

# FDA Complete Response Letter Received for REMOXY

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"Pfizer is working to understand and address the issues in the FDA Complete Response Letter,"

([BUSINESS WIRE](#))--Pfizer (NYSE: PFE) and Pain Therapeutics, Inc. (NASDAQ: PTIE) announced that a Complete Response Letter was received from the U.S. Food and Drug Administration (FDA) on the resubmission to the new drug application (NDA) for REMOXY<sup>®</sup> (oxycodone) Extended-Release Capsules CII. Pfizer is working to evaluate the issues described in the Complete Response Letter and plans to have further discussions with FDA around them.

REMOXY is an investigational extended-release oral formulation of oxycodone for the relief of moderate to severe pain requiring continuous, around-the-clock opioid treatment. REMOXY was developed by Pain Therapeutics, Inc. using DURECT Corporation's (NASDAQ: DRRX) ORADUR<sup>®</sup> technology, which is designed to discourage common methods of tampering. In 2005, King Pharmaceuticals, Inc. entered into an agreement with Pain Therapeutics, Inc. to develop and commercialize REMOXY. Pain Therapeutics, Inc. filed the initial NDA for REMOXY in June 2008 and received a Complete Response Letter in December 2008. King Pharmaceuticals, Inc. assumed full control of the development of REMOXY in March 2009 and filed a resubmission to the REMOXY NDA on December 23, 2010. Pfizer obtained rights to REMOXY upon the close of its acquisition of King Pharmaceuticals, Inc. on February 28, 2011.

"Pfizer is working to understand and address the issues in the FDA Complete Response Letter," said Olivier Brandicourt, Pfizer President and General Manager, Primary Care. "Pain is an important strategic disease area for Pfizer. We share the concern about misuse and abuse of opioid medicines and are committed to being part of the solution to address this important public health and safety issue."

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At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at [www.pfizer.com](http://www.pfizer.com).

## **About Pain Therapeutics, Inc.**

Pain Therapeutics, Inc. is a biopharmaceutical company that develops novel drugs. The FDA has not approved any of its drug candidates for commercial sale. For more information, please visit [www.paintrials.com](http://www.paintrials.com).

## **PFIZER DISCLOSURE NOTICE:**

*The information contained in this release is as of June 24, 2011. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information that involves substantial risks and uncertainties regarding REMOXY, including its potential benefits and Pfizer's effort to address the issues set forth in the FDA's Complete Response Letter concerning REMOXY. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; Pfizer's ability to resolve the issues set forth in the FDA's Complete Response Letter; decisions by the FDA and regulatory authorities in other jurisdictions regarding whether and when to approve any drug applications that have been or may be filed for REMOXY as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; as well as competitive developments.*

*A further list and description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in its reports on Form 10-Q and Form 8-K.*

## **PAIN THERAPEUTICS, INC. DISCLOSURE NOTICE:**

*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, any statements relating to the potential benefits of REMOXY and Pfizer's plans regarding assessment and resolution of the issues set forth in the FDA's Complete Response Letter concerning REMOXY. 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 and pursuit of regulatory approval of REMOXY; unexpected adverse side effects or inadequate therapeutic efficacy of REMOXY; Pfizer's potential allocation of inadequate resources for, or potential diversion of resources from, the pursuit of regulatory approval of REMOXY; and the potential for abuse resistant pain medications or other competing products or therapies to be developed by competitors, potential competitors or others. For further information regarding these and other risks related to Pain Therapeutics' business, investors should consult Pain Therapeutics' filings with the Securities and Exchange Commission.*

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