



ASX RELEASE
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QRxPHARMA REPORTS POSITIVE MEETING WITH THE FDA ON MOXDUO®

FDA Provides Clear Objectives for Refiling NDA and Data Validation Documents

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the results of its meeting on October 3 with the United States Food and Drug Administration (FDA) to discuss the Company's MOXDUO New Drug Application (NDA). At the end-of-review meeting, the FDA provided the Company with a more complete understanding of their requirements for submission of the revised NDA and data validation documentation.

The FDA reaffirmed that the safety and efficacy of MOXDUO are not at question, and that the Company's presentation of the totality of the respiratory safety advantages to an Advisory Committee of experts would help guide their final decision. Accordingly, the FDA encouraged QRxPharma to submit its validated data and updated NDA. The Agency will then schedule an Advisory Committee meeting preceding a Prescription Drug User Fee Act (PDUFA) date six months following NDA resubmission.

"The tone of the meeting with the FDA was cordial and constructive, providing clear recommendations on how we should revise our NDA and document our validated data from the respiratory safety Study 022," said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. "We are highly confident in the integrity of the data defining the respiratory safety advantages of MOXDUO, and are now completing the documents for refiling by mid-November 2013."

The revised 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 USD segment of the \$8 billion USD spent annually on prescription opioids in the United States. The revised NDA also serves as the regulatory foundation for submitting MOXDUO for approval in Europe, Australia, Canada and other markets in the upcoming months. Assuming approval, the Company anticipates that MOXDUO will be launched in the United States during 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 pain management and abuse prevention products. Based on a development strategy that focuses on enhancing the clinical utility of currently approved compounds as well as bringing new products to market, 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. In Q4 2013, the Company plans to refile with the US Food and Drug Administration a New Drug Application for its lead product candidate, immediate release MOXDUO[®] for the treatment of acute pain. QRxPharma entered into strategic collaborations with Actavis Inc. in December 2011, Paladin Labs Inc. in October 2012 and Aspen Group in September 2013 for the commercialisation of immediate release MOXDUO in the United States, Canadian and Australian (including New Zealand and Oceania) acute pain markets respectively. The Company's clinical pipeline includes an intravenous (IV) and controlled release (CR) formulation of MOXDUO. In July 2013, the Company also established a collaboration agreement with Aesica Formulation Development Limited, for the worldwide promotion of QRxPharma's proprietary Stealth Beadlets[®] abuse deterrence technology. 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.