



ASX RELEASE
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QRxPharma Resubmits MOXDUO® New Drug Application to the FDA *Successful NDA Review to Position Product for Approval in Q3 2013*

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today that the Company resubmitted its MOXDUO® New Drug Application (NDA). As disclosed on 16 January 2013, at its last meeting with the Company, the US Food and Drug Administration (FDA) requested the resubmission of the NDA to include the respiratory safety results of Study 022.

“We believe the revised documents effectively address the FDA’s request for additional data resulting from their review of the initial MOXDUO NDA filed in mid-2011,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “To this end, and as recommended by the FDA, a comprehensive analysis of Study 022 was included as part of the resubmitted NDA. This study demonstrated the lower risks of respiratory depression for MOXDUO when compared to either morphine or oxycodone.”

QRxPharma believes the resubmitted clinical data demonstrate safety advantages of MOXDUO over its components, morphine and oxycodone, and that MOXDUO provides as good or better analgesia as indicated by past studies involving more than 1,600 patients experiencing moderate to severe acute post-operative pain.

The primary safety advantage of MOXDUO over its components is a reduction in respiratory risks evident in the data from Study 022. Furthermore, cross study analyses of all patients in the NDA programme demonstrate that MOXDUO is associated with less vomiting and a lower incidence of other side effects than comparable analgesic doses of morphine or oxycodone. MOXDUO also provides a safer starting dose and finer dose titration steps than either of its components, thus giving greater flexibility to physicians and patients as the need for pain relief is balanced with the lower risks of side effects.

“In addition to the results of Study 022, this revised NDA includes the results of five other Phase 2 and 3 clinical trials conducted by the Company over the past six years showing less nausea, vomiting, itching and headache in patients treated with MOXDUO,” added Holaday.



The FDA confirmed that there were no efficacy or safety issues in any of the studies that were part of the original NDA. The resubmitted application, including new results from Study 022, will undergo review by an Advisory Committee to evaluate the approvability of MOXDUO in the management of acute pain. By the end of this quarter, the Company expects to be notified of the new Prescription Drug User Fee Act (PDUFA) date for action by the FDA, as well as the date for the Advisory Committee meeting.

“We will keep our shareholders informed as we receive feedback from the FDA, and assuming approval, we anticipate product launch with our US commercialisation partner, Actavis, before the end of this calendar year,” concluded Holaday.

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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. Additionally, the Company’s clinical pipeline includes an intravenous (IV) and continuous 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.

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