



## **Pain Therapeutics Announces 2010 Financial Results and Outlines Business Goals for 2011**

February 3, 2011

**REMOXY NDA: PDUFA Date in June**  
**LIKEABILITY STUDY RESULTS: APS Meeting in May**  
**MELANOMA SURVIVAL DATA: ASCO Meeting in June**

**\$91 Million in Cash, No Debt, Cash Requirements in 2011 under \$5 Million**

SAN MATEO, Calif., Feb. 3, 2011 (GLOBE NEWSWIRE) -- Pain Therapeutics, Inc. (Nasdaq:PTIE), a biopharmaceutical company, today reported financial results for the year ended December 31, 2010, provided an update on its cash position and outlined its business strategy for 2011.

Net loss for 2010 was \$12.0 million, or \$0.28 per share, (including a one-time, non-cash expense of \$14.8 million related to our special cash distribution to shareholders), compared to net loss for 2009 of \$3.5 million, or \$0.08 per share. At December 31, 2010, we had \$91 million of cash and no debt. We believe our cash requirements in 2011 will be under \$5 million, before giving effect to the approval and commercial launch of REMOXY®, our lead drug candidate.

Key expectations for 2011 include the regulatory review of REMOXY and its commercial launch by King Pharmaceuticals, Inc. ("King"), a wholly owned subsidiary of Pfizer, Inc. (NYSE:PFE), and the release of new clinical data on certain of our drug candidates.

"I see 2011 as a landmark year for Pain Therapeutics," said Remi Barbier, Chairman, President & CEO. "We have established a reputation as a leader in drug development for breakthrough products and we think this is the year when some of our key innovations come to fruition."

### **About REMOXY**

Our lead drug candidate, REMOXY (controlled-release oxycodone), is a strong painkiller with a unique abuse-resistant formulation designed to reduce potential risks of intentional abuse or accidental misuse.

- King Pharmaceuticals, a wholly owned subsidiary of Pfizer, is our exclusive, worldwide commercial partner for REMOXY and three other abuse-resistant prescription pain medications (except in Australia/New Zealand, where we retain commercial rights).
- In January 2011, we announced that the U.S. Food and Drug Administration (FDA) had accepted a New Drug Application (NDA) resubmission for REMOXY.
- The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of June 23, 2011.
- An advisory committee meeting for REMOXY is not expected at this time.
- King's funding obligations include reimbursing all of our development expenses for REMOXY and three other abuse-resistant pain medications that are in various stages of development, including hydrocodone, hydromorphone and oxymorphone.
- A Likeability Study was recently completed to evaluate the abuse potential of REMOXY in adults with histories of drug abuse. We anticipate results of this Likeability Study will be presented at the American Pain Society Annual Scientific Meeting, or APS, May 19-21 in Austin, Texas.
- Pain Therapeutics retains commercial rights to REMOXY and abuse-resistant drug candidates in Australia/New Zealand. We have not yet announced a market entry strategy for these territories.

### **REMOXY Related Milestone Payments and Royalty**

- To date, we have received from King total cash payments of \$185.0 million in program fees and milestone payments in connection with the development of REMOXY and other abuse-resistant drug candidates. We are eligible to receive up to \$120.0 million in additional 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 running royalty equal to 20% of net sales in the U.S., except as to the first \$1.0 billion in cumulative net sales, which royalty is set at 15%. Outside the U.S., the royalty rate is set at 10%.
- In addition, we will also receive from Pfizer a supplemental royalty fee payment of 6 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.

**Science Strategy** Our science strategy in 2011 is to spend carefully while keeping innovation at the top of our agenda. In general, we prefer to partner with academic groups to explore new scientific ideas, with reduced emphasis on internal discovery efforts that might create high fixed costs. Our R&D goals in 2011 will be to continue to focus on clinical stage drugs that can benefit from our core expertise in drug development, to outsource certain functions that permit the efficient deployment of our resources and to develop promising but un-partnered biotech assets.

In 2010, we made disciplined investments in two important disease areas — hemophilia and melanoma. We own commercial rights to all of our drug candidates in hematology/oncology.

Our biotechnology pipeline includes:

- A radio-labeled monoclonal antibody program, developed at Albert Einstein College of Medicine, is aimed at treating patients with late-stage (metastatic) melanoma. This drug candidate is called PTI-188.
- We've previously reported Phase I clinical data with PTI-188 in metastatic melanoma. Although efficacy was not a primary endpoint, clinical investigators were encouraged by the number of melanoma tumors that had either stabilized or decreased in size after a single dose of PTI-188.
- We expect survival results from two Phase I studies with PTI-188 will be presented at the 2011 American Society of Clinical Oncology Meeting, or ASCO, June 3-7<sup>th</sup> in Chicago, IL.
- We are developing a gene transfer program, developed at Stanford University, aimed at correcting an underlying genetic defect in patients with hemophilia. Importantly, no viral vector is utilized. Pre-clinical studies are on-going with this early-stage drug candidate.

## 2010 Financial Results

- On October 27, 2010, we declared a cash distribution of \$2.00 per share to shareholders, or an aggregate of about \$86 million. We completed this special, one-time nondividend distribution in December 2010. The nondividend distribution was paid entirely from cash reserves.
- In January 2011, we received \$2.1 million in research grants by the U.S. government under the Qualifying Therapeutic Discovery Project Program. These grants are planned to support on-going biomedical research for nervous system disorders and oncology.
- In January 2011, King paid us a \$5.0 million milestone payment in connection with the FDA's acceptance of our Investigational New Drug Application for abuse resistant oxymorphone, the fourth product candidate under our strategic alliance.
- Collaboration revenue for 2010 was \$1.3 million and reflects reimbursement of our development expenses under our strategic alliance with King.
- Research and development expenses for 2010 decreased to \$15.7 million from \$21.1 million for 2009. This decrease was primarily due to decreases in development activities for REMOXY, the timing of development activities for our other product candidates and reduction in research and development costs for grants awarded to us by the U.S. government. The decrease was offset in part by higher non-cash stock related compensation costs of \$10.3 million in 2010 (including \$7.4 million for one-time modifications made to stock options related to the special, one-time nondividend distribution), increased from \$4.0 million in 2009.
- General and administrative expenses for 2010 increased to \$14.8 million from \$6.3 million for 2009. This increase was mostly due to non-cash stock related compensation costs of \$9.9 million in 2010 (including \$7.4 million for one-time modifications made to stock options related to the special, one-time nondividend distribution), increased from \$2.7 million in 2009.
- We are in the process of relocating our principal place of business to Austin, Texas. In order to minimize potential

disruptions to our on-going operations, this relocation will take place gradually throughout 2011. Our intentions are to shift the Company's permanent headquarters and the entire actual direction, control, and coordination of our operations, from California to Texas.

#### About Pain Therapeutics, Inc.

Pain Therapeutics, Inc. is a biopharmaceutical company that develops novel drugs. In addition to REMOXY, a unique abuse-resistant controlled-release oxycodone, we have three drug candidates in clinical programs, including abuse-resistant formulations of hydromorphone, hydrocodone and oxymorphone, as well as a novel radio-labeled monoclonal antibody to treat metastatic melanoma. Pain Therapeutics is also working on a new treatment for patients with hemophilia, a genetic disorder in which patients are unable to stop bleeding. For more information, please visit [www.paintrials.com](http://www.paintrials.com).

The term "abuse-resistant" as used in this announcement is not intended to designate an indication or a medical claim but rather a general description of agents designed to address the misuse, abuse and diversion of opioids. The FDA has not approved any of our drug candidates for commercial sale.

REMOXY® is a registered trademark of Pain Therapeutics, Inc.

#### 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 timing of the FDA's review of the NDA for REMOXY; our anticipation that there will be no advisory committee meeting around REMOXY prior to the June PDUFA date; the timing associated with the completion of Pfizer's acquisition of King; expected cash requirements for 2011; potential milestone payments or other payments from King or Pfizer under the terms of our strategic alliance with King; the benefits of our lead drug candidate, REMOXY, including statements concerning its clinical efficacy; research and development and scientific goals; the presentation of clinical and other data at future scientific meetings; and our plans to relocate our corporate offices to Austin, Texas. 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 and pursuit of regulatory approval of our drug candidates, unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates (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 our intellectual property or trade secrets, unanticipated additional research and development and other costs; potential delay or prevention of the completion of the acquisition of King by Pfizer; the timing and receipt of funds from our commercial partner, the potential for abuse resistant pain medications to be developed by competitors and potential competitors. For further information regarding these and other risks related to our business, investors should consult our filings with the Securities and Exchange Commission.*

#### PAIN THERAPEUTICS, INC.

#### CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2010	2009	2010	2009 <sup>(1)</sup>
Revenue				
Program fee revenue	\$ 2,724	\$ 3,587	\$ 10,496	\$ 14,348
Collaboration revenue	285	142	1,313	6,215
Milestone revenue	5,000	--	5,000	--
Total revenue	8,009	3,729	16,809	20,563
Operating expenses				
Research and development	8,010	3,811	15,746	21,059
General and administrative	9,510	1,584	14,766	6,258
Total operating expenses	17,520	5,395	30,512	27,317
Operating loss	(9,511)	(1,666)	(13,703)	(6,754)
Interest income	340	544	1,680	1,777
Loss before benefit from income taxes	(9,171)	(1,122)	(12,023)	(4,977)
Benefit from income taxes	--	(825)	--	(1,510)
Net loss	\$ (9,171)	\$ (297)	\$ (12,023)	\$ (3,467)
Net loss per share - basic and diluted	\$ (0.21)	\$ (0.01)	\$ (0.28)	\$ (0.08)

Weighted-average shares used in computing net income loss per share - basic and diluted	42,797	42,275	42,644	42,165
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CONDENSED BALANCE SHEETS

	December 31,	
	2010	2009 <sup>(1)</sup>
	(Unaudited)	
<b>Assets</b>		
Current assets		
Cash, cash equivalents and marketable securities	\$ 91,226	\$ 175,759
Receivables	7,114	2,302
Other current assets	144	410
Total current assets	98,484	178,471
Non-current assets		
Property and equipment, net	285	517
Other assets	426	3,017
Total assets	\$ 99,195	\$ 182,005
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable and accrued development expenses	\$ 1,365	\$ 2,538
Deferred program fee revenue - current portion	10,897	14,348
Other accrued liabilities	1,809	1,625
Total current liabilities	14,071	18,511
Non-current liabilities		
Deferred program fee revenue - non-current portion	51,760	53,805
Other liabilities	431	1,437
Total liabilities	66,262	73,753
Stockholders' equity		
Common stock	43	42
Additional paid-in-capital	161,957	225,432
Accumulated other comprehensive income	525	347
Accumulated deficit	(129,592)	(117,569)
Total stockholders' equity	32,933	108,252
Total liabilities and stockholders' equity	\$ 99,195	\$ 182,005

(1) Derived from the Company's annual financial statements as of December 31, 2009, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

CONTACT: Judy Ishida

Administrative Manager

Pain Therapeutics, Inc.

IR@paintrials.com

650-645-1924