



Pain Therapeutics Reports 2017 Financial Results and Corporate Update

February 5, 2018

– 2018 Focus will be on REMOXY, Fiscal Discipline and Advancing Pipeline –

AUSTIN, Texas, Feb. 05, 2018 (GLOBE NEWSWIRE) -- Pain Therapeutics, Inc. (Nasdaq:PTIE) today reported financial results for the year ended December 31, 2017. Net loss in 2017 was \$11.9 million, or \$1.82 per share, compared to a net loss in 2016 of \$14.9 million, or \$2.28 per share.

Net cash used during the year ended December 31, 2017 was \$8.2 million. Cash and investments were \$10.5 million as of December 31, 2017, with no debt. We believe net cash usage in 2018 will decrease significantly compare to 2017 and may be in the range of \$5-6 million.

"In 2018, our focus will be on REMOXY and its potential to receive marketing clearance this year," said Remi Barbier, Chairman, President & CEO. "As part of this focus, we intend to resubmit the REMOXY NDA to the FDA in Q1 with Priority Review; to maintain fiscal discipline; and to advance the progress of our earlier-stage programs with non-dilutive funding."

Financial Highlights for 2017

- At December 31, 2017, cash and investments were \$10.5 million, compared to \$18.7 million for the same period in 2016. We have no debt.
- Net cash used in the year ended December 31, 2017 was \$8.2 million.
- We received \$1.4 million in research grant funding in the year ended December 31, 2017 from the National Institutes of Health (NIH) that we recorded as a reduction to our research and development expenses.
- Research and development expenses for the year ended December 31, 2017 decreased to \$7.6 million, from \$9.2 million for the same period in 2016, primarily due to decreases in REMOXY® ER (oxycodone CII) related expenses and non-cash stock related compensation costs as compared to the same period in 2016. Research and development expenses included non-cash stock related compensation costs of \$1.2 million for the year ended December 31, 2017 and \$1.8 million for the same period in 2016.
- General and administrative expenses for the year ended December 31, 2017 decreased to \$4.3 million, respectively, from \$5.8 million for the same period in 2016, primarily due to a decrease in non-cash stock related compensation costs as compared to the same period in 2016. General and administrative expenses included non-cash stock-related compensation costs of \$1.8 million in the year ended December 31, 2017 and \$2.6 million for the same period in 2016.

Operating Highlights for 2017

- In Q4, we concluded a 'pre-NDA' meeting with the U.S. Food and Drug Administration (FDA), which gives us regulatory clearance to resubmit the New Drug Application (NDA) for REMOXY in Q1 2018 with Priority (six-month) Review.
- In Q4, we concluded a successful nasal abuse potential study with REMOXY, whereby peak oxycodone concentrations (Cmax) were at least 4-fold lower for REMOXY compared to crushed OxyContin® ER (oxycodone HCl) or oxycodone immediate-release (p<0.01).
- In Q4, we concluded a series of successful in vitro studies comparing the abuse potential of REMOXY to OxyContin® ER and Xtampza® ER (oxycodone) in various household liquids.
- In Q2, we filed an Investigational New Drug (IND) application with the FDA for PTI-125, a small molecule drug to treat Alzheimer's disease. In Q4, we announced successful results of a first-in-human, Phase I clinical study with PTI-125.
- In Q2 and in Q4, we announce new scientific publications in peer-reviewed journals regarding our program in Alzheimer's disease.
- In Q1, we announced written agreement was reached with the FDA on additional studies needed for REMOXY's regulatory approval.
- Throughout 2017, we announced that the National Institutes of Health (NIH) had awarded us research grants following a competitive, peer-reviewed evaluation of our technology for scientific and technical merit. Research awards included a grant to develop a simple blood-test to detect Alzheimer's disease; a grant to study PTI-125, our clinical drug candidate to treat Alzheimer's disease; and a grant to further develop FENROCK, an abuse-deterrent transdermal patch.

Our Pipeline of Drug Assets Includes:

REMOXY ER (extended-release oxycodone CII) – Proprietary abuse-deterrent, twice-daily, oral oxycodone capsules for severe chronic pain. NDA resubmission remains on-track for resubmission to the FDA in Q1 2018.

FENROCK™ (transdermal fentanyl patch system) – Proprietary abuse-deterrent skin patch for severe pain. Early-stage program, substantially funded by a research grant award from National Institute on Drug Abuse (NIDA).

PTI-125 – Proprietary small molecule drug for the treatment of Alzheimer's disease. Phase I clinical-stage program, substantially funded by a research grant award from the National Institutes of Health (NIH).

PTI-125Dx – Blood-based diagnostic/biomarker to detect Alzheimer's disease. Early-stage program, substantially funded by a research grant award from the NIH.

We own worldwide commercial rights to all of our drug assets.

About REMOXY ER (extended-release oxycodone capsules CII)

REMOXY ER is a proprietary, abuse-deterrent, extended-release oral formulation of oxycodone. The proposed indication for this drug candidate is for "the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." We developed REMOXY to make oxycodone difficult to abuse yet provide 12 hours of steady pain relief when used appropriately by patients. In particular, REMOXY's thick, sticky, high-viscosity gel-cap formulation may deter unapproved routes of drug administration, such as injection, snorting or smoking.

About Opioid Abuse

Opioid drugs such as oxycodone are an important treatment option for patients with severe chronic pain. However, oxycodone abuse and diversion remain serious, persistent problems. Drug overdose deaths exceeded 64,000 in 2016, according to the Center for Disease Control (CDC). For over a decade, we have pioneered Abuse-Deterrent Formulations (ADFs) to help in the fight against prescription drug abuse. ADFs attempt to raise the bar on prescription drug abuse by making it more difficult, longer or aversive to tamper with long-acting opioid formulations, recognizing that no drug can be made abuse-proof.

About Pain Therapeutics, Inc.

We develop proprietary drugs that offer significant improvements to patients and physicians. Our expertise consists of developing new drugs and guiding these through various regulatory and development pathways in preparation for their eventual commercialization. We generally focus our drug development efforts around disorders of the nervous system. The FDA has not yet established the safety or efficacy of our drug candidates.

NOTE: REMOXY™ ER and FENROCK™ are trademarks 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, statements regarding the abuse potential of our drug candidates; the planned resubmission of the REMOXY NDA in a timely matter or our expected use of cash in 2018. 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 development and testing of our drug candidates; unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates; the uncertainty of patent protection for our intellectual property or trade secrets; unanticipated additional research and development, litigation and other costs; and the potential for abuse-deterrent pain medications or other competing products to be developed by competitors and potential competitors or others. For further information regarding these and other risks related to our business, investors should consult our filings with the U.S. Securities and Exchange Commission.*

– Financial Tables Follow –

PAIN THERAPEUTICS, INC.

CONDENSED STATEMENTS OF OPERATIONS

(unaudited, in thousands, except per share amounts)

	Three Months Ended December 31,		Years Ended December 31,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	1,544	1,335	7,615	9,176
General and administrative	879	1,208	4,334	5,781
Total operating expenses	2,423	2,543	11,949	14,957
Operating loss	(2,423)	(2,543)	(11,949)	(14,957)
Interest income	5	21	38	107
Net loss	\$ (2,418)	\$ (2,522)	\$ (11,911)	\$ (14,850)
Net loss per share, basic and diluted	\$ (0.37)	\$ (0.39)	\$ (1.82)	\$ (2.28)
Weighted-average shares used in computing net loss per share, basic and diluted	6,538	6,535	6,537	6,520

CONDENSED BALANCE SHEETS

(in thousands)

	December 31, 2017	2016
Assets		
Current assets		
Cash, cash equivalents	\$ 10,479	\$ 16,615
Marketable securities	—	2,099

Other current assets	184		356
Total current assets	10,663		19,070
Other non-current assets	168		232
Total assets	\$ 10,831		\$ 19,302
Liabilities and stockholders' equity			
Current liabilities			
Accounts payable	\$ 424		\$ 303
Accrued development expense	399		27
Other accrued liabilities	309		335
Total current liabilities	1,132		665
Total liabilities	1,132		665
Stockholders' equity			
Common stock	7		7
Additional paid-in-capital	167,091		164,118
Accumulated other comprehensive income	—		—
Accumulated deficit	(157,399)	(145,488
Total stockholders' equity	9,699		18,637
Total liabilities and stockholders' equity	\$ 10,831		\$ 19,302

For More Information Contact:

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