



Pain Therapeutics, Inc.

For More Information Contact:

Peter S. Roddy
Vice President and Chief Financial Officer
Pain Therapeutics, Inc.
proddy@paintrials.com
512-501-2450

FOR IMMEDIATE RELEASE

Pain Therapeutics Announces Update on Drug Portfolio

- Conference Call Tomorrow, Tuesday, at 4:30 p.m. Eastern Time -

AUSTIN, TX – May 11, 2015 – Pain Therapeutics, Inc., (Nasdaq:PTIE) today announced an update regarding its portfolio of drug candidates. After staying quiet for the past six months, management expects an uptick in news flow for the rest of 2015. Expected milestones include a clear path to the FDA for re-filing the REMOXY NDA, announcement of proof-of-concept results for an abuse deterrent transdermal pain patch and announcement of non-dilutive funding for a new drug development initiative in a major indication.

“We’ve substantially completed the transition of REMOXY from our previous corporate partner,” said Remi Barbier, President and CEO of Pain Therapeutics. “We believe the data we’ve seen absolutely supports re-filing the REMOXY NDA. We expect to do so in Q1 2016.”

-more-

REMOXY® Update

General Comments

- We believe REMOXY's previous sponsor undertook substantial studies and expenses to address the deficiencies previously noted in REMOXY's 2011 Complete Response letter. We also believe the collective data generated from these new studies form the basis to re-file the REMOXY NDA.

- We believe the adequacy of the clinical data generated by REMOXY's previous sponsor will not require us to conduct any new clinical studies to re-file the REMOXY NDA.

- We plan to conduct certain non-clinical activities prior to re-filing the REMOXY NDA. This includes in vitro work that was initiated but never completed by REMOXY's previous sponsor due to the timing of their decision to return REMOXY. It may take us up to six months to conduct such work, depending on the workflow and availability of our consultants and vendors.

Results of Clinical and Non-Clinical Studies

- REMOXY's previous sponsor conducted several studies prior to returning REMOXY to us. We believe results of these studies all support a resubmission of the REMOXY NDA, including:
 - Comparative Bioequivalence Study
 - Dose Proportionality Study
 - Alcohol Interaction Study
 - Effect of Food Study
 - Human Abuse Potential Study

-more-

Regulatory Strategy

- REMOXY's previous sponsor reached agreement with the FDA on the specific contents of an acceptable NDA resubmission. As with all regulatory documents, this agreement is now assigned to us as part of the REMOXY transition. We believe these regulatory documents create a clear path to the FDA for re-filing the REMOXY NDA.
- We plan to refile the REMOXY NDA with FDA in Q1 2016. If accepted by the FDA, we believe the REMOXY NDA will undergo a six-month review cycle.
- We have assembled a highly experienced team of experts, consultants and vendors from a range of disciplines to handle the complexities of preparing an electronic NDA submission.

Manufacturing and Supply Chain Strategy

- REMOXY's previous sponsor contracted drug manufacturing to Mallinckrodt, a global company with distinctive manufacturing skills around opioids. The long-term drug supply agreement between REMOXY's previous sponsor and Mallinckrodt is now assigned to us as part of the REMOXY transition. We intend to continue retention of Mallinckrodt for contract manufacturing and supply chain support for REMOXY.

Marketing and Commercialization Strategy

- We believe REMOXY targets a large market that requires significant expertise and marketing resources.

- We plan to select a commercialization strategy as REMOXY moves closer to a potential regulatory approval. We have identified several potential commercialization strategies that we have under review. These potential strategies include consummating a strategic transaction that monetizes our pipeline of drug candidates, forming a commercial collaboration or building a small, highly focused sales and marketing team.

Publication

- The following clinical manuscript was recently published in *Journal of Opioid Management*¹:

The pharmacokinetics of oxycodone and its metabolites following single oral doses of REMOXY[®], an abuse-deterrent formulation of extended-release oxycodone, in patients with hepatic or renal impairment.

by Bimal K Malhotra, PhD; Grant L. Schoenhard, PhD²; Annelies W. de Kater², PhD;
Nadav Friedmann², PhD, MD.

-more-

¹ March/April 2015; Volume 11, Number 2, pages 157-169

² Pain Therapeutics employee or consultant.

FENROCK™ Update

- Over 10 years ago, we pioneered new abuse deterrent technology for oral opioid formulations.

Today, we are pioneering new abuse deterrent technology for transdermal patch formulations.

We believe the annual market for transdermal pain patches exceeds \$1 billion in the U.S., and includes such opioid analgesic drugs as fentanyl, sufentanil, buprenorphine, etc. We believe the abuse deterrent technology that underlies FENROCK addresses a portion of these markets.

- We own world-wide commercial rights to our drug candidate FENROCK, which is a proprietary abuse-deterrent fentanyl pain patch. This drug candidate is in pre-IND stage of development.
- In Q3 2015, we expect to announce pre-clinical proof-of-concept data for FENROCK.

NEW DRUG INITIATIVE

- In Q2 2015, we expect to announce a major new drug development initiative for CNS diseases. Our undisclosed new drug candidate targets a large, non-pain, and underserved chronic market. We own all world-wide commercial rights to our new drug candidate.

- In Q2 2015, we also expect to announce a new, non-dilutive source of funding that is intended to substantially fund all IND-enabling activities for our undisclosed new drug candidate.

-more-

CONFERENCE CALL

Pain Therapeutics will host a conference call on Tuesday, May 12th at 4:30 pm Eastern Time to discuss progress across its portfolio of drug candidates and to respond to questions.

To participate in the conference call, please dial 1-877-407-4018 prior to the start of the call.

Those interested in listening to the conference call live via the internet may do so by visiting the Company's website at www.paintrials.com.

A playback of the call will be available for about 7 days after the live event. To access the playback, please dial toll free 1-877-870-5176 (or international toll-free number 1-858-384-5517) and enter code 1360-9974.

About REMOXY®

We own world-wide commercial rights to our lead drug candidate, REMOXY Extended-Release Capsules CII, which is a unique, twice-a-day formulation of oral oxycodone. REMOXY's intended indication is for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time and for which alternative treatments are inadequate. We specifically developed REMOXY to discourage certain common methods of drug tampering and misuse. The REMOXY NDA is supported by multiple clinical trials, including a successful Phase III efficacy program conducted under a Special Protocol Assessment.

-more-

About Pain Therapeutics, Inc.

Pain Therapeutics, Inc. is a clinical-stage biopharmaceutical company that develops novel drugs.

The FDA has not approved our drug candidates for commercial sale. For more information, please visit www.paintrials.com.

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 resubmission of an NDA for REMOXY with the U.S. Food and Drug Administration, or FDA, and the timing of such resubmission; proposed non-clinical studies with respect to REMOXY; the sufficiency of data and other information to support the resubmission and approval of an NDA for REMOXY; potential commercialization strategies for REMOXY; intended sources of commercial supply for REMOXY; the size and scope of target markets for REMOXY, FENROCK and our unannounced pre-clinical drug candidate; the timing of announcement of pre-clinical data for FENROCK; the announcement, including announcement timing, of a new pre-clinical drug candidate; potential arrangements, and the timing for announcement, for non-dilutive funding with respect to our unannounced pre-clinical drug candidate; and statements regarding the benefits of our drug candidates. 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, difficulties or delays in development, testing, regulatory approval, production and marketing of our drug candidates, including REMOXY and FENROCK; unexpected delays in the submission and regulatory review of a proposed NDA for REMOXY; unexpected adverse side-effects or inadequate therapeutic efficacy of our drug candidates and other factors that could slow or prevent, development, product approval or market acceptance (including the risk that current and past results of clinical trials may be found to be insufficient for marketing approval and the risk that current and past results of clinical trials and non-clinical studies may be insufficient to support continued development); developments of products or technologies by current or future competitors; the development of competing or alternative therapies, and difficulties or delays in obtaining non-dilutive sources of funding.*

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.

###