



Pain Therapeutics, Inc.

## **Pain Therapeutics Receives Complete Response Letter From FDA for REMOXY(R)**

SAN MATEO, Calif., Dec 11, 2008 /PRNewswire-FirstCall via COMTEX News Network/ --

Pain Therapeutics, Inc. (Nasdaq: PTIE) has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for REMOXY(R), an abuse-resistant controlled-release form of oxycodone. Based on its review, the FDA has determined that the NDA is not approved in its present form.

The FDA believes additional non-clinical data will be required to support the approval of REMOXY. The FDA has not requested or recommended additional clinical efficacy studies prior to approval.

Pain Therapeutics, its commercial partner, King Pharmaceuticals, Inc. (NYSE: KG) and outside technical advisors are evaluating the FDA Complete Response Letter, will discuss the Letter with the FDA, and will provide an update when appropriate.

Pain Therapeutics and King Pharmaceuticals remain diligently committed to their strategic alliance to develop and commercialize REMOXY and other abuse-resistant pain medications.

### About REMOXY

REMOXY, an investigational drug, is a unique, abuse-resistant controlled-release oxycodone for moderate-to-severe chronic pain. REMOXY's high viscosity, liquid formulation in a hard gelatin capsule is designed to resist common methods of misuse and abuse.

### About the Alliance Between Pain Therapeutics, Inc. and King Pharmaceuticals, Inc.

In 2005, Pain Therapeutics and King entered into a strategic alliance to develop and commercialize REMOXY and other abuse-resistant opioid painkillers. Pain Therapeutics is substantially responsible for drug formulation, clinical development and regulatory filings for REMOXY and other abuse-resistant opioid painkillers developed under this alliance. Upon regulatory approval, King will assume sole control of and worldwide responsibility to exclusively commercialize REMOXY and other abuse-resistant opioid painkillers. Pain Therapeutics retains all development and commercial rights in Australia and New Zealand. Drug candidates developed under this alliance are unique formulations of the patented Oradur(TM) technology licensed from Durect Corporation (Nasdaq: DRRX).

### About Pain Therapeutics, Inc.

Pain Therapeutics is a biopharmaceutical company that develops novel drugs. In addition to REMOXY, the Company has four drug candidates in clinical programs including, PTI-202, PTI-721, Oxytrex(TM) and a novel radio-labeled monoclonal antibody to treat metastatic melanoma. Pain Therapeutics is also working on a new treatment for patients with hemophilia. The FDA has not yet evaluated the merits, safety or efficacy of the Company's drug candidates. For more information, please visit [www.paintrials.com](http://www.paintrials.com).

### About King Pharmaceuticals, Inc.

King, headquartered in Bristol, Tennessee, is a vertically integrated branded pharmaceutical company. King, an S&P 500 Index company, seeks to capitalize on opportunities in the pharmaceutical industry through the development, including through in-licensing arrangements and acquisitions, of novel branded prescription pharmaceutical products that complement the Company's focus in specialty-driven markets, particularly neuroscience, hospital and acute care. King strives to be a leader and partner of choice in bringing innovative, clinically-differentiated medicines and technologies to market.

### 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, Inc. and King Pharmaceuticals, Inc. disclaim any intent or obligation to update these forward-looking statements, and claim the protection of the Safe Harbor for forward-looking statements contained in the Act. Examples

of such statements include, but are not limited to, any statements relating to the Companies' plan to discuss the Complete Response Letter with the FDA and provide an update when appropriate; the size and scope of the potential market for REMOXY and the potential benefits of REMOXY or the Companies' other 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, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of the Companies' drug candidates and unexpected adverse side-effects of the Companies' drug candidates and other factors that could slow or prevent product approval or market acceptance. For further information regarding these and other risks related to the Companies' business, investors should consult the Companies' respective filings with the U.S. Securities and Exchange Commission.

SOURCE King Pharmaceuticals, Inc.

<http://www.paintrials.com>

Copyright (C) 2008 PR Newswire. All rights reserved

News Provided by COMTEX