responsibility did not change any economic term of the King Agreements. In December 2010, King resubmitted the REMOXY NDA. In January 2011, we announced that the FDA had accepted the resubmission of the REMOXY NDA. In June 2011, we and Pfizer announced that King received a Complete Response Letter from the FDA in response to King's resubmission of the REMOXY NDA. The FDA's Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. Certain drug lots showed inconsistent release performance during *in vitro* testing. It is not known at this time whether this is an artifact of the testing method or a manufacturing deficiency. Sufficient information does not yet exist to accurately assess the time required to resolve the concerns raised in the FDA's Complete Response Letter.

In January 2011, we announced that the FDA had accepted our IND for abuse-resistant oxymorphone and that we had received a $5.0 million milestone payment under the King Agreements for this milestone.

All of our collaboration, contract and milestone revenues are recognized pursuant to payments we've received from the King Agreements, including:

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

We will receive a $15.0 million cash milestone payment from King upon regulatory approval of REMOXY in the United States. We could also receive from King up to $105.0 million in additional milestone payments in the course of clinical development of the other abuse-resistant opioid painkillers under the strategic alliance. In addition, subject to certain limitations, King is obligated to fund development expenses incurred by us 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. The royalty rate for net sales of REMOXY and other products covered by the strategic alliance with King in the United States is 20%, except as to the first $1.0 billion in cumulative net sales in the United States, for which the royalty is set at 15%. The royalty rate for net sales of products covered by the strategic alliance with King outside the United States is 10% on all of net sales.

Although we were profitable in 2006, 2007 and 2008 based on payments received from King and interest income, we have yet to generate any revenues from product sales. We have recorded an accumulated deficit of $132.2 million at December 31, 2011. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of preclinical and clinical trials as well as clinical supplies associated with our drug candidates. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options and other equity awards granted to employees and non-employees. Our operating results may fluctuate substantially from period to period as a result of the timing and enrollment rates of clinical trials for our drug candidates and our need for clinical supplies.

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

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

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

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

	Years Ended December 31,		
	2011	2010	2009
Compensation	$5,785	$14,203	$10,165
Contractor fees[1]	1,163	266	7,165
Supplies[2]	13	21	1,150
Other common costs[3]	1,339	1,256	2,579
	$8,300	$15,746	$21,059

(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 certain of our portfolio of drug candidates. Data, know-how, personnel, clinical results, research results and other matters related to the research and development of any one of our drug candidates also relate to, and further the development of, our other drug candidates. For example, we expect that results of non-clinical studies, such as pharmacokinetics, toxicology and other studies, regarding certain components of our drug candidate REMOXY to be applicable to the other potential drug candidates that may arise out of our collaboration with King since all such potential drug candidates are expected to utilize such components. As a result, costs allocated to a specific drug candidate may not necessarily reflect the actual costs surrounding research and development of that drug candidate due to cross application of the foregoing.

Our contractor fees and supplies expenses in 2011 related to programs outside of the King Agreements were limited to approximately $0.4 million. In July 2011, we terminated our license to certain technology from Albert Einstein College of Medicine, including technology we used in our monoclonal antibody program for the treatment of metastatic melanoma. We did not incur any expenses as a result of this termination.

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.

In 2011, we relocated our principal place of business to Austin, Texas.

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

On December 22, 2011, Anders Goldfarb filed a derivative action on behalf of Pain Therapeutics, Inc. against us and our directors in the U.S. District Court for the Western District of Texas. This action alleges, among other things, breach of fiduciary duties, waste of corporate assets and unjust enrichment by our directors in connection with allegedly untrue or misleading statements of material facts made by us regarding REMOXY's development and regulatory status from February 3, 2011 through June 23, 2011. The complaint states that monetary damages are being sought, but no amounts are specified. The complaint also seeks equitable relief on behalf of us against our directors as well as alterations to our corporate governance and internal procedures.

Critical Accounting Policies

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

- *Expenses for clinical trials.* We incur expenses for clinical trials from the planning phase through patient enrollment to reporting of the underlying data. We estimate expenses incurred for clinical trials

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

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

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

- *Revenue recognition and deferred program fee revenue*. We recognize program fee revenue, collaboration revenue and milestone revenue in connection with our strategic alliance with King. Program fee revenue is derived from upfront payments from King, including the $150.0 million paid to us at the beginning of the strategic alliance and the $5.0 million King paid us in July 2010 in connection with an amendment to our strategic alliance. These payments are recognized from receipt ratably over our estimate of the development period for the fourth of four drug candidates expected to be developed under the strategic alliance with King. We currently estimate the development period for all four expected drug candidates to end in the quarter ended September 30, 2016. We review the estimated development period on a quarterly basis and change it if appropriate based upon our latest expectations. In the first quarter of 2010 we determined that our estimate of the development period should be extended from the third quarter of 2014. Collaboration revenues from reimbursement of development expenses pursuant to our collaboration agreement with King are generally recognized when King has completed its review of the expenses invoiced to them. King is obligated to pay us milestone payments contingent upon the achievement of certain substantive events in the development of REMOXY and the other opioid painkillers under the strategic alliance. We recognize milestone payments from King as revenue when we achieve the underlying developmental milestone as the milestone payments are not dependent upon any other future activities or achievement of any other future milestones and the achievement of each of the developmental milestones were substantively at risk and contingent at the effective date of the collaboration. Substantial effort is involved in achieving each of the developmental milestones. These milestones represent the culmination of discrete earnings processes and the amount of each milestone payment is reasonable in relation with the level of effort associated with the achievement of the milestone. Each milestone payment is non-refundable and non-creditable when made. The ongoing research and development services being provided to King under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration with King.

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

Results of Operations

Years Ended December 31, 2011 and 2010

Revenue—Program fee revenue

King paid us a $150.0 million upfront fee in connection with the closing of our strategic alliance with King and $5.0 million in July 2010 in connection with an amendment to our strategic alliance. Revenues recognized from amortization of this upfront fee were $10.9 million in 2011 and $10.5 million in 2010. We expect to recognize the rest of the program fee ratably over our estimate of the remainder of the development period under the strategic alliance with King. We currently estimate the development period for all four expected drug candidates to extend through September 2016.

Revenue—Collaboration revenue

Collaboration revenues were $0.6 million in 2011 and $1.3 million in 2010. These revenues related to reimbursement of our development expenses incurred pursuant to the King strategic alliance. Collaboration revenues were lower in 2011 as compared to 2010 primarily because the reimbursable expenses we incurred pursuant to the strategic alliance with King were lower in 2011 as compared to 2010.

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

Revenue—Milestone revenue

Milestone revenue of $5.0 million in 2010 was related to acceptance by the FDA of the IND for abuse-resistant oxymorphone under the King Agreements.

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.

In October 2010, we were awarded $2.1 million in research grants by the U.S. government under the Qualifying Therapeutic Discovery Project Program. The research grants were awarded following a competitive review of thousands of applications. According to guidance released by the U.S. Department of the Treasury, the U.S. Department of Health and Human Services evaluated each project for its potential to produce new therapies, reduce long-term health care costs or cure cancer. We recognized these grants as a reduction in research and development expenses for the fourth quarter 2010.

Research and development expense decreased to $8.3 million in 2011 from $15.7 million in 2010. The decrease was primarily due to decreases in non-cash stock related compensation costs as well as the timing of development activities for our product candidates, offset in part by the reduction in research and development costs in 2010 for grants awarded to us by the U.S. government.

Research and development expenses included non-cash stock related compensation costs of $2.7 million in 2011 and $10.3 million in 2010. These costs in 2010 included $7.4 million for one-time modifications made to outstanding stock options to prevent diminution of the benefit of these options from the special, one-time nondividend distribution to stockholders in the fourth quarter of 2010.

We expect our development efforts to result in our drug candidates progressing through various stages of clinical trials, including current and potential clinical trials for our other abuse-resistant drug candidates, as well as further clinical development of our product candidates in metastatic melanoma and hemophilia. Pfizer reimburses certain development expenses for our abuse-resistant drug candidates pursuant to our collaboration agreement. Our research and development expenses may fluctuate from period to period due to the timing and scope of our development activities and the results of clinical trials and preclinical studies.

General and Administrative Expense

General and administrative expenses consist primarily of compensation and other general corporate expenses. General and administrative expenses decreased to $6.7 million in 2011 from $14.8 million in 2010. The decrease was primarily due to decreased non-cash stock-related compensation costs in 2011 as compared to 2010.

General and administrative expenses included non-cash stock related compensation costs of $2.8 million in 2011 and $9.9 million in 2010. These costs in 2010 included $7.4 million for one-time modifications made to outstanding stock options to prevent diminution of the benefit of these options from the special, one-time nondividend distribution to stockholders in the fourth quarter of 2010. We expect other general and administrative expenses to increase over the next several years in connection with support of precommercialization and commercialization activities for our drug candidates. The increase may fluctuate from period to period due to the timing and scope of these activities and the results of clinical trials and preclinical studies.

Interest and Other Income, Net

Interest and other income, net, decreased to $0.9 million in 2011 from $1.7 million in 2010. This decrease was primarily due to decreased average balances of marketable securities. We expect our interest income to decrease in the future as we use cash to fund our operations.

Provision for Income Taxes

We did not provide for federal income taxes in 2011 or 2010 because we had a tax loss for both 2011 and 2010.

Years Ended December 31, 2010 and 2009

Revenue—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 this upfront fee were $10.5 million in 2010 and $14.3 million in 2009.

Revenue—Collaboration revenue

Collaboration revenues were $1.3 million in 2010 and $6.2 million in 2009. These revenues related to reimbursement of our development expenses incurred pursuant to the King strategic alliance. Collaboration revenues were lower in 2010 as compared to 2009 primarily because the reimbursable expenses we incurred pursuant to the strategic alliance with King were lower in 2010 as compared to 2009.

Revenue—Milestone revenue

Milestone revenue of $5.0 million in 2010 was related to acceptance by the FDA of the IND for abuse-resistant oxymorphone under the King Agreements.

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.

In October 2010, we were awarded $2.1 million in research grants by the U.S. government under the Qualifying Therapeutic Discovery Project Program. The research grants were awarded following a competitive review of thousands of applications. According to guidance released by the U.S. Department of the Treasury, the U.S. Department of Health and Human Services evaluated each project for its potential to produce new therapies, reduce long-term health care costs or cure cancer. We recognized these grants as a reduction in research and development expenses for the fourth quarter 2010.

Research and development expense decreased to $15.7 million in 2010 from $21.1 million in 2009. The decrease was primarily due to decreases in development activities for REMOXY, the timing of development activities for our other product candidates and reduction in research and development costs for grants awarded to us by the U.S. government, offset in part by increased non-cash stock related compensation costs.

Research and development expenses included non-cash stock related compensation costs of $10.3 million in 2010 and $4.0 million in 2009. These costs in 2010 included $7.4 million for one-time modifications made to outstanding stock options to prevent diminution of the benefit of these options from the special, one-time nondividend distribution to stockholders in the fourth quarter of 2010.

General and Administrative Expense

General and administrative expenses consist primarily of compensation and other general corporate expenses. General and administrative expenses increased to $14.8 million in 2010 from $6.2 million in 2009. The increase was primarily due to increases in non-cash stock-related compensation costs.

General and administrative expenses included non-cash stock related compensation costs of $9.9 million in 2010 and $2.7 million in 2009. These costs in 2010 included $7.4 million for one-time modifications made to outstanding stock options to prevent diminution of the benefit of these options from the special, one-time nondividend distribution to stockholders in the fourth quarter of 2010.

Interest and Other Income, Net

Interest and other income, net, decreased to $1.7 million in 2010 from $1.8 million in 2009. This decrease was primarily due to decreased average balances of marketable securities and to a lesser extent decreases in prevailing interest rates on investments in marketable securities.

Benefit from Income Taxes

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

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through public and private stock offerings, payments received under our strategic alliance with King and interest earned on our investments. We intend to continue to use our capital resources to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes. As of December 31, 2011, cash, cash equivalents and marketable securities were $98.1 million.

Net cash used in operating activities was $0.3 million for 2011 and $0.1 million for 2010.

Net cash provided by investing activities was $59.9 million for 2011 compared to $52.5 million for 2010. Investing activities for both years consisted primarily of the purchase, sale and maturities of marketable securities. We did not use any cash to purchase property, equipment and leasehold improvements in 2011 and 2010.

Net cash provided by financing activities was $8.7 million for 2011 and net cash used by financing activities was $83.3 million in 2010. Cash from financing activities in 2011 consisted primarily of cash from stock option exercises. Cash used by financing activities in 2010 consisted primarily of cash used for the special, one-time nondividend distribution of approximately $85.7 million, offset in part by cash from stock option exercises.

Realization of our other deferred tax assets is dependent on future earnings, if any. We are uncertain about the timing and amount of any future earnings. Accordingly, we offset these net deferred tax assets with a valuation allowance. There is a high degree of uncertainty regarding the timing of future cash outflows associated with our liabilities related to uncertain tax positions. Our liability at December 31, 2011 related to our uncertain tax positions is immaterial.

In early 2011, we received $2.1 million in grants awarded to us in 2010 under the Qualifying Therapeutic Discovery Project Program.

In 2010, we were selected for an audit of our 2008 federal tax return. This audit was completed in early 2011 with no changes in any of our tax positions.

We currently lease approximately 36,400 square feet of office space pursuant to non-cancelable operating leases. Our lease in Austin, TX expires in 2014. Our lease in San Mateo, CA expires in 2012. Future minimum lease payments are as follows for the years ended December 31, (in thousands):

	2012	2013	2014	Total
Future minimum lease payments	$450	$115	$81	$646

In December 2011, we entered into a sublease for all of our facility in San Mateo. This sublease is coterminous with our lease in San Mateo. We expect to receive approximately $0.3 million pursuant to this sublease.

We have license agreements that require us to make milestone payments upon the successful achievement of milestones, including clinical milestones. Our license agreements also require us to pay certain royalties to our licensors if we succeed in fully commercializing products under these license agreements. All of these potential future payments are cancelable as of December 31, 2011. 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 $132.2 million at December 31, 2011. We expect our cash requirements to be significant in the future. The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our drug candidates and the resources we devote to researching and developing, formulating, manufacturing, commercializing and supporting our products. We believe that our current resources should be sufficient to fund our operations for at least the next 12 months. We may seek additional future funding through public or private financing within this timeframe, if such funding is available and on terms acceptable to us.

Off-balance Sheet Arrangements

As of December 31, 2011, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not materially exposed to financing, liquidity, market or credit risk that could arise if we had engaged in these relationships. We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties.

Item 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, 2011 by approximately $53,000. 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, 2011, our investments consisted of investments in corporate notes and obligations or in money market accounts and checking funds with variable market rates of interest. We believe our credit risk is immaterial.

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, 2011 and 2010, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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), Pain Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2011, 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 9, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Austin, Texas
February 9, 2012

PAIN THERAPEUTICS, INC.

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

	December 31, 2011	December 31, 2010
ASSETS		
Current assets		
Cash and cash equivalents	$ 73,144	$ 4,798
Marketable securities	24,987	86,428
Receivables	—	7,114
Other current assets	358	144
Total current assets	98,489	98,484
Property and equipment, net	122	285
Other assets	352	426
Total assets	$ 98,963	$ 99,195
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 464	$ 1,107
Accrued development expense	914	258
Deferred program fee revenue—current portion	10,897	10,897
Accrued compensation and benefits	915	1,712
Other accrued liabilities	82	97
Total current liabilities	13,272	14,071
Non-current liabilities		
Deferred program fee revenue—non-current portion	40,863	51,760
Deferred tax liabilities	435	431
Total liabilities	54,570	66,262
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; 44,732,017 and 42,910,164 shares issued and outstanding in 2011 and 2010, respectively	45	43
Additional paid-in-capital	176,425	161,957
Accumulated other comprehensive income	128	525
Accumulated deficit	(132,205)	(129,592)
Total stockholders' equity	44,393	32,933
Total liabilities and stockholders' equity	$ 98,963	$ 99,195

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Years ended December 31,		
	2011	2010	2009
Revenue			
Program fee revenue	$10,897	$ 10,496	$14,348
Collaboration revenue	587	1,313	6,215
Milestone revenue	—	5,000	—
Total revenue	11,484	16,809	20,563
Operating expenses			
Research and development	8,300	15,746	21,059
General and administrative	6,698	14,766	6,258
Total operating expenses	14,998	30,512	27,317
Operating loss	(3,514)	(13,703)	(6,754)
Interest and other income, net	901	1,680	1,777
Loss before income taxes	(2,613)	(12,023)	(4,977)
Benefit from income taxes	—	—	(1,510)
Net loss	$ (2,613)	$(12,023)	$ (3,467)
Net loss per share, basic and diluted	$ (0.06)	$ (0.28)	$ (0.08)
Weighted-average shares used in computing net loss per share, basic and diluted	44,160	42,644	42,165

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except per share data)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Par value				
Balance at December 31, 2008	42,068,752	$ 42	$218,021	$ 325	$ (114,102)	$ 104,286
Issuance of common stock pursuant to exercise of stock options	194,311	—	436	—	—	436
Issuance of common stock related to employee stock purchase plan	38,838	—	128	—	—	128
Compensation with respect to non-employee option grants	—	—	(22)	—	—	(22)
Compensation with respect to employee option grants and share based awards	—	—	6,681	—	—	6,681
Tax benefits from the exercise of options	—	—	188	—	—	188
Net unrealized gains on investments in marketable securities	—	—	—	22	—	22
Net loss	—	—	—	—	(3,467)	(3,467)
Comprehensive loss						(3,445)
Balance at December 31, 2009	42,301,901	42	225,432	347	(117,569)	108,252
Issuance of common stock pursuant to exercise of stock options and awards	569,935	1	1,940	—	—	1,941
Issuance of common stock related to employee stock purchase plan	38,328	—	144	—	—	144
Compensation with respect to non-employee option grants	—	—	35	—	—	35
Compensation with respect to employee option grants and share based awards	—	—	20,097	—	—	20,097
Non-dividend cash distribution ($2.00 per share)	—	—	(85,691)	—	—	(85,691)
Net unrealized gains on investments in marketable securities	—	—	—	178	—	178
Net loss	—	—	—	—	(12,023)	(12,023)
Comprehensive loss						(11,845)
Balance at December 31, 2010	42,910,164	43	161,957	525	(129,592)	32,933
Issuance of common stock pursuant to exercise of stock options and awards	1,781,769	2	8,908	—	—	8,910
Issuance of common stock related to employee stock purchase plan	40,084	—	122	—	—	122
Compensation with respect to non-employee option grants	—	—	60	—	—	60
Compensation with respect to employee option grants and share based awards	—	—	5,378	—	—	5,378
Net unrealized losses on investments in marketable securities	—	—	—	(397)	—	(397)
Net loss	—	—	—	—	(2,613)	(2,613)
Comprehensive loss						(3,010)
Balance at December 31, 2011	44,732,017	$ 45	$176,425	$ 128	$ (132,205)	$ 44,393

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC

STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended December 31,		
	2011	2010	2009
Cash flows used in operating activities:			
Net loss	$ (2,613)	$ (12,023)	$ (3,467)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash stock based compensation	5,428	20,132	6,659
Depreciation and amortization	163	232	257
Non-cash net interest income	1,141	1,252	22
Deferred program fee revenue	(10,897)	(10,496)	(14,348)
Changes in operating assets and liabilities:			
Receivables	7,114	(4,812)	(2,104)
Other current assets	(214)	266	132
Other non-current assets	74	1,585	(440)
Accounts payable	(643)	(210)	(899)
Accrued development expense	656	(963)	192
Deferred program fee revenue	—	5,000	—
Tax benefits from equity-based compensation plans	—	—	188
Excess tax benefits from equity-based compensation plans	339	(290)	9
Accrued compensation and benefits	(797)	574	(552)
Other accrued liabilities	(15)	(390)	(344)
Other non-current liabilities	4	—	4
Net cash used in operating activities	(260)	(143)	(14,691)
Cash flows provided by (used in) investing activities:			
Purchase of marketable securities	(2,497)	(65,753)	(154,000)
Sales of marketable securities	—	7,407	2,422
Maturities of marketable securities	62,400	110,809	48,350
Net cash provided by (used in) investing activities	59,903	52,463	(103,228)
Cash flows provided by (used in) financing activities:			
Nondividend distribution	—	(85,691)	—
Excess tax benefits from equity-based compensation plans	(339)	290	(9)
Proceeds from issuance of common stock, net	9,042	2,085	564
Net cash provided by (used in) financing activities	8,703	(83,316)	555
Net increase (decrease) in cash and cash equivalents	68,346	(30,996)	(117,364)
Cash and cash equivalents at beginning of the year	4,798	35,794	153,158
Cash and cash equivalents at end of the year	$ 73,144	$ 4,798	$ 35,794
Supplemental cash flow information:			
Cash paid (received) for income taxes	$ —	$ (3,765)	$ 1,177

See accompanying notes to financial statements.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

1. General

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

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

2. Summary of Significant Accounting Policies

Use of Estimates

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

Revenue Recognition and Deferred Program Fee Revenue

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

We and King have a strategic alliance to develop and commercialize REMOXY and up to three other opioid painkillers designed to reduce potential risks of unintended use. In connection with the strategic alliance, we recognize program fee revenue, collaboration revenue and milestone revenue. Program fee revenue is derived from the upfront payment received under the strategic alliance in December 2005 and a payment in July 2010 in connection with an amendment to our strategic alliance and is recognized ratably over our estimate of the development period of the four drug candidates expected to be developed under the strategic alliance. We currently estimate the development period for all four expected drug candidates to extend through September 2016. We review the estimated development period on a quarterly basis and change it if appropriate based upon our latest expectations. Deferred program fee revenue represents the amount of the upfront payment that has not yet been recognized as revenue.

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

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

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Cash, Cash Equivalents and Concentration of Credit Risk

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

Marketable Securities and Fair Value Measurements

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

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

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

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. 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.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Business Segments

We report segment information based on how we internally evaluate the operating performance of our business units, or segments. Our operations are confined to one business segment: the development of novel drugs.

Stock-based Compensation

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

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

Government Grants

In October 2010, we were awarded $2.1 million in research grants by the U.S. government under the Qualifying Therapeutic Discovery Project Program. We recorded a receivable and reduced our research and development expenses for 2010 related to these grant awards.

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

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Net Loss per Share

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

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

	Years Ended December 31,		
	2011	2010	2009
Numerator			
Net loss	$ (2,613)	$(12,023)	$ (3,467)
Denominator			
Weighted average shares used to compute basic net loss per share, basic and diluted	44,160	42,644	42,165
Net loss per share, basic and diluted	$ (0.06)	$ (0.28)	$ (0.08)

We excluded weighted options outstanding to purchase common stock of 13.7 million for 2011, 7.3 million for 2010 and 10.6 million for 2009 from the calculation of diluted net loss per share because the effect of including these shares in this calculation would be anti-dilutive.

Comprehensive Loss

Comprehensive loss combines net loss and other comprehensive income (loss), as follows (in thousands):

	Years Ended December 31,		
	2011	2010	2009
Net loss	$(2,613)	$(12,023)	$(3,467)
Other comprehensive income (loss)	(397)	178	22
Comprehensive loss	$(3,010)	$(11,845)	$(3,445)

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

Income Taxes

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

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Recent Accounting Pronouncements

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

3. Collaboration Agreements

King Pharmaceuticals, Inc. and Pfizer, Inc.

In November 2005, we and King announced a strategic alliance to develop and commercialize REMOXY and other abuse-resistant opioid painkillers. Pfizer acquired King in early 2011. King made an upfront cash payment of $150.0 million to us in 2005 and $5.0 million in July 2010 in connection with an amendment to our strategic alliance, of which we recorded as program fee revenue $10.9 million in 2011, $10.5 million in 2010 and $14.3 million in 2009. In January 2011, we received $5.0 million from King for the acceptance by the FDA in 2010 of the IND for abuse-resistant oxymorphone. In 2008, we received $15.0 million related to acceptance by the FDA of the NDA for REMOXY, and $5.0 million of acceptance by the FDA of the IND for abuse-resistant hydrocodone. In 2006, we received $5.0 million for the acceptance by the FDA of the IND for abuse-resistant hydromorphone.

We could also receive from King up to $120.0 million in additional milestone payments in the course of clinical development of the other abuse-resistant opioid painkillers under the strategic alliance. In addition, subject to certain limitations, King is obligated to fund development expenses incurred by us pursuant to the collaboration agreement, of which we recorded as collaboration revenue $0.6 million in 2011, $1.3 million in 2010 and $6.2 million in 2009. 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. The royalty rate for net sales of REMOXY and other products covered by the strategic alliance with King in the United States is 20%, except as to the first $1.0 billion in cumulative net sales in the United States, for which the royalty is set at 15%. The royalty rate for net sales of products covered by the strategic alliance with King outside the United States is 10% on all of net sales.

Durect Corporation

We have an exclusive, worldwide licensing agreement with Durect Corporation to use a patented technology that forms the basis for certain 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. 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 Marketable Securities					
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Accrued Interest	Total Value
December 31, 2011						
Cash and cash equivalents	$ 73,144	$ —	$ —	$ 73,144	$ —	$73,144
Corporate securities	24,583	128	—	24,711	276	24,987
	$ 97,727	$ 128	$ —	$ 97,855	$ 276	$98,131
Reported as:						
Cash and cash equivalents	$ 73,144	$ —	$ —	$ 73,144	$ —	$73,144
Marketable Securities	24,583	128	—	24,711	276	24,987
	$ 97,727	$ 128	$ —	$ 97,855	$ 276	$98,131
Maturities:						
Matures in one year or less	$ 97,727	$ 128	$ —	$ 97,855	$ 276	$98,131
Matures one to three years	—	—	—	—	—	—
	$ 97,727	$ 128	$ —	$ 97,855	$ 276	$98,131
December 31, 2010						
Cash and cash equivalents	$ 4,798	$ —	$ —	$ 4,798	$ —	$ 4,798
Certificates of deposit	10,131	—	—	10,131	31	10,162
Corporate securities	75,063	525	—	75,588	678	76,266
	$ 89,992	$ 525	$ —	$ 90,517	$ 709	$91,226
Reported as:						
Cash and cash equivalents	$ 4,798	$ —	$ —	$ 4,798	$ —	$ 4,798
Marketable Securities	85,194	525	—	85,719	709	86,428
	$ 89,992	$ 525	$ —	$ 90,517	$ 709	$91,226
Maturities:						
Matures in one year or less	$ 67,557	$ 106	$ —	$ 67,663	433	$68,096
Matures one to three years	22,435	419	—	22,854	276	23,130
	$ 89,992	$ 525	$ —	$ 90,517	$ 709	$91,226

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. Our realized gains and losses on our marketable securities were immaterial in 2011, 2010 and 2009.

Our assets measured at fair value at December 31, 2011 and 2010 were (in thousands):

	Level 1	Level 2	Level 3	Total
December 31, 2011				
Cash and money market fund	$62,446	$ —	$ —	$62,446
Commercial paper	$ —	10,698	—	10,698
Corporate securities	—	24,987	—	24,987
	$62,446	$35,685	$ —	$98,131
December 31, 2010				
Cash and cash equivalents	$ 4,798	$ —	$ —	$ 4,798
Corporate securities	—	76,266	—	76,266
Certificates of deposit	10,162	—	—	10,162
	$14,960	$76,266	$ —	$91,226

5. Property and Equipment

Property and equipment at December 31, 2011 and 2010 consisted of the following (in thousands):

	December 31,	
	2011	2010
Furniture, fixtures and equipment	$ 672	$ 672
Leasehold improvement	658	658
	1,330	1,330
Accumulated depreciation and amortization	(1,208)	(1,045)
	$ 122	$ 285

Depreciation and amortization expenses were $0.2 million in 2011, $0.2 million in 2010 and $0.3 million in 2009.

6. Stockholders' Equity and Stock-Based Compensation

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.

We have 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 the Company's 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 our 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.

Stock-Based Compensation

Stock based compensation costs for the 2008 Equity Incentive Plan, the 1998 Stock Option Plan and 2000 Employee Stock Purchase Plan was $5.4 million in 2011, $20.1 million in 2010 and $6.7 million in 2009. Stock

based compensation in 2010 included $14.8 million for modifications made to options outstanding under the 1998 Stock to prevent diminution of the benefit of these options from the special, one-time nondividend distribution to stockholders in the fourth quarter of 2010.

2008 Equity Incentive Plan

Under our 2008 Equity Incentive Plan, or 2008 Equity 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, 2011 a total of 26,633,961 shares of common stock were authorized for issuance under these plans including adjustments related to the nondividend distribution in 2010. Shares reserved for issuance and available for grant under the 2008 Equity Incentive Plan were 5.8 million as of December 31, 2011. The 2008 Equity Plan terminates in 2018.

Our Board of Directors or a designated Committee of the Board is responsible for administration of the 2008 Equity Plan and determines the terms and conditions of each option granted, consistent with the terms of the plan. Incentive stock options may be granted 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 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.

The 2008 Equity 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)

Our stock option activity for 2011, 2010 and 2009 was:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term In years	Aggregate Intrinsic Value In millions
Options outstanding as of December 31, 2008	11,457,815	$ 7.58	6.52	$ 1.8
Granted	1,339,100	$ 4.54		
Exercised	(194,311)	$ 2.25		
Forfeited	(1,005,316)	$ 8.09		
Options outstanding as of December 31, 2009	11,597,288	$ 7.28	5.95	$ 1.5
Granted	1,225,000	$ 4.66		
Exercised	(448,402)	$ 5.20		
Forfeited	(1,126,201)	$ 8.96		
Increase related to nondividend distribution	3,537,258			
Options outstanding as of December 31, 2010	14,784,943	$ 5.38	5.49	$ 20.9
Granted	1,130,000	$ 9.53		
Exercised	(1,857,198)	$ 5.45		
Forfeited	(1,500,602)	$ 5.60		
Options outstanding as of December 31, 2011	12,557,143	$ 5.71	5.16	$ 0.5
Vested and expected to vest at December 31, 2011	12,353,691	$ 5.70	5.10	$ 0.5
Exercisable at December 31, 2011	9,835,172	$ 5.60	4.23	$ 0.3

In 2010, options and Performance Awards outstanding under the 2008 Equity Plan were automatically adjusted to prevent diminution of the benefit of the options and restricted stock units from the special, one-time nondividend distribution of $2.00 per share paid to our stockholders in December 2010. In addition, the Compensation Committee of our Board of Directors adjusted the options outstanding under the 1998 Equity Plan to prevent diminution of the benefit of these options from the distribution on the same basis as the adjustments made to options and restricted stock units under the 2008 Equity Plan. The adjustments increased the number of shares available for purchase under each option and decreased the exercise price of each option based on the ratio of (a) the fair market value of our common stock immediately prior to the distribution over (b) the fair market value of our common stock immediately prior to the distribution less the $2.00 per share distribution.

The pre-tax intrinsic value of options exercised was approximately $5.9 million in 2011, $0.7 million in 2010, and $0.6 million in 2009, calculated by multiplying options exercised each year by the difference between our stock price on the date of exercise and the exercise price of the options.

As of December 31, 2011, we expect to recognize compensation costs prior to forfeiture of $8.8 million related to non-vested options over the weighted average remaining recognition period of 2.4 years.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

The following summarizes information about stock options outstanding at December 31, 2011:

Range of exercise prices		Options outstanding			Options exercisable	
From	To	Number of outstanding options	Weighted average remaining contractual life (in years)	Weighted average exercise price	Number of vested options	Weighted average exercise price
$ 1.76	$ 4.45	3,583,680	6.66	$ 3.94	2,092,430	$ 3.89
$ 4.55	$ 5.73	3,310,324	3.50	$ 5.46	3,033,440	$ 5.47
$ 5.86	$ 6.29	2,746,069	4.34	$ 6.15	2,713,257	$ 6.15
$ 6.37	$ 9.14	2,033,945	4.49	$ 6.80	1,882,920	$ 6.68
$10.00	$ 10.00	883,125	9.39	$ 10.00	113,125	$ 10.00
		12,557,143	5.16	$ 5.71	9,835,172	$ 5.60

Determining the Fair Value of Options

We use Black-Scholes to estimate the fair value of options granted. Black-Scholes considers a number of factors, including the market price of our common stock. For options granted to employees and directors, we used certain factors to value each stock option granted, which resulted in a weighted average fair value of options granted during 2011, 2010 and 2009, as follows:

	2011	2010	2009
Volatility	50% to 60%	48% to 50%	50% to 53%
Risk-free interest rates	1% to 3%	1% to 3%	2% to 3%
Expected life of option	6 years	5 to 6 years	5 to 6 years
Dividend yield	—	—	—
Forfeiture rate	6%	7% to 8%	4% to 5%
Weighted average fair value of stock options granted	$4.68	$2.23	$1.71

Volatility is based on reviews of the historical volatility of our common stock. Risk-free interest rates are based on yields of U.S. treasury notes in effect at the date of grant. Expected life of option is based on actual historical option exercises. Dividend yield is zero because we do not anticipate paying cash dividends in the foreseeable future. Forfeiture rate is based primarily on historical cancellations of options. The Weighted average fair value of options granted to employees and directors in 2010 and 2009 includes the effect of the increase related to the nondividend distribution in 2010.

For options granted to non-employees, we estimate the fair value of stock options granted using factors similar to those used for stock options granted to employees and directors and appropriate for the terms underlying the stock options granted to non-employees. We re-measure the compensation expense for options granted to non-employees over the related vesting period.

Performance Awards

At December 31, 2011, we have outstanding 2,085,930 shares of performance awards granted in 2008 and 13,124 shares of performance awards granted in 2010 and amended in 2011. If the performance based awards granted in 2008 vest, we would recognize an additional $13.8 million in stock compensation expense. If the performance based awards granted in 2010 vest, we would recognize an additional $0.1 million in stock

compensation expense. If the performance awards granted in 2008 do not vest within four years of the date of grant, the awards expire and the underlying shares will be returned to the 2008 Equity Incentive Plan. If the performance awards granted in 2010 do not vest by December 31, 2014, the awards expire and the underlying shares will be returned to the 2008 Equity Incentive Plan.

In 2011, we granted performance awards valued at $0.7 million. During 2011, all 70,000 of these awards vested and we recognized related stock-based compensation expense of $0.1 million in research and development expenses and $0.6 million in general and administrative expenses.

In 2010, we granted performance awards valued at $0.7 million. During 2010, 78,748 shares of these awards vested and we recognized related stock-based compensation expense of $0.1 million in research and development expenses and $0.3 million in general and administrative expenses. During 2011, 45,934 shares of these awards were forfeited and returned to the 2008 Equity Incentive Plan.

In 2009, we granted performance awards valued at $1.2 million. In 2009, 0.1 million shares of these awards vested and we recognized related stock-based compensation expense of $0.2 million in research and development expenses and $0.3 million in general and administrative expenses. The remaining 0.2 million shares in performance awards were returned to the 2008 Equity Incentive Plan in 2010.

2000 Employee Stock Purchase Plan

Under the amended and restated 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. We have 443,137 shares reserved for issuance under the Purchase Plan at December 31, 2011.

We use Black-Scholes to estimate the fair value of rights granted under the Purchase Plan, using assumptions similar to those used in determining the fair value of options. Stock based compensation costs related to the Purchase Plan was immaterial in 2011.

Warrants

As of December 31, 2011, we have no outstanding exercisable warrants.

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 contribute up to 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, 2011, we have not made any matching contributions.

8. Income Taxes

We did not provide for income taxes in 2011, 2010 and 2009 because we did not have taxable income in those years.

We elected to carry back part of our federal tax loss for 2009 against all federal taxes paid for 2008 and a portion of federal taxes paid for 2006. As a result of this election, in 2010 we received a combined federal tax refund of $1.6 million. All of our benefit from income taxes in 2009 is federal. All of our net income is domestic.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

Our election to carryback our 2009 tax loss to 2008 and 2006 eliminated the use of federal tax credits to reduce our federal tax liability for both 2008 and 2006. As a result, our deferred tax liabilities decreased by $1.0 million and our current assets related to our deferred tax assets decreased by $1.0 million.

A reconciliation between our benefit from income taxes for 2009 and the amounts computed by multiplying loss before income taxes by the U.S. statutory tax rate follows (in thousands):

	2009
Tax at U.S. statutory tax rate of 34%	$(1,692)
State taxes	8
Research credits	(373)
Equity-based compensation	794
Change in valuation allowance	(288)
Other	41
Benefit from income taxes	$(1,510)

Unrecognized tax benefits

We have unrecognized tax benefits related primarily to tax credits. A reconciliation of the beginning and ending unrecognized tax benefits recorded for 2011, 2010 and 2009 follows (in thousands):

	2011	2010	2009
Beginning balance	$4,800	$4,600	$4,200
Additions based on tax positions related to the current year	300	200	400
Ending balance	$5,100	$4,800	$4,600

The total amount of unrecognized tax benefit that, if recognized, would benefit our effective tax rate, is $67 thousand.

In 2010, we were selected for an audit of our 2008 federal tax return. This audit was completed in early 2011 with no changes in any of our tax positions. Because of net operating loss and research credit carryforwards, all of our tax years, from 1998 through 2011, remain open to U.S. federal and California state tax examinations. Our tax year 2011 is open to Texas state tax examination.

Interest expense related to our tax positions was immaterial for 2011, 2010 and 2009.

Deferred tax assets and valuation allowance

Deferred tax assets 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,		
	2011	2010	2009
Deferred tax assets:			
Net operating loss carryforwards	$ 6,500	$ 3,000	$ 6,000
Deferred license fee revenue	19,900	22,900	27,100
Research & development credits	6,300	5,800	3,200
Stock-related compensation	12,000	14,000	7,300
Other	900	700	800
Total deferred tax assets	45,600	46,400	44,400
Valuation allowance	(45,300)	(46,100)	(41,600)
Net deferred tax assets	$ 300	$ 300	$ 2,800

Except for certain of our research and development credits, realization of deferred tax assets is dependent upon future earnings. We are uncertain about the timing and amount of any future earnings. Accordingly, these deferred tax assets have been offset by a valuation allowance.

The federal portion of our pre-tax net operating loss carryforwards of $14.8 million expires between 2029 and 2031. The California state portion of our pre-tax net operating loss carryforwards of $27.8 million expires in 2017 and between 2029 and 2031.

Approximately $0.2 million of the valuation allowance at December 31, 2011 relates to the tax benefits associated with stock option transactions where tax deductions exceeded related expenses in our financial statements. This amount will be credited to additional paid-in capital when realized as a reduction to income taxes payable. The valuation allowance decreased by $0.8 million in 2011, increased by $4.5 million in 2010 and did not change materially in 2009.

As of December 31, 2011, we had federal research and development tax credits of approximately $9.1 million, which expire in the years 2023 through 2031 and California state research and development tax credits of approximately $2.1 million.

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 approximately 36,400 square feet of office space pursuant to non-cancelable operating leases. Our lease in Austin, TX expires in 2014. Our lease in San Mateo, CA expires in 2012. Future minimum lease payments are as follows for the years ended December 31, (in thousands):

	2012	2013	2014	Total
Future minimum lease payments	$450	$115	$81	$646

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

In December 2012, we entered into a sublease for all of our facility in San Mateo. This sublease is conterminous with our lease in San Mateo. This sublease may reduce our related expenses by approximately $0.3 million. We believe that our facilities are adequate and suitable for our current needs. Rent expense was $0.6 million for 2011, $0.9 million for 2010, and $0.7 million for 2009.

10. Legal proceedings

Charles Southey, Individually and On Behalf of All Others Similarly Situated v. Pain Therapeutics, Inc., Remi Barbier, Nadav Friedman, Grant L. Schoenhard and Peter S. Roddy.

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

Anders Goldfarb, derivatively on behalf of Pain Therapeutics, Inc. v. Remi Barbier, Nadav Friedmann, Michael J. O'Donnell, Patrick J. Scannon, Robert Z. Gussin, and Sanford R. Robinson.

On December 22, 2011, Anders Goldfarb filed a derivative action on behalf of Pain Therapeutics, Inc. against us and our directors listed above in the U.S. District Court for the Western District of Texas. This action alleges, among other things, breach of fiduciary duties, waste of corporate assets and unjust enrichment by our directors in connection with allegedly untrue or misleading statements of material facts made by us regarding REMOXY's development and regulatory status from February 3, 2011 through June 23, 2011. The complaint states that monetary damages are being sought, but no amounts are specified. The complaint also seeks equitable relief on behalf of us against our directors as well as alterations to our corporate governance and internal procedures.

We have not accrued any loss related to these legal proceedings because at this time the amount of a loss, if any, cannot be reasonably determined.

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

	Quarters Ended			
	March 31	June 30	September 30	December 31
2011				
Total revenue	$ 3,236	$ 2,752	$ 2,749	$ 2,747
Net loss	$ (207)	$(1,200)	$ (815)	$ (391)
Basic net loss per share	$ 0.00	$ (0.03)	$ (0.02)	$ (0.01)
Diluted net loss per share	$ 0.00	$ (0.03)	$ (0.02)	$ (0.01)
2010				
Total revenue	$ 3,249	$ 2,656	$ 2,895	$ 8,009
Net loss	$(1,020)	$ (804)	$ (1,028)	$ (9,171)
Basic net loss per share	$ (0.02)	$ (0.02)	$ (0.02)	$ (0.21)
Diluted net loss per share	$ (0.02)	$ (0.02)	$ (0.02)	$ (0.21)

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

None.

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, 2011. 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, 2011 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, 2011 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 the effectiveness of our internal control over financial reporting. The attestation report of Ernst & Young LLP is included below.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Pain Therapeutics, Inc.

We have audited Pain Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Pain Therapeutic, 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 included in the accompanying Management's annual report on internal control over financial reporting. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, 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, Pain Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, 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, 2011 and 2010, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011 of Pain Therapeutics, Inc. and our report dated February 9, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Austin, Texas
February 9, 2012

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

None.

PART III

Item 10. ***Directors and Executive Officers and Corporate Governance***

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 2012 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. 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 2011.

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 following table summarizes the securities authorized for issuance under our equity compensation plans as of December 31, 2011:

	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	12,557,143	$ 5.71	5,731,254
Equity compensation plans not approved by stockholders .	—	—	—
Total	12,557,143	$ 5.71	5,731,254

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

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 Accountant 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):*

Report of Independent Registered Public Accounting Firm

Balance Sheets

Statements of Operations

Statements 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(2)	Amended and Restated Bylaws.
4.1(1)	Specimen Common Stock Certificate.
4.2(3)	Preferred Stock Rights Agreement, dated as of April 28, 2005, between the Company 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 Pain Therapeutics and each of its directors and officers.
10.2(4)	1998 Equity Incentive Plan and form of agreements thereunder.
10.3(5)	Employment Agreement dated October 23, 2001, between Registrant and Nadav Friedmann, PhD. M.D.
10.4+	Collaboration Agreement dated November 9, 2005, between Registrant and King Pharmaceuticals, Inc.

Exhibit Number	Description of Document
10.5+	License Agreement dated November 9, 2005, between Registrant and King Pharmaceuticals, Inc.
10.6(7)+	Development and License Agreement dated December 19, 2002 between Registrant and DURECT Corporation and Southern Biosystems, Inc.
10.7(7)+	Amendment dated December 15, 2005 to Development and License Agreement dated December 19, 2002 between Registrant and DURECT Corporation and Southern Biosystems, Inc.
10.8(8)	Sublease Agreement, dated as of July 17, 2007, between Registrant and Oracle USA, Inc.
10.9(9)	2008 Equity Incentive Plan.
10.10(10)	Form of Restricted Stock Unit Award Agreement under 2008 Equity Incentive Plan.
10.11(10)	Form of Performance Share Award Agreement under 2008 Equity Incentive Plan.
10.12(10)	Form of Restricted Stock Award Agreement under 2008 Equity Incentive Plan.
10.13(10)	Form of Stock Option Award Agreement under 2008 Equity Incentive Plan.
10.14(11)	Employment Agreement dated July 1, 1998 and amended December 17, 2008 between Registrant and Remi Barbier.
10.15(11)	Employment Agreement dated August 29, 2000 and amended December 30, 2008 between Registrant and Grant L. Schoenhard, Ph.D.
10.16(11)	Employment Agreement dated November 18, 2002 and amended December 30, 2008 between Registrant and Peter S. Roddy.
10.17(12)+	Letter Agreement dated June 24, 2010 with Amendments to the License and Collaboration Agreements between the Registrant and King Pharmaceuticals, Inc.
10.18(12)	2000 Employee Stock Purchase Plan, as amended and restated.
10.19(13)	Lease agreement, dated as of February 14, 2011 between Registrant and StoneCliff Office, L.P.
10.20	Amended Lease agreement, dated as of December 20, 2011 between Registrant and StoneCliff Office, L.P.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see page 68).
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference from exhibits to our report on Form 10-Q for the period 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 SEC on May 3, 2005.
(4) Incorporated by reference from our registration statement on Form S-1, registration number 333-32370, declared effective by the SEC 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 exhibits to our report on Form 10-Q for the period ending September 30, 2000.
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+ Confidential treatment has been requested or granted for certain portions of this exhibit. The omitted portions have been filed separately with the Securities and Exchange Commission.

(b) *Exhibits*

The exhibits listed under Item 15(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 9, 2012

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 9, 2012
/S/ PETER S. RODDY **Peter S. Roddy**	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 9, 2012
/S/ NADAV FRIEDMANN, PH.D., M.D. **Nadav Friedmann, Ph.D., M.D.**	Chief Operating and Medical Officer and Director	February 9, 2012
/S/ ROBERT Z. GUSSIN, PH.D. **Robert Z. Gussin, Ph.D**	Director	February 9, 2012
/S/ MICHAEL J. O'DONNELL, ESQ. **Michael J. O'Donnell, Esq.**	Director and Secretary	February 9, 2012
/S/ SANFORD R. ROBERTSON **Sanford R. Robertson**	Director	February 9, 2012
/S/ PATRICK SCANNON, M.D, PH.D. **Patrick Scannon, M.D., Ph.D.**	Director	February 9, 2012

EXHIBIT INDEX

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

Exhibit 10.4

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 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.

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(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 hydromorphone as its opioid API, and the third such Product shall be a product within the Field containing hydrocodone as its opioid API. The fourth Product, and all additional Products, shall be selected as set forth in Section 3.1.2 below.

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

3.1.3 **Minimum Development and Marketing Obligations**.

(a) King shall ensure that it is Marketing or funding the Development of a minimum of at least [***] 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 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.

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(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 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.

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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 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.

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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 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.

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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 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.

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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 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 [***].

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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.

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3.6 **Yearly Brand Plans.** King will prepare each Yearly Brand Plan for each Product and provide a copy to the JOC for its review and comment. King, in Consultation with PTI, will have control and responsibility for Marketing each Product and for all matters under the Yearly Brand Plan, including determining the packaging, trade dress, and labeling (to the extent not dictated by any applicable Regulatory Approval) for the distribution and sale of Product. Subject to Section 2.1.4 of the License Agreement, King shall use commercially reasonable efforts and diligence to Market the Product commensurate with industry standards; provided that in no event shall such level of efforts and diligence be less than King uses in marketing its own products of similar market potential and at a similar stage in development as the applicable Product, taking into account the competitiveness of the marketplace, the proprietary position of the Product, and the efforts and resources available to a company having a comparable market capitalization and taking into account then-current market conditions. King will spend at least [***] 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 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.

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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 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.

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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. 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.

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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 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.

*** 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.

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.

*** 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.

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

17. "**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 [oxycodone, hydromorphone, oxymorphone or hydrocodone] as the only opioid agonist API and (b) is covered by the rights granted to PTI under the DLA.

24. "**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 [hydromorphone] as the opioid API, and one (1) Product having [hydrocodone] 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.

*** 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.

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 10.5

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 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.

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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 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.

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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 [***] [***] 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).

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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.

*** 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. ***

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 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.

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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 [oxycodone, hydromorphone, oxymorphone or hydrocodone] as the only opioid agonist API and (b) is covered by the rights granted to PTI under the DLA.

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

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

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

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

*** 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. ***

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 10.20

SEPTEMBER 21, 2011

FIRST AMENDMENT TO LEASE AGREEMENT

Re: Lease Agreement dated December 28, 2010, by and between STONECLIFF OFFICE, L.P., as Lessor, and PAIN THERAPEUTICS, INC., as Lessee, (herein after referred to as the "Lease Agreement"), demising 5,679 rentable square feet of space locally known as Suite 260 in the StoneCliff building, located at 7801 Capital of Texas Highway, Austin, Travis County, Texas, 78731.

This First Amendment shall amend and modify the Lease Agreement as follows:

1. Lease Term. Lessor and Lessee acknowledge and agree that Lessee's lease term shall be extended twenty-eight (28) months from the current expiration of March 31, 2012 to July 31, 2014.

2. Base Rent. Effective April 1, 2012, Lessee shall pay to Lessor Base Rent as set forth in the rent schedule below:

Term	Monthly Rent	Term Rent	Annual Rent psf
04/01/2012 to 05/31/2012	$ 0.00	$ 0.00	$ 0.00
06/01/2012 to 05/31/2013	$ 11,358.00	$ 136,296.00	$ 24.00
06/01/2013 to 07/31/2013	$ 0.00	$ 0.00	$ 0.00
08/01/2013 to 07/31/2014	$ 11,594.63	$ 139,135.50	$ 24.50

3. Additional Rents. Effective April 1, 2012 Lessee's expense stop shall adjust to a 2012 Base Year.

Except as provided to the contrary herein, all the remaining terms, covenants, and provisions of the Lease Agreement shall remain in full force and effect and unmodified hereby. Each party hereby acknowledges that the other is not in default under the Lease Agreement in any respect. Each signatory hereto represents and warrants that he or she is authorized to execute this document and that upon said execution by both parties, this document will constitute the binding obligation of the party on behalf of whom such person has signed, without the necessity of joinder of any other person or entity.

EXECUTED on the dates set forth below our respective signatures.

LESSOR:

STONECLIFF OFFICE, L.P.

By:_____

Darrell R. Spaulding
Executive Vice President

Kucera Management, Inc.
As Authorized Managing Agent

Date:_____

LESSEE:

PAIN THERAPEUTICS, INC.

By:_____

Name:_____

Title:_____

Date:_____

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Form S-3 No. 333-164648, No. 333-127882, No. 333-115362, No. 333-108145, No. 333-106396) of Pain Therapeutics, Inc. and in the related Prospectus, and in the Registration Statements (Form S-8 No. 333-168390, No. 333-152676, No. 333-147336, No. 333-134364, No. 333-115361, No. 333-105138, No. 333-68118 and No. 333-41660) pertaining to the 2008 Equity Incentive Plan, the 1998 Stock Plan and 2000 Employee Stock Purchase Plan of Pain Therapeutics, Inc. of our reports dated February 9, 2012, with respect to the financial statements of Pain Therapeutics, Inc., 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, 2011.

/s/ Ernst & Young LLP

Austin, Texas
February 9, 2012

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 9, 2012

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 9, 2012

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, 2011, 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 9, 2012

/S/ REMI BARBIER

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

/S/ PETER S. RODDY

Peter S. Roddy,
Vice President and Chief Financial Officer