Pain Therapeutics, Inc.

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Complete Response Letter for REMOXY®

- Company Will Host Conference Call Monday, September 26th at 9:00am EDT -

AUSTIN, TX – September 26, 2016 – Pain Therapeutics, Inc. (Nasdaq: PTIE) announced today that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) on the resubmission of its new drug application (NDA) for REMOXY ER (oxycodone capsules CII). The CRL informs that REMOXY ER cannot be approved in its present form and specifies additional actions and data that are needed for drug approval.

The CRL focuses on the abuse-deterrent properties of REMOXY ER and proposed drug labeling. The CRL makes no mention of clinical safety, drug efficacy, manufacturing, stability, bioequivalence or any other issues from a prior Complete Response Letter.

Pain Therapeutics is evaluating the CRL and plan further discussions with the FDA. The CRL specifies additional actions that are needed in order to obtain approval of REMOXY ER with label claims against three routes of abuse (i.e., injection, inhalation and snorting). These actions may take approximately a year to conduct and may cost approximately $5MM, pending discussions with the FDA and outside clinical/regulatory consultants.

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Conference Call

Pain Therapeutics will host a conference call on **Monday, September 26th at 9:00am Eastern time** to discuss the Complete Response Letter. 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. About two hours following the live call, a replay of the conference call will be available by phone through October 3, 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 1212590.

Details of the Complete Response Letter (CRL)

The CRL focuses on the actions and studies that are needed in order to obtain approval of REMOXY ER with label claims on three routes of abuse (i.e., injection, inhalation and snorting). In conducting the following studies, we will generally compare REMOXY ER vs. one or more commercially available oxycodone ER drug product:

- **To support a potential drug label claim against abuse by injection:** Repeat an injectability/syringeability study using thin films of drug, smaller volumes of solvents, additional mixed solvents and alternative extraction methods and syringe filter.

- **To support a potential drug label claim against abuse by inhalation:** Repeat a volatilization study using the same thickness for each drug to increase surface area.

- **To support a potential drug label claim against abuse by snorting:** Conduct an intranasal abuse potential study in human volunteers (i.e., not the animal data we had submitted) with drug applied directly inside the human nasal cavity.

In addition, we had proposed in the REMOXY NDA a label claim against abuse by chewing. Our proposal was based on clinical results of an oral human abuse potential study that met all four co-primary endpoints with statistical significance and that also met several, but not all, secondary endpoints. The CRL asks us to submit a revised proposed label to indicate results of this study do not support a label claim against abuse by chewing.

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.

Important 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 potential discussions with the FDA; the abuse-deterrent properties and potential benefits of REMOXY ER; the estimated time period that may be required to take the actions requested by the FDA and the estimated cost of taking such actions. Such statements are based on management's current expectations but actual results may vary materially due to various factors, many of which are beyond the control of management. Drug development involves substantial risks and uncertainties, including but not limited to those risks and uncertainties relating to successfully completing the activities required to address the issues raised by the FDA in the CRL and the time required to do so, including the time required to reach resolution with the FDA on the scope of the appropriate actions to be undertaken, the FDA's continuing review of REMOXY ER, the possibility that the FDA may raise additional issues in the future that were not raised in the past, unexpected adverse side effects and inadequate therapeutic efficacy. In addition, the development of abuse-deterrent drug products is a young and still emerging area of drug development, with regulatory guidance that may be inconsistent, unclear or still in development. Such statements are based on management's current expectations, but actual results may differ materially due to various factors. 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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