



## **Pain Therapeutics, Inc.**

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### **FDA Accepts REMOXY NDA for Review, Sets PDUFA Date of September 25, 2016**

- Company Will Host Conference Call on Wednesday, April 13<sup>th</sup>, 8:30am EDT -**
- Guest Speaker Invited to Discuss REMOXY's Target Market -**

AUSTIN, Texas, April 12, 2016 – Pain Therapeutics, Inc. (Nasdaq: PTIE) announced today that the U.S. Food and Drug Administration (FDA) has determined that the New Drug Application (NDA) resubmission for REMOXY<sup>®</sup>, an abuse-deterrent formulation of extended-release oxycodone (CII) capsules, is sufficiently complete to permit a substantive review. September 25, 2016 is the target action date under the Prescription Drug User Fee Act (PDUFA).

“The acceptance of the REMOXY NDA marks another important milestone for Pain Therapeutics,” said Remi Barbier, President and Chief Executive Officer of Pain Therapeutics. “We are grateful to the people, partners and patient investors who are helping to make this innovation a reality. We look forward to working closely with the FDA during the regulatory review process.”

### **About the Conference Call**

Pain Therapeutics will host a conference call on **Wednesday, April 13<sup>th</sup> at 8:30am EDT** to discuss the REMOXY NDA and this drug candidate's target market. Guest speaker Mr. John LaLota, a consultant to Pain Therapeutics, will join the call. Mr. LaLota has over 25 years of management experience in the analgesic marketplace. Having directed 6 major launch campaigns in the analgesic area, he is recognized as a foremost expert in the commercialization of analgesics. Major brands under Mr. LaLota's direction during his tenure at Johnson & Johnson, Wyeth and Knoll included the pain drugs Duragesic<sup>®</sup>, Orudis<sup>®</sup> and Vicodin<sup>®</sup>. Under his commercial direction, all three drugs became market leaders within 2 years of launch.

**To participate in this conference call please dial toll-free 1-877-407-4018 (U.S.) or 1-201-689-8471 (international).**

Those interested in listening to the conference call live via the internet may do so by visiting [www.paintrials.com](http://www.paintrials.com). About two hours following the live call, a replay of the conference call will be available by phone through April 20, 2016. To listen to a replay of the call, please dial toll-free 1-877-870-5176 (U.S.) or 1-858-384-5517 (international) and press pin number 1363-5239.

### **About REMOXY (oxycodone capsules CII)**

REMOXY is a proprietary, abuse-deterrent, oral formulation of extended-release oxycodone (CII). 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 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.

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### **About Opioid Abuse**

Opioid drugs such as oxycodone are an important treatment option for patients with severe chronic pain. However, oxycodone abuse and diversion remains a serious, persistent problem. Nearly 19,000 people died from opioid overdose in 2014, according to the National Institute on Drug Abuse. For over a decade, Pain Therapeutics has 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 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, such as chronic pain. The FDA has not yet established the safety or efficacy of our drug candidates.

*NOTE: REMOXY® is a 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, statements regarding the PDUFA target action date; potential marketing clearance, and any potential timing for regulatory approval, for REMOXY; the proposed indication for REMOXY; and the potential for REMOXY to deter unapproved routes of administration. 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 gaining full regulatory approval for REMOXY; 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 results of our clinical or pre-clinical studies with REMOXY not supporting further development. 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.***

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