**ASX RELEASE**
8 November 2011

# QRxPharma Granted Target Date for FDA Action on MoxDuo® IR NDA

*NDA Accepted for Review; PDUFA Date Set for June 25, 2012*

**Sydney, Australia and Bedminster, New Jersey** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today it received written acceptance from the United States Food and Drug Administration (FDA) for review of the MoxDuo IR New Drug Application (NDA) filed earlier this year. The FDA also set June 25, 2012 as the PDUFA (Prescription Drug User Fee Act) target date for action on the approval of the MoxDuo IR NDA.

"We are extremely pleased with this important milestone from the FDA and – subject to approval – making plans to launch MoxDuo IR in the second half of 2012 for the treatment to moderate to severe acute pain," said Dr. John Holaday, Managing Director and CEO, QRxPharma. "This is a testament to the successful clinical trial program conducted by the Company and indicates the path to market is on track, adding value for shareholders and strategic partners."

The FDA letter stated the agency had completed their filing review of the MoxDuo IR NDA submitted on August 24, 2011 and determined the application was sufficiently complete to permit a substantive review. The FDA notification included useful technical information on chemistry, manufacturing and controls (CMC), as well as the pediatric program to be conducted after drug approval that would enable further marketing exclusivity. The NDA is the basis for US regulatory approval of MoxDuo IR for the treatment of moderate to severe acute pain, a $2.5 billion segment of the $8 billion spent annually on prescription opioids in the US.

QRxPharma initiated its MoxDuo IR NDA with the FDA in July 2011 with submission of the CMC module and completed the filing requirements in August with the Clinical and Non-Clinical Data package. The NDA was submitted under 505(b)(2) regulations wherein approval for a new drug may be expedited by citing historical published evidence supporting each of MoxDuo's already approved components to supplement the data derived from QRxPharma's robust development program.

To date, more than 700 patients have been treated with MoxDuo IR in seven late-stage clinical trials over the Company's successful Phase 3 program. Clinical data have consistently demonstrated that MoxDuo IR achieves equal or better pain relief with fewer incidences of moderate to severe opioid-related side effects compared to current standards of care.

The US NDA package will also serve as the core component of MoxDuo registration submissions in Europe, Australia, Canada and elsewhere. The Company believes the recently completed Study 022 which demonstrated a clinically significant reduction in respiratory depression compared to equi-analgesic doses of morphine and of oxycodone, the major cause of death from opioids, will add further value for strategic partners, regulators and prescribers. This study will be submitted to the FDA as a NDA safety update at the end of 2011 and facilitate label claim advantages for MoxDuo IR when the European Marketing Authorisation Application (MAA) is submitted in 2012.

###

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**

QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) is a commercial-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 US and seeks strategic partnerships for worldwide markets. QRxPharma's lead product candidate, immediate release MoxDuo, now awaits approval by the US Food and Drug Administration (FDA). Additionally, the Company's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MoxDuo, as well as other pipeline 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.