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ROXRO Announces FDA Accepts for Review NDA for ROX-888 for the Management of Acute Moderate to Severe Pain; Potential to be the First Non-narcotic Intranasal Analgesic

MENLO PARK, CA (February 06, 2009) ROXRO announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for its lead investigational prescription drug candidate, ROX-888, for the management of acute moderate to severe pain. ROX-888 is an intranasal formulation of ketorolac, a non-steroidal anti-inflammatory drug (NSAID), designed to provide ambulatory patients with a convenient, potent, and fast-acting option for acute pain relief, without the risk of addiction or the other negative effects of narcotics. The NDA package for ROX-888 includes data from more than 1,000 subjects and 14 clinical trials. If approved, ROX-888 is expected to be the first non-narcotic intranasal analgesic indicated for the management of acute moderate to severe pain.

"This milestone for ROX-888 is a significant business accomplishment for ROXRO. Our virtual operating structure has enabled us to develop an extensive NDA package for our lead product candidate in an extremely capital-efficient manner," said Roberto Rosenkranz, Chief Executive Officer of ROXRO. "We believe that ROX-888 has the potential to fill important needs in the large and growing market for acute moderate to severe pain treatments. Currently approved forms of ketorolac are already well accepted by the physician community for in-hospital use, and we believe physicians will quickly adopt this investigational intranasal form of ketorolac as a new therapeutic option to replace or minimize oral opioid use for take-home prescriptions. As we plan a potential product launch at the end of 2009, pending FDA approval, we are now seeking a commercialization partner to help us realize the full benefit of this drug."

ROX-888 has been tested in four controlled efficacy studies, and met the primary endpoints in each trial. Additionally, ROX-888 has demonstrated a good safety profile, as would be expected with short-term use of an NSAID. Mild, transient nasal irritation was the most common side-effect of ROX-888 usage. As with other NSAIDs, ROX-888 should not be used in patients with renal insufficiency, active peptic ulcers, or a history of GI bleeding.

"ROX-888 could fulfill a compelling medical need for both clinicians and patients — an analgesic that provides potent, rapid-onset pain control while minimizing the potential for abuse and the negative side-effects perceived to be associated with narcotic pain relievers," said Dr. Neil Singla, CEO of Lotus Clinical Development, Inc. and lead investigator for ROXRO's second Phase 3 study. "If approved, the nasal spray product, formulated for convenient use, will provide patients pain relief at home or in an out-patient or ambulatory setting, without the need for injections or intravenous administration."



About ROX-888

ROX-888 is a novel, investigational intranasal formulation of the potent non-steroidal anti-inflammatory drug (NSAID) ketorolac. Currently, ketorolac is most often administered in the hospital setting as an intramuscular injection or intravenously for the short-term treatment of moderate to severe pain. The analgesic efficacy of ketorolac is primarily associated with the inhibition of prostaglandin synthesis via non-selective inhibition of COX-1/COX-2 enzymes. Based on clinical studies conducted to date,

ROX-888 is expected to allow patients to receive the same benefits of hospital-strength ketorolac in a convenient form that can be used at home. Formulated as an easy-to-use spray, ROX-888 is rapidly absorbed through the nasal mucosa, achieving peak blood levels as fast as an intramuscular injection. The pharmacokinetic properties of ROX-888 have been demonstrated in clinical trials to provide rapid relief of acute moderate to severe pain.

About ROXRO PHARMA

ROXRO PHARMA, Inc. is a late-stage specialty pharmaceutical company developing hospital strength acute pain products for convenient use by patients in the home setting. The company is led by a seasoned management team that has discovered, developed and commercialized several pain and cardiovascular medicines that are widely prescribed today.
www.roxropharma.com

“Safe Harbor” Statement under the Private Securities Litigation Reform Act of 1995

Statements in this press release that are not historical facts are forward-looking statements that involve risks and uncertainties. The inclusion of forward-looking statements, including those related to expectations regarding clinical programs, potential business transactions, product development, and potential benefits of our products and product candidates, should not be regarded as a representation that any of our plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our business, including, without limitation, risks and uncertainties related to: our research and development efforts, including pre-clinical and clinical testing; the timing of regulatory submissions and approvals; and our need for and ability to raise additional capital. You are cautioned not to place undue reliance on these forward-looking statements which speak only as of the date hereof. We undertake no obligation to revise or update this release to reflect events or circumstances that occur after the date of this release.