



**FOR IMMEDIATE RELEASE**

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**MoxDuo™ IR Demonstrates Fewer Side Effects than Percocet®**

*Pain relieving effects of MoxDuo™ IR are dose-related with a better safety profile than Percocet® in patients with post-operative pain following total knee replacement*

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the successful completion of its pilot study to evaluate the analgesic efficacy and safety profile of MoxDuo™ IR (immediate release) capsules in patients with moderate to severe pain following total knee replacement surgery. When compared at equianalgesic doses with Percocet®, the second most widely prescribed opioid in the US, MoxDuo™ IR demonstrated greater overall tolerability with substantially fewer incidences of moderate to severe nausea, vomiting, constipation, and hypotension than Percocet®. Scheduled for launch in 2011, MoxDuo™ IR targets the acute pain market; a \$2.5 billion segment of the \$7 billion spent annually on prescription opioids in the US.

“This study serves to reinforce earlier clinical findings that showed improved tolerability and again demonstrates the value of our Dual-Opioid™ platform as MoxDuo™ IR opens the therapeutic window for treating patients suffering from acute post-surgical pain,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “We believe the MoxDuo™ product portfolio, including immediate release, controlled release and intravenous formulations, will significantly improve patient care, providing equal or better analgesia with fewer and/or less intense side effects than current standards of care.”

MoxDuo™ IR is the first patented analgesic product in the world that consists of two opioid drugs (a fixed ratio of morphine and oxycodone). While many analgesic combination drugs exist that contain opioids with mild pain drugs such as aspirin, ibuprofen or acetaminophen, combination products such as Percocet® which contains an opioid (oxycodone) combined with acetaminophen (like Tylenol®) have been the subject of recent FDA scrutiny due to their potential for causing significant adverse effects on liver and gastrointestinal function.

To date, more than 400 patients in six clinical trials have received MoxDuo™ IR for different forms of post-surgical pain (bunionectomy and total knee replacement). Study results with MoxDuo™ IR consistently demonstrate fewer side effects than observed with morphine alone, oxycodone alone and now with Percocet®.



In this open label trial, each group of patients who experienced moderate to severe post-operative pain following total knee replacement surgery were treated every four to six hours over a 48-hour period. The study enrolled a total of 44 patients at five US clinical research sites.

All primary study objectives were met comparing: (1) the analgesic efficacy and safety profile of MoxDuo™ IR against control groups of patients receiving Percocet®, a frequently used opioid for the treatment of pain; and (2) a flexible dosing regimen of MoxDuo™ IR against a fixed low dose (3/2mg). Patients receiving the flexible dosing regimen of MoxDuo™ IR achieved significantly greater pain relief than those receiving the low dose formulation ( $p < 0.05$ ).

Data collected from this study provide additional guidance for optimising the design and implementation of pending pivotal Phase 3 studies as the Company prepares for New Drug Application (NDA) filings with the US Food and Drug Administration (FDA) in 2010.

MoxDuo™ IR, the Company's lead product candidate, is part of a larger Dual-Opioid™ portfolio including intravenous (MoxDuo™ IV) and controlled release (MoxDuo™ CR) formulations. These formulations are designed to incorporate tamper resistance and reduced abuse liability as appropriate.

Dr. Bruce Nicholson, a leading pain physician in the US, commented on these results: “The concept of combining morphine and oxycodone makes sense based on the clinical data generated to date, and has benefited my patients in managing their acute and chronic pain needs. Results of this study reinforce that the clinical advantages of MoxDuo™ IR have the potential to change the traditional methods of treating moderate to severe pain by providing better pain relief without many of the debilitating side effects seen with traditional opioid drugs.”

Based on the Company's July 2008 FDA meeting, final Phase 3 studies for MoxDuo™ IR will include: (1) a “double-blind combination rule” trial in patients experiencing post-surgical (bunionectomy) pain that compares MoxDuo™ IR against morphine alone and oxycodone alone and (2) a double-blind controlled study to evaluate the effectiveness of MoxDuo™ IR in patients following total knee replacement. 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, MoxDuo™ IR, 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, please visit [www.QRxPharma.com](http://www.QRxPharma.com).