



**FOR IMMEDIATE RELEASE**

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## **QRxPharma Initiates Comparative Study for MoxDuoIR™ Dual-Opioid™ Pain Therapy**

*Efficacy and Safety Study to Support Phase 3 Combination Rule Trial for NDA  
Submission*

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY), a clinical-stage specialty pharmaceutical company focused on the development and commercialisation of therapies for pain and central nervous system (CNS) disorders, announced today initiation of a comparative study to evaluate the efficacy and safety profile of MoxDuoIR™ against equivalent analgesic doses of morphine and oxycodone alone for the treatment of acute moderate to severe pain. Data collected from this study will also be used to support final Phase 3 trials required for NDA submission. The Company expects to complete dosing prior to April 2009.

“While successful clinical trials to date have shown the potential of MoxDuo™ to provide equal or better analgesia with a reduction of total opioid dose and improved tolerability, this study is designed to provide direct evidence of enhanced efficacy when compared to equivalent analgesic doses of morphine and oxycodone alone,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “Our goal is to demonstrate the clinical value and superiority of MoxDuoIR™ over its individual components in post-surgical acute pain relief.”

The double-blind, randomized and repeated fixed-dose study compares MoxDuoIR's™ efficacy and safety to corresponding doses of oxycodone and morphine in patients experiencing moderate to severe pain following a scheduled surgical procedure (bunionectomy). The study is targeted to enroll 180 patients at 6 US clinical research sites.

The primary clinical endpoints for this study focus on pain relief and intensity scores of MoxDuoIR™ versus equivalent doses of morphine and oxycodone alone during the first 24 hours following surgery. Secondary endpoints include: (1) efficacy relating to the time to onset of analgesia and global assessment of effect; and (2) safety as measured by the incidence and intensity of opioid-related adverse events.

MoxDuoIR™ is a patented combination of morphine and oxycodone which has been clinically shown to provide synergistic effects on pain relief, resulting in a significant reduction of total opioid dose and side effects.

Based on the Company's July 2008 FDA meeting, final Phase 3 studies for MoxDuoIR™ will include a combination rule trial in patients experiencing post-surgery (bunionectomy) pain. Data collected from this comparative study will be used to select the optimal dose regimen and sample sizes for the combination rule trial. No additional



pharmacology, toxicology or long-term clinical safety studies will be required for regulatory submission and market approval.

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### **Forward Looking Statements**

This press release contains forward-looking statements that involve risks and uncertainties. The forward-looking statements contained herein represent the judgment of QRxPharma as of the date of this release. These forward-looking statements are not guarantees for future performance. Actual results could differ materially from those currently anticipated due to a number of factors including risks relating to the stage of products under development; uncertainties relating to clinical trials; dependence on third parties; future capital needs; and risks relating to the commercialisation of the Company's proposed products.

### **About QRxPharma**

QRxPharma (ASX: QRX and OTCQX: QRXPY) is a clinical-stage specialty pharmaceutical company focused on the development and commercialisation of new treatments for pain management and central nervous system (CNS) disorders. Based on a development strategy which focuses on enhancing and expanding the clinical utility of currently marketed compounds, the Company's product portfolio includes both late and early stage clinical drug candidates with the potential for reduced risk, abbreviated development paths, and improved patient outcomes. The Company intends to directly commercialise its products in the US and seek strategic partnerships abroad. QRxPharma's lead compound, MoxDuoIR™, successfully completed a Phase 3 study and met primary and secondary endpoints. The Company's preclinical and clinical pipeline includes other technologies in the fields of pain management, neurodegenerative disease and venomics. For more information: [www.QRxPharma.com](http://www.QRxPharma.com).