ASX RELEASE
28 August 2013

QRXPHARMA RECEIVES COMPLETE RESPONSE LETTER FROM FDA REGARDING MOXDUO® NDA

Additional time required to prepare and review respiratory data from Study 022

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. We will also have an "end of review" meeting with the FDA in the coming weeks that is currently being scheduled.

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"The importance of these documents and their impact on the approval process in terms of accuracy of data, clarity of clinical benefit and comprehensiveness of response, cannot be overstated," said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. "In our market update of 26 June, we announced timing misalignments in our oxygen desaturation data as the reason for the Advisory Committee meeting delay. At that time, the duration of the delay was not clear. We now have clarity from the FDA as to next steps, and a six month clock will begin upon refiling the NDA."

Investor Conference Call
An investor conference call will be held on Wednesday 28 August 2013 at 9.45am Australian Eastern Standard Time (United States: Tuesday 27 August 2013 at 7.45pm EST / 4.45pm PST) with Dr. John Holaday, Managing Director and CEO QRxPharma and Dr. Edward Rudnic, COO.

Conference participant ID 37083512

Australia	1800 123 296
Hong Kong	800 908 865
New Zealand	0800 452 782
Singapore	800 616 2288
United Kingdom	0808 234 0757
United States	1855 293 1544
Canada	1855 5616 766

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In late June 2013, the FDA requested additional information regarding Study 022 data, which demonstrated a respiratory safety advantage for MOXDUO over equi-analgesic doses of morphine or oxycodone. While the Company submitted amendments to its NDA on 9 and 14 August 2013, the Agency acknowledged that additional time is required to complete and evaluate supporting documentation. This effort requires individual validation of over 30 million oxygen saturation data values obtained from all of the 375 patients who received either MOXDUO, morphine or oxycodone.

The FDA previously confirmed that the Company's Combination Rule Trial (Study 008) satisfied efficacy requirements, and that there were no safety issues in any of the studies submitted as part of the original NDA.

"We remain confident in MOXDUO as a potential therapeutic option for the millions of patients suffering from moderate to severe acute pain and will continue our efforts and work with the FDA and our partners to bring this therapy to market; the Company believes we are on track to launch in 2014. We will keep our shareholders promptly informed as we continue to engage with the FDA, resubmit our NDA and progress through the approval process," 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 USD segment of the $8 billion USD spent annually on prescription opioids in the United States. MOXDUO, an immediate release Dual Opioid® 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® 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.