Pain Therapeutics Announces 2009 Financial Results, Outlines Business Priorities

- $176 Million of Cash, No Debt -

- Cash Requirement in 2010 Under $10 Million -

- REMOXY® NDA Resubmission Still Anticipated in 2010 -

SAN MATEO, Calif., Jan. 28, 2010 (GLOBE NEWSWIRE) -- Pain Therapeutics, Inc. (Nasdaq:PTIE), a biopharmaceutical company, today reported financial results for the year ended December 31, 2009, provided an update on its cash position and outlined its business strategy for maintaining financial strength in 2010.

Net loss for 2009 was $3.5 million, or $0.08 per share, compared to net income of $15.3 million, or $0.35 per share, for 2008.

At December 31, 2009, Pain Therapeutics had cash, cash equivalents and marketable securities of $175.8 million, or about $4.16 per share, no debt and approximately 42.3 million shares outstanding. We expect our cash requirements in 2010 to be under $10.0 million.

“We think our business model is performing well,” said Remi Barbier, Pain Therapeutics’ chairman, president and chief executive officer. “We continue to operate the business with discipline, to focus on innovation and to advance our pipeline. These are also core elements of our business strategy for 2010. We’re a small company taking on some of the toughest challenges in medical research, yet with a REMOXY NDA resubmission within sight and new hematology/oncology data coming this quarter, we think we’re positioned to win in 2010.”

REMOXY in 2010

Pain Therapeutics remains committed to the regulatory success of REMOXY, our lead drug candidate. REMOXY is a strong painkiller with a unique formulation designed to reduce potential risks of unintended use. REMOXY and other abuse-resistant painkillers are being developed pursuant to a strategic alliance we have with King Pharmaceuticals, Inc. We believe REMOXY represents the rare combination of a well-partnered, late-stage drug asset with a unique profile, and whose clinical efficacy has been substantially de-risked.

- Pursuant to the terms of the strategic alliance, King funds our development expenses incurred by us for REMOXY and three other abuse-resistant pain medications.
- From 2005 to 2008, we and King jointly managed a Phase III clinical program and New Drug Application (NDA) for REMOXY. In mid-2008, the U.S. Food and Drug Administration (FDA) accepted an NDA for REMOXY with Priority Review.
- In December 2008, we received from the FDA a Complete Response Letter which indicated additional non-clinical data is required to support the approval of REMOXY. The FDA has not requested or recommended additional clinical efficacy studies prior to approval.
- In March 2009, King assumed sole responsibility for the regulatory approval of REMOXY. This shift of responsibility does not change the economic terms of our strategic alliance with King.
- In July 2009, King met with the FDA to discuss REMOXY. As a result of this meeting, King anticipates a resubmission of the REMOXY NDA in 2010.
- Upon FDA approval of REMOXY, we will receive a $15.0 million cash milestone payment and a running royalty equal to 20% of net sales of drugs developed under this strategic alliance, except as to the first $1.0 billion in cumulative net sales, which royalty is set at 15%.
- To date, King has made milestone payments to us of $25.0 million. We could receive from King up to $125.0 million in additional milestone payments in the course of the clinical and regulatory development of REMOXY and three other abuse-resistant pain medications.

Hematology/Oncology in 2010

Our corporate strategy is to spend carefully but to keep innovation at the top of our agenda. In 2009, we made disciplined investments in two important disease areas -- hemophilia and melanoma. We expect to announce new data in both disease areas in Q1 2010. We own commercial rights to all of our drug candidates in hematology/oncology.

- 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.
- In Q4 2009, we completed enrollment in our second Phase I study in Israel with PTI-188. In this study, researchers treated three cohorts of patients with metastatic melanoma using PTI-188.
- We have 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.
- In Q4 2009, we completed a pre-clinical study with our gene transfer technology.

2009 Financial Results

- Collaboration revenue for 2009 was $6.2 million, compared to $29.4 million for 2008, and reflects reimbursement of our development expenses under our strategic alliance with King.
- Research and development expenses for 2009 decreased to $21.1 million from $45.8 million for 2008. This decrease was mostly due to decreased spending by us for REMOXY and other abuse-resistant product candidates under our strategic alliance with King, as well as lower non-cash stock-related compensation. Research and development expenses included non-cash stock-related compensation of $4.0 million for 2009 and $6.1 million for 2008.
- General and administrative expenses for 2009 decreased to $6.3 million from $9.2 million for 2008. This decrease was mostly due to lower non-cash equity related costs as well as lower operating costs. General and administrative expenses included non-cash stock-related compensation of $2.7 million for 2009 and $4.1 million for 2008.
- Interest income for 2009 decreased to $1.8 million from $6.0 million for 2008. This decrease was mostly due to decreases in interest rates on our investments in marketable securities.

About Pain Therapeutics, Inc.

Pain Therapeutics, Inc. is a biopharmaceutical company that develops novel drugs. Our lead drug candidate, REMOXY, is a strong painkiller with a unique formulation designed to reduce potential risks of unintended use. We are also developing novel drugs in the area of hematology/oncology. We have in clinical development a monoclonal antibody to treat metastatic melanoma, a deadly form of skin cancer. We also have in pre-clinical development a drug candidate to treat hemophilia, a genetic disorder in which patients are unable to stop bleeding. 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 timing of King's resubmission of the NDA for REMOXY in 2010; our cash requirements for 2010; expected timing of announcements regarding clinical trials and non-clinical studies; our expected receipt of milestone payment or other revenue under our collaboration with King, including reimbursement of our ongoing development activities under the collaboration with King; and the benefits of our drug candidate, REMOXY, including statements concerning its clinical efficacy. 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 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), unanticipated additional research and development and other costs and the timing and receipt of funds from our commercial partner, potential disputes arising with our strategic partners, potential claims of violating the patent rights of third parties, the uncertainty of patent protection for our intellectual property or trade secrets, and the potential for abuse and misuse 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,	
	2009	2008	2009	2008
Revenue				
Collaboration revenue	$142	$4,658	$6,215	$29,377
Program fee revenue	3,587	3,587	14,348	14,348
Milestone revenue	--	--	--	20,000
Total revenue	3,729	8,245	20,563	63,725
Operating expenses				
Research and development	3,811	9,190	21,059	45,817
General and administrative	1,584	1,927	6,258	9,196
Total operating expenses	5,395	11,117	27,317	55,013
Operating income (loss)	(1,666)	(2,872)	(6,754)	8,712
Interest income	544	866	1,777	6,018
Income (loss) before income taxes	(1,122)	(2,006)	(4,977)	14,730
Benefit from income taxes	(825)	(617)	(1,510)	(617)
Net income (loss)	$(297)	$(1,389)	$(3,467)	$15,347
Net income (loss) per share				
Basic	$(0.01)	$(0.03)	$(0.08)	$0.36
Diluted	$(0.01)	$(0.03)	$(0.08)	$0.35
Weighted-average shares used in computing net income (loss) per share				
Basic	42,275	42,044	42,165	42,252
Diluted	42,275	42,044	42,165	43,857

CONDENSED BALANCE SHEETS

	December 31,	
	2009	2008[1]
	(Unaudited)	
Assets		
Current assets		
Cash, cash equivalents and marketable securities	$175,759	$190,095
Other current assets	2,712	541
Total current assets	178,471	190,636
Non-current assets		
Property and equipment, net	517	774
Other assets	3,017	2,026
Total assets	$182,005	$193,436
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued development expenses	$2,538	$3,245
Deferred program fee revenue - current portion	14,348	14,348

Other accrued liabilities	1,625	2,521
Total current liabilities	18,511	20,114
Non-current liabilities		
Deferred program fee revenue - non-current portion	53,805	68,154
Other liabilities	1,437	882
Total liabilities	73,753	89,150
Stockholders' equity		
Common stock	42	42
Additional paid-in-capital	225,432	218,021
Accumulated other comprehensive income	347	325
Accumulated deficit	(117,569)	(114,102)
Total stockholders' equity	108,252	104,286
Total liabilities and stockholders' equity	$182,005	$193,436

(1) Derived from the Company’s annual financial Statements as of December 31, 2008, included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission.

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