Complete Response Letter Issued for REMOXY™

August 6, 2018

- Corporate Reorganization Expected Shortly -

AUSTIN, Texas, Aug. 06, 2018 (GLOBE NEWSWIRE) -- Pain Therapeutics, Inc. (Nasdaq: PTIE) today announced it had received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for REMOXY, an abuse-deterrent, extended-release form of oxycodone. According to FDA, "The data submitted in [the] NDA do not support the conclusion that the benefits of [REMOXY] Extended-Release Capsules outweigh the risks."

"This is a bizarre conclusion to reach, especially during a time of staggering human and economic toll created by opioid abuse and addiction," said Remi Barbier, President & CEO. "We have an innovative drug with a social purpose, and a staggering amount of data that easily supports best-in-class abuse deterrence versus OxyContin. We relied on the criteria of a fair, neutral and impartial regulatory review, as any sponsor would. Instead, I believe REMOXY received an ideological judgement call that is vague in nature but conclusive in its damaging effects."

Strategic Reorganization Expected to be Announced Shortly
The Company has initiated a strategic reorganization to align its resources on advancing its drug and diagnostic assets in Alzheimer's disease. Full details of the Company's reorganization plan, including specific milestones and measures of clinical progress, will be shared with the public via conference call within weeks, after the reorganization is finalized.

The Company believes its program in Alzheimer's disease has game-changing characteristics. PTI-125, the lead drug candidate, is a small molecule that has a unique mechanism of action for treating Alzheimer's disease. The underlying science for PTI-125 is published in prestigious technical journals, including *Journal of Neuroscience*, *Neurobiology of Aging,* and *Neuroimmunology and Neuroinflammation*, with additional publications pending. PTI-125 recently completed a successful Phase I clinical-stage program, funded by a peer-reviewed research grant from the National Institutes of Health (NIH).

The Company's other asset in Alzheimer's is a simple blood test, called PTI-125DX, to detect or confirm whether a person has Alzheimer's, even years before symptoms appear. An early diagnosis of Alzheimer's could allow treatment to start sooner, optimize treatment options for each individual and improve chances to slow or halt the disease. This promising early-stage program is substantially funded by a research grant award from the NIH.

"Alzheimer's disease is a therapeutic indication with a profound need for new treatments," said Remi Barbier, President & CEO. "A reorganization of the Company represents a natural and timely evolution of the strength of our program in Alzheimer's disease."

About Pain Therapeutics, Inc.
We develop proprietary drugs that offer significant improvements to patients and physicians. 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 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 future of REMOXY following the FDA's issuance of another Complete Response Letter; the reorganization of the Company's resources, and the timing of public announcements regarding such reorganization; and the potential benefits of the Company's program in Alzheimer's disease. 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 our financial and operational ability to carry out development activities around Alzheimer's disease. 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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