

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) January 26, 2005

PAIN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

000-29959

91-1911336

*(State or other jurisdiction
of incorporation)*

*(Commission
File Number)*

*(I.R.S. Employer
Identification No.)*

416 Browning Way South San Francisco, CA

94080

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code

(650) 624-8200

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13a-4(c))

Item 2.02. Results of Operations and Financial Condition.

On January 26, 2005, Pain Therapeutics, Inc., (the “Company”) issued a press release announcing the Company’s financial results for the fourth quarter and year ended December 31, 2004. A copy of the Press Release has been furnished as an exhibit to this report and is incorporated by reference herein.

The information in this Item 2.02, in Item 9.01 hereof and in Exhibit 99.1 shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference into any registration statement or other document filed or furnished pursuant to the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such document.

Item 9.01. Financial Statement and Exhibits.

The following exhibit is furnished as part of this report in accordance with the provisions of Item 601 of Regulation S-K:

Exhibit Number	Description
99.1	Press Release of Pain Therapeutics, Inc. dated January 26, 2005

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PAIN THERAPEUTICS, INC.

Date **January 26, 2005**

/s/PETER S. RODDY

Peter S. Roddy
Chief Financial Officer

Pain Therapeutics Announces Fourth Quarter and Year End 2004 Financial Results

Company Expects Phase III Results for Three Drug Candidates in 2005

SOUTH SAN FRANCISCO, Calif., Jan. 26 /PRNewswire-FirstCall/ -- Pain Therapeutics, Inc. (Nasdaq: PTIE), a biopharmaceutical company, today reported financial results for the fourth quarter and year ended December 31, 2004.

The net loss for the quarter ended December 31, 2004 was \$9.3 million, or \$0.22 per share, compared to a net loss of \$6.7 million, or \$0.19 per share for the fourth quarter of 2003. The net loss for the year ended December 31, 2004 was \$37.8 million, or \$1.01 per share, compared to a net loss of \$21.6 million, or \$0.73 per share, for the same period of 2003.

At December 31, 2004 Pain Therapeutics' cash, cash equivalents and marketable securities were \$99.4 million.

"We ended 2004 in great shape," said Remi Barbier, Pain Therapeutics' president and chief executive officer. "We ended the year with three drugs in Phase III clinical trials, nearly \$100 million of cash, ownership of all commercial rights to our drugs and a track record of meeting written milestones on-time and on-budget. These results now set the stage for a series of Phase III clinical announcements in 2005. After six years of drug development effort, we look forward to unblinding data from our Phase III trials and announcing clinical results for Oxytrex(TM), PTI-901 and Remoxy(TM) throughout 2005."

Research and development expenses increased to \$8.9 million in the fourth quarter of 2004 from \$6.1 million in the fourth quarter of 2003. Research and development expenses increased to \$35.1 million for the year 2004 from \$18.9 million for the year 2003. Research and development expenses in the fourth quarter of 2004 included on-going Phase III trial costs for Oxytrex and PTI-901 and costs associated with the initiation of the Phase III trial with Remoxy.

General and administrative expenses increased to \$1.0 million in the fourth quarter of 2004 from \$0.9 million in the fourth quarter of 2003. General and administrative expenses increased to \$3.9 million for the year 2004 from \$3.3 million for the year 2003.

Financial Outlook

Our clinical goals for 2005 are to complete Phase III trials with Oxytrex, PTI-901 and Remoxy and to report on the progress and results of these trials throughout the year. To achieve these clinical goals and other development activities we believe cash requirements for 2005 will be \$40 million, plus or minus 10 percent.

We expect our net loss for 2005 to be approximately \$41 million, plus or minus 10 percent. The projected net loss for 2005 is higher than the projected cash requirements primarily due to non-cash expenses included in the net loss.

Clinical Outlook

Our near-term clinical goal is to announce top-line results of a large Phase III clinical study with Oxytrex. We believe we remain on-track to unblind data and to announce the results of this study in March 2005. This Phase III randomized, double-blind, multi-center study is designed to compare the analgesic efficacy of Oxytrex against oxycodone or placebo in over 700 patients with moderate-to-severe low-back pain.

In Q2 2005, we also expect to complete patient enrollment of a second Phase III study with Oxytrex. This Phase III study plans to enroll over 700 patients with moderate-to-severe osteoarthritic pain.

In the second half of 2005 we expect to make the following clinical announcements:

Drug Candidate	Patient Population	Expected Announcement
Oxytrex	Osteoarthritic Pain	Report top-line results of Phase III
PTI-901	Irritable Bowel Syndrome	Complete enrollment of first Phase III
PTI-901	Irritable Bowel Syndrome	Report top-line results of first Phase III
Remoxy	Severe Chronic Pain	Complete enrollment of first Phase III
Remoxy	Severe Chronic Pain	Report top-line results of first Phase III
Remoxy	Severe Chronic Pain	Initiate second Phase III

Conference Call and Webcast Information

Pain Therapeutics will be hosting a conference call today at 11:00 a.m. Pacific Time/2:00 p.m. Eastern Time to discuss these financial results and to review the Company's clinical programs. Participants can listen to the conference call via webcast on the Company's website, www.paintrials.com or by dialing 800-299-6183 or 617-801-9713, code 70173506. A replay of the webcast will remain on the Company's site for at least 30 days.

About Pain Therapeutics, Inc.

We are a biopharmaceutical company that develops novel drugs. Our drugs target severe chronic pain, such as pain associated with osteoarthritis, low-back pain or irritable bowel syndrome. We have three unique drug candidates in clinical development: Oxytrex, Remoxy and PTI-901, all of which are in Phase III clinical trials. We believe the target market for our three drug candidates exceeds \$3 billion per year. We currently retain commercial rights to our drug candidates. For more information please visit our website at www.paintrials.com.

Note Regarding Forward-Looking Statements: This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). PTI disclaims any intent or obligation to update these forward-looking statements, and claims the protection of the Safe Harbor for forward-looking statements contained in the Act. Examples of such statements include, but are not limited to, any statements relating to the timing, scope or expected outcome of the Company's clinical development of its drug candidates, the Company's clinical guidance for 2005, the Company's expected cash requirements in 2005 and through late-stage development of its drug candidates, the Company's net loss for 2005, the completion of clinical trials, the potential benefits of the Company's drug candidates, and the size of the potential market for the Company's products. Such statements are based on management's current expectations, but actual results may differ materially due to various factors. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of the Company's drug candidates, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug candidates that could slow or prevent product approval or market acceptance (including the risk that current and past results of clinical trials are not necessarily indicative of future results of clinical trials), the uncertainty of patent protection for the Company's intellectual property or trade secrets, the Company's ability to obtain additional financing if necessary and unanticipated research and development and other costs. For further information regarding these and other risks related to the Company's business, investors should consult the Company's filings with the Securities and Exchange Commission, including its prospectus supplement dated October 6, 2004 and its subsequent filings.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2004	2003	2004	2003
Operating expenses (1):				
Research and development	\$ 8,869	\$ 6,052	\$ 35,093	\$ 18,913
General and administrative	964	882	3,868	3,338
Total operating expenses	9,833	6,934	38,961	22,251
Operating loss	(9,833)	(6,934)	(38,961)	(22,251)
Other income:				
Interest income	517	250	1,185	634
Net loss	\$ (9,316)	\$ (6,684)	\$ (37,776)	\$ (21,617)
Basic and diluted loss per common share	\$ (0.22)	\$ (0.19)	\$ (1.01)	\$ (0.73)
Weighted-average shares used in computing basic and diluted loss per common share	42,509	35,362	37,267	29,483

(1) Included in research and development and general and administrative expenses are stock based compensation expenses of \$69 thousand and \$79 thousand for the quarters ended December 31, 2004 and 2003, respectively, and \$401 thousand and \$139 thousand for the years ended December 31, 2004 and 2003, respectively.

PAIN THERAPEUTICS, INC.
(A Development Stage Enterprise)
CONDENSED BALANCE SHEETS
(in thousands)

	December 31,	
	2004	2003(2)
	(Unaudited)	
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 99,397	\$ 77,429
Prepaid expenses	259	1,321
Total current assets	99,656	78,750
Property and equipment, net	1,461	1,688
Other assets	75	75
Total assets	\$ 101,192	\$ 80,513
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 877	\$ 2,231
Accrued development expense	6,358	1,210
Accrued compensation and benefits	415	369
Other accrued liabilities	146	141
Total liabilities	7,796	3,951
Stockholders' equity:		
Common stock	44	35
Additional paid-in-capital	205,920	150,732
Deferred compensation	—	(7)
Accumulated other comprehensive income (loss)	(544)	50
Deficit accumulated during the development stage	(112,024)	(74,248)
Total stockholders' equity	93,396	76,562
Total liabilities and stockholders' equity	\$ 101,192	\$ 80,513

(2) Derived from audited financial statements.

SOURCE Pain Therapeutics, Inc.

-0- 01/26/2005

/CONTACT: Christi Waarich, Senior Manager of Investor Relations, of Pain Therapeutics, Inc., +1-650-825-3324, or cwaarich@paintrials.com; or Kathy Nugent, Ph.D. (Media), of Burns McClellan, +1-212-213-0006, for Pain Therapeutics/

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