

ASX RELEASE 1 September 2010

## QRxPharma Announces Interim Analysis of Final Pivotal Phase 3 Study for MoxDuo<sup>®</sup>IR

On track to achieve primary pain relief endpoint in patients following total knee replacement

**Sydney, Australia and Bedminster, New Jersey** – QRxPharma (ASX: QRX and OTCQX: QRXPY) announced today a successful interim analysis of its final MoxDuo IR pivotal Phase 3 study required for New Drug Application (NDA) submission. The analysis indicated the planned sample size of 140 patients has greater than 90% power to detect differences of analgesic effect, indicating there is no need to enrol additional patients. QRxPharma anticipates completing analysis of this study in Q4 CY2010 and filing a New Drug Application (NDA) for MoxDuo IR in Q1 CY2011.

"It's certainly exciting – as we near completion of our MoxDuo IR clinical program – that interim analysis of the final pivotal study indicates we're on track to obtain significant results," said Dr. John Holaday, Managing Director and CEO. "In study after study this product has performed consistently, successfully achieving every primary end-point. Our emphasis has been to de-risk the MoxDuo IR clinical development program, and these data give us confidence that completion of this study will achieve primary pain relief endpoints and satisfy requirements for NDA filing."

QRxPharma is currently completing its product registration clinical program for MoxDuo IR (a 3:2 ratio of morphine to oxycodone) in the management of moderate to severe acute pain. This comparative study conducted at 10 centres in the US, now well over halfway complete, is evaluating analgesic efficacy and tolerability of a flexible dose regimen (12 mg/8 mg) versus a fixed low dose (3 mg/2 mg) of MoxDuo IR in 140 patients with moderate to severe pain following total knee replacement surgery.

The study design included a blinded interim analysis (70 completed patients) to be conducted by an independent statistician for the purpose of sample size confirmation. This interim analysis indicated that the projected sample size of 140 patients is likely to provide sufficient power to distinguish the analgesic effects of flexible dose versus fixed low dose of MoxDuo IR over a 48 hour study period. Since the blinded interim analysis was based on how much variability was observed when both dosage groups were combined and did not evaluate the magnitude of the difference between the two treatment groups *per se*, one must be cautious in drawing conclusions that the expected endpoints will be met. This type of interim analysis conducted for the purpose of sample size re-estimation, which was accepted by the FDA, does not result in a statistical penalty in the p-values of the final analysis to be conducted upon study completion.

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## **Forward Looking Statements**

This release contains forward-looking statements. Forward-looking statements are statements that are not historical facts; they include statements about our beliefs and expectations. Any statement in this release that states our intentions, beliefs, expectations or predictions (and the assumptions underlying them) is a forward-looking statement. These statements are based on plans, estimates and projections as they are currently available to the management of QRxPharma. Forward-looking statements therefore speak only as of the date they are made, and we undertake no obligation to update publicly any of them in light of new information or future events. By their very nature, forward-looking statements involve risks and uncertainties. A number of important factors could therefore cause actual results to differ materially from those contained in any forward-looking statement. Such factors include 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 co-promote its products in the US and seeks strategic partnerships for worldwide markets. QRxPharma's lead product candidate, MoxDuo<sup>®</sup>IR, is in Phase 3 clinical development and has successfully completed multiple comparative studies evaluating its efficacy and safety against equi-analgesic doses of morphine, oxycodone and Percocet<sup>®</sup> for the treatment of acute pain. QRxPharma expects to complete its Phase 3 program in Q4 CY2010 and file its New Drug Application (NDA) with the US Food and Drug Administration (FDA) for MoxDuo IR in Q1 CY2011. The Company's preclinical and clinical pipeline includes other technologies in the fields of pain management, neurodegenerative disease and venomics. For more information, visit



www.qrxpharma.com.





