PAIN THERAPEUTICS INC
Form 10-K
February 08, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2012

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)

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 x

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 x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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 x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $179,724,336 computed by reference to the last sales price of $4.69 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, 2012.

The number of shares outstanding of the Registrant s common stock on January 31, 2013 was 45,332,131.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s Proxy Statement for its 2013 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.

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FORM 10-K

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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:

activities of Pfizer, Inc., or Pfizer, or its subsidiary King Pharmaceuticals, Inc., or King, with respect to obtaining approval of REMOXY® (oxycodone) Extended-Release Capsules CII, by the U.S. Food and Drug Administration, or FDA, including planned discussions between Pfizer and the FDA regarding REMOXY;

royalty, milestone or collaboration revenue we may receive from Pfizer and other payments we may receive from our collaboration agreements;

the potential for development of a noninvasive, blood-based biomarker and clinical diagnostic for Alzheimer s disease based on our published preclinical data;

the duration of the development period for drug candidates being developed pursuant to our collaboration agreement and license agreement with King, or the Pfizer Agreements, and the effect of changes in our estimate of such period on recognition of program fee revenue under the Pfizer Agreements;

expectations regarding REMOXY commercialization activities of Pfizer and Pfizer s acquisition of King potentially facilitating commercial success of REMOXY, if approved by the FDA;

expansion of our potential product line, including the formulation of additional dosage forms of our drug candidates;

operating losses and anticipated operating and capital expenditures;

expected uses of capital resources;

the potential benefits of our drug candidates;

the utility of protection of our intellectual property and the timing of expiration of patents covering our product candidates;

expected future sources of revenue and capital and increasing cash needs;

potential competitors or competitive products;

- market acceptance of our drug candidates and potential drug candidates;
- expenses increasing, interest income decreasing or fluctuations in our operating results;
- expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;
- anticipated hiring and development of our internal systems and infrastructure;
- the sufficiency of our current resources to fund our operations over the next twelve months;
- assumptions and estimates used for our disclosures regarding stock-based compensation; and
- estimates concerning the realization of deferred tax assets.

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

- difficulties or delays in the potential regulatory approval of the REMOXY NDA and in planned activities with respect to REMOXY development, including the potential for a request by the FDA of additional data which may require an extended period of time to obtain and submit, that could significantly delay or prevent such approval;

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- the successful development and commercialization of REMOXY and other drug candidates pursuant to the Pfizer Agreements;
- difficulties or delays in research, development, testing and pursuit of regulatory approval of a biomarker and diagnostic for Alzheimer s disease;
- 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® (oxycodone) Extended-Release Capsules CII. REMOXY is a strong painkiller with a unique formulation designed to reduce potential risks of unintended use. REMOXY and three other abuse-resistant painkillers are being developed pursuant to the Pfizer Agreements.

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 our agreements with Pfizer. 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 early 2011, Pfizer acquired King. References to Pfizer in this annual report also reference King where appropriate. 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. Sufficient information does not yet exist to accurately assess the time required to resolve the concerns raised in the FDA s Complete

Response Letter.

Pfizer recently announced its plans to meet with the FDA in March 2013 to discuss REMOXY.

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 2009.

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.

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 Pfizer 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 addition, the FDA has 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.

On July 18, 2012, we announced the publication of preclinical data with respect to a new approach to treat Alzheimer s disease. The publication also suggests the usefulness of our approach to develop a noninvasive, blood-based biomarker and clinical diagnostic for Alzheimer s disease.

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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 the Pfizer Agreements. 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 $15.7 million in 2010 and $8.3 million in 2011 and $7.6 million in 2012. We recorded contract revenue related to customer-sponsored research activities under the Pfizer Agreements of $1.3 million in 2010 and $0.6 million in 2011 and $0.2 million in 2012.

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 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, allowed patents, 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 the following U.S. patents issued for REMOXY: 5,747,058; 8,133,507; 8,168,217; 8,153,152; 8,147,870 and 8,354,124. These patents extend to 2025 and beyond. In Europe, REMOXY is covered by two granted patents that expire in 2016 and 2026, respectively, plus any eligible patent term extensions.

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. 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 2025. 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 Pfizer

Our strategic alliance with Pfizer includes a collaboration agreement and a license agreement with King, its subsidiary, to develop and commercialize REMOXY and other abuse-resistant opioid painkillers.

We and Pfizer have a joint oversight committee, or JOC, to oversee drug development and commercialization strategies for the strategic alliance. Pfizer retains sole responsibility for the regulatory approval of REMOXY. Pfizer 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 Pfizer 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, Pfizer will assume sole control and worldwide responsibility to exclusively commercialize abuse-resistant opioid drugs developed pursuant to the strategic alliance. Pfizer has responsibility for all development activities outside the United States. We retain all development and commercial rights in Australia and New Zealand.

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

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

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

Pfizer 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%. Pfizer is also obligated to reimburse us for our payment of third-party royalty obligations related to this strategic alliance.

The collaboration agreement with Pfizer 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 beyond 2025; however, such date may be extended by the issuance of any additional patents pursuant to pending patent applications. We and Pfizer can terminate the collaboration agreement under certain circumstances, including material breach and insolvency. Our license agreement with Pfizer 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, 2012 were approximately $37.2 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 Pfizer certain rights to develop and to commercialize REMOXY and certain other opioid drugs formulated in part with technology we licensed from Durect. Pfizer 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, Pfizer is obligated to reimburse us for all royalty expenses we incur under the agreement with Durect for product sales under our strategic alliance with Pfizer. Durect is obligated to supply Pfizer 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 beyond 2025. 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 Pfizer, we are obligated not to amend or terminate our agreement with Durect if an amendment or termination would alter the rights or obligations of Pfizer under the Pfizer Agreements.

Manufacturing

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

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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 Pfizer 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. Pfizer is responsible for all manufacturing and supply of REMOXY. REMOXY and other product candidates under our strategic alliance with Pfizer 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

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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 diagnostic product is similar to the process for FDA approval of an NDA. The FDA requires that medical devices introduced to the United States market, unless exempted by regulation, be the subject of either a pre-market notification clearance, known as a 510(k) clearance, or 510(k) de novo clearance, or a Premarket Approval.

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 may 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, 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

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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, 2012, we had 8 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.

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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 an NDA for REMOXY (even with additional data) or that the FDA will not require additional clinical or non-clinical data to be submitted. If the FDA were to require additional clinical or non-clinical data, providing such data may significantly delay the potential approval of REMOXY.

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

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

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

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

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

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

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

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

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

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

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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, on July 9, 2012, the FDA approved a risk management program, known as a Risk Evaluation and Mitigation Strategy, or REMS, for extended-release and long-acting opioid analgesics, or ER/LA opioid analgesics. This REMS will require companies affected by the REMS to make available training for health care professionals who prescribe ER/LA opioid analgesics on proper prescribing practices and also to distribute educational materials to prescribers and patients on the safe use of ER/LA opioid analgesics.

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

Risks Relating to our Collaboration Agreements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Relating to Commercialization

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- developing drugs;

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

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

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

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

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

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

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

Risks Relating to our Intellectual Property

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

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

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In addition, because patent applications are published some time after filing, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. If a third-party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process and can divert management s attention from our core business strategy;

- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor s patent or other proprietary rights;

- a court order prohibiting us from commercializing our products or technologies unless the holder licenses the patent or other proprietary rights to us, which such holder is not required to do;

- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and

- redesigning our process so that it does not infringe the third-party intellectual property rights, which may not be possible, or which may require substantial time and expense including delays in bringing our own products to market. Such actions could harm our competitive position and our ability to generate revenue and could result in increased costs.

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

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

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

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

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

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

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

Our technology could infringe upon claims of patents owned by others. If we were found to be infringing on a patent held by another, we might have to seek a license to use the patented technology. In that case, we might

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

Risks Relating to our Business and Strategy

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

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

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

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

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

- Contract commercial manufacturers, their sub-contractors or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy clinical needs or commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations.

- Our contract manufacturers could default on their agreements with us to provide clinical supplies or meet our requirements for commercialization of our products.

- For certain of our drug candidates, the use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of our products before we may use the alternative manufacturer to produce our supplies.

- It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturers and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products.

If any contract manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to such innovation.

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

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

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

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

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

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

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

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

Business interruptions could limit our ability to operate our business.

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

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

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

Risks Relating to Manufacturing

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

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

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

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

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

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

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

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

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

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

Risks Relating to our Financial Position and Need for Financing

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

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

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

Although we were profitable in some years in the past based on payments received pursuant to the Pfizer Agreements and interest income, we have yet to generate any revenues from product sales. We have an accumulated deficit of $135.7 million at December 31, 2012. Even if we succeed in developing and commercializing one or more of our drug candidates, we expect to continue to use significant cash resources in our operations for the foreseeable future. We anticipate that our expenses will increase substantially in the foreseeable future as we:

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

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

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

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

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

Risks Relating to an Investment in our Common Stock

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

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

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

litigation, including with respect to the lawsuit currently filed against us and our officers, or threats of litigation;

economic and other external factors or other disaster or crises;

the departure of any of our officers, directors or key employees;

period-to-period fluctuations in financial results; and

limited daily trading volume.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

None.

Item 2. ***Properties***

We currently lease approximately 6,000 square feet of office space pursuant to a non-cancelable operating lease in Austin, TX that expires in 2014. We believe that our facilities are adequate and suitable for our current needs.

Item 3. ***Legal Proceedings***

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

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

Item 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.

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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 Nasdaq for the periods indicated.

	Sales Prices	
	High	**Low**
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
Fiscal 2012:		
First Quarter	$ 4.53	$ 3.45
Second Quarter	$ 5.03	$ 3.41
Third Quarter	$ 5.37	$ 3.50
Fourth Quarter	$ 5.86	$ 2.34

We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and, notwithstanding our special nondividend distributions in December 2012 (of $0.75 per share of common stock totaling $34.0 million) and December 2010 (of $2.00 per share of common stock totaling $85.7 million), we have not paid and do not anticipate paying any cash dividends in the foreseeable future. As of January 12, 2013, there were approximately 58 holders of record of our common stock.

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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, 2007.

The graph assumes that $100 was invested on December 31, 2007 in our common stock or an index, and that all dividends were reinvested. Notwithstanding our special nondividend distributions completed in 2012 and 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.

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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, 2012 and 2011 and the selected statement of operations data for 2012, 2011 and 2010 have been derived from our audited financial statements that are included elsewhere in this report. The selected balance sheet data at December 31, 2010, 2009 and 2008 and the statements of operations for 2009 and 2008 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,				
	2012	2011	2010	2009	2008
Statement of operations data:					
Program fee revenue	$ 10,641	$ 10,897	$ 10,496	$ 14,348	$ 14,348
Collaboration revenue	249	587	1,313	6,215	29,377
Milestone revenue			5,000		20,000
Total revenue	10,890	11,484	16,809	20,563	63,725
Research and development expense	7,605	8,300	15,746	21,059	45,817
General and administrative expense	7,182	6,698	14,766	6,258	9,196
Total operating expenses	14,787	14,998	30,512	27,317	55,013
Operating income (loss)	(3,897)	(3,514)	(13,703)	(6,754)	8,712
Interest and other income, net	451	901	1,680	1,777	6,018
Income (loss) before provision for (benefit from) income taxes	(3,446)	(2,613)	(12,023)	(4,977)	14,730
Provision for (benefit from) income taxes				(1,510)	(617)
Net income (loss)	$ (3,446)	$ (2,613)	$ (12,023)	$ (3,467)	$ 15,347
Net income (loss) per share:					
Basic	$ (0.08)	$ (0.06)	$ (0.28)	$ (0.08)	$ 0.36
Diluted	$ (0.08)	$ (0.06)	$ (0.28)	$ (0.08)	$ 0.35
Weighted average shares used in computing net income (loss) per share:					
Basic	44,753	44,160	42,644	42,165	42,252
Diluted	44,753	44,160	42,644	42,165	43,857

	December 31,				
	2012	2011	2010	2009	2008
Balance sheet data:					
Cash and cash equivalents	$ 49,355	$ 73,144	$ 4,798	$ 35,794	$ 153,158
Marketable securities	6,899	24,987	86,428	139,965	36,937
Working capital	46,508	85,217	84,414	159,959	170,522
Total assets	56,859	98,963	99,195	182,005	193,436
Deferred program fee revenue	41,119	51,760	62,657	68,153	82,502
Total liabilities	43,723	54,570	66,262	73,753	89,150
Total stockholders equity	13,136	44,393	32,933	108,252	104,286

In 2012, our Board of Directors approved a special nondividend distribution of $0.75 per share, totaling $34.0 million. In 2010, our Board of Directors approved a special nondividend distribution of $2.00 per share, totaling $85.7 million.

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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 Pfizer Agreements.

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

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

Pfizer recently announced that it plans to meet with the FDA in March 2013 to discuss REMOXY.

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

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

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

Pfizer 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%. Pfizer is also obligated to reimburse us for our payment of third-party royalty obligations related to this strategic alliance.

Although we were profitable in 2006, 2007 and 2008 based on payments received pursuant to the Pfizer Agreements and interest income, we have yet to generate any revenues from product sales. We have recorded an accumulated deficit of $135.7 million at December 31, 2012. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of preclinical and clinical trials as well as clinical supplies associated with our drug candidates. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options and other equity awards granted to employees and non-employees. Our operating results may fluctuate substantially from period to period as a result of the timing of preclinical activities, enrollment rates of clinical trials for our drug candidates and our need for clinical supplies.

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

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

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

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

	Years Ended December 31,		
	2012	**2011**	**2010**
Compensation	$ 5,756	$ 5,785	$ 14,203
Contractor fees and supplies	1,099	1,176	287
Other common costs	750	1,339	1,256

	$ 7,605	$ 8,300	$ 15,746

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

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

Our contractor fees and supplies expenses in 2012 related to programs outside of the strategic alliance with Pfizer were approximately $0.3 million.

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

In December 2012, we paid our stockholders a special non-dividend distribution of $0.75 per share, totaling $34.0 million.

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

Critical Accounting Policies

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

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

We have granted share-based awards that vest upon achievement of certain performance criteria, or Performance Awards. The value of these awards is the product of the number of shares of our common stock to be issued under the award multiplied by the fair market value of a share of our common stock on the date of grant. These awards include future performance conditions. We estimate an implicit service period for achieving these performance conditions. Performance Awards vest and common stock

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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 Pfizer. Program fee revenue is derived from upfront payments under the Pfizer Agreements, including the $150.0 million paid to us at the beginning of the strategic alliance and the $5.0 million we received in July 2010 in connection with an amendment the Pfizer Agreements. 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 Pfizer. We currently estimate the development period for all four expected drug candidates to end in the quarter ended March, 2018. We review the estimated development period on a quarterly basis and change it if appropriate based upon our latest expectations. In the fourth quarter of 2012 we determined that our estimate of the development period should be extended from the third quarter of 2016 to the first quarter of 2018. Deferred program fee revenue represents the amount of the upfront payment that has not yet been recognized as program fee revenue. As a result of the change in estimate in the fourth quarter of 2012, program fee revenue was $0.3 million lower in 2012. Collaboration revenues from reimbursement of development expenses pursuant to our collaboration agreement with Pfizer are generally recognized when Pfizer has completed its review of the expenses invoiced to them. Pfizer is obligated to pay us milestone payments contingent upon the achievement of certain substantive events in the development of REMOXY and the other opioid painkillers under the strategic alliance. We recognize milestone payments from Pfizer 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 Pfizer under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration with Pfizer.

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, 2012 and 2011

Revenue Program fee revenue

We received a $150.0 million upfront fee in 2005 in connection with the closing of the Pfizer Agreements and $5.0 million in July 2010 in connection with an amendment to the Pfizer Agreements. Revenues recognized

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from amortization of upfront fees were $10.6 million in 2012 and $10.9 million in 2011. 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 Pfizer. We currently estimate the development period for all four expected drug candidates to extend through March 2018.

Revenue Collaboration revenue

Collaboration revenues were $0.2 million in 2012 and $0.6 million in 2011. These revenues related to reimbursement of our development expenses incurred pursuant to the Pfizer Agreements. Collaboration revenues were lower in 2012 as compared to 2011 primarily because the reimbursement of expenses we incurred pursuant to the Pfizer Agreements was lower in 2012 as compared to 2011.

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 Pfizer s review of submitted expenses. We incurred $0.4 million of expenses in 2012 that continue to be subject to Pfizer s review as of December 31, 2012. We expect Pfizer will reimburse us for these expenses in 2013.

Research and Development Expense

Research and development expense consists primarily of costs of development work associated with our drug candidates. Research and development expenses decreased to $7.6 million in 2012 from $8.3 million in 2011, primarily due to lower headcount and facilities-related costs. Research and development expenses included $3.2 million in non-cash stock related compensation expense in 2012 (including $0.8 million related to the nondividend distribution in December 2012) and $2.7 million in 2011. We expect non-cash stock-related compensation expense to decrease in 2013.

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

General and Administrative Expense

General and administrative expenses consist primarily of compensation and other general corporate expenses. General and administrative expenses increased to $7.2 million in 2012 from $6.7 million in 2011, primarily due to higher non-cash stock related compensation expense, offset in part by lower headcount and facilities-related costs. General and administrative expenses included $3.4 million in non-cash stock related compensation expense in 2012 (including $1.0 million related to the nondividend distribution in December 2012) and $2.8 million in 2011. We expect non-cash stock-related compensation costs to decrease in 2013.

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 $0.5 million in 2012 from $0.9 million in 2011. 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 2012 or 2011 because we had a tax loss for both 2012 and 2011.

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Years Ended December 31, 2011 and 2010

Revenue Program fee revenue

We received a $150.0 million upfront fee in 2005 in connection with the closing of the Pfizer Agreements and $5.0 million in July 2010 in connection with an amendment to the Pfizer Agreements. Revenues recognized from amortization of upfront fees were $10.9 million in 2011 and $10.5 million in 2010.

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 Pfizer Agreements. Collaboration revenues were lower in 2011 as compared to 2010 primarily because the reimbursable expenses we incurred pursuant to the Pfizer Agreements were lower in 2011 as compared to 2010.

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 Pfizer 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 modifications made to outstanding stock options to prevent diminution of the benefit of these options from the special 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 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.

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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 modifications made to outstanding stock options to prevent diminution of the benefit of these options from the special nondividend distribution to stockholders in the fourth quarter of 2010.

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.

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.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through public and private stock offerings, payments received under the Pfizer Agreements and interest earned on our investments. We intend to continue to use our capital resources to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes. As of December 31, 2012, cash, cash equivalents and marketable securities were $56.3 million.

Net cash used in operating activities was $7.2 million for 2012 and $0.3 million for 2011. In 2011, we collected $7.1 million from receivables at December 31, 2010.

Net cash provided by investing activities was $17.6 million for 2012 compared to $59.9 million for 2011. 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 2012 and 2011.

Net cash used by financing activities was $34.2 million for 2012 and cash provided by financing activities was $8.7 million for 2011. In December 2012, we paid our stockholders $34.0 million in a special non-dividend distribution of $0.75 per share. Other cash used in financing activities in 2012 consisted of $0.5 million in cash used to pay statutory taxes on Performance Awards that were exercised net of taxes, offset in part by $0.2 million received from stock option exercises. Other cash provided by financing activities in 2011 consisted primarily of cash from stock option exercises. We expect cash used to pay for statutory taxes on stock options and Performance Awards may increase in the future.

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

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

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

We have license agreements that require us to make milestone payments upon the successful achievement of milestones, including clinical milestones. Our license agreements also require us to pay certain royalties to our licensors if we succeed in fully commercializing products under these license agreements. All of these potential future payments are cancelable as of December 31, 2012. Our formulation agreement with Durect Corporation obligates us to make certain milestone payments upon achieving clinical milestones and regulatory milestones. Pfizer is obligated to reimburse us for any of our milestone payments and royalty payments to Durect Corporation.

We have an accumulated deficit of $135.7 million at December 31, 2012. 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, 2012, 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, 2012 by an immaterial amount. 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, 2012, 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.

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

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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, 2012 and 2011, and the related statements of operations, comprehensive income, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2012. 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, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, 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, 2012, 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 8, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Austin, Texas

February 8, 2013

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PAIN THERAPEUTICS, INC.

BALANCE SHEETS

(in thousands, except share and per share data)

	December 31, 2012	December 31, 2011
ASSETS		
Current assets		
Cash and cash equivalents	$ 49,355	$ 73,144
Marketable securities	6,899	24,987
Other current assets	253	358
Total current assets	56,507	98,489
Property and equipment, net		122
Other assets	352	352
Total assets	$ 56,859	$ 98,963
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable	$ 361	$ 464
Accrued development expense	929	914
Deferred program fee revenue current portion	7,832	10,897
Accrued compensation and benefits	853	915
Other accrued liabilities	24	82
Total current liabilities	9,999	13,272
Non-current liabilities		
Deferred program fee revenue non-current portion	33,287	40,863
Deferred tax liabilities	437	435
Total liabilities	43,723	54,570
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; 45,326,940 and 44,732,017 shares issued and outstanding at December 31, 2012 and 2011, respectively	45	45
Additional paid-in-capital	148,738	176,425
Accumulated other comprehensive income	4	128
Accumulated deficit	(135,651)	(132,205)
Total stockholders equity	13,136	44,393
Total liabilities and stockholders equity	$ 56,859	$ 98,963

See accompanying notes to financial statements.

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PAIN THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Years ended December 31,		
	2012	**2011**	**2010**
Revenue			
Program fee revenue	$ 10,641	$ 10,897	$ 10,496
Collaboration revenue	249	587	1,313
Milestone revenue			5,000
Total revenue	10,890	11,484	16,809
Operating expenses			
Research and development	7,605	8,300	15,746
General and administrative	7,182	6,698	14,766
Total operating expenses	14,787	14,998	30,512
Operating loss	(3,897)	(3,514)	(13,703)
Interest and other income, net	451	901	1,680
Net loss	$ (3,446)	$ (2,613)	$ (12,023)
Net loss per share, basic and diluted	$ (0.08)	$ (0.06)	$ (0.28)
Weighted-average shares used in computing net loss per share, basic and diluted	44,753	44,160	42,644

See accompanying notes to financial statements.

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PAIN THERAPEUTICS, INC.

STATEMENTS OF COMPREHENSIVE INCOME

(in thousands)

	Years ended December 31,		
	2012	**2011**	**2010**
Net loss	$ (3,446)	$ (2,613)	$ (12,023)
Other comprehensive income (loss):			
Net unrealized gains (losses) on marketable securities	(124)	(397)	178
Comprehensive loss	$ (3,570)	$ (3,010)	$ (11,845)

See accompanying notes to financial statements.

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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, 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 of $2.00 per share			(85,691)			(85,691)
Other comprehensive income				178		178
Net loss					(12,023)	(12,023)
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
Other comprehensive loss				(397)		(397)
Net loss					(2,613)	(2,613)
Balance at December 31, 2011	44,732,017	$ 45	$ 176,425	$ 128	$ (132,205)	$ 44,393
Issuance of common stock pursuant to exercise of stock options and awards, net of taxes paid on net issuance of stock options and awards	574,370		(366)			(366)
Issuance of common stock related to employee stock purchase plan	20,553		64			64
Compensation with respect to non-employee option grants			75			75
Compensation with respect to employee option grants and share based awards			6,535			6,535
Non-dividend cash distribution of $0.75 per share			(33,995)			(33,995)
Other comprehensive loss				(124)		(124)
Net loss					(3,446)	(3,446)
Balance at December 31, 2012	45,326,940	$ 45	$ 148,738	$ 4	$ (135,651)	$ 13,136

See accompanying notes to financial statements.

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PAIN THERAPEUTICS, INC

STATEMENTS OF CASH FLOWS

(in thousands)

	Years ended December 31,		
	2012	**2011**	**2010**
Cash flows used in operating activities:			
Net loss	$ (3,446)	$ (2,613)	$ (12,023)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash stock based compensation	6,610	5,428	20,132
Depreciation and amortization	122	163	232
Non-cash net interest income	342	1,141	1,252
Deferred program fee revenue	(10,641)	(10,897)	(10,496)
Changes in operating assets and liabilities:			
Receivables		7,114	(4,812)
Other current assets	105	(214)	266
Other non-current assets		74	1,585
Accounts payable	(103)	(643)	(210)
Accrued development expense	15	656	(963)
Deferred program fee revenue			5,000
Excess tax benefits from equity-based compensation plans	(57)	339	(290)
Accrued compensation and benefits	(62)	(797)	574
Other accrued liabilities	(58)	(15)	(390)
Other non-current liabilities	2	4	
Net cash used in operating activities	(7,171)	(260)	(143)
Cash flows provided by investing activities:			
Purchase of marketable securities	(20,768)	(2,497)	(65,753)
Sales of marketable securities			7,407
Maturities of marketable securities	38,390	62,400	110,809
Net cash provided by investing activities	17,622	59,903	52,463
Cash flows provided by (used in) financing activities:			
Nondividend distribution	(33,995)		(85,691)
Excess tax benefits from equity-based compensation plans	57	(339)	290
Proceeds from (cash used in) issuance of common stock, net	(302)	9,042	2,085
Net cash provided by (used in) financing activities	(34,240)	8,703	(83,316)
Net increase (decrease) in cash and cash equivalents	(23,789)	68,346	(30,996)
Cash and cash equivalents at beginning of the year	73,144	4,798	35,794
Cash and cash equivalents at end of the year	$ 49,355	$ 73,144	$ 4,798
Supplemental cash flow information:			
Cash received for income taxes	$	$	$ 3,765

See accompanying notes to financial statements.

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

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

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 Pfizer 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 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 March 2018. We review the estimated development period on a quarterly basis and change it if appropriate based upon our latest expectations. In the fourth quarter of 2012 we determined that our estimate of the development period should be extended from the third quarter of 2016 to the first quarter of 2018. Deferred program fee revenue represents the amount of the upfront payment that has not yet been recognized as program fee revenue. As a result of the change in estimate in the fourth quarter of 2012, program fee revenue was $0.3 million lower in 2012.

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

Pfizer 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

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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 Pfizer under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration with Pfizer.

Cash, Cash Equivalents and Concentration of Credit Risk

We consider all highly liquid financial instruments with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist of cash maintained at two financial institutions and in money market funds. We believe the financial risks associated with these instruments are minimal. We have not 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 one financial institution and are governed by our investment policy as approved by our Board of Directors.

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

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PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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.

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 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.

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,		
	2012	**2011**	**2010**
Numerator			
Net loss	$ (3,446)	$ (2,613)	$ (12,023)
Denominator			
Weighted average shares used to compute basic net loss per share, basic and diluted	44,753	44,160	42,644
Net loss per share, basic and diluted	$ (0.08)	$ (0.06)	$ (0.28)

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PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

We excluded weighted options outstanding to purchase common stock of 13.2 million for 2012, 13.7 million for 2011 and 7.3 million for 2010 from the calculation of diluted net loss per share because the effect of including these shares in this calculation would be anti-dilutive.

Income Taxes

We make estimates and judgments in determining the need for a provision for income taxes, including the estimation of our taxable income or loss for each full fiscal year. We have accumulated significant deferred tax assets. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of certain deferred tax assets is dependent upon future earnings, 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.

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

Pfizer, Inc.

Our strategic alliance with Pfizer includes a collaboration agreement and a license agreement to develop and commercialize REMOXY and other abuse-resistant opioid painkillers. We received a $150.0 million upfront fee in connection with the closing of this strategic alliance and $5.0 million in July 2010 in connection with an amendment to this strategic alliance, of which we recorded as program fee revenue $10.6 million in 2012, $10.9 million in 2011 and $10.5 million in 2010. In January 2011, we received $5.0 million for the acceptance by the FDA in 2010 of the IND for abuse-resistant oxymorphone. We could also receive from Pfizer 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, Pfizer is obligated to fund development expenses incurred by us pursuant to the collaboration agreement, of which we recorded as collaboration revenue $0.2 million in 2012, $0.6 million in 2011 and $1.3 million in 2010. Pfizer 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 Pfizer 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 Pfizer 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 Pfizer certain rights to develop and to commercialize REMOXY and certain other opioid drugs formulated in part with

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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. Pfizer is obligated to reimburse us for costs we incur under the agreement with Durect, including royalties.

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, 2012						
Cash and cash equivalents	$ 49,352	$ 3	$	$ 49,355	$	$ 49,355
Corporate securities	$ 6,898	1		6,899		6,899
	$ 56,250	$ 4	$	$ 56,254	$	$ 56,254
Reported as:						
Cash and cash equivalents	$ 49,352	$ 3	$	$ 49,355	$	$ 49,355
Marketable securities	6,898	1		6,899		6,899
	$ 56,250	$ 4	$	$ 56,254	$	$ 56,254
Maturities:						
Matures in one year or less	$ 56,250	$ 4	$	$ 56,254	$	$ 56,254
Matures one to three years						
	$ 56,250	$ 4	$	$ 56,254	$	$ 56,254
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

To date we have not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value. Our realized gains and losses on our marketable securities were immaterial in 2012, 2011 and 2010.

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PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Our assets measured at fair value (in thousands):

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

5. Property and Equipment

Property and equipment at December 31, 2012 and 2011 consisted of the following (in thousands):

	December 31, 2012	December 31, 2011
Furniture, fixtures and equipment	$ 629	$ 672
Leasehold improvement		658
	629	1,330
Accumulated depreciation and amortization	(629)	(1,208)
	$	$ 122

Depreciation and amortization expenses were $0.1 million in 2012, $0.2 million in 2011, and $0.2 million in 2010.

6. Stockholders Equity and Stock-Based Compensation

In 2012, our Board of Directors approved a special nondividend distribution of $0.75 per share, totaling $34.0 million. In 2010, our Board of Directors approved a special nondividend distribution of $2.00 per share, totaling $85.7 million.

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.

PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Stock-Based Compensation

Our non-cash stock-based compensation costs for the 1998 Equity Incentive Plan, the 2008 Equity Incentive Plan and the 2000 Employee Stock Purchase Plan were $6.6 million in 2012, $5.4 million in 2011 and $20.1 million in 2010. Stock based compensation in 2012 and 2010 included $1.8 million and $14.8 million, respectively, for modifications made to options outstanding under the 1998 Equity Incentive Plan to prevent diminution of the benefit of these options from the nondividend distributions to stockholders in 2012 and 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. Shares reserved for issuance and available for grant under the 2008 Equity Incentive Plan were 5.7 million as of December 31, 2012, including adjustments related to the nondividend distributions in 2010 and 2012. 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.

In 2010 and 2012, stock options and Performance Awards outstanding under the 2008 Equity Plan were automatically adjusted to prevent diminution of the benefit of the options and Performance Awards for nondividend distributions to stockholders. In addition, the Compensation Committee of our Board of Directors adjusted the options outstanding under the 1998 Equity Incentive Plan to prevent diminution of the benefit of these options from the distributions on the same basis as the adjustments made to options and restricted stock units under the 2008 Equity Plan. Adjusting options outstanding under the 1998 Equity Incentive Plan resulted in additional non-cash equity related compensation expense of $1.8 million in 2012 and $14.8 million in 2010.

When stock options or Performance Awards are exercised net of the exercise price and taxes, the number of shares of stock issued is reduced by the number of shares equal to the amount of taxes owed by the award recipient and that number of shares are cancelled and returned to the 2008 Equity Plan. We then use our cash to pay tax authorities the amount of statutory taxes owed by and on behalf of the award recipient. For stock options and Performance Awards issued in 2012 in a net exercise, 108,641 shares were returned to the 2008 Equity Plan and we paid $0.5 million to tax authorities on behalf of award recipients.

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PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Stock Options

Our stock option activity for 2012 was:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term In years	Aggregate Intrinsic Value In millions
Outstanding as of December 31, 2011	12,557,143	$ 5.71	5.2	$ 0.5
Granted	1,080,000	$ 4.19		
Exercised	(51,502)	$ 2.99		
Cancelled	(1,714,795)	$ 5.82		
Increase related to nondividend distribution	3,648,716			
Outstanding as of December 31, 2012	15,519,562	$ 4.27	5.0	$ 0.2
Vested and expected to vest at December 31, 2012	15,261,348	$ 4.27	4.9	$ 0.2
Exercisable at December 31, 2012	12,536,405	$ 4.28	4.2	$ 0.1

Exercised Options includes actual shares issued. Cancelled Options includes options returned to the 2008 Equity Plan for the effect of options exercised net of the exercise price and taxes.

The pre-tax intrinsic value of options exercised was immaterial in 2012, 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, 2012, we expect to recognize compensation costs prior to forfeiture of $7.0 million related to non-vested options over the weighted average remaining recognition period of 2.4 years.

The following summarizes information about stock options outstanding at December 31, 2012 by a range of exercise prices:

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
$1.35	$ 3.12	3,135,356	5.09	$ 2.83	2,560,614	$ 2.85
$3.18	$ 4.18	3,929,397	5.92	$ 3.61	2,249,436	$ 3.78
$4.27	$ 4.75	3,261,069	3.76	$ 4.47	3,261,069	$ 4.47
$4.77	$ 4.88	3,545,050	3.95	$ 4.84	3,545,050	$ 4.84

$4.90	$	7.65	1,648,690	7.34	$	6.95	920,236	$ 6.55
			15,519,562	5.00	$	4.27	12,536,405	$ 4.28

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PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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 2012, 2011 and 2010, as follows:

	2012	2011	2010
Volatility	56% to 64%	50% to 60%	48% to 50%
Risk-free interest rates	1%	1% to 3%	1% to 3%
Expected life of option	6 years	6 years	5 to 6 years
Dividend yield			
Forfeiture rate	7%	6%	7% to 8%
Weighted average fair value of stock options granted	$1.70	$4.68	$2.23

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. We estimate forfeitures and adjust this estimate periodically based in part on the extent to which actual forfeitures differ from our estimates. Weighted average fair value of options granted includes the effect in 2012 and 2010 of the increase related to nondividend distributions.

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, 2012, we have outstanding 3,250,065 shares of Performance Awards granted in 2012. If these Performance Awards vest, we would recognize $11.2 million in non-cash stock compensation expense. These Performance Awards expire in 2022. If the awards expire, the underlying shares will be returned to the 2008 Equity Incentive Plan.

In 2012, all of the 2,099,054 Performance Awards that were outstanding at December 31, 2011 were cancelled. All of these shares were returned to the 2008 Equity Incentive Plan.

In 2012, we granted 371,000 Performance Awards that vested in 2012 and for which we recognized stock-based compensation of $1.6 million in non-cash stock compensation expense.

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. During 2011, 45,934 shares of the Performance Awards granted in 2010 were cancelled and returned to the 2008 Equity Incentive Plan.

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.

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PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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 422,584 shares reserved for issuance under the Purchase Plan at December 31, 2012.

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 2012.

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, 2012, we have not made any matching contributions.

8. Income Taxes

We did not provide for income taxes in 2012, 2011 and 2010 because we did not have taxable income in those years.

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,		
	2012	**2011**	**2010**
Deferred tax assets:			
Net operating loss carryforwards	$ 9,200	$ 6,500	$ 3,000
Deferred license fee revenue	14,600	19,900	22,900
Research & development credits	6,400	6,300	5,800
Stock-related compensation	11,700	12,000	14,000
Other	600	900	700
Total deferred tax assets	42,500	45,600	46,400
Valuation allowance	(42,200)	(45,300)	(46,100)
Net deferred tax assets	$ 300	$ 300	$ 300

Except for certain of our research and development credits, we won t realize our deferred tax assets until we are profitable. We are uncertain about the timing and amount of any future profits. Accordingly, we offset our deferred tax assets by a valuation allowance. The valuation allowance decreased by $3.1 million in 2012, decreased by $0.8 million in 2011 and increased by $4.5 million in 2010.

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PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

The federal portion of our pre-tax net operating loss carryforwards of $25.5 million expires between 2029 and 2032. The California state portion of our pre-tax net operating loss carryforwards of $30.9 million expires between 2017 and 2032.

We have taken federal tax deductions associated with stock option transactions over and above the stock related compensation expenses in our financial statements by approximately $3.6 million. We exclude this amount from our net operating loss carryforwards. If and when we are able to reduce our income taxes payable with these tax deductions, we will credit additional paid-in capital.

As of December 31, 2012, we had federal research and development tax credits of approximately $9.3 million, which expire in the years 2023 through 2032 and California state research and development tax credits of approximately $2.1 million.

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 2012, 2011 and 2010 follows (in thousands):

	2012	2011	2010
Beginning balance	$ 5,100	$ 4,800	$ 4,600
Additions based on tax positions related to the current year	100	300	200
Reductions for tax positions related to prior years			
Ending balance	$ 5,200	$ 5,100	$ 4,800

Our deferred tax liabilities result from reserves for credits used to reduce state taxes paid for 2006 and 2008. The total amount of unrecognized tax benefit that, if recognized if and when these reserves are never realized, would benefit our effective tax rate, is approximately $0.1 million. Interest expense related to our tax positions was immaterial for 2012, 2011 and 2010.

9. Leases and Commitments

We currently lease approximately 6,000 square feet of office space pursuant to a non-cancelable operating lease in Austin, TX that expires in 2014. Future minimum lease payments are as follows for the years ended December 31, (in thousands):

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

We believe that our facilities are adequate and suitable for our current needs. Rent expense was $0.1 million for 2012, $0.6 million for 2011 and $0.9 million for 2010.

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.

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PAIN THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

10. Legal proceedings

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

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

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

	Quarters Ended			
	March 31	June 30	September 30	December 31
2012				
Total revenue	$ 2,973	$ 2,724	$ 2,725	$ 2,468
Net loss	$ 30	$ (130)	$ (1,550)	$ (1,796)
Basic and diluted net loss per share	$ (0.00)	$ (0.00)	$ (0.03)	$ (0.04)
2011				
Total revenue	$ 3,236	$ 2,752	$ 2,749	$ 2,747
Net loss	$ (207)	$ (1,200)	$ (815)	$ (391)
Basic and diluted net loss per share	$	$ (0.03)	$ (0.02)	$ (0.01)

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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, 2012. 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, 2012 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, 2012 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.

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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, 2012, 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, 2012, 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, 2012 and 2011, and the related statements of operations, comprehensive income, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2012 of Pain Therapeutics, Inc. and our report dated February 8, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Austin, Texas

February 8, 2013

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

5.02(e) On December 7, 2012, our Board of Directors approved adjustments to outstanding stock options and Performance Awards under our 2008 Equity Plan and 1998 Equity Incentive Plan to prevent diminution of the benefit of such awards in connection with our nondividend distribution on shares of common stock in December 2012. Adjustments for outstanding awards under the 2008 Equity Plan were made automatically pursuant to the existing terms of such plan and awards, and adjustments of outstanding awards under the 1998 Equity Incentive Plan were made by modification of such awards. Awards were adjusted by increasing the number of shares underlying such awards by 31% (with the aggregate adjustment increasing the number of shares of common stock outstanding under such awards by 4,318,781 shares), and adjusting the exercise price, as applicable, down by 76%. These adjustments were based on the proportionate effect that the nondividend distribution had on our commons stock trading price on the ex-dividend date.

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 2013 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 2012.

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.

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The following table summarizes the securities authorized for issuance under our equity compensation plans as of December 31, 2012:

	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 .	18,769,627	$ 3.54	6,119,595
Equity compensation plans not approved by stockholders .			
Total	18,769,627	$ 3.54	6,119,595

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 Comprehensive Income

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) *Management Contracts, Compensatory Plans and Arrangements*.

Management contracts, compensatory plans and arrangements are indicated by the symbol * in the applicable exhibits listed in Item 15(b), below.

(b) *Exhibits*

The exhibits listed below are filed as part of this Form 10-K other than Exhibit 32.1, which shall be deemed furnished.

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(6)	Collaboration Agreement dated November 9, 2005, between Registrant and King Pharmaceuticals, Inc.
10.5(6)	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.
10.9(8)	2008 Equity Incentive Plan.
10.10(9)*	Form of Restricted Stock Unit Award Agreement under 2008 Equity Incentive Plan.
10.11(9)*	Form of Performance Share Award Agreement under 2008 Equity Incentive Plan.
10.12(9)*	Form of Restricted Stock Award Agreement under 2008 Equity Incentive Plan.
10.13(9)*	Form of Stock Option Award Agreement under 2008 Equity Incentive Plan.
10.14(10)*	Employment Agreement dated July 1, 1998 and amended December 17, 2008 between Registrant and Remi Barbier.
10.15(10)*	Employment Agreement dated August 29, 2000 and amended December 30, 2008 between Registrant and Grant L. Schoenhard, Ph.D.
10.16(10)*	Employment Agreement dated November 18, 2002 and amended December 30, 2008 between Registrant and Peter S. Roddy.
10.17(11)+	Letter Agreement dated June 24, 2010 with Amendments to the License and Collaboration Agreements between the Registrant and King Pharmaceuticals, Inc.
10.18(11)*	2000 Employee Stock Purchase Plan, as amended and restated.
10.19(12)	Lease agreement, dated as of February 14, 2011 between Registrant and StoneCliff Office, L.P.
10.20(6)	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 65).

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Exhibit Number	Description of Document
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-K for the period ending December 31, 2011.
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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.
* Management contract, compensatory plan or arrangement.

(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.

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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 8, 2013

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 8, 2013
/s/ PETER S. RODDY **Peter S. Roddy**	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 8, 2013
/s/ NADAV FRIEDMANN, PH.D., M.D. **Nadav Friedmann, Ph.D., M.D.**	Chief Operating and Medical Officer and Director	February 8, 2013
Robert Z. Gussin, Ph.D	Director	
/s/ MICHAEL J. O DONNELL, ESQ. **Michael J. O Donnell, Esq.**	Director and Secretary	February 8, 2013
/s/ SANFORD R. ROBERTSON **Sanford R. Robertson**	Director	February 8, 2013
/s/ PATRICK SCANNON, M.D, PH.D.	Director	February 8, 2013

Patrick Scannon, M.D., Ph.D.

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