



ASX RELEASE
6 September 2013

FDA SCHEDULES REVIEW MEETING WITH QRXPHARMA REGARDING MOXDUO® NDA

Meeting on 3 October to discuss remaining issues before refiling NDA

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the United States Food and Drug Administration (FDA) has scheduled a meeting on 3 October to discuss the Company's MOXDUO New Drug Application (NDA) for the treatment of moderate to severe acute pain. The meeting was granted by the FDA after issuance of a Complete Response Letter (CRL) last month, and will focus on outstanding issues that need to be addressed in the revised NDA and data validation documentation.

The Company is nearing completion of its full audit of the over 30 million data points for oxygen saturation from Study 022 to ensure data integrity. Subject to advice from the FDA on 3 October, we shall refile our NDA incorporating this analysis as soon as possible after the meeting. At this stage we anticipate a new PDUFA (Prescription Drug User Fee Act) date in Q2 2014, preceded by an Advisory Committee meeting.

“We are encouraged by the prompt response by the FDA to engage in a face-to-face review of the remaining issues to be resolved prior to our resubmission of the NDA and accompanying data analyses,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “After the meeting, we hope to have a clear agreement on next steps that will guide us in continuing the regulatory process to achieve MOXDUO approval.”

The revised NDA is the basis for recommending the regulatory approval process for MOXDUO for the treatment of moderate to severe acute pain, a \$2.5 billion USD segment of the \$8 billion USD spent annually on prescription opioids in the United States. The Company believes that MOXDUO is on track to launch in the United States in 2014.

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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. In July 2013, QRxPharma announced a collaboration agreement with Aesica Formulation Development Limited, for the world-wide promotion of QRxPharma's proprietary Stealth Beadlets[®] abuse deterrence technology. Additionally, the Company's clinical pipeline includes an intravenous (IV) and controlled 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.