



ASX RELEASE
11 December 2013

**QRxPharma Announces 25 May 2014 as New PDUFA Date
for MOXDUO[®] NDA**

Pending US FDA Approval, Expected Product Launch with Actavis in Second Half of 2014

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today that the United States Food and Drug Administration (FDA) has established 25 May 2014 as the new Prescription Drug User Fee Act (PDUFA) date for action on the Company's refiled New Drug Application (NDA) for immediate release MOXDUO. The FDA will schedule an Advisory Committee meeting prior to this date, and assuming approval, the Company plans to launch the product in the US in the second half of 2014.

"We are pleased that the FDA has assigned a PDUFA date indicating its timetable for evaluating the revised NDA and validated data," said Dr. John Holaday, managing director and chief executive officer, QRxPharma. "As 25 May 2014 falls on a Sunday the FDA will most likely issue the action letter on the preceding Friday being 23 May" added Holaday.

"Pending US approval, we are well prepared and poised to launch MOXDUO in the US with Actavis. Actavis' proven track record in the launching and marketing of opioid products will facilitate rapid uptake and significant sales in the US and maximise value for our shareholders."

In March 2012, QRxPharma finalised a license and option agreement with Actavis, which is a leading global specialty pharmaceutical company, for exclusive commercialisation and development rights of MOXDUO in the US.

QRxPharma refiled its NDA in late November. The revised NDA is the basis for recommencing the regulatory approval for MOXDUO for the treatment of moderate to severe acute pain, a US\$2.5 billion segment of the US\$8 billion spent annually on prescription opioids in the US. It also serves as the regulatory foundation for submitting MOXDUO for approval in Europe, Australia, Canada and other markets in the upcoming months. 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 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., Aspen Group and Teva for the commercialisation of immediate release MOXDUO in the US, Canada, Australia (including New Zealand and Oceania), South Africa and Israel. 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.