



ASX RELEASE
28 August 2013

QRXPHARMA CEO DISCUSSES COMPLETE RESPONSE LETTER FROM FDA REGARDING MOXDUO[®] NDA ON OPEN BRIEFING

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the United States Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the Company's MOXDUO New Drug Application (NDA) for the treatment of moderate to severe acute pain. The Company confirmed the issuance of the CRL was to allow time to submit and evaluate further information required for the FDA to fully consider the respiratory safety advantages of MOXDUO from Study 022.

With the issue of the CRL, in order to maintain FDA review, the Company is required to resubmit its NDA. QRxPharma plans to complete its refiling in Q4 2013, inclusive of the additional information and analysis as requested by the FDA. QRxPharma anticipates a new PDUFA (Prescription Drug User Fee Act) date in Q2 2014, preceded by an Advisory Committee meeting.

An audio broadcast recorded today with Dr. John Holaday, Managing Director and Chief Executive Officer; Dr. Edward Rudnic, Chief Operating Officer; and Chris Campbell, Chief Financial Officer of QRxPharma discussing the CRL, is available on Open Briefing.

To listen, copy the following details into your web browser: www.openbriefing.com and click on the QRxPharma icon.

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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.