



ASX RELEASE
26 November 2013

QRxPharma Refiles MOXDUO® New Drug Application with the FDA

Provides Additional Documentation Requested to Position Product for Approval in Q2 2014

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). At a meeting in early October, the United States Food and Drug Administration (FDA) provided QRxPharma with guidance on its requirements for the NDA refiling as well as data validation documentation.

“We are confident that our refiled NDA will confirm the validity of the data defining the product’s respiratory safety advantages and we are hopeful that the FDA will view them favourably in their consideration of the benefits of immediate release MOXDUO as a therapeutic option for the millions of patients who suffer from acute pain,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “We were encouraged by our candid dialogue with the FDA throughout this process, and will continue to liaise closely with the Agency to bring MOXDUO to market.”

The FDA previously confirmed that the Company’s Combination Rule Trial, Study 008, satisfied efficacy requirements and that there were no efficacy or safety issues identified in any of the studies submitted in the original NDA.

QRxPharma completed an audit of the more than 30 million data points for oxygen desaturation from Study 022. We believe these data demonstrate a significant respiratory safety advantage for MOXDUO over equi-analgesic doses of morphine or oxycodone. Furthermore, MOXDUO provides a lower starting dose and finer dose titration steps than acute pain opioids presently available, giving greater flexibility to physicians and patients as the need for pain relief is balanced with lower risks of side effects.

We expect the FDA to schedule an Advisory Committee meeting preceding a Prescription Drug User Fee Act (PDUFA) date six months following this submission, projected for late May, 2014.

“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, in the second half of CY2014,” added Holaday.

The revised NDA is the basis for recommending the regulatory approval for MOXDUO for the treatment of moderate to severe pain, a US\$2.5 billion segment of the US\$8 billion spent annually on prescription opioids in the US.

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Media Contact Information:

Lisa Fels
Brightline Strategies
Tel: +1 703 739 2424 x110
Email: lfels@brightlinestrategies.com

Rebecca Wilson
Buchan Consulting
Tel: +61 417 382 391
Email: rwilson@buchanwe.com.au



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 risks and improved patient outcomes. The Company's New Drug Application for its lead product candidate immediate release MOXDUO[®] for the treatment of acute pain, was refiled with the US Food and Drug Administration in November 2013. QRxPharma has entered into strategic agreements with Actavis Inc., Paladin Labs Inc. and Aspen Group for the commercialisation of immediate release MOXDUO in the US, Canada, Australia (including New Zealand and Oceania) and South Africa. The Company's clinical pipeline includes an intravenous (IV) and controlled release (CR) formulation of MOXDUO. QRxPharma is also collaborating 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.