

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)

November 8, 2012

Pain Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

000-29959

(Commission File Number)

91-1911336

(IRS Employer
Identification No.)

7801 N Capital of Texas Highway, Suite 260, Austin, TX 78731

(Address of principal executive offices, including zip code)

512-501-2444

(Registrant's telephone number, including area code)

Not Applicable

(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 (see General Instruction A.2. below):

- ☐ 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 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On November 8, 2012 the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated November 8, 2012

SIGNATURE

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

Pain Therapeutics, Inc.

/s/ PETER S. RODDY

Peter S. Roddy

Vice President & Chief Financial Officer

Dated: November 8, 2012

Pain Therapeutics Reports Q3 2012 Financial Results

On Track With Financial Guidance for 2012

AUSTIN, Texas, Nov. 8, 2012 (GLOBE NEWSWIRE) -- Pain Therapeutics, Inc. (Nasdaq:PTIE) today reported financial results for the quarter and nine months ended September 30, 2012. Net loss for Q3 2012 was \$1.6 million, or \$0.03 per share, as compared to the net loss in Q3 2011 of \$0.8 million, or \$0.02 per share. Net loss for the first nine months of 2012 was \$1.7 million, or \$0.04 per share, as compared to net loss for the first nine months of 2011 of \$2.2 million, or \$0.05 per share.

Cash and investments were \$92.5 million at September 30, 2012. The Company has no debt. Management continues to believe net cash usage for full-year 2012 will be under \$10.0 million.

"Our financial strategy is to maintain tight fiscal discipline while awaiting the resubmission of REMOXY to the FDA by our commercial partner, Pfizer," said Remi Barbier, President & CEO. "We believe this drug candidate is well-partnered, has succeeded in a Phase III efficacy study, has published results of abuse-resistance, has four issued patents and targets a large marketplace. The value of these success factors may become more apparent as Pfizer updates regulatory guidance for REMOXY in the first half of 2013."

Based on management's review of recent written correspondence between Pfizer and the FDA, management believes Pfizer is well-positioned to address the concerns described in the FDA's Complete Response Letter for REMOXY.

Q3 2012 Financial Detail

Research and development expenses increased to \$2.4 million in Q3 2012 from \$2.0 million in Q3 2011, primarily due to higher non-cash stock-related compensation costs. Research and development expenses decreased to \$5.5 million in the first nine months of 2012 from \$6.6 million in the first nine months of 2011, primarily due to lower headcount and facilities costs.

General and administrative expenses increased to \$2.0 million in Q3 2012 from \$1.8 million in Q3 2011, primarily due to higher non-cash stock-related compensation costs. General and administrative expenses decreased to \$5.0 million in the first nine months of 2012 from \$5.1 million in the first nine months of 2011, primarily due to lower headcount and facilities costs.

About REMOXY

Our lead drug candidate is called REMOXY (oxycodone) Extended-Release Capsules CII. REMOXY is an investigational drug with a unique, controlled release formulation of oxycodone for patients with moderate-to-severe chronic pain. REMOXY is designed to discourage common methods of tampering associated with prescription analgesic misuse and abuse.

- Pfizer is our exclusive, worldwide commercial partner for REMOXY and three other abuse-resistant prescription pain medications (except in Australia/New Zealand).
- REMOXY received a Complete Response Letter in December 2008 and in June 2011. Pfizer has sole responsibility for addressing the concerns described in the FDA's Complete Response Letter, at its own expense.
- On November 1, 2012, Pfizer announced it plans to meet with the FDA in March 2013 to discuss REMOXY. Pfizer also announced the initiation of a new pharmacokinetic study with REMOXY.

REMOXY Deal Economics

- To date, we have received total cash payments of \$185.0 million in program fees and milestone payments under the strategic alliance with Pfizer in connection with the development of REMOXY and three other abuse-resistant drug candidates.
- We are also eligible to receive up to an additional \$120.0 million in clinical/regulatory milestone payments, including a \$15 million payment upon FDA approval of REMOXY.
- Upon the commercial launch of REMOXY, we will receive from Pfizer a royalty of 20% of net sales in the United States, except as to the first \$1.0 billion in cumulative net sales, which royalty is set at 15%. Outside the United States, the royalty rate is 10%.
- We will also receive from Pfizer a supplemental royalty fee payment of 6.0% to 11.5% of net sales, depending on the range of total dollar sales in each year. This supplemental payment is equal to the full amount of our financial obligations to Durect Corporation (Nasdaq: DRRX), our exclusive supplier of certain excipients in REMOXY.
- Our development expenses for REMOXY and three other abuse-resistant pain medications that are in various stages of development, including hydrocodone, hydromorphone and oxymorphone, are reimbursed by Pfizer.
- Pain Therapeutics retains commercial rights to REMOXY and three other abuse-resistant drug candidates in Australia/New Zealand. We have not yet announced a market entry strategy for these territories.

About Pain Therapeutics, Inc.

Pain Therapeutics, Inc. is a biopharmaceutical company that develops novel drugs. The FDA has not approved any of our drug candidates for commercial sale. For more information, please visit 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"). Pain Therapeutics 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 size and potential markets for REMOXY, the development and commercialization prospects of REMOXY, our projected net cash usage for 2012, Pfizer's plans with respect to development of REMOXY, potential future milestone payments and royalties based on revenue from REMOXY, the potential development of other abuse resistant drug candidates, funding obligations of Pfizer, or the benefits of REMOXY. 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 obtaining regulatory approval of REMOXY and in development, testing and pursuit of regulatory approval of our other drug candidates, unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates, difficulties or delays in commercialization efforts with respect to our products, if any are approved for marketing, or failure of such products to gain market acceptance, the uncertainty of patent protection for our intellectual property or trade secrets, unanticipated additional research and development and other costs, potential diversion of resources from the pursuit of development and commercialization of drug candidates subject to our strategic alliance with Pfizer as a result of the acquisition of King Pharmaceuticals, Inc. by Pfizer, the potential for abuse resistant pain medications or other competing products or therapies to be developed by competitors and potential competitors or others and difficulties resulting from, or risks associated with, pending litigation, including diversion of resources and potential adverse judgments. 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.

-Financial Tables Follow-

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

	Three months ended September 30, 2012		Nine months ended September 30, 2012	
Revenue				
Program fee revenue	\$ 2,725	\$ 2,725	\$ 8,173	\$ 8,173
Collaboration revenue	--	24	249	564
Total revenue	2,725	2,749	8,422	8,737
Operating expenses				
Research and development	2,379	2,019	5,504	6,589
General and administrative	2,001	1,753	4,975	5,078
Total operating expenses	4,380	3,772	10,479	11,667
Operating loss	(1,655)	(1,023)	(2,057)	(2,930)
Interest income	105	208	405	708
Net loss	<u>\$ (1,550)</u>	<u>\$ (815)</u>	<u>\$ (1,652)</u>	<u>\$ (2,222)</u>
Net loss per share, basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.02)</u>	<u>\$ (0.04)</u>	<u>\$ (0.05)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>44,601</u>	<u>44,631</u>	<u>44,703</u>	<u>43,987</u>

CONDENSED BALANCE SHEETS
(in thousands)

	September 30, 2012	December 31, 2011 ⁽¹⁾
	(Unaudited)	
Assets		
Current assets		
Cash, cash equivalents and marketable securities	\$ 92,529	\$ 98,131
Other current assets	378	358
Total current assets	92,907	98,489
Non-current assets		
Property and equipment, net and other assets	352	474
Total assets	<u>\$ 93,259</u>	<u>\$ 98,963</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued development expenses	\$ 1,300	\$ 1,378
Deferred program fee revenue - current portion	10,897	10,897
Other accrued liabilities	1,603	997
Total current liabilities	13,800	13,272

Non-current liabilities		
Deferred program fee revenue - non-current portion	32,690	40,863
Other liabilities	<u>437</u>	<u>435</u>
Total liabilities	<u>46,927</u>	<u>54,570</u>
Stockholders' equity		
Common Stock and additional paid-in-capital	180,187	176,470
Accumulated other comprehensive income	2	128
Accumulated deficit	<u>(133,857)</u>	<u>(132,205)</u>
Total stockholders' equity	<u>46,332</u>	<u>44,393</u>
Total liabilities and stockholders' equity	<u>\$ 93,259</u>	<u>\$ 98,963</u>

(1) Derived from the Company's annual financial statements as of December 31, 2011, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

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