



**ASX RELEASE**  
**14 March 2013**

**FDA SETS 26 AUGUST 2013 AS NEW PDUFA  
DATE FOR MOXDUO<sup>®</sup> NDA**

*Product Launch Anticipated Before End of Calendar Year Pending  
Successful NDA Review*

**Sydney, Australia and Bedminster, New Jersey** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the US Food and Drug Administration (FDA) has set 26 August 2013 as the Prescription Drug User Fee Act (PDUFA) date for action on the Company's resubmitted MOXDUO New Drug Application (NDA).

"We are pleased that the FDA has formally accepted our resubmitted MOXDUO NDA" said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. "We expect the Advisory Committee meeting to be scheduled between late June and late July and will update shareholders once formal notification has been received," added Holaday.

The NDA is the basis for recommencing the regulatory approval process for MOXDUO 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. MOXDUO, an immediate release Dual Opioid<sup>®</sup> pain therapy, is a patented 3:2 fixed ratio combination of morphine and oxycodone.

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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<sup>®</sup> 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<sup>®</sup> 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](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.