PAIN THERAPEUTICS INC
Form 10-K/A
June 24, 2004
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

(Amendment No. 2)

ANNUAL REPORT UNDER SECTION 13 or 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the Fiscal Year Ended December 31, 2003

or

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

Commission File Number: 000-29959

Pain Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

Remi Barbier

President and Chief Executive Officer

416 Browning Way

South San Francisco, CA 94080

(650) 624-8200

(Address, including zip code, or registrant s principal executive offices and telephone number, including area code)

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $177,038,020 computed by reference to the last sales price of $6.45 as reported by the Nasdaq National Market System, as of the last business day of the Registrant s most recently completed second fiscal quarter, June 30, 2003.

The number of shares outstanding of the Registrant s common stock on February 19, 2004 was 35,392,434 shares.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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PAIN THERAPEUTICS, INC.

FORM 10-K/A

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EXPLANATORY NOTE

This Amendment No. 2 on Form 10-K/A (this Amendment) amends Pain Therapeutics, Inc. s (the Company) Annual Report on Form 10-K for the year ended December 31, 2003, originally filed on March 12, 2004 (the Original Filing). The Company is refiling Item 7 of Part II in response to certain comments made by the Securities and Exchange Commission to the Company s Management Discussion and Analysis section of the Original Filing. In addition, pursuant to the rules of the Securities and Exchange Commission, the Company is including with this Amendment certain currently dated certifications.

Except as described above, no other changes have been made to the Original Filing. The filing of this Form 10-K/A is not a representation that any statements contained in items of Form 10-K other than Part II, Item 7 are true or complete as of any date subsequent to the Original Filing.

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

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

Overview

We are a biopharmaceutical research company that develops novel drugs. Our drugs target severe chronic pain, such as pain associated with advanced osteoarthritis, low-back pain or IBS. We have three proprietary drug candidates in clinical development: Oxytrex, Remoxy and PTI-901. Our two most advanced drugs, Oxytrex and PTI-901, are in Phase III clinical trials. Remoxy is in Phase I clinical trials in the United Kingdom. We believe the target market for our three drug candidates exceeds $3 billion per year. We currently retain all commercial rights to our drug candidates.

We have yet to generate any revenues from product sales. We have not been profitable and, since our inception on May 4, 1998 through December 31, 2003, we have incurred an accumulated deficit of approximately $74.2 million. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel related costs and general corporate expenses. Research and development activities include costs of preclinical and clinical trials as well as clinical supplies associated with our drug candidates. Salaries and other personnel related costs include non-cash stock based compensation associated with options granted to employees and non-employees. Our operating results may fluctuate substantially from period to period as a result of the timing and enrollment rates of clinical trials for our drug candidates and our need for clinical supplies.

We expect to incur significant additional operating losses for the next several years. Our cash requirements for operating activities and capital expenditures will increase substantially in the future as we:

- continue to conduct preclinical and clinical trials for our drug candidates, including the Phase III trials of Oxytrex and PTI-901 and formulation activities and Phase I trials of Remoxy;
- seek regulatory approvals for our drug candidates;
- develop, formulate, manufacture and commercialize our drug candidates and drugs;
- implement additional internal systems and develop new infrastructure;
- acquire or in-license additional products or technologies, or expand the use of our technology;
- maintain, defend and expand the scope of our intellectual property; and
- hire additional personnel.

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

Recent Developments

Oxytrex and PTI-901 are in Phase III clinical trials. Remoxy is in Phase I clinical trials. In 2003, we:

completed a 21-day Phase II clinical trial of Oxytrex in 350 patients with severe osteoarthritic pain;

announced that the 350-patient Phase II study met its primary and secondary efficacy endpoints, showing a statistically significant reduction in chronic pain and in functional scores for patients on Oxytrex;

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initiated a 700-patient Phase III clinical trial of Oxytrex to demonstrate its safety and efficacy in patients with severe chronic low back pain;

announced clinical results of a 50-patient pilot study using PTI-901, a proprietary new drug we are developing to treat IBS in both men and women;

presented the final clinical results of the pilot study using PTI-901 at the Scientific Meeting of the American College of Gastroenterology, disclosing that PTI-901 significantly improved symptoms commonly associated with IBS without drug-related safety issues;

initiated a 1,200-patient Phase III clinical program of PTI-901 in both men and women; and,

announced a new drug candidate, Remoxy.

Since our inception, we have focused all our research and development efforts on the research and development of opioid drugs for the treatment of pain. Research and development expenses related to our efforts for this project total $58.8 million for the period from inception through December 31, 2003. The following table summarizes expenses by category of research and development efforts (in thousands):

	Years Ended December 31,			May 4, 1998 (Inception) Through December 31,
	2003	2002	2001	2003
Compensation	$ 3,690	$ 3,097	$ 3,056	$ 16,919
Contractor fees (1)	10,049	5,281	5,615	28,411
Supplies (2)	3,262	2,357	2,218	9,546
Other (3)	1,912	661	779	3,964
	$ 18,913	$ 11,396	$ 11,668	$ 58,840

(1) Contractor fees generally include expenses for pre-clinical studies and clinical trials.

(2) Supplies generally include costs for formulation and manufacturing activities.

(3) Other generally includes the allocation of common costs such as facilities.

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

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

Critical Accounting Policies

The preparation of our financial statements in accordance with accounting principles generally accepted in the U.S. requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and interest income in our financial statements and accompanying notes. On an on-going basis, we evaluate our estimates, including those related to contract agreements, research collaborations and investments. We base our estimates on historical experience and various other assumptions that we believe to be reasonable

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under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The following items in our financial statements require significant estimates and judgments:

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

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

Results of Operations

Years Ended December 31, 2003 and 2002

Research and Development

Research and development expense consists primarily of drug development work associated with our drug candidates, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs and salaries and other personnel related expenses. Research and development expense increased to $18.9 million from $11.4 million in the years ended December 31, 2003 and 2002, respectively. The $7.5 million increase in expense was primarily due to the development costs related to our new drug candidate Remoxy as well as for the ongoing development and Phase III programs for Oxytrex and PTI-901.

We expect research and development expenses to increase significantly over the next several years as we expand our development efforts and as our drug candidates progress through various stages of clinical trials, including the Phase III trials of Oxytrex and PTI-901 as well as the continued development and clinical studies of Remoxy. The increase may fluctuate from period to period due to the timing and scope of these activities and the results of clinical trials and studies.

General and Administrative

General and administrative expense consists primarily of compensation and other general corporate expenses as well as non-cash stock based compensation. General and administrative expense decreased to

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$3.3 million from $5.5 million for the year ended December 31, 2003 and 2002, respectively. The decrease in general and administrative expense resulted primarily from lower non-cash equity related expense as well as a reclassification of certain occupancy and other expenses to research and development.

Interest Income

Interest income decreased to $0.6 million from $1.0 million for the years ended December 31, 2003 and 2002, respectively. The decrease in interest income is primarily the result of lower average balances of cash and cash equivalents and marketable securities as well as lower returns on the investment of our cash and cash equivalents and marketable securities.

Years Ended December 31, 2002 and 2001

Research and Development

Research and development expense was $11.4 million for the year ended December 31, 2002 compared to $11.7 million in the year ended December 31, 2001. The $0.3 million decrease from year-to-year was primarily due to a decrease in non-cash stock based compensation. At December 31, 2002 our research and development activities were primarily related to Oxytrex.

General and Administrative

General and administrative expenses were $5.5 million for the year ended December 31, 2002 compared to $5.6 million for the year ended December 31, 2001. General and administrative expense consists primarily of compensation, facilities expenses and other general corporate expenses as well as non-cash stock based compensation. The year-to-year decrease of $0.1 million was primarily due to a decrease in non-cash stock based compensation, partially offset by increases in depreciation and general corporate expenses.

Interest Income

Interest income decreased to $1.0 million for the year ended December 31, 2002 from $3.0 million for the year ended December 31, 2001. This decrease resulted from the lower average balances of cash and cash equivalents and to a lesser extent from the decline in interest rates during 2002.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through public and private securities offerings. We intend to continue to use the proceeds from these offerings to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes. As of December 31, 2003, cash, cash equivalents and marketable securities were $77.4 million. During 2003, we issued 7,730,500 shares of common stock at $6.50 per share in a follow-on public offering and received approximately $46.7 million in net proceeds, after deducting underwriting discounts and related expenses.

Net cash used in operating activities was $20.5 million for the year ended December 31, 2003 compared to $15.6 million in 2002 and $12.7 million in 2001. Cash used in operating activities related primarily to the funding of operating losses.

Our investing activities to purchase property, equipment and leasehold improvements used cash of $26,000, $7,000 and $1.3 million in the years ended December 31, 2003, 2002 and 2001, respectively. Other investing activities in 2003 consisted primarily of the purchase and sale of marketable securities. We expect to continue to invest in our infrastructure to support our operations. At December 31, 2003, our investments consist of cash and cash equivalents as well as marketable securities that are held as short-term, available-for-sale securities.

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Our financing activities provided cash of $47.8 million, $0.3 million and $0.1 million in the years ended December 31, 2003, 2002 and 2001, respectively. Financing activities in the 2003 period consisted primarily of the proceeds of $46.7 million from our follow-on public offering in September 2003 and $1.0 million from exercise of warrants and stock options from our stock plans. In the years ended December 31, 2002 and 2001, cash provided by financing activities was primarily from the exercise of stock options from our stock plans.

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

	2004	2005	2006	2007	2008	2009 and Thereafter	Total
Future minimum lease payments	$ 183	$ 187	$ 191	$ 187	$ 196	$ 366	$ 1,310

We have license agreements that require us to make milestone payments upon the successful achievement of milestones, including clinical milestones. Our formulation agreement with Durect Corporation obligates us to make certain milestone payments upon achieving clinical milestones and regulatory milestones. We believe the amount of each milestone payment will be immaterial within the period such milestone is achieved. Our license agreements also require us to pay certain royalties to our licensors if we succeed in fully commercializing products under these license agreements. All of these potential future milestone and royalty payments are cancelable as of December 31, 2003.

Since our inception we have incurred a cumulative deficit of approximately $74.2 million, including a net loss of $21.6 million in 2003, and we expect to incur significant additional operating losses for the next several years. Since inception we have used $58.7 million of cash in operating activities. We expect our cash requirements to increase 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 drugs; 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. The amount and timing of cash requirements will depend on regulatory and market acceptance of our products candidates and the resources we devote to researching and developing, formulating, manufacturing, commercializing and supporting our products. We believe that our current resources should be sufficient to fund our operations for at least the next twelve months. We may seek additional future funding through public or private financing within this timeframe, if such funding is available and on terms acceptable to us.

RISK FACTORS

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

Risks Relating to our Financial Position and Need for Financing

Our operating history may make it difficult for you to evaluate the success of 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

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preclinical studies and clinical trials of our drug candidates. We have not yet demonstrated our ability to obtain regulatory approval, formulate and manufacture commercial-scale product or conduct sales and marketing activities. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

We have incurred net losses each year since our inception. As a result of ongoing operating losses, we had an accumulated deficit of $74.2 million as of December 31, 2003. 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, including the Phase III trials of Oxytrex and PTI-901 and formulation activities and Phase I trials of Remoxy;
- seek regulatory approvals for our drug candidates;
- develop, formulate, manufacture and commercialize our drugs;
- 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 and commercialize our products, we will not be able to generate such revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the market price of our common stock.

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

We have funded all of our operations and capital expenditures with the proceeds from public and private stock offerings. We expect that our current cash, cash equivalent and marketable securities on hand will be sufficient to meet our working capital and capital expenditure needs for at least the next twelve months. However, we may need to raise additional funds sooner and additional financing may not be available on favorable terms, if at all. Even if we succeed in selling additional securities to raise funds, our existing stockholders ownership percentage would be reduced and new investors may demand rights, preferences or privileges senior to those of existing stockholders.

If we 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 obtain FDA approval of our drug candidates, and we could be forced to discontinue product development, enter into a relationship with a strategic partner earlier than currently intended, reduce sales and marketing efforts and forego attractive business opportunities.

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Clinical and Regulatory Risks

If we fail to obtain the necessary regulatory approvals, we will not be allowed to commercialize our drugs, 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. 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.

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 of any of our drug candidates we will have fewer saleable products and corresponding lower product revenues. Even if we receive regulatory approval of our products, such approval may involve limitations on the indicated uses or marketing claims we may make for our products. Further, later discovery of previously unknown problems could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us to commit to perform lengthy 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 foreign jurisdictions, we must receive marketing authorizations from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes 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 products.

In order to obtain FDA approval of any of our drug candidates, we must submit to the FDA a 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. Two of our drug candidates, Oxytrex and PTI-901, are in Phase III clinical trials. Remoxy is in Phase I clinical trials.

Our Phase III 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. Even if the results of our Phase III trials are positive, we may have to commit substantial time and additional resources to conducting further preclinical and clinical studies before we can submit NDAs or obtain FDA approvals for our drug candidates.

Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous requirements. The clinical trial process is also time consuming. Furthermore, if participating patients in clinical 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 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.

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Even if our clinical trials are completed as planned, their results may not support our product 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.

If we are unable to satisfy the FDA s request for additional information on Remoxy, we will not be allowed to conduct clinical testing of this product in the United States.

In November 2003, we filed an IND for Remoxy with the FDA. The FDA responded to our IND with a request for additional information on certain excipients used in formulations of Remoxy. We are not able to conduct human clinical studies with Remoxy in the United States until the FDA notifies us that their request for additional information is satisfied. If we are unable to conduct human clinical studies of Remoxy in the United States, we may determine that the commercial opportunity for Remoxy in certain dosage forms is too limited to warrant further investment.

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.

The DEA limits the availability of the active ingredients in our current drug candidates and, as a result, our quota may not be sufficient to complete clinical trials, 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 or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of 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 products.

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

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Conducting clinical trials of our drug candidates exposes 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. 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.

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;
- 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, 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 significant number of recent business combinations among pharmaceutical companies has resulted in a reduced number of potential future 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 product revenues are likely to be lower than if we marketed and sold our products ourselves.

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

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

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

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

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

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

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

- government and health administration authorities;

private health maintenance organizations and health insurers; and

other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, health maintenance organizations and managed care organizations, are challenging the prices charged for medical products and services and/or are seeking pharmacoeconomic data to justify formulary acceptance and reimbursement practices. 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. 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 them could be limited.

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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. In January 2003, PTO disclosed that a law firm for an unidentified third-party filed requests for an Ex Parte Reexamination related to certain claims on patents we exclusively licensed from Albert Einstein College of Medicine. In each of the reexaminations, the PTO issued a first/initial office action and responses to those office actions were filed. In certain of the reexaminations, the PTO issued second/final office actions in which the PTO affirmed the patentability of certain claims related to uses of our drugs under development while maintaining rejections with respect to other claims, and responses to those office actions have been filed. A reexamination certificate has been issued in one of the proceedings confirming the patentability of the claims, and a notice of intent to issue a reexamination certificate confirming the patentability of the claims has been issued in another of the proceedings. We cannot provide any assurance as to the outcome of the remaining ongoing PTO proceedings. An adverse outcome of the reexamination process could result in loss of claims of these patents that pertain to certain drugs we currently have under development and could have a material adverse impact on our future revenues.

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

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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.

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

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

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

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

Business interruptions could limit our ability to operate our business.

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

Risks Relating to Manufacturing

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

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

clinical trials, and, consequently, FDA approval of our drug candidates and commercialization of our products, result in higher costs, or deprive us of potential product revenues:

Contract commercial manufacturers, their sub-contractors or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy clinical needs or commercial demand, may experience technical issues that impact quality, 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.

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

We 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.

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.

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.

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,

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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

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

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

- results of our preclinical and clinical trials;
- publicity regarding actual or potential medical results relating to products under development by us or others;
- announcements of technological innovations or new commercial products by us or others;
- developments in patent or other proprietary rights by us or others;
- comments or opinions by securities analysts or major stockholders;
- future sales of our common stock by existing stockholders;
- regulatory developments or changes in regulatory guidance;
- litigation or threats of litigation;
- economic and other external factors or other disaster or crises;

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

period-to-period fluctuations in financial results; and

limited daily trading volume.

The National Association of Securities Dealers, Inc., or NASD, and the 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 such market, 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.

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

The stock market in general, and the NASDAQ National Market 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

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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 shareholders (shareholders holding greater than 5% of our common stock) acting collectively may have the ability to exercise significant influence over matters requiring shareholder 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 shareholders.

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 operating results may not meet the expectations of securities analysts and investors which could result in a decline in the price of our stock.

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

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

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PART IV

Item 15. ***Exhibits, Financial Statement Schedules, and Reports on Form 8-K***

(a) (3) *Exhibits:*

Exhibit Number	Description of Document
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).

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SIGNATURES

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

PAIN THERAPEUTICS, INC.

By: /s/ REMI BARBIER
Remi Barbier

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

Dated: June 24, 2004

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

Signature	Title	Date
/s/ REMI BARBIER **Remi Barbier**	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	June 24, 2004
/s/ PETER S. RODDY **Peter S. Roddy**	Chief Financial Officer (Principal Financial and Accounting Officer)	June 24, 2004
* **Nadav Friedmann, Ph.D., M.D.**	Chief Operating Officer and Director	June 24, 2004
* **Robert Z. Gussin, Ph.D.**	Director	June 24, 2004
* **Vernon R. Loucks, Jr.**	Director	June 24, 2004
* **Michael J. O Donnell, Esq.**	Director and Secretary	June 24, 2004

*	Director	June 24, 2004
Sanford R. Robertson		
*	Director	June 24, 2004
Richard G. Stevens		

*By: /s/ PETER S. RODDY
Peter S. Roddy

Attorney-in-Fact

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