ASX RELEASE
16 January 2013

QRXPHARMA AND FDA ESTABLISH PATH FORWARD FOR RESUBMISSION OF MOXDUO® NEW DRUG APPLICATION

Successful NDA Review to Position Product for Approval and Subsequent Launch in Q3 of this Year

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today that the steps necessary for approval of immediate release MOXDUO have been clarified with the United States Food and Drug Administration (FDA). QRxPharma will resubmit its MOXDUO NDA this quarter, with an expected new PDUFA date to be set for Q3 2013.

During the Company's most recent FDA review meeting, QRxPharma presented a position that although the Combination Rule does not require a demonstration of greater efficacy or safety, the data submitted to date indicate a safety advantage for MOXDUO compared to either morphine or oxycodone alone. Results from Study 022, which demonstrated that oxygen desaturation was less severe with MOXDUO than with oxycodone or morphine, were presented to the full review committee and noted with interest. The FDA recommended the Company provide a more extensive analysis of Study 022 when the revised MOXDUO New Drug Application (NDA) is resubmitted.

"Throughout the last several years of FDA interactions on MOXDUO, we have followed the Agency's recommendations in designing and implementing clinical trials that demonstrated its effectiveness and safety in acute pain patients," said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. "Recent feedback provided clarity as to the complete response action taken on 25 June, 2012 and, based on the FDA's advice and recommendations, we are now preparing our revised NDA for submission this quarter."

The FDA also voiced for the first time that no precedent exists for their review of combination products where two drugs in the same category are combined (e.g. morphine and oxycodone as "opioids"). Therefore, despite the Agency previously confirming that there were no safety issues in any of the studies that were part of the original NDA, the resubmitted application, including new results from Study 022, will likely undergo review by an Advisory Committee in late Q2 2013. The Advisory Committee will evaluate the approvability of MOXDUO in the management of acute pain. The reliance on Advisory Committees has been made more common or compulsory since the FDA Amendments Act of 2007.

"While US approval of MOXDUO remains our foremost priority and we are optimistic about next steps with the FDA, we also look forward to submitting regulatory filings in Canada, Europe and Australia before the end of the fiscal year that will further support the Company's strategies for commercialising the product around the world," concluded Holaday.

Investor Conference Call
An investor conference call will be held on Thursday 17 January 2013 at 10.30am Australian Eastern Daylight Time (United States: Wednesday 16 January 2013 at 6.30pm EST / 3.30pm PST) with Dr. John Holaday, Managing Director and CEO QRxPharma and Dr. Edward Rudnic COO.

Conference participant ID 9025 3452

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Hong Kong	800 908 865
New Zealand	0800 452 782
Singapore	800 616 2288
United Kingdom	0808 234 0757
United States	1855 293 1544

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About QRxPharma

QRxPharma Limited is an Australian based, commercial-stage specialty pharmaceutical company focused on the development and commercialisation of new treatments for pain management. 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's lead product candidate, immediate release MOXDUO® for the treatment of acute pain, is presently under review at the US Food and Drug Administration. QRxPharma entered into strategic collaborations with Actavis Inc. in December 2011 and Paladin Labs Inc. in October 2012 for the commercialisation of immediate release MOXDUO® in the US and Canadian acute pain markets respectively. Additionally, the Company's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MOXDUO. 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.

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