PAIN THERAPEUTICS INC
Form S-3
August 26, 2005
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As filed with the Securities and Exchange Commission on August 26, 2005

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

Under

THE SECURITIES ACT OF 1933

PAIN THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charters)

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

416 Browning Way

South San Francisco, CA 94080

(650) 624-8200

(Address, including zip code, and telephone number, including area code, of Registrants principal executive offices)

Remi Barbier

President, Chief Executive Officer and Director

416 Browning Way

South San Francisco, CA 94080

(650) 624-8000

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Professional Corporation

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Palo Alto, California 94304

(650) 493-9300

Approximate date of commencement of proposed sale to the public: From time to time, after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨ _____

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨ _____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount To Be Registered	Proposed Maximum Offering Price per Unit	Proposed Maximum Offering Price(1)(2)	Amount of Registration Fee
Common Stock, $0.001 par value per share(3)(4)				
Preferred Stock, $0.001 par value per share(4)				
Depositary Shares(4)				
Warrants(5)				
Debt Securities				
Total(6)	$ 150,000,000(6)	100%(7)	$ 150,000,000	$ 17,655

(1) Or (i) if any debt securities are issued at an original issue discount, such greater principal amount at maturity as shall result in an aggregate initial offering price equal to the amount to be registered or (ii) if any securities are issued in an amount denominated in a foreign currency or composite currency, such amount as shall result in an aggregate initial offering price equivalent thereto in United States dollars at the time of initial offering.

(2) These figures are estimates made solely for the purpose of calculating the registration fee pursuant to Rule 457(o). Exclusive of accrued interest, if any, on the debt securities.

(3) Each share of Common Stock includes a right to purchase one one-thousandth of a share of Series A Participating Preferred Stock.

(4) In addition to any securities that may be registered hereunder, we are also registering an indeterminate number of shares of common stock, preferred stock, or depositary shares as may be issued upon conversion or exchange of the securities issued directly hereunder. No separate consideration will be received for any shares of common stock, preferred stock or depositary shares so issued upon conversion or exchange.

(5) Includes warrants to purchase common stock, warrants to purchase preferred stock and warrants to purchase debt securities.

(6) The securities registered hereunder may be sold separately, or as units with other securities registered hereby. The proposed maximum offering price per unit will be determined by us in connection with the issuance of the Securities. In no event will the aggregate offering price of all securities issued from time to time pursuant to this Registration Statement exceed $150,000,000 or the equivalent thereof in one or more foreign currencies, foreign currency units or composite currencies.

(7) We will determine the proposed maximum offering price per unit in connection with the issuance of the above listed securities.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrants shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell the securities until the Registration Statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED AUGUST 26, 2005

PROSPECTUS

$150,000,000

PAIN THERAPEUTICS, INC.

By this prospectus, we may offer, from time to time

Common Stock
Preferred Stock
Depositary Shares
Warrants
Debt Securities

See Risk Factors beginning on page 6 for information you should consider before buying our securities.

Our common stock is quoted on the Nasdaq National Market under the symbol PTIE. On August 25, 2005, the last reported sale price of our common stock on the Nasdaq National Market was $6.15 per share.

We will provide specific terms of these securities in supplements to this prospectus. You should read this prospectus and any supplement carefully before you purchase any of our securities.

This prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We may offer the securities in amounts, at prices and on terms determined at the time of offering. We may sell the securities directly to you, through agents we select, or through underwriters and dealers we select. If we use agents, underwriters or dealers to sell the securities, we will name them and describe their compensation in a prospectus supplement.

This prospectus is dated , 2005

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No person has been authorized to give any information or make any representations in connection with this offering other than those contained or incorporated by reference in this prospectus and any accompanying prospectus supplement in connection with the offering described in this prospectus and any accompanying prospectus supplement, and, if given or made, such information or representations must not be relied upon as having been authorized by us. Neither this prospectus nor any prospectus supplement shall constitute an offer to sell or a solicitation of an offer to buy offered securities in any jurisdiction in which it is unlawful for such person to make such an offering or solicitation. Neither the delivery of this prospectus or any prospectus supplement nor any sale made hereunder shall under any circumstances imply that the information contained or incorporated by reference in this prospectus or in any prospectus supplement is correct as of any date subsequent to the date of this prospectus supplement or of any prospectus supplement.

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SUMMARY

The following summary is qualified in its entirety by the more detailed information, including our consolidated financial statements and related notes, included in this prospectus and incorporated in this prospectus by reference. You should carefully consider the information set forth in this entire prospectus, including the Risk Factors section, the applicable prospectus supplement for such securities and the other documents we refer to and incorporate by reference, including but not limited to the section entitled Risk Factors in our 2004 Annual Report on Form 10-K and in our other filings with the Securities Exchange Commission. Unless the context otherwise requires, the terms Pain Therapeutics, we, us and our refer to Pain Therapeutics, Inc., a Delaware corporation.

This prospectus is part of a Registration Statement on Form S-3 that we filed with the Securities and Exchange Commission using a shelf registration process. Under this shelf process, we may sell any combination of securities described in this prospectus in one or more offerings, up to a total dollar amount of $150,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may, along with information that is incorporated by reference as described under the heading Where You Can Find More Information, also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described below under the heading Where You Can Find More Information.

Pain Therapeutics, Inc.

Overview

We are a biopharmaceutical company dedicated to the development of innovative drugs. We specialize in developing safer or more efficacious drugs for use in pain management, particularly in the area of opioid painkillers.

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

Our drug candidates are:

- Oxytrex, a new oral opioid painkiller for the treatment of severe chronic pain;
- PTI-901, a drug candidate to treat men and women with IBS; and
- Remoxy, a long-acting formulation of oxycodone designed to deter opioid abuse.

Oxytrex

Oxytrex is an oral opioid painkiller with a novel mechanism of action. We believe Oxytrex could be an effective substitute for oxycodone, a narcotic painkiller widely used today to treat severe chronic pain.

Our clinical results to date have shown that Oxytrex provides superior and prolonged pain relief compared to oxycodone. Published pre-clinical results also demonstrate that the technology used in Oxytrex results in a lack of opioid addiction, tolerance or physical dependence in animals. However, for ethical reasons we have not conducted anti-addiction studies in humans.

Oxytrex is formulated with two active drug ingredients: oxycodone and low-dose naltrexone. Oxycodone is a strong narcotic painkiller that was developed around 1920 as a substitute for morphine. When used as prescribed, oxycodone can relieve severe chronic pain.

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PTI-901

PTI-901 is intended to treat men or women who suffer from chronic IBS. Chronic IBS is a painful abdominal disorder that leads to major changes in bowel habits. Published presentations estimate that IBS afflicts over 10% of the U.S. population and accounts for about 20% to 50% of referrals to gastroenterology clinics. The causes of IBS are not known and currently there is no cure. For unknown reasons, IBS predominantly affects women.

There are no FDA-approved drugs to treat men with IBS. There are two FDA-approved drugs to treat women with IBS: Lotronex® (GlaxoSmithKline) and Zelnorm® (Novartis). The FDA approved Lotronex® in February 2000 for use in female patients with diarrhea-predominant IBS. The FDA approved Zelnorm® in July 2002 for short-term use by female patients who have constipation-predominant IBS. Both of these drugs impact gut motility. These motility drugs slow down or speed up the gut, thereby relieving diarrhea or constipation, respectively.

In contrast, we view IBS as a nervous system disorder with gut-related symptoms. We believe an appropriate dose of PTI-901 modulates aberrant neuronal communication within the gut, thus restoring proper bowel function and relieving abdominal pain. In this regard, we believe PTI-901 represents a novel mechanism of action.

Our clinical results to date have shown in a 50-patient open-label study that patients with IBS reported a 76% response rate to PTI-901. This response rate was observed in men and women and occurred without drug-related safety issues.

Remoxy

In November 2003, we announced a novel drug candidate that we named Remoxy. Remoxy is being developed as an anti-abuse version of long-acting oral oxycodone.

The active drug ingredient in Remoxy is oxycodone. Oxycodone has an abuse potential similar to morphine. The U.S. Drug Enforcement Administration, or the DEA, and the national media have linked illicit oxycodone use to widespread patterns of drug abuse, addiction, diversion and drug overdose. In the United States, drug-abuse related emergency room visits are reported by the Department of Health and Human Service s Drug Abuse Warning Network, or DAWN. DAWN reports 22,000 oxycodone mentions in emergency room visits in 2002, a 450% increase from 4,000 oxycodone mentions in emergency room visits in 1994.

Remoxy s novel formulation is specifically designed to foil abusers who attempt to tamper with the drug in order to induce a powerful euphoric high.

We were incorporated in Delaware in May 1998. Our principal executive offices are located at 416 Browning Way, South San Francisco, California 94080 and our telephone number at that address is (650) 624-8200. Our website is www.paintrials.com. The information contained or incorporated in our website is not part of this registration statement.

The butterfly design/logo is registered as a trademark of Pain Therapeutics, Inc. Oxytrex and Remoxy are trademarks of Pain Therapeutics, Inc. This prospectus also includes product names, trade names and trademarks of other companies. All other products names, trade names and trademarks appearing in this prospectus are the property of their respective holders.

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The Securities We May Offer

We may offer up to $150,000,000 of common stock, preferred stock, depositary shares, warrants and debt securities in one or more offerings and in any combination. A prospectus supplement, which we will provide each time we offer securities, will describe the specific amounts, prices and terms of these securities.

We may sell the securities to or through underwriters, dealers or agents or directly to purchasers. We, as well as any agents acting on our behalf, reserve the sole right to accept and to reject in whole or in part any proposed purchase of securities. Each prospectus supplement will set forth the names of any underwriters, dealers or agents involved in the sale of securities described in that prospectus supplement and any applicable fee, commission or discount arrangements with them.

Common Stock

We may offer shares of our common stock, par value $0.001 per share, either alone or underlying other registered securities convertible into our common stock. Holders of our common stock are entitled to receive dividends declared by our board of directors out of funds legally available for the payment of dividends, subject to rights, if any, of preferred stockholders. Currently, we do not pay a dividend. Each holder of common stock is entitled to one vote per share. The holders of common stock have no preemptive rights.

Preferred Stock and Depositary Shares

We may issue preferred stock in one or more series. Our board of directors or a committee designated by the board will determine the dividend, voting and conversion rights and other provisions at the time of sale. Each series of preferred stock will be more fully described in the particular prospectus supplement that will accompany this prospectus, including redemption provisions, rights in the event of liquidation, dissolution or the winding up of Pain Therapeutics, Inc., voting rights and rights to convert into common stock. We may also issue fractional shares of preferred stock that will be represented by depositary shares and depositary receipts. Each particular series of depositary shares will be more fully described in the prospectus supplement that will accompany this prospectus.

Warrants

We may issue warrants for the purchase of common stock, preferred stock or debt securities. We may issue warrants independently or together with other securities.

Debt Securities

We may offer secured or unsecured obligations in the form of one or more of senior or subordinated debt. The senior debt securities and the subordinated debt securities are together referred to in this prospectus as the debt securities. The senior debt securities will have the same rank as all of our other unsubordinated debt. The subordinated debt securities generally will be entitled to payment only after payment of our senior debt. Senior debt generally includes all debt for money borrowed by us, except debt that is stated in the instrument governing the terms of that debt to be not senior to, or to have the same rank in right of payment as, or to be expressly junior to, the subordinated debt securities. We may issue debt securities that are convertible into shares of our common stock.

The senior and subordinated debt securities will be issued under separate indentures between us and a trustee. We have summarized the general features of the debt securities to be governed by the indentures. These indentures have been filed as exhibits to registration statement (No. 333-) that we have filed with the SEC (this prospectus being part of that registration statement). We encourage you to read these indentures. Instructions on how you can get copies of these documents are provided under the heading Where You Can Find More Information.

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General Indenture Provisions that Apply to Senior and Subordinated Debt

Each indenture allows debt to be issued in series with terms particular to each series.

None of the indentures limit the amount of debt that we may issue or generally provide holders any protection should there be a highly leveraged transaction involving our company.

The indentures allow us to merge or to consolidate with another United States business entity or convey, transfer or lease our properties and assets substantially as an entirety to another United States business entity, as long as certain conditions are met. If these events occur, the other United States business entity will be required to assume our responsibilities on the debt securities, and we will be released from all liabilities and obligations, except in the case of a lease.

The indentures provide we and the trustee may generally amend the indentures with the consent of holders of a majority of the total principal amount of the debt outstanding in any series to change certain of our obligations or your rights concerning the debt. However, to change the payment of principal or interest, to adversely affect any right to convert, or to change certain matters, every holder in that series must consent.

We may discharge the indentures and defease restrictive covenants by depositing sufficient funds with the trustee to pay the obligations when due, as long as certain conditions are met. The trustee would pay all amounts due to you on the debt from the deposited funds.

Events of Default

Each of the following is an event of default under the indentures:

principal not paid when due;

any sinking fund payment not made when due;

failure to pay interest for 30 days;

covenants not performed for 60 days after notice; and

certain events of bankruptcy, insolvency or reorganization of Pain Therapeutics, Inc.

A prospectus supplement may describe deletions of, or changes or additions to, the events of default.

Remedies

Upon an event of default, other than a bankruptcy, insolvency or reorganization, the trustee or holders of 25% of the principal amount outstanding in a series may declare the outstanding principal and premium, if any, plus accrued and unpaid interest, if any, immediately payable. However, the holders of a majority in principal amount may, under certain circumstances, rescind this action. If a bankruptcy, insolvency or reorganization event of default were to occur, the principal amount and premium, if any, or all debt securities of that series, together with the accrued and unpaid interest, if any, will automatically become due and payable.

Indenture Provisions that Apply Only to the Subordinated Debt Securities

The subordinated debt securities indenture provides that the subordinated debt securities will be subordinated to all senior debt as defined in the subordinated indenture.

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RATIO OF EARNINGS TO FIXED CHARGES AND PREFERRED STOCK DIVIDENDS

The ratio of earnings to cover fixed charges and the ratio of earnings to combined fixed charges and preferred stock dividends for each of the periods indicated are as follows:

Pain Therapeutics, Inc.

Computation of Ratio of Earnings to Fixed Charges and Preferred Stock Dividends

(in thousands)

	Year Ended December 31,					Six Months Ended
	2000	2001	2002	2003	2004	June 30, 2005
Ratio of earnings available to cover fixed charges (1)						
Ratio of earnings available to combined fixed charges and preferred stock dividends (1)						

(1) Due to our losses in years ended December 31, 2000, 2001, 2002, 2003 and 2004 and the six months ended June 30, 2005, the ratio coverage was less than 1:1. Additional earnings of less than $0.1 million in each individual period would have been required to achieve a ratio coverage of 1:1.

In calculating the ratio of earnings available to cover fixed charges and the ratio of earnings available to cover combined fixed charges and preferred stock dividends, earnings consists of net income (loss) before provisions for income taxes plus fixed charges. Fixed charges consists of the portion of our rental expense that we believe represents interest expense.

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RISK FACTORS

Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently believe are immaterial may also impair our business operations and financial results. If any of the following risks actually occur, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our common stock could decline and you could lose all or part of your investment. In assessing these risks, investors should also refer to the other information contained or incorporated by reference herein.

Risks Relating to our Financial Position and Need for Financing

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

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

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

We have incurred net losses each year since our inception. Even if we succeed in developing and commercializing one or more of our drug candidates, we expect to continue to incur substantial losses for the foreseeable future, and we may never become profitable. We anticipate that our expenses will increase substantially in the foreseeable future as we:

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

hire additional personnel.

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

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

We have funded all of our operations and capital expenditures with the proceeds from public and private stock offerings. However, we may need to raise additional funds through private or public equity offerings, strategic alliances or debt financing, such additional financing may not be available on favorable terms, or at all. Even if we succeed in selling additional securities to raise funds, our existing stockholders ownership percentage

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would be reduced and new investors may demand rights, preferences or privileges senior to those of existing stockholders. If we raise additional capital through strategic alliance and license arrangements, we may have to trade our rights to our technology, intellectual property or drug candidates to others in such arrangements on terms that may not be favorable to us. If we raise additional capital through debt financing, such financing may involve covenants that restrict our business activities.

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

Clinical and Regulatory Risks

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the indicated uses for which the drug may be marketed or contain requirements for potentially costly post-marketing follow-up studies. In addition, if the FDA approves any of our drug candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drug, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

The FDA s policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse

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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 Commercialization

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

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

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

Because we expect to rely on sales generated by our current lead drug candidates for substantially all of our product 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 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. 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 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 collaborators, we may not be able to enter into any collaborative arrangements on favorable terms, or at all.

In addition, due to the nature of the market for pain management products, it may be necessary for us to license all or substantially all of our drug candidates to a single collaborator, thereby eliminating our opportunity to commercialize other pain management products independently. If we enter into any collaborative arrangements, our revenues are likely to be lower than if we marketed and sold our products ourselves.

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

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

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

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

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

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

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

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

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

Risks Relating to our Intellectual Property

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

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

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

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

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

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

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

Risks Relating to our Business and Strategy

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

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

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

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

Contract commercial manufacturers, their sub-contractors or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy clinical needs or

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commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations.

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

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

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

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

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

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

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

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

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

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

more effective drugs that would compete with our product candidates or reach market with competing drugs before we are able to reach market with our drug candidates. These organizations also compete with us to attract qualified personnel and partners for acquisitions, joint ventures or other collaborations.

Business interruptions could limit our ability to operate our business.

Our operations as well as those of our collaborators on which we depend are vulnerable to damage or interruption from computer viruses, human error, natural disasters, electrical and telecommunication failures, international acts of terror and similar events. We have not established a formal disaster recovery plan and our

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back-up operations and our business interruption insurance may not be adequate to compensate us for losses we may suffer. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

Risks Relating to Manufacturing

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

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

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

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

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

We plan to formulate and scale-up a wide range of dosage forms of Remoxy. We may not be able to successfully complete our formulation or scale-up activities or we may determine that the commercial opportunity for Remoxy in certain dosage forms is too limited to warrant further investment. If we are unsuccessful in our formulation or scale-up activities with Remoxy, our future sales may be less than expected and our operations may suffer.

Risks Relating to our Collaboration Agreements

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

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

if their performance is substandard, the approval of our regulatory submissions and our introductions of new drugs will be delayed.

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 will be less than expected.

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

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

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

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

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

Risks Relating to an Investment in our Common Stock

We expect that our stock price will fluctuate significantly, and you may not be able to resell your shares at or above your investment price.

The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. In addition, our common stock has experienced significant price and volume fluctuations and may continue to experience volatility in the future. 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 from, and delays in, the clinical trials for our drug candidates;
- publicity regarding actual or potential medical results relating to products under development by us or others;
- introductions or announcements of technological innovations or new commercial products by us or others;
- developments or disputes concerning our patent or other proprietary rights;
- issuance of new or changed securities analysts reports or recommendations;

FDA or other United States or foreign regulatory actions, including changes in guidance, affecting us or our industry;

issues in manufacturing our drug candidates and drugs;

market acceptance of our drugs;

third-party healthcare reimbursement policies;

litigation or threats of litigation including the risk of class action lawsuits related to opioid misuse or abuse;

litigation or public concern about the safety of our drug candidates or drugs, or the drugs of other companies in our industry;

economic and other external factors, including market conditions in the pharmaceutical and biotechnology sectors, or other disasters or crises;

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- the departure of any of our officers, directors or key employees;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- volatility in the stock prices of other companies; and
- limited daily trading volume.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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. In addition, there is no guarantee that any active trading market will develop for any of the other securities we may issue pursuant to this prospectus.

Risks Relating to the Offered Securities

Our stock price may continue to experience fluctuations, which may significantly affect the market price of our common stock and securities convertible into or exchangeable for our common stock.

The market price of our common stock fluctuates and is expected to continue to be volatile in the future. These price fluctuations may be rapid and severe and may leave investors little time to react. Factors that may affect the market price of our common stock include the risks and uncertainties described above in this

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prospectus or described in any applicable prospectus supplement, as well as changes in securities analysts earnings projections or recommendations. These factors could lead to a significant decrease in the market price of our common stock and securities convertible into or exchangeable for our common stock.

The securities we are offering may not develop an active public market, which could depress the resale price of the securities.

The securities we are offering, other than our common stock, will be new issues of securities for which there is currently no trading market. We cannot predict whether an active trading market for the securities will develop or be sustained. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. If an active trading market were to develop, the securities could trade at prices that may be lower than the initial offering price of the securities. We cannot guarantee the liquidity of the trading markets for any securities.

We will have broad discretion over the use of the proceeds to us from this offering and may apply it to uses that do not improve our operating results or the value of your securities.

We will have broad discretion to use the net proceeds to us from this offering, and investors will be relying solely on the judgment of our board of directors and management regarding the application of these proceeds. Although we expect to use the net proceeds from this offering for general corporate purposes, we have not allocated these net proceeds for specific purposes. Investors will not have the opportunity, as part of their investment decision, to assess whether the proceeds are being used appropriately. Our use of the proceeds may not improve our operating results or increase the value of the securities being offered hereby.

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DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

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. It is our intent 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:

- the potential benefits of our drug candidates;
- future operating losses and anticipated operating and capital expenditures;
- expected uses of proceeds from our securities offerings;
- formulation activities in relation to Remoxy;
- the utility of protection of our intellectual property;
- expected future sources of revenue and capital;
- potential competitors or competitive products;
- future market acceptance of our drugs, if any;
- expenses increasing substantially;
- future expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions; and
- anticipated hiring.

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

- difficulties or delays in development, testing, clinical trials (including patient enrollment), regulatory approval, production and commercialization of our drug candidates;

unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product approval (including the risk that current and past results of clinical trials are not indicative of future results of clinical trials);

the uncertainty of patent protection for our intellectual property or trade secrets;

potential infringement of the intellectual property rights or trade secrets of third parties;

pursuing in-license and acquisition opportunities;

hiring and retaining personnel; and

our financial position and our ability to obtain additional financing if necessary.

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

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USE OF PROCEEDS

Unless otherwise indicated in the prospectus supplement, the net proceeds from the sale of securities offered by this prospectus will be used for general corporate purposes and working capital requirements. We may also use a portion of the net proceeds to fund possible investments in and acquisitions of complimentary businesses, partnerships, minority investments, products or technologies. Currently, there are no commitments or agreements regarding such acquisitions or investments that are material. Pending their ultimate use, we intend to invest the net proceeds in money market funds, commercial paper and governmental and non-governmental debt securities with maturities generally up to one year.

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DESCRIPTION OF COMMON STOCK

We are authorized to issue up to 120,000,000 shares of common stock, $0.001 par value. The following is a summary of the material provisions of the common stock contained in our certificate of incorporation and by-laws. For more information about our common stock, please refer to our certificate of incorporation and by-laws.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of common stock are entitled to receive ratably dividends, if any, as may be declared from time to time by the board of directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, whether voluntary or involuntary, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding. The common stock has no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and nonassessable, and the shares of common stock to be issued upon the closing of this offering will be fully paid and nonassessable.

Delaware Law and Certain Provisions of Our Certificate of Incorporation and By-laws

Certain provisions of Delaware law and our certificate of incorporation and by-laws could make it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise and the removal of incumbent officers and directors. These provisions, summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of us to first negotiate with us. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because, among other things, negotiation of these proposals could result in an improvement of their terms.

We are subject to Section 203 of the Delaware General Corporation Law, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder, unless, with exceptions, the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status, did own, 15% or more of a corporation s voting stock. The existence of this provision would be expected to have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Our certificate of incorporation and by-laws require that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of the stockholders and may not be effected by a consent in writing. Special meetings of our stockholders may be called only by Chairman of the Board, a majority of the Board of Directors or our President. Our certificate of incorporation and by-laws also provide that our board of directors will be divided into three classes, with each class serving staggered three-year terms. Except as otherwise set forth in our certificate of incorporation and by-laws, the stockholders may amend or repeal certain provisions of our certificate of incorporation and may amend, alter or repeal our by-laws only with the affirmative vote of the holders of seventy-five percent (75%) of the shares of Pain Therapeutics, Inc. s capital stock issued and outstanding and entitled to vote at a general or special meeting of our stockholders, as applicable. These provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of Pain Therapeutics, Inc.

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Transfer agent

The transfer agent for our common stock is Mellon Investor Services. Its address is 235 Montgomery Street, 23rd Floor, San Francisco, CA 94104, and its telephone number is (415) 743-1422.

Listing

Our common stock is quoted on the Nasdaq National Market under the trading symbol PTIE.

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DESCRIPTION OF PREFERRED STOCK

We are authorized to issue up to 10,000,000 shares of preferred stock, $0.001 par value. Other than the Series A preferred stock associated with Pain Therapeutics, Inc. s rights plan described below under the Stockholders Rights Plan, no shares of preferred stock of Pain Therapeutics, Inc. are outstanding.

The following description of preferred stock and the description of the terms of a particular series of preferred stock that will be set forth in the related prospectus supplement are not complete. These descriptions are qualified in their entirety by reference to the certificate of designation relating to that series. The rights, preferences, privileges and restrictions of the preferred stock of each series will be fixed by the certificate of designation relating to that series. The prospectus supplement also will contain a description of certain United States federal income tax consequences relating to the purchase and ownership of the series of preferred stock that is described in the prospectus supplement.

Undesignated preferred stock

Pursuant to our certificate of incorporation, our board of directors has the authority without further action by our stockholders to issue one or more additional series of preferred stock. Our board of directors has the authority to fix the number of shares of any series of preferred stock and to determine the designation of any such series. The board of directors is also authorized to determine and alter the powers, rights, preferences and privileges and the qualifications, limitations and restrictions granted to or imposed upon any wholly unissued series of preferred stock. In addition, within the limitations or restrictions stated in any resolution or resolutions of the board of directors originally fixing the number of shares constituting any series, the board of directors has the authority to increase or decrease, but not below the number of shares of such series then outstanding, the number of shares of any series subsequent to the issue of shares of that series.

The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of delaying, deferring or preventing a change in control without further action by our stockholders and may adversely affect the market price of, and the voting and other rights of, the holders of our common stock.

The prospectus supplement with respect to any issuance of preferred stock will specify:

- the maximum number of shares;
- the designation of the shares;
- the annual dividend rate, if any, whether the dividend rate is fixed or variable, the date dividends will accrue, the dividend payment dates, and whether dividends will be cumulative;
- the price and the terms and conditions for redemption, if any, including redemption at our option or at the option of the holders, including the time period for redemption, and any accumulated dividends or premiums;

the liquidation preference, if any, and any accumulated dividends upon the liquidation, dissolution or winding up of our affairs;

any sinking fund or similar provision, and, if so, the terms and provisions relating to the purpose and operation of the fund;

the terms and conditions, if any, for conversion or exchange of shares of any other class or classes of our capital stock or any series of any other class or classes, or of any other series of the same class, or any other securities or assets, including the price or the rate of conversion or exchange and the method, if any, of adjustment;

the voting rights; and

any or all other preferences and relative, participating, optional or other special rights, privileges or qualifications, limitations or restrictions.

Preferred stock, if any, will be fully paid and nonassessable upon issuance.

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Stockholder rights plan

In April 2005, pursuant to a Preferred Stock Rights Agreement between us and Mellon Investor Services, acting as rights agent, our board of directors declared a dividend of one right to purchase one one-thousandth of a share of Series A preferred stock for each outstanding share of our common stock. The dividend was paid on May 12, 2005 to stockholders of record as of the close of business on that date. Each right entitles the registered holder to purchase from us one one-thousandth of a share of Series A preferred stock at an exercise price of $40.00, subject to adjustment upon specified events set forth in the rights agreement.

Rights evidenced by common stock certificates. The rights will not be exercisable until the distribution date. Certificates for the rights have not been sent to stockholders and the rights will attach to and trade together with our common stock. Accordingly, common stock certificates outstanding on May 12, 2005 will evidence the related rights, and common stock certificates issued after the record date will contain a notation incorporating the rights agreement by reference. Until the distribution date (or earlier redemption or expiration of the rights), the surrender or transfer of any certificates for common stock outstanding as of the record date, even without notation or a copy of the summary of rights being attached to such certificate, will also constitute the transfer of the rights associated with the common stock represented by such certificate.

Distribution date. The rights will be separated from the our common stock, rights certificates will be issued and the rights will become exercisable upon the earlier of (a) the tenth day (or such later date as may be determined by our board of directors) after a person or group of affiliated or associated persons has acquired, or obtained the right to acquire, beneficial ownership of 15% or more of our common stock then outstanding, (or with respect to Eastbourne Capital Management, LLC, and its affiliates, or any of them, become the beneficial owner of 20% or more of our then outstanding common stock) or (b) the tenth business day (or such later date as may be determined by our board of directors) after a person or group announces a tender or exchange offer, the consummation of which would result in ownership by a person or group of 15% or more of our then outstanding common stock.

Issuance of rights certificates; expiration of rights. As soon as practicable following the distribution date, a rights certificate will be mailed to holders of record of the common stock as of the close of business on the distribution date and such separate rights certificate alone will evidence the rights from and after the distribution date. The rights will expire on the earliest of (i) May 12, 2015, the final expiration date, or (ii) redemption or exchange of the rights as described below.

Initial exercise of the rights. Following the distribution date, and until one of the further events described below, holders of the rights will be entitled to receive, upon exercise and the payment of the purchase price, one one-thousandth share of the Series A preferred stock. In the event that we do not have sufficient Series A preferred stock available for all rights to be exercised, or our board decides that such action is necessary and not contrary to the interests of rights holders, we may instead substitute cash, assets or other securities for the Series A preferred stock for which the rights would have been exercisable under this provision or as described below.

Right to buy our common stock. Unless the rights are earlier redeemed, in the event that an acquiring person or group obtains 15% or more of our then outstanding common stock (or with respect to Eastbourne Capital Management, LLC, and its affiliates, or any of them, become the beneficial owner of 20% or more of our then outstanding common stock), then each holder of a right which has not theretofore been exercised (other than rights beneficially owned by the acquiring person, which will thereafter be void) will thereafter have the right to receive, upon exercise, common stock having a value equal to two times the purchase price. Rights are not exercisable following the occurrence of an event as described above until such time as the rights are no longer redeemable by us as set forth below.

Right to buy acquiring company shares. Similarly, unless the rights are earlier redeemed, in the event that, after an acquiring person or group obtains 15% or more of our then outstanding common stock (or with respect to Eastbourne Capital Management, LLC, and its affiliates, or any of them, become the beneficial owner of 20% or

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more of our then outstanding common stock), (i) we are acquired in a merger or other business combination transaction, or (ii) 50% or more of our consolidated assets or earning power is sold (other than in transactions in the ordinary course of business), proper provision must be made so that each holder of a right which has not theretofore been exercised (other than rights beneficially owned by the acquiring person, which will thereafter be void) will thereafter have the right to receive, upon exercise, shares of common stock of the acquiring company having a value equal to two times the purchase price.

Exchange provision. At any time after an acquiring person or group obtains 15% or more of our then outstanding common stock (or with respect to Eastbourne Capital Management, LLC, and its affiliates, or any of them, become the beneficial owner of 20% or more of our then outstanding common stock) and prior to the acquisition by such acquiring person of 50% or more of our outstanding common stock, our board of directors may exchange the rights (other than rights owned by the acquiring person), in whole or in part, at an exchange ratio of one common stock per right.

Redemption. At any time on or prior to the close of business on the earlier of (i) the fifth day following the attainment of 15% or more of our then outstanding common stock (or with respect to Eastbourne Capital Management, LLC, and its affiliates, or any of them, become the beneficial owner of 20% or more of our then outstanding common stock) by an acquiring person (or such later date as may be determined by action of our board of directors and publicly announced by us), or (ii) May 12, 2015, we may redeem the rights in whole, but not in part, at a price of $0.001 per right.

Adjustments to prevent dilution. The purchase price payable, the number of rights, and the number of Series A preferred stock or common stock or other securities or property issuable upon exercise of the rights are subject to adjustment from time to time in connection with the dilutive issuances by us as set forth in the rights agreement. With certain exceptions, no adjustment in the purchase price will be required until cumulative adjustments require an adjustment of at least 1% in such purchase price.

Cash paid instead of issuing fractional shares. No fractional common stock will be issued upon exercise of a right and, in lieu thereof, an adjustment in cash will be made based on the market price of the common stock on the last trading date prior to the date of exercise.

No stockholders rights prior to exercise. Until a right is exercised, the holder, as such, will have no rights as a stockholder (other than any rights resulting from such holder s ownership of common stock), including, without limitation, the right to vote or to receive dividends.

Amendment of rights agreement. The terms of the rights and the Rights Agreement may be amended in any respect without the consent of the rights holders on or prior to the distribution date. Thereafter, the terms of the rights and the rights agreement may be amended without the consent of the rights holders in order to cure any ambiguities or to make changes which do not adversely affect the interests of rights holders (other than the acquiring person).

Rights and preferences of the Series A preferred stock. Each one one-thousandth of a share of Series A preferred stock has rights and preferences substantially equivalent to those of one share of common stock.

No voting rights. The rights will not have any voting rights.

Certain anti-takeover effects. The rights approved by our board of directors are designed to protect and maximize the value of our outstanding equity interests in the event of an unsolicited attempt by an acquirer to take over our company in a manner or on terms not approved by our board of directors. Takeover attempts frequently include coercive tactics to deprive our board of directors and its stockholders of any real opportunity to determine our destiny. The rights have been declared by our board in order to deter such tactics, including a gradual accumulation of shares in the open market of 15% or greater position (or 20% with respect to Eastbourne

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Capital Management, LLC, and its affiliates, or any of them) to be followed by a merger or a partial or two-tier tender offer that does not treat all stockholders equally. These tactics unfairly pressure stockholders, squeeze them out of their investment without giving them any real choice and deprive them of the full value of their shares.

The rights are not intended to prevent a takeover and will not do so. Subject to the restrictions described above, the rights may be redeemed by us at $0.001 per right at any time prior to the distribution date. Accordingly, the rights should not interfere with any merger or business combination approved by our board of directors.

However, the rights may have the effect of rendering more difficult or discouraging our acquisition if such acquisition is deemed undesirable by our board of directors. The rights may cause substantial dilution to a person or group that attempts to acquire us on terms or in a manner not approved by our board of directors, except pursuant to an offer conditioned upon the negation, purchase or redemption of the rights.

Issuance of the rights does not in any way weaken our financial strength or interfere with our business plans. The issuance of the rights themselves has no dilutive effect, will not affect reported earnings per share, should not be taxable to us or to our stockholders, and will not change the way in which our shares are presently traded.

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DESCRIPTION OF THE DEPOSITARY SHARES

General

At our option, we may elect to offer fractional shares of preferred stock, rather than full shares of preferred stock. If we do elect to offer fractional shares of preferred stock, we will issue to the public receipts for depositary shares and each of these depositary shares will represent a fraction of a share of a particular series of preferred stock, as specified in the applicable prospectus supplement. Each owner of a depositary share will be entitled, in proportion to the applicable fractional interest in shares of preferred stock underlying that depositary share, to all rights and preferences of the preferred stock underlying that depositary share. These rights may include dividend, voting, redemption and liquidation rights.

The shares of preferred stock underlying the depositary shares will be deposited with a bank or trust company selected by us to act as depositary, under a deposit agreement between us, the depositary and the holders of the depositary receipts. The depositary will be the transfer agent, registrar and dividend disbursing agent for the depositary shares.

The depositary shares will be evidenced by depositary receipts issued pursuant to the depositary agreement. Holders of depositary receipts agree to be bound by the deposit agreement, which requires holders to take certain actions such as filing proof of residence and paying certain charges.

The summary of terms of the depositary shares contained in this prospectus is not complete. You should refer to the forms of the deposit agreement, our certificate of incorporation and the certificate of designation for the applicable series of preferred stock that are, or will be, filed with the SEC.

Dividends

The depositary will distribute cash dividends or other cash distributions, if any, received in respect of the series of preferred stock underlying the depositary shares to the record holders of depositary receipts in proportion to the number of depositary shares owned by those holders on the relevant record date. The relevant record date for depositary shares will be the same date as the record date for the preferred stock.

In the event of a distribution other than in cash, the depositary will distribute property received by it to the record holders of depositary receipts that are entitled to receive the distribution, unless the depositary determines that it is not feasible to make the distribution. If this occurs, the depositary, with our approval, may adopt another method for the distribution, including selling the property and distributing the net proceeds to the holders.

Liquidation preference

If a series of preferred stock underlying the depositary shares has a liquidation preference, in the event of our voluntary or involuntary liquidation, dissolution or winding up, holders of depositary shares will be entitled to receive the fraction of the liquidation preference accorded each share of the applicable series of preferred stock, as set forth in the applicable prospectus supplement.

Redemption

If a series of preferred stock underlying the depositary shares is subject to redemption, the depositary shares will be redeemed from the proceeds received by the depositary resulting from the redemption, in whole or in part, of the preferred stock held by the depositary. Whenever we redeem any preferred stock held by the depositary, the depositary will redeem, as of the same redemption date, the number of depositary shares representing the preferred stock so redeemed. The depositary will mail the notice of redemption to the record holders of the depositary receipts promptly upon receiving the notice from us and no fewer than 20 nor more than 60 days, unless otherwise provided in the applicable prospectus supplement, prior to the date fixed for redemption of the preferred stock.

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Voting

Upon receipt of notice of any meeting at which the holders of preferred stock are entitled to vote, the depositary will mail the information contained in the notice of meeting to the record holders of the depositary receipts underlying the preferred stock. Each record holder of those depositary receipts on the record date will be entitled to instruct the depositary as to the exercise of the voting rights pertaining to the amount of preferred stock underlying that holder s depositary shares. The record date for the depositary will be the same date as the record date for the preferred stock. The depositary will try, as far as practicable, to vote the preferred stock underlying the depositary shares in accordance with these instructions. We will agree to take all action that may be deemed necessary by the depositary in order to enable the depositary to vote the preferred stock in accordance with these instructions. The depositary will not vote the preferred stock to the extent that it does not receive specific instructions from the holders of depositary receipts.

Withdrawal of Preferred Stock

Owners of depositary shares will be entitled to receive upon surrender of depositary receipts at the principal office of the depositary and payment of any unpaid amount due to the depositary, the number of whole shares of preferred stock underlying their depositary shares.

Partial shares of preferred stock will not be issued. Holders of preferred stock will not be entitled to deposit the shares under the deposit agreement or to receive depositary receipts evidencing depositary shares for the preferred stock.

Amendment and termination of the deposit agreement

The form of depositary receipt evidencing the depositary shares and any provision of the deposit agreement may be amended by agreement between the depositary and us. However, any amendment which materially and adversely alters the rights of the holders of depositary shares, other than fee changes, will not be effective unless the amendment has been approved by at least a majority of the outstanding depositary shares. The deposit agreement may be terminated by the depositary or us only if:

- all outstanding depositary shares have been redeemed; or
- there has been a final distribution of the preferred stock in connection with our dissolution and such distribution has been made to all the holders of depositary shares.

Charges of depositary

We will pay all transfer and other taxes and governmental charges arising solely from the existence of the depositary arrangement. We will also pay charges of the depositary in connection with:

the initial deposit of the preferred stock;

the initial issuance of the depositary shares;

any redemption of the preferred stock; and

all withdrawals of preferred stock by owners of depositary shares.

Holders of depositary receipts will pay transfer, income and other taxes and governmental charges and other specified charges as provided in the deposit agreement for their accounts. If these charges have not been paid, the depositary may:

refuse to transfer depositary shares;

withhold dividends and distributions; and

sell the depositary shares evidenced by the depositary receipt.

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Miscellaneous

The depositary will forward to the holders of depositary receipts all reports and communications we deliver to the depositary that we are required to furnish to the holders of the preferred stock. In addition, the depositary will make available for inspection by holders of depositary receipts at the principal office of the depositary, and at such other places as it may from time to time deem advisable, any reports and communications we deliver to the depositary as the holder of preferred stock.

Neither the depositary nor we will be liable if either the depositary or we are prevented or delayed by law or any circumstance beyond the control of either the depositary or us in performing our respective obligations under the deposit agreement. Our obligations and the depositary s obligations will be limited to the performance in good faith of our or the depositary s respective duties under the deposit agreement. Neither the depositary nor we will be obligated to prosecute or defend any legal proceeding in respect of any depositary shares or preferred stock unless satisfactory indemnity is furnished. The depositary and we may rely on:

written advice of counsel or accountants;

information provided by holders of depositary receipts or other persons believed in good faith to be competent to give such information; and

documents believed to be genuine and to have been signed or presented by the proper party or parties.

Resignation and removal of depositary

The depositary may resign at any time by delivering a notice to us. We may remove the depositary at any time. Any such resignation or removal will take effect upon the appointment of a successor depositary and its acceptance of such appointment. The successor depositary must be appointed within 60 days after delivery of the notice for resignation or removal. The successor depositary must be a bank and trust company having its principal office in the United States of America and having a combined capital and surplus of at least $50,000,000.

Federal income tax consequences

Owners of the depositary shares will be treated for U.S. federal income tax purposes as if they were owners of the preferred stock underlying the depositary shares. As a result, owners will be entitled to take into account for U.S. federal income tax purposes any deductions to which they would be entitled if they were holders of such preferred stock. No gain or loss will be recognized for U.S. federal income tax purposes upon the withdrawal of preferred stock in exchange for depositary shares. The tax basis of each share of preferred stock to an exchanging owner of depositary shares will, upon such exchange, be the same as the aggregate tax basis of the depositary shares exchanged. The holding period for preferred stock in the hands of an exchanging owner of depositary shares will include the period during which such person owned such depositary shares.

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DESCRIPTION OF THE WARRANTS

General

We may issue warrants for the purchase of our common stock, preferred stock or debt securities or any combination thereof. Warrants may be issued independently or together with our common stock, preferred stock or debt securities and may be attached to or separate from any offered securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and a bank or trust company, as warrant agent. The warrant agent will act solely as our agent in connection with the warrants. The warrant agent will not have any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants. This summary of certain provisions of the warrants is not complete. For the terms of a particular series of warrants, you should refer to the prospectus supplement for that series of warrants and the warrant agreement for that particular series.

Stock warrants

The prospectus supplement relating to a particular series of warrants to purchase our common stock or preferred stock will describe the terms of the warrants, including the following:

- the title of the warrants;
- the offering price for the warrants, if any;
- the aggregate number of the warrants;
- the designation and terms of the common stock or preferred stock that may be purchased upon exercise of the warrants;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each security;
- if applicable, the date from and after which the warrants and any securities issued with the warrants will be separately transferable;
- the number of shares of common stock or preferred stock that may be purchased upon exercise of a warrant and the exercise price for the warrants;
- the dates on which the right to exercise the warrants shall commence and expire;
- if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;

the currency or currency units in which the offering price, if any, and the exercise price are payable;

if applicable, a discussion of material U.S. federal income tax considerations;

the antidilution provisions of the warrants, if any;

the redemption or call provisions, if any, applicable to the warrants;

any provisions with respect to holder s right to require us to repurchase the warrants upon a change in control; and

any additional terms of the warrants, including terms, procedures, and limitations relating to the exchange, exercise and settlement of the warrants.

Holders of equity warrants will not be entitled:

to vote, consent or receive dividends;

receive notice as stockholders with respect to any meeting of stockholders for the election of our directors or any other matter; or

exercise any rights as stockholders of Pain Therapeutics, Inc..

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Debt warrants

The prospectus supplement relating to a particular issue of warrants to purchase debt securities will describe the terms of the debt warrants, including the following:

- the title of the debt warrants;
- the offering price for the debt warrants, if any;
- the aggregate number of the debt warrants;
- the designation and terms of the debt securities, including any conversion rights, purchasable upon exercise of the debt warrants;
- if applicable, the date from and after which the debt warrants and any debt securities issued with them will be separately transferable;
- the principal amount of debt securities that may be purchased upon exercise of a debt warrant and the exercise price for the warrants, which may be payable in cash, securities or other property;
- the dates on which the right to exercise the debt warrants will commence and expire;
- if applicable, the minimum or maximum amount of the debt warrants that may be exercised at any one time;
- whether the debt warrants represented by the debt warrant certificates or debt securities that may be issued upon exercise of the debt warrants will be issued in registered or bearer form;
- information with respect to book-entry procedures, if any; the currency or currency units in which the offering price, if any, and the exercise price are payable;
- if applicable, a discussion of material U.S. federal income tax considerations;
- the antidilution provisions of the debt warrants, if any;
- the redemption or call provisions, if any, applicable to the debt warrants;
- any provisions with respect to the holder s right to require us to repurchase the warrants upon a change in control; and

any additional terms of the debt warrants, including terms, procedures, and limitations relating to the exchange, exercise and settlement of the debt warrants.

Debt warrant certificates will be exchangeable for new debt warrant certificates of different denominations. Debt warrants may be exercised at the corporate trust office of the warrant agent or any other office indicated in the prospectus supplement. Prior to the exercise of their debt warrants, holders of debt warrants will not have any of the rights of holders of the debt securities purchasable upon exercise and will not be entitled to payment of principal or any premium, if any, or interest on the debt securities purchasable upon exercise.

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DESCRIPTION OF THE DEBT SECURITIES

The debt securities may be either secured or unsecured and will either be our senior debt securities or our subordinated debt securities. The debt securities will be issued under one or more separate indentures between us and a trustee to be specified in an accompanying prospectus supplement. Senior debt securities will be issued under a senior indenture and subordinated debt securities will be issued under a subordinated indenture. Together, the senior indenture and the subordinated indenture are called indentures. This prospectus, together with the applicable prospectus supplement, will describe the terms of a particular series of debt securities.

The following is a summary of selected provisions and definitions of the indentures and debt securities to which any prospectus supplement may relate. The summary of selected provisions of the indentures and the debt securities appearing below is not complete and is subject to, and qualified entirely by reference to, all of the provisions of the applicable indenture and certificates evidencing the applicable debt securities. For additional information, you should look at the applicable indenture and the certificate evidencing the applicable debt security that is filed as an exhibit to the registration statement that includes the prospectus. In this description of the debt securities, the words Pain Therapeutics, Inc., we, us or our refer only to Pain Therapeutics, Inc., unless we otherwise expressly state or the context otherwise requires.

The following description sets forth selected general terms and provisions of the applicable indenture and debt securities to which any prospectus supplement may relate. Other specific terms of the applicable indenture and debt securities will be described in the applicable prospectus supplement. If any particular terms of the indenture or debt securities described in a prospectus supplement differ from any of the terms described below, then the terms described below will be deemed to have been superseded by that prospectus supplement.

General

Debt securities may be issued in separate series without limitation as to aggregate principal amount. We may specify a maximum aggregate principal amount for the debt securities of any series.

We are not limited as to the amount of debt securities we may issue under the indentures. Unless otherwise provided in a prospectus supplement, a series of debt securities may be reopened to issue additional debt securities of such series.

The prospectus supplement relating to a particular series of debt securities will set forth:

- whether the debt securities are senior or subordinated;
- the offering price;
- the title;

any limit on the aggregate principal amount;

the person who shall be entitled to receive interest, if other than the record holder on the record date;

the date or dates the principal will be payable;

the interest rate or rates, which may be fixed or variable, if any, the date from which interest will accrue, the interest payment dates and the regular record dates, or the method for calculating the dates and rates;

the place where payments may be made;

any mandatory or optional redemption provisions or sinking fund provisions and any applicable redemption or purchase prices associated with these provisions;

if issued other than in denominations of U.S. $1,000 or any multiple of U.S. $1,000, the denominations in which the debt securities shall be issuable;

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if applicable, the method for determining how the principal, premium, if any, or interest will be calculated by reference to an index or formula;

if other than U.S. currency, the currency or currency units in which principal, premium, if any, or interest will be payable and whether we or a holder may elect payment to be made in a different currency;

the portion of the principal amount that will be payable upon acceleration of maturity, if other than the entire principal amount;

if the principal amount payable at stated maturity will not be determinable as of any date prior to stated maturity, the amount or method for determining the amount which will be deemed to be the principal amount;

if applicable, whether the debt securities shall be subject to the defeasance provisions described below under Satisfaction and discharge; defeasance or such other defeasance provisions specified in the applicable prospectus supplement for the debt securities;

any conversion or exchange provisions;

whether the debt securities will be issuable in the form of a global security;

any subordination provisions applicable to the subordinated debt securities if different from those described below under Subordinated debt securities ;

any paying agents, authenticating agents, security registrars or other agents for the debt securities, if other than the trustee;

any provisions relating to any security provided for the debt securities, including any provisions regarding the circumstances under which collateral may be released or substituted;

any deletions of, or changes or additions to, the events of default, acceleration provisions or covenants;

any provisions relating to guaranties for the securities and any circumstances under which there may be additional obligors; and

any other specific terms of such debt securities.

Unless otherwise specified in the prospectus supplement, the debt securities will be registered debt securities. Debt securities may be sold at a substantial discount below their stated principal amount, bearing no interest or interest at a rate which at time of issuance is below market rates. The U.S. federal income tax considerations applicable to debt securities sold at a discount will be described in the applicable prospectus supplement.

Exchange and transfer

Debt securities may be transferred or exchanged at the office of the security registrar or at the office of any transfer agent designated by us.

We will not impose a service charge for any transfer or exchange, but we may require holders to pay any tax or other governmental charges associated with any transfer or exchange.

In the event of any partial redemption of debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange, any debt security of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption and ending at the close of business on the day of the mailing; or

- register the transfer of or exchange any debt security of that series selected for redemption, in whole or in part, except the unredeemed portion being redeemed in part.

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Initially, we will appoint the trustee as the security registrar. Any transfer agent, in addition to the security registrar initially designated by us, will be named in the prospectus supplement. We may designate additional transfer agents or change transfer agents or change the office of the transfer agent. However, we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

Global securities

The debt securities of any series may be represented, in whole or in part, by one or more global securities. Each global security will:

- be registered in the name of a depositary, or its nominee, that we will identify in a prospectus supplement;
- be deposited with the depositary or nominee or custodian; and
- bear any required legends.

No global security may be exchanged in whole or in part for debt securities registered in the name of any person other than the depositary or any nominee unless:

- the depositary has notified us that it is unwilling or unable to continue as depositary or has ceased to be qualified to act as depositary;
- an event of default is continuing with respect to the debt securities of the applicable series; or
- any other circumstance described in a prospectus supplement has occurred permitting or requiring the issuance of any such security.

As long as the depositary, or its nominee, is the registered owner of a global security, the depositary or nominee will be considered the sole owner and holder of the debt securities represented by the global security for all purposes under the indentures. Except in the above limited circumstances, owners of beneficial interests in a global security will not be:

- entitled to have the debt securities registered in their names;
- entitled to physical delivery of certificated debt securities; or
- considered to be holders of those debt securities under the indenture.

Payments on a global security will be made to the depositary or its nominee as the holder of the global security. Some jurisdictions have laws that require that certain purchasers of securities take physical delivery of such securities in definitive form. These laws may impair the ability to

transfer beneficial interests in a global security.

Institutions that have accounts with the depositary or its nominee are referred to as participants. Ownership of beneficial interests in a global security will be limited to participants and to persons that may hold beneficial interests through participants. The depositary will credit, on its book-entry registration and transfer system, the respective principal amounts of debt securities represented by the global security to the accounts of its participants.

Ownership of beneficial interests in a global security will be shown on and effected through records maintained by the depositary, with respect to participants interests, or any participant, with respect to interests of persons held by participants on their behalf.

Payments, transfers and exchanges relating to beneficial interests in a global security will be subject to policies and procedures of the depositary. The depositary policies and procedures may change from time to time. Neither any trustee nor we will have any responsibility or liability for the depositary s or any participant s records with respect to beneficial interests in a global security.

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Payment and paying agents

Unless otherwise indicated in a prospectus supplement, the provisions described in this paragraph will apply to the debt securities. Payment of interest on a debt security on any interest payment date will be made to the person in whose name the debt security is registered at the close of business on the regular record date. Payment on debt securities of a particular series will be payable at the office of a paying agent or paying agents designated by us. However, at our option, we may pay interest by mailing a check to the record holder. The trustee will be designated as our initial paying agent.

We may also name any other paying agents in a prospectus supplement. We may designate additional paying agents, change paying agents or change the office of any paying agent. However, we will be required to maintain a paying agent in each place of payment for the debt securities of a particular series.

All moneys paid by us to a paying agent for payment on any debt security that remain unclaimed for a period ending the earlier of:

10 business days prior to the date the money would be turned over to the applicable state; or

at the end of two years after such payment was due, will be repaid to us. Thereafter, the holder may look only to us for such payment.

No protection in the event of a change of control

Unless otherwise indicated in a prospectus supplement with respect to a particular series of debt securities, the debt securities will not contain any provisions that may afford holders of the debt securities protection in the event we have a change in control or in the event of a highly leveraged transaction, whether or not such transaction results in a change in control.

Covenants

Unless otherwise indicated in a prospectus supplement, the debt securities will not contain any financial or restrictive covenants.

Consolidation, merger and sale of assets

Unless we indicate otherwise in a prospectus supplement, we may not consolidate with or merge into any other person, in a transaction in which we are not the surviving corporation, or convey, transfer or lease our properties and assets substantially as an entirety to, any entity, unless:

the successor entity, if any, is a limited liability company, partnership, trust or other business entity existing under the laws of the United States, any state within the United States or the District of Columbia;

the successor entity assumes our obligations on the debt securities and under the indentures;

immediately after giving effect to the transaction, no default or event of default shall have occurred and be continuing; and

certain other conditions are met.

Events of default

Unless we indicate otherwise in a prospectus supplement, the following will be events of default for any series of debt securities under the indentures:

(1) we fail to pay principal of or any premium on any debt security of that series when due;

(2) we fail to pay any interest on any debt security of that series for 30 days after it becomes due;

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(3) we fail to deposit any sinking fund payment when due;

(4) we fail to perform any other covenant in the indenture and such failure continues for 60 days after we are given the notice required in the indentures; and

(5) certain events including our bankruptcy, insolvency or reorganization.

Additional or different events of default applicable to a series of debt securities may be described in a prospectus supplement. An event of default of one series of debt securities is not necessarily an event of default for any other series of debt securities.

The trustee may withhold notice to the holders of any default, except defaults in the payment of principal, premium, if any, interest, any sinking fund installment on, or with respect to any conversion right of, the debt securities of such series. However, the trustee must consider it to be in the interest of the holders of the debt securities of such series to withhold this notice.

Unless we indicate otherwise in a prospectus supplement, if an event of default, other than an event of default described in clause (5) above, shall occur and be continuing with respect to any series of debt securities, either the trustee or the holders of at least a 25 percent in aggregate principal amount of the outstanding securities of that series may declare the principal amount and premium, if any, of the debt securities of that series, or if any debt securities of that series are original issue discount securities, such other amount as may be specified in the applicable prospectus supplement, in each case together with accrued and unpaid interest, if any, thereon, to be due and payable immediately.

If an event of default described in clause (5) above shall occur, the principal amount and premium, if any, of all the debt securities of that series, or if any debt securities of that series are original issue discount securities, such other amount as may be specified in the applicable prospectus supplement, in each case together with accrued and unpaid interest, if any, thereon, will automatically become immediately due and payable. Any payment by us on the subordinated debt securities following any such acceleration will be subject to the subordination provisions described below under Subordinated debt securities.

After acceleration the holders of a majority in aggregate principal amount of the outstanding securities of that series may, under certain circumstances, rescind and annul such acceleration if all events of default, other than the non-payment of accelerated principal, or other specified amounts or interest, have been cured or waived.

Other than the duty to act with the required care during an event of default, the trustee will not be obligated to exercise any of its rights or powers at the request of the holders unless the holders shall have offered to the trustee reasonable indemnity. Generally, the holders of a majority in aggregate principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee or exercising any trust or power conferred on the trustee.

A holder of debt securities of any series will not have any right to institute any proceeding under the indentures, or for the appointment of a receiver or a trustee, or for any other remedy under the indentures, unless:

(1) the holder has previously given to the trustee written notice of a continuing event of default with respect to the debt securities of that series;

(2) the holders of at least a majority in aggregate principal amount of the outstanding debt securities of that series have made a written request and have offered reasonable indemnity to the trustee to institute the proceeding; and

(3) the trustee has failed to institute the proceeding and has not received direction inconsistent with the original request from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series within 60 days after the original request.

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Holders may, however, sue to enforce the payment of principal, premium or interest on any debt security on or after the due date or to enforce the right, if any, to convert any debt security (if the debt security is convertible) without following the procedures listed in (1) through (3) above.

We will furnish the trustee an annual statement by our officers as to whether or not we are in default in the performance of the conditions and covenants under the indenture and, if so, specifying all known defaults.

Modification and waiver

Unless we indicate otherwise in a prospectus supplement, the applicable trustee and we may make modifications and amendments to an indenture with the consent of the holders of a majority in aggregate principal amount of the outstanding securities of each series affected by the modification or amendment.

We may also make modifications and amendments to the indentures for the benefit of holders without their consent, for certain purposes including, but not limited to:

providing for our successor to assume the covenants under the indenture;

adding covenants or events of default;

making certain changes to facilitate the issuance of the securities;

securing the securities;

providing for a successor trustee or additional trustees;

curing any ambiguities or inconsistencies;

providing for guaranties of, or additional obligors on, the securities;

permitting or facilitating the defeasance and discharge of the securities; and

other changes specified in the indenture.

However, neither the trustee nor we may make any modification or amendment without the consent of the holder of each outstanding security of that series affected by the modification or amendment if such modification or amendment would:

change the stated maturity of any debt security;

reduce the principal, premium, if any, or interest on any debt security or any amount payable upon redemption or repurchase, whether at our option or the option of any holder, or reduce the amount of any sinking fund payments;

reduce the principal of an original issue discount security or any other debt security payable on acceleration of maturity;

change the place of payment or the currency in which any debt security is payable;

impair the right to enforce any payment after the stated maturity or redemption date;

if subordinated debt securities, modify the subordination provisions in a materially adverse manner to the holders;

adversely affect the right to convert any debt security if the debt security is a convertible debt security; or

change the provisions in the indenture that relate to modifying or amending the indenture.

Satisfaction and discharge; defeasance

We may be discharged from our obligations on the debt securities, subject to limited exceptions, of any series that have matured or will mature or be redeemed within one year if we deposit enough money with the trustee to pay all the principal, interest and any premium due to the stated maturity date or redemption date of the debt securities.

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Each indenture contains a provision that permits us to elect either or both of the following:

- We may elect to be discharged from all of our obligations, subject to limited exceptions, with respect to any series of debt securities then outstanding. If we make this election, the holders of the debt securities of the series will not be entitled to the benefits of the indenture, except for the rights of holders to receive payments on debt securities or the registration of transfer and exchange of debt securities and replacement of lost, stolen or mutilated debt securities.

- We may elect to be released from our obligations under some or all of any financial or restrictive covenants applicable to the series of debt securities to which the election relates and from the consequences of an event of default resulting from a breach of those covenants.

To make either of the above elections, we must irrevocably deposit in trust with the trustee enough money to pay in full the principal, interest and premium on the debt securities. This amount may be made in cash and/or U.S. government obligations or, in the case of debt securities denominated in a currency other than U.S. dollars, cash in the currency in which such series of securities is denominated and/or foreign government obligations. As a condition to either of the above elections, for debt securities denominated in U.S. dollars we must deliver to the trustee an opinion of counsel that the holders of the debt securities will not recognize income, gain or loss for U.S. federal income tax purposes as a result of the action.

The term foreign government obligations means, with respect to debt securities of any series that are denominated in a currency other than United States dollars:

- direct obligations of the government that issued or caused to be issued the currency in which such securities are denominated and for the payment of which obligations its full faith and credit is pledged, or, with respect to debt securities of any series which are denominated in euros, direct obligations of certain members of the European Union for the payment of which obligations the full faith and credit of such members is pledged, which in each case are not callable or redeemable at the option of the issuer thereof; or

- obligations of a person controlled or supervised by or acting as an agency or instrumentality of a government described in the bullet above the timely payment of which is unconditionally guaranteed as a full faith and credit obligation by such government, which are not callable or redeemable at the option of the issuer thereof.

Notices

Notices to holders will be given by mail to the addresses of the holders in the security register.

Governing law

The indentures and the debt securities will be governed by, and construed under, the laws of the State of New York.

No personal liability of directors, officers, employees and stockholders

No incorporator, stockholder, employee, agent, officer, director or subsidiary of ours will have any liability for any obligations of ours, or because of the creation of any indebtedness under the debt securities, the indentures or supplemental indentures. The indentures provide that all such liability is expressly waived and released as a condition of, and as a consideration for, the execution of such indentures and the issuance of the debt securities.

Regarding the trustee

The indentures limit the right of the trustee, should it become our creditor, to obtain payment of claims or secure its claims.

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The trustee is permitted to engage in certain other transactions with us. However, if the trustee acquires any conflicting interest, and there is a default under the debt securities of any series for which it is trustee, the trustee must eliminate the conflict or resign.

The accompanying prospectus supplement will specify the trustee for the particular series of debt securities to be issued under the indentures.

Subordinated debt securities

The following provisions will be applicable with respect to each series of subordinated debt securities, unless otherwise stated in the prospectus supplement relating to that series of subordinated debt securities.

The indebtedness evidenced by the subordinated debt securities of any series is subordinated, to the extent provided in the subordinated indenture and the applicable prospectus supplement, to the prior payment in full, in cash or other payment satisfactory to the holders of senior debt, of all senior debt, including any senior debt securities.

Upon any distribution of our assets upon any dissolution, winding up, liquidation or reorganization, whether voluntary or involuntary, marshalling of assets, assignment for the benefit of creditors, or in bankruptcy, insolvency, receivership or other similar proceedings, payments on the subordinated debt securities will be subordinated in right of payment to the prior payment in full in cash or other payment satisfactory to holders of senior debt of all senior debt.

In the event of any acceleration of the subordinated debt securities of any series because of an event of default with respect to the subordinated debt securities of that series, holders of any senior debt would be entitled to payment in full in cash or other payment satisfactory to holders of senior debt of all senior debt before the holders of subordinated debt securities are entitled to receive any payment or distribution.

In addition, the subordinated debt securities will be structurally subordinated to all indebtedness and other liabilities of our subsidiaries, including trade payables and lease obligations. This occurs because our right to receive any assets of our subsidiaries upon their liquidation or reorganization, and your right to participate in those assets, will be effectively subordinated to the claims of that subsidiary s creditors, including trade creditors, except to the extent that we are recognized as a creditor of such subsidiary. If we are recognized as a creditor of that subsidiary, our claims would still be subordinate to any security interest in the assets of the subsidiary and any indebtedness of the subsidiary senior to us.

We are required to promptly notify holders of senior debt or their representatives under the subordinated indenture if payment of the subordinated debt securities is accelerated because of an event of default.

Under the subordinated indenture, we may also not make payment on the subordinated debt securities if:

a default in our obligations to pay principal, premium, interest or other amounts on our senior debt occurs and the default continues beyond any applicable grace period, which we refer to as a payment default; or

any other default occurs and is continuing with respect to designated senior debt that permits holders of designated senior debt to accelerate its maturity, and the trustee receives a payment blockage notice from us or some other person permitted to give the notice under the subordinated indenture, which we refer to as a non-payment default.

We may and shall resume payments on the subordinated debt securities:

in case of a payment default, when the default is cured or waived or ceases to exist, and

in case of a nonpayment default, the earlier of when the default is cured or waived or ceases to exist or 179 days after the receipt of the payment blockage notice.

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No new payment blockage period may start on the basis of a nonpayment default unless 365 days have elapsed from the effectiveness of the immediately prior payment blockage notice. No nonpayment default that existed or was continuing on the date of delivery of any payment blockage notice to the trustee shall be the basis for a subsequent payment blockage notice.

As a result of these subordination provisions, in the event of our bankruptcy, dissolution or reorganization, holders of senior debt may receive more, ratably, and holders of the subordinated debt securities may receive less, ratably, than our other creditors. The subordination provisions will not prevent the occurrence of any event of default under the subordinated indenture.

The subordination provisions will not apply to payments from money or government obligations held in trust by the trustee for the payment of principal, interest and premium, if any, on subordinated debt securities pursuant to the provisions described under Satisfaction and discharge; defeasance, if the subordination provisions were not violated at the time the money or government obligations were deposited into trust.

If the trustee or any holder receives any payment that should not have been made to them in contravention of subordination provisions before all senior debt is paid in full in cash or other payment satisfactory to holders of senior debt, then such payment will be held in trust for the holders of senior debt.

Senior debt securities will constitute senior debt under the subordinated indenture.

Additional or different subordination provisions may be described in a prospectus supplement relating to a particular series of debt securities.

Definitions

The term designated senior debt means our obligations under any particular senior debt in which the instrument creating or evidencing the same or the assumption or guarantee thereof, or related agreements or documents to which we are a party, expressly provides that such indebtedness shall be designated senior debt for purposes of the subordinated indenture. The instrument, agreement or other document evidencing any designated senior debt may place limitations and conditions on the right of such senior debt to exercise the rights of designated senior debt.

The term indebtedness means the following, whether absolute or contingent, secured or unsecured, due or to become due, outstanding on the date of the indenture for such series of securities or thereafter created, incurred or assumed:

- our indebtedness evidenced by a credit or loan agreement, note, bond, debenture or other written obligation;
- all of our obligations for money borrowed;

all of our obligations evidenced by a note or similar instrument given in connection with the acquisition of any businesses, properties or assets of any kind,

our obligations:

- as lessee under leases required to be capitalized on the balance sheet of the lessee under generally accepted accounting principles, or

- as lessee under other leases for facilities, capital equipment or related assets, whether or not capitalized, entered into or leased for financing purposes;

all of our obligations under interest rate and currency swaps, caps, floors, collars, hedge agreements, forward contracts or similar agreements or arrangements;

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all of our obligations with respect to letters of credit, bankers acceptances and similar facilities, including reimbursement obligations with respect to the foregoing;

all of our obligations issued or assumed as the deferred purchase price of property or services, but excluding trade accounts payable and accrued liabilities arising in the ordinary course of business;

all obligations of the type referred to in the above clauses of another person and all dividends of another person, the payment of which, in either case, we have assumed or guaranteed, of for which we are responsible or liable, directly or indirectly, jointly or severally, as obligor, guarantor or otherwise, or which are secured by a lien on our property; and

renewals, extensions, modifications, replacements, restatements and refundings of, or any indebtedness or obligation issued in exchange for, any such indebtedness or obligation described in the above clauses of this definition.

The term senior debt means the principal of, premium, if any, and interest, including all interest accruing subsequent to the commencement of any bankruptcy or similar proceeding, whether or not a claim for post-petition interest is allowable as a claim in any such proceeding, on, and all fees and other amounts payable in connection with, our indebtedness. Senior debt shall not include:

any debt or obligation if its terms or the terms of the instrument under which or pursuant to which it is issued expressly provide it shall not be senior in right of payment to the subordinated debt securities or expressly provide that such indebtedness is on the same basis or junior to the subordinated debt securities; or

debt to any of our subsidiaries, a majority of the voting stock of which is owned, directly or indirectly, by us.

The term subsidiary means an entity more than 50% of the outstanding voting stock of which is owned, directly or indirectly, by us or by one or more or our other subsidiaries or by a combination of us and our other subsidiaries. For purposes of this definition, voting stock means stock or other similar interests to us which ordinarily has or have voting power for the election of directors, or persons performing similar functions, whether at all times or only so long as no senior class of stock or other interests has or have such voting power by reason of any contingency.

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PLAN OF DISTRIBUTION

We may sell the securities offered through this prospectus (i) to or through underwriters or dealers, (ii) directly to purchasers, including our affiliates, (iii) through agents, or (iv) through a combination of any these methods. The securities may be distributed at a fixed price or prices, which may be changed, market prices prevailing at the time of sale, prices related to the prevailing market prices, or negotiated prices. The prospectus supplement will include the following information:

- the terms of the offering;
- the names of any underwriters or agents;
- the name or names of any managing underwriter or underwriters;
- the purchase price of the securities;
- the net proceeds from the sale of the securities;
- any delayed delivery arrangements;
- any underwriting discounts, commissions and other items constituting underwriters compensation;
- any initial public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any commissions paid to agents.

Sale Through Underwriters or Dealers

If underwriters are used in the sale, the underwriters will acquire the securities for their own account, including through underwriting, purchase, security lending or repurchase agreements with us. The underwriters may resell the securities from time to time in one or more transactions, including negotiated transactions. Underwriters may sell the securities in order to facilitate transactions in any of our other securities (described in this prospectus or otherwise), including other public or private transactions and short sales. Underwriters may offer securities to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. Unless otherwise indicated in the prospectus supplement, the obligations of the underwriters to purchase the securities will be subject to certain conditions, and the underwriters will be obligated to purchase all the offered securities if they purchase any of them. The underwriters may change from time to time any initial public offering price and any discounts or concessions allowed or reallowed or paid to dealers.

If dealers are used in the sale of securities offered through this prospectus, we will sell the securities to them as principals. They may then resell those securities to the public at varying prices determined by the dealers at the time of resale. The prospectus supplement will include the names of the dealers and the terms of the transaction.

Direct Sales and Sales Through Agents

We may sell the securities offered through this prospectus directly. In this case, no underwriters or agents would be involved. Such securities may also be sold through agents designated from time to time. The prospectus supplement will name any agent involved in the offer or sale of the offered securities and will describe any commissions payable to the agent. Unless otherwise indicated in the prospectus supplement, any agent will agree to use its reasonable best efforts to solicit purchases for the period of its appointment.

We may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act with respect to any sale of those securities. The terms of any such sales will be described in the prospectus supplement.

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Delayed Delivery Contracts

If the prospectus supplement indicates, we may authorize agents, underwriters or dealers to solicit offers from certain types of institutions to purchase securities at the public offering price under delayed delivery contracts. These contracts would provide for payment and delivery on a specified date in the future. The contracts would be subject only to those conditions described in the prospectus supplement. The applicable prospectus supplement will describe the commission payable for solicitation of those contracts.

Market Making, Stabilization and Other Transactions

Unless the applicable prospectus supplement states otherwise, each series of offered securities will be a new issue and will have no established trading market. We may elect to list any series of offered securities on an exchange. Any underwriters that we use in the sale of offered securities may make a market in such securities, but may discontinue such market making at any time without notice. Therefore, we cannot assure you that the securities will have a liquid trading market.

Any underwriter may also engage in stabilizing transactions, syndicate covering transactions and penalty bids in accordance with Rule 104 under the Securities Exchange Act. Stabilizing transactions involve bids to purchase the underlying security in the open market for the purpose of pegging, fixing or maintaining the price of the securities. Syndicate covering transactions involve purchases of the securities in the open market after the distribution has been completed in order to cover syndicate short positions.

Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the securities to be higher than it would be in the absence of the transactions. The underwriters may, if they commence these transactions, discontinue them at any time.

Derivative Transactions and Hedging

We, the underwriters or other agents may engage in derivative transactions involving the securities. These derivatives may consist of short sale transactions and other hedging activities. The underwriters or agents may acquire a long or short position in the securities, hold or resell securities acquired and purchase options or futures on the securities and other derivative instruments with returns linked to or related to changes in the price of the securities. In order to facilitate these derivative transactions, we may enter into security lending or repurchase agreements with the underwriters or agents. The underwriters or agents may effect the derivative transactions through sales of the securities to the public, including short sales, or by lending the securities in order to facilitate short sale transactions by others. The underwriters or agents may also use the securities purchased or borrowed from us or others (or, in the case of derivatives, securities received from us in settlement of those derivatives) to directly or indirectly settle sales of the securities or close out any related open borrowings of the securities.

Electronic Auctions

We may also make sales through the Internet or through other electronic means. Since we may from time to time elect to offer securities directly to the public, with or without the involvement of agents, underwriters or dealers, utilizing the Internet (sometimes referred to as the world wide web) or other forms of electronic bidding or ordering systems for the pricing and allocation of such securities, you will want to pay particular attention to the description of that system we will provide in a prospectus supplement.

Such electronic system may allow bidders to directly participate, through electronic access to an auction site, by submitting conditional offers to buy that are subject to acceptance by us, and which may directly affect the price or other terms and conditions at which such securities are sold. These bidding or ordering systems may

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present to each bidder, on a so-called real-time basis, relevant information to assist in making a bid, such as the clearing spread at which the offering would be sold, based on the bids submitted, and whether a bidder s individual bids would be accepted, prorated or rejected. For example, in the case of debt security, the clearing spread could be indicated as a number of basis points above an index treasury note. Of course, many pricing methods can and may also be used.

Upon completion of such an electronic auction process, securities will be allocated based on prices bid, terms of bid or other factors. The final offering price at which securities would be sold and the allocation of securities among bidders would be based in whole or in part on the results of the Internet or other electronic bidding process or auction.

General Information

Agents, underwriters, and dealers may be entitled, under agreements entered into with us, to indemnification by us against certain liabilities, including liabilities under the Securities Act. Our agents, underwriters, and dealers, or their affiliates, may be customers of, engage in transactions with or perform services for us, in the ordinary course of business.

LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon by Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2004, and management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and management s assessment are incorporated by reference in reliance on Ernst & Young LLP s reports, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file reports, proxy statements and other information with the Securities and Exchange Commission, or the Commission, in accordance with the Securities Exchange Act of 1934, or the Exchange Act. You may read and copy our reports, proxy statements and other information filed by us at the public reference room of the Commission located at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information about the public reference rooms. Our reports, proxy statements and other information filed with the Commission are available free of charge to the public over the Internet at the Commission s website at http://www.sec.gov.

The Commission allows us to incorporate by reference certain information we file with them, which means that we can disclose important information by referring you to those documents. The information incorporated by reference is considered to be a part of this prospectus, and information that we file later with the Commission will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made by us with the Commission under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until our offering is complete:

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2004 filed on February 16, 2005.

Our Definitive Proxy Statement on Schedule 14A, filed on April 6, 2005.

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Our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2005 filed on May 2, 2005.

Our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2005 filed on July 29, 2005.

Our Current Report on Form 8-K filed on May 3, 2005.

The description of our common stock contained in our Registration Statement of Form 8-A, filed with the Commission on March 15, 2000, and any further amendment or report filed hereafter for the purpose of updating any such description.

The description of our Series A preferred stock contained in our Registration Statement of Form 8-A, filed with the Commission on May 3, 2005, and any further amendment or report filed hereafter for the purpose of updating any such description.

You may request a copy of these filings, at no cost, by telephoning us at (650) 624-8200 or by writing us at the following address:

Pain Therapeutics, Inc.

416 Browning Way

South San Francisco, California 94080

United States of America

Attn: Investor Relations

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Part II

Information Not Required in the Prospectus

Item 14. Other Expenses of Issuance and Distribution

The aggregate estimated (other than the registration fee) expenses to be paid in connection with this offering are as follows:

Securities and Exchange Commission registration fee	$ 17,655
Trustee s fees and expenses	15,000
Accounting fees and expenses	200,000
Legal fees and expenses	250,000
Printing and engraving	50,000
Blue sky fees and expenses	15,000
Transfer agent fees and expenses	15,000
Miscellaneous	15,995
Total	$ 578,650

Item 15. Indemnification of Directors and Officers

The Delaware General Corporation Law and the Company s charter provide for indemnification of the Company s directors and officers for liabilities and expenses that they may incur in such capacities. In general, directors and officers are indemnified with respect to actions taken in good faith in a manner reasonably believed to be in, or not opposed to, the Company s best interests and, with respect to any criminal action or proceeding, actions that the indemnitee had no reasonable cause to believe were unlawful. Reference is made to the Company s amended and restated charter filed as Exhibit 3.1 to this Registration Statement.

In addition to the indemnification provided by the Delaware General Corporation Law and the Company s charter, the Company has entered into an Indemnification Agreement with each of its directors pursuant to which the Company agrees to indemnify each director (1) for all expenses (including attorneys fees), judgments, fines and amounts paid in settlement (if such settlement is approved in advance by the Company, which approval shall not be unreasonably withheld) actually and reasonably incurred by such director by reason of any action or inaction on the part of such director while an officer or director or by reason of the fact that such director is or was serving at the request of the Company as a director, officer, employee or agent of the Company or other enterprise if such director acted in good faith and in a manner such director reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such conduct was unlawful, and (2) for all expenses (including attorneys fees) and, to the fullest extent permitted by law, amounts paid in settlement, in each case to the extent actually and reasonably incurred by the director in connection with the defense or settlement of any threatened, pending or completed action or proceeding by or in the right of the Company or any subsidiary of the Company to procure a judgment in its favor by reason of the fact that such director is or was a director, officer, employee or agent of the Company or any subsidiary of the Company, by reason of any action or inaction on the part of such director while an officer or director or by reason of the fact that such director is or was serving at the request of the Company as a director, officer, employee or agent of another enterprise if such director acted in good faith and in a manner such director reasonably believed to be in or not opposed to the best interest of the Company and its shareholders, except that no indemnification will be provided in respect of any claim, issue or mater as to which such Director is finally adjudicated by court orders or judgment to be liable to the Company in the performance of such director s duty to the Company and its

shareholders unless and only to the extent that the Delaware Court of Chancery or any other court in which such action or proceeding is or was brought determines upon application, that despite the adjudication of liability such director is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or other such court deems proper. The Company is not obligated

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under the terms of the Indemnification Agreement to indemnify its directors (1) for proceedings or claims initiated or brought voluntarily by such director and not by way of defense, except for proceedings brought to establish or enforce a right of indemnification under the Indemnification Agreement or any other statute or law or otherwise as required under Section 145 of the Delaware General Corporation Law, (but such indemnification or advancement of expenses may be provided if the Company s Board of Directors has approved the initiation of any such suit), (2) for any expenses incurred by a director with respect to any proceedings instituted by such director to enforce or interpret such director s Indemnification Agreement, if a court of competent jurisdiction determines that each of the material assertions made by such director in such proceeding was not made in good faith or was frivolous, (3) for expenses or liabilities paid directly to the directors by directors and officers insurance, (4) on account of any claims for an accounting of profits made from the purchase or sale by any director of securities of the Company pursuant to Section 16(b) of the Securities Exchange Act, as amended, or (5) if indemnification would not be lawful.

Directors and officers of the Company are also insured up to an aggregate of $15 million under a directors and officers liability insurance policy.

Item 16. Exhibits

The following exhibits are filed herewith or incorporated by reference herein:

Exhibit Number	Title
1.1	Form of Underwriting Agreement.*
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated By-laws.
4.1(2)	Form of 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 the Summary of Rights attached thereto as Exhibits A, B and C, respectively.
4.3	Form of Senior Indenture.
4.4	Form of Subordinated Indenture.
4.5	Form of Senior Debt Security (included in Exhibit 4.2).
4.6	Form of Subordinated Debt Security (included in Exhibit 4.4).
4.7	Form of Certificate of Designation.*
4.8	Form of Preferred Stock Certificate.*
4.9	Form of Deposit Agreement.*
4.10	Form of Depositary Receipt.*
4.11	Form of Warrant Agreement.*
4.12	Form of Warrant Certificate.*
5.1	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.
12.1	Computation of Ratio of Earnings to Fixed Charges.
23.1	Consent of independent registered public accounting firm.

23.2 Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (included in Exhibit 5.1).

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Exhibit Number	Title
24.1	Power of Attorney of certain directors and officers of Pain Therapeutics, Inc. (see page II-5 of this Form S-3).
25.1	Form T-1 Statement of Eligibility of Trustee for Senior Indenture under the Trust Indenture Act of 1939.*
25.2	Form T-1 Statement of Eligibility of Trustee for Subordinated Indenture under the Trust Indenture Act of 1939.*

* To be filed by amendment or as an exhibit to a report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and incorporated herein by reference.
(1) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2005.
(2) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2005.
(3) Incorporated by reference to our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2005.

Item 17. Undertakings

(a) The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective Registration Statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

provided, however, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the information required to be included in a post-effective amendment by such those paragraphs is contained in periodic reports filed with or furnished to the Securities and Exchange Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant s annual report pursuant to Section 13(a) or Section 15(d) of

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the Securities Exchange Act of 1934 (and, where applicable, each filing of our employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities, (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding), is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

(d) The undersigned Registrant hereby undertakes to file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the SEC under Section 305(b)(2) of the Trust Indenture Act.

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Signatures

Pursuant to the requirements of the Securities Act, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of South San Francisco, State of California, on August 26, 2005.

PAIN THERAPEUTICS, INC.

By: /s/ REMI BARBIER

Remi Barbier

President and Chief Executive Officer

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 individually, as his true and lawful attorneys-in-fact and agents with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities to sign the Registration Statement filed herewith and any or all amendments to said Registration Statement (including post-effective amendments and registration statements filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and otherwise), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission granting unto said attorneys-in-fact and agents the full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the foregoing, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or her substitute, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
/s/ REMI BARBIER **Remi Barbier**	Chief Executive Officer, President and Director (Principal Executive Officer)	August 26, 2005
/s/ PETER S. RODDY **Peter S. Roddy**	Chief Financial Officer (Principal Financial and Accounting Officer)	August 26, 2005
/s/ NADAV FRIEDMANN, PH.D., M.D. **Nadav Friedmann, Ph.D., M.D.**	Director	August 26, 2005

/s/ Robert Z. Gussin, Ph.D. **Robert Z. Gussin, Ph.D.**	Director	August 26, 2005
/s/ Vernon R. Loucks, Jr. **Vernon R. Loucks, Jr.**	Director	August 26, 2005
/s/ Michael J. O Donnell **Michael J. O Donnell**	Director	August 26, 2005
/s/ Sanford R. Robertson **Sanford R. Robertson**	Director	August 26, 2005

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Exhibit Index

Exhibit Number	Title
1.1	Form of Underwriting Agreement.*
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated By-laws.
4.1(2)	Form of 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 the Summary of Rights attached thereto as Exhibits A, B and C, respectively.
4.3	Form of Senior Indenture.
4.4	Form of Subordinated Indenture.
4.5	Form of Senior Debt Security (included in Exhibit 4.3).
4.6	Form of Subordinated Debt Security (included in Exhibit 4.4).
4.7	Form of Certificate of Designation.*
4.8	Form of Preferred Stock Certificate.*
4.9	Form of Deposit Agreement.*
4.10	Form of Depositary Receipt.*
4.11	Form of Warrant Agreement.*
4.12	Form of Warrant Certificate.*
5.1	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.
12.1	Computation of Ratio of Earnings to Fixed Charges.
23.1	Consent of independent registered public accounting firm.
23.2	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (included in Exhibit 5.1).
24.1	Power of Attorney of certain directors and officers of Pain Therapeutics, Inc. (see page II-5 of this Form S-3).
25.1	Form T-1 Statement of Eligibility of Trustee for Senior Indenture under the Trust Indenture Act of 1939.*
25.2	Form T-1 Statement of Eligibility of Trustee for Subordinated Indenture under the Trust Indenture Act of 1939.*

* To be filed by amendment or as an exhibit to a report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and incorporated herein by reference.

(1) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2005.

(2) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2005.

(3) Incorporated by reference to our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2005.