




ASX RELEASE
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QRxPharma Completes NDA Submission for MoxDuo[®] IR *Clinical Data Package to US FDA as Follow-Up to Initial CMC Filing*

Sydney, Australia and Bedminster, New Jersey -- QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today submission of its New Drug Application (NDA) clinical data package to the United States Food and Drug Administration (FDA) for MoxDuo IR, an immediate-release Dual Opioid[®] pain therapy comprised of a patented 3:2 fixed ratio combination of morphine and oxycodone. The NDA Chemistry, Manufacturing and Controls (CMC) module was submitted to the FDA on 18 July and is currently under review. The Company believes submission of the clinical data from MoxDuo IR's successful Phase 3 clinical program completes its NDA filing requirements; the FDA typically takes 10-12 months to review these applications. The NDA filing is the basis for US regulatory approval of MoxDuo IR for the treatment of moderate to severe pain, a \$2.5 billion segment of the \$8 billion spent annually on prescription opioids in the US.

"Since QRxPharma's initial public offering in 2007, we have strived towards an aggressive commercialisation strategy for MoxDuo – one that streamlined development timelines, was capital efficient, demonstrated clinical advantages of the product, and set the stage for commercial benefits to the company," said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. "We are pleased to have met this significant NDA milestone in just four years, and look forward to the regulatory approval process that may enable product sales in 2012."

This completed NDA submission is based on a full non-clinical, clinical and manufacturing program for MoxDuo IR, and is being filed 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 the robust QRxPharma development program. Consistent with the United States Federal Code of Regulations and as agreed with the FDA, the Company previously initiated the NDA review process by filing its completed CMC module in July 2011.



The Company has requested a Priority (accelerated) FDA review for MoxDuo IR based on favourable clinical data from several head-to-head comparisons with morphine, oxycodone, Percocet[®] and placebo. To date, more than 700 patients have been treated with MoxDuo IR in seven 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 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, the major cause of death from opioids, will be attractive to strategic partners, regulators and prescribers. This study will be submitted to the FDA as part of a 2011 NDA update filing and will also facilitate label claim advantages for MoxDuo IR when the European Marketing Authorisation Application (MAA) is submitted in 2012.

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About QRxPharma

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, successfully completed pivotal Phase 3 studies and the Company has filed its New Drug Application (NDA) with the US Food and Drug Administration (FDA). 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.