ASX RELEASE
21 February 2011

FDA Grants QRxPharma Pre-New Drug Application Meeting in March 2011

Company Successfully Completes Third Pivotal MoxDuo® Phase 3 Study

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the granting of a pre-New Drug Application (NDA) meeting with the United States Food and Drug Administration (FDA) and successful completion of its third pivotal Phase 3 registration trial (study 009) for immediate-release MoxDuo.

Designed to evaluate the analgesic efficacy and safety of MoxDuo, study 009 compared a flexible dose against a fixed low-dose regimen for managing moderate to severe pain following total knee replacement surgery (TKR). QRxPharma's analysis of data indicate that patients in the flexible dose treatment group achieved statistically superior pain reduction ($p<0.02$) compared to those receiving the lower dose. Side effects were similar to those observed in earlier MoxDuo studies. The pre-NDA meeting with the FDA is scheduled for 22 March 2011. At that meeting, the Company and the FDA will review the adequacy of QRxPharma's planned NDA submission including efficacy and safety findings and statistical analyses from this study and earlier trials, as well as technical organisation and proposed data summarisation methods.

"This is a major milestone for QRxPharma. We not only achieved the primary analgesic endpoint, but also believe the basic clinical requirements for NDA filing have been satisfied. We can see the goal line," said Dr. John Holaday, Managing Director and CEO, QRxPharma. "Our upcoming pre-NDA meeting with the FDA will explore QRxPharma's regulatory strategy and provide preliminary feedback about the sufficiency of our studies to set the stage for MoxDuo approval."

MoxDuo is a patented 3:2 ratio fixed dose combination of morphine and oxycodone. Clinical trials conducted to date have consistently demonstrated the benefits of MoxDuo, achieving as good or better pain relief with fewer incidences of moderate to severe side effects compared to current standards of care.

This double-blind, two-arm study compared a flexible dose regimen (range: 6 mg/4 mg to 24 mg/16 mg) versus a fixed low dose (3 mg/2 mg after an initial 6 mg/4 mg loading dose) of MoxDuo. Following TKR surgery, all patients received morphine IV for up to 24 hours. 142 patients at 10 clinical centres in the U.S. were then randomised into one of two MoxDuo treatment regimens, with doses given once every 4-6 hours for up to 48 hours. After the initial treatment period, patients were eligible to continue dosing as an outpatient with study medication for up to 10 days.

The Company's analysis shows that reductions in pain intensity scores following surgery relative to baseline in patients receiving the flexible MoxDuo dose regimen (12 mg/8 mg was the most common dose) were significantly greater using the primary efficacy endpoint $SPID_{48}$ (the sum of the changes in pain intensity from baseline over the 48 hour treatment period) than those in the low dose group.

With the successful completion of this pivotal study, QRxPharma believes it has met the basic clinical data requirements to enable NDA filing for MoxDuo as targeted for the first half of CY2011. The Company also expects that additional data from the recently initiated Phase 3 trial (Study 022) comparing the tolerability and safety profile of MoxDuo to equi-analgesic doses of either morphine or oxycodone given alone should further reinforce the Company's regulatory filings in Europe and the US. Immediate-release MoxDuo targets the acute pain market, a $2.5 billion segment of the $7 billion spent annually on prescription opioids in the US.

###

For more information please contact:

John W Holaday, Ph.D.
Managing Director and Chief Executive Officer
Tel: +1 301 908 3086
Email: john.holaday@qrxpharma.com

Chris J Campbell
Chief Financial Officer and Company Secretary
Tel: +61 2 9492 8021
Email: chris.campbell@qrxpharma.com

About QRxPharma Limited

QRxPharma Limited (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 that 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 U.S. and seeks strategic partnerships for worldwide markets. QRxPharma's lead product candidate, immediate release MoxDuo, has successfully completed pivotal Phase 3 studies and the Company expects to file its New Drug Application (NDA) with the US Food and Drug Administration (FDA) in the first half of CY2011. The Company's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MoxDuo, as well as other technologies in the fields of pain management, neurodegenerative disease and venomics. For more information, visit www.qrxpharma.com.

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.