

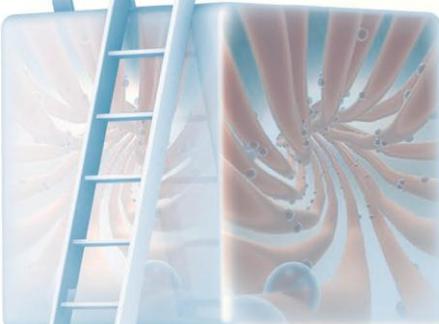


**ASX RELEASE**  
**20 August 2012**

## **QRxPHARMA REPORTS PRODUCTIVE MEETING WITH FDA REGARDING MOXDUO® NDA**

*Company Believes FDA Analysis of Additional Information May Prove Sufficient for  
Approval*

**Sydney, Australia and Bedminster, New Jersey** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the United States Food and Drug Administration (FDA) clarified to Company representatives during a post submission review meeting the steps required for approval of immediate release MOXDUO. The FDA requested further information regarding data filed as part of the MOXDUO New Drug Application (NDA) and additional analysis of trials completed to date, including Study 022 which evaluated oxygen desaturation levels in patients receiving MOXDUO compared to those administered morphine or oxycodone alone at equi-analgesic doses. Oxygen desaturation is a medically important adverse event and a leading cause of death from high doses of opioids.



“We were encouraged by our reception at the FDA; the Agency confirmed our Combination Rule Study (Study 008) satisfied efficacy requirements and there were no unexpected or problematic safety issues in any of the studies submitted as part of the MOXDUO NDA,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “Additionally, at the FDA’s invitation, we agreed to submit more extensive information on Study 022 and believe the results of this study provide further safety data to support approval of MOXDUO.”

Analysis of Study 022 was completed after the MOXDUO NDA filing in August 2011, although early safety data were included in the 120-day update filed last December. Accordingly, additional efficacy and safety information from this study was of significant interest to the FDA.

The Company is presently preparing an additional data package for review and is considering further strategies to optimally manage the regulatory process. QRxPharma believes that the review of additional data and subsequent refile of the NDA could result in a positive decision from the FDA by mid-2013.

### **Investor Conference Call**

An investor conference call will be held Tuesday 21 August at 9.00am Australian EST (United States: Monday 20 August at 7.00pm EST / 4.00pm PST) with Dr. John Holaday, Managing Director and CEO QRxPharma and Dr. Edward Rudnic COO.

Conference participant ID 2252 2184

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

All other international locations call + 61 2 8314 8370.

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#### **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. 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. QRxPharma entered into a strategic collaboration with Actavis Inc. in December 2011 for the commercialisation of MOXDUO<sup>®</sup> in the US acute pain market. Additionally, the Company's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MOXDUO<sup>®</sup>. For more information, visit [www.qrxpharma.com](http://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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