



Pain Therapeutics, Inc.

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Pain Therapeutics Reports 2015 Financial Results and Corporate Update

– Focus in 2016 will be on REMOXY, Fiscal Discipline and Advancing Pipeline –

AUSTIN, Texas – March 1, 2016 – Pain Therapeutics, Inc. (Nasdaq: PTIE) today reported financial results for the year ended December 31, 2015. Net loss in 2015 was \$14.1 million, or \$0.31 per share, compared to a net loss in 2014 of \$12.4 million, or \$0.27 per share.

Cash and investments were \$31.3 million as of December 31, 2015, with no debt. We expect net cash usage for the first half of 2016 will be approximately \$8 million.

“In 2016, our focus will be on REMOXY and its potential to receive marketing clearance in the second half of this year”, said Remi Barbier, Chairman, President & CEO. “As part of this focus, we intend to select a commercialization strategy for REMOXY, to maintain fiscal discipline and to advance the progress of our two earlier-stage drug candidates, FENROCK and PTI-125.”

About the NDA for REMOXY® (oxycodone capsules CII)

The REMOXY New Drug Application (NDA) is on schedule to be filed with the FDA in March 2016. The NDA has priority review status with the FDA. We expect a review cycle of about six months. This is a 505(b)(2) NDA resubmission for five dosage strengths of REMOXY (5, 10, 20, 30, 40 mg). The drug's proposed indication 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". The safety and clinical efficacy of REMOXY is supported by multiple studies, including a successful Phase III efficacy program conducted under an FDA Special Protocol Assessment. REMOXY's abuse-deterrence is supported by a body of clinical and non-clinical data, including data comparing REMOXY against currently marketed oxycodone products. The NDA will propose label claims that properly characterize REMOXY's abuse-deterrent properties, including certain routes of abuse that REMOXY may deter, such as injection, snorting or smoking. The NDA also includes stability data that we believe meet FDA guidance criteria in support of a 24-month shelf life.

About REMOXY's Potential Commercialization

REMOXY targets the \$2.5 billion marketplace for long-acting oxycodone. Despite this impressive commercial figure, we believe opioid abuse in the U.S. remains a serious, persistent problem. We own exclusive, worldwide rights to REMOXY. We continue to review potential launch and commercialization strategies for REMOXY. Options include a potential strategic transaction around all of our drug candidates; a commercial collaboration for REMOXY; or establishing commercial capabilities in-house to launch REMOXY on our own. If approved and granted appropriate label claims, we believe REMOXY may have potential to distinguish itself from competitors with:

- ✓ best-in-class abuse-deterrent properties;
- ✓ true twice-daily dosing;
- ✓ minimal food effect;
- ✓ lack of generic drug substitution; and
- ✓ over 15 years of intellectual property protection.

Pipeline Update

- **FENROCK™** - This drug candidate is a proprietary, abuse-deterrent pain patch. FENROCK's active drug ingredient is extended-release transdermal fentanyl (CII), a highly addictive opioid drug that is up to 50 times more powerful than morphine. Currently marketed transdermal fentanyl patches are typically used to manage severe chronic pain, but are also easily abused and have been blamed for thousands of deaths across the U.S. Fentanyl abuse is dangerous. A single episode of fentanyl abuse can lead to overdose, respiratory depression or death. Our goal with FENROCK is to make the fentanyl pain patch difficult to abuse yet provide 72 hours of steady pain relief when used appropriately by patients. We developed FENROCK in-house. We are currently working with outside collaborators on the development of a final formulation of FENROCK. We believe a final formulation will enable us to file an Investigational New Drug Application (IND) with the FDA. Pain Therapeutics owns exclusive, worldwide rights to FENROCK without royalty or milestone obligations to any third-party.

- **PTI-125** - This small molecule drug candidate offers a promising new approach to treat Alzheimer's Disease and other neurological disorders. PTI-125, an oral drug, was designed in-house and characterized by outside collaborators. The science that underlies PTI-125 was initially published in *The Journal of Neuroscience* (2012-32:9773-9784). The National Institutes of Health (NIH) awarded us a \$1,725,000 innovation grant in September 2015. This grant was awarded to us following an in-depth evaluation of PTI-125 for scientific and technical merit by academic, clinical and industry experts in neurological disorders. The NIH grant award enables us to fund and conduct pre-clinical studies around PTI-125. We expect results of these on-going studies may enable us to file an IND with the FDA. Pain Therapeutics owns exclusive, worldwide rights to PTI-125 without royalty or milestone obligations to any third-party.

Financial Highlights for 2015

- At December 31, 2015, cash and investments were \$31.3 million, compared to \$34.9 million at September 30, 2015. The Company has no debt.
- Net cash used in 2015 was \$9.3 million.
- Research and development expenses increased to \$9.1 million in 2015 from \$7.3 million in 2014, primarily due to increased activities related to REMOXY, and included non-cash stock-related compensation costs of \$1.2 million in 2015 and \$1.6 million in 2014.
- General and administrative expenses were \$5.1 million in both 2015 and 2014 and included non-cash stock-related compensation costs of \$2.3 million in 2015 and \$2.1 million in 2014.

About REMOXY (oxycodone capsules CII)

REMOXY is a proprietary, abuse-deterrent, oral formulation of extended-release oxycodone (CII). The drug's proposed indication 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 formulation may deter unapproved routes of drug administration, such as injection, snorting or smoking. REMOXY targets the \$2.5 billion marketplace for long-acting oxycodone. We own exclusive, worldwide rights to REMOXY. The FDA has not yet established the safety or efficacy of REMOXY.

About Opioid Abuse

Opioid drugs are an important treatment option for patients with severe chronic pain. However, misuse, abuse and diversion of these prescription drugs remains a serious, persistent problem. Nearly 19,000 people died from opioid overdose in 2014, according to the NIH's National Institute on Drug Abuse. 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 a long-acting opioid formulation, recognizing that no drug or drug formulation 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, such as chronic pain. The FDA has not yet established the safety or efficacy of our drug candidates.

NOTE: REMOXY[®] 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 our projected net cash usage in the first half of 2016; potential marketing clearance in the second half of this year for REMOXY; our intention to select a commercialization strategy for REMOXY; the filing of the REMOXY NDA in March 2016; the proposed indication for REMOXY; actual contents of the REMOXY NDA; the potential for REMOXY to distinguish itself from competitors; plans to develop FENROCK and PTI-125; and the potential benefits of FENROCK and PTI-125. 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 completion of non-clinical activities for REMOXY and development and testing of our other 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; the potential for abuse-deterrent pain medications or other competing products to be developed by competitors and potential competitors or others; and difficulties or delays in developing FENROCK and PTI-125 and the results of our pre-clinical studies of PTI-125 not supporting further development, which could result in termination of NIH funding prior to receipt of the entire \$1.7 million grant. 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.*

| PAIN THERAPEUTICS, INC. | | | | |
|---|------------------------------------|---------------------|-----------------------------|---------------------|
| CONDENSED STATEMENTS OF OPERATIONS | | | | |
| (unaudited, in thousands, except per share amounts) | | | | |
| | Three Months Ended December 31, | | Years Ended December 31, | |
| | 2015 | 2014 ⁽¹⁾ | 2015 | 2014 ⁽¹⁾ |
| Operating expenses: | | | | |
| Research and development | 3,620 | 1,108 | 9,100 | 7,306 |
| General and administrative | 914 | 1,059 | 5,102 | 5,127 |
| Total operating expenses | 4,534 | 2,167 | 14,202 | 12,433 |
| Operating loss | (4,534) | (2,167) | (14,202) | (12,433) |
| Interest income | 17 | 11 | 57 | 47 |
| Net loss | \$ (4,517) | \$ (2,156) | \$ (14,145) | \$ (12,386) |
| Net loss per share, basic and diluted | \$ (0.10) | \$ (0.05) | \$ (0.31) | \$ (0.27) |
| Weighted-average shares used in computing net loss per share, basic and diluted | 45,756 | 45,356 | 45,756 | 45,269 |
| CONDENSED BALANCE SHEETS | | | | |
| (in thousands) | | | | |
| | December 31, | | | |
| | | | 2015 | 2014 ⁽¹⁾ |
| | | | (Unaudited) | |
| Assets | | | | |
| Current assets | | | | |
| Cash, cash equivalents and marketable securities | | | \$ 31,299 | \$ 40,590 |
| Other current assets | | | 392 | 239 |
| Total current assets | | | 31,691 | 40,829 |
| Other non-current assets | | | 227 | 77 |
| Total assets | | | \$ 31,918 | \$ 40,906 |
| Liabilities and stockholders' equity | | | | |
| Current liabilities | | | | |
| Accounts payable and accrued development expenses | | | \$ 1,928 | \$ 198 |
| Other accrued liabilities | | | 623 | 652 |
| Total current liabilities | | | 2,551 | 850 |
| Total liabilities | | | 2,551 | 850 |
| Stockholders' equity | | | | |
| Common stock | | | 46 | 46 |
| Additional paid-in-capital | | | 159,959 | 156,502 |
| Accumulated other comprehensive income | | | — | 1 |
| Accumulated deficit | | | (130,638) | (116,493) |
| Total stockholders' equity | | | 29,367 | 40,056 |
| Total liabilities and stockholders' equity | | | \$ 31,918 | \$ 40,906 |

(1) Derived from the Company's annual financial statements as of December 31, 2014, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

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