



**ASX RELEASE**

**26 May 2014**

**QRxPHARMA RECEIVES COMPLETE RESPONSE LETTER FROM FDA  
REGARDING MOXDUO® NDA**

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRPY) announced today the United States Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the Moxduo New Drug Application (NDA) for the treatment of moderate to severe acute pain. The Agency stated that there was not sufficient evidence to support approval of Moxduo at this time. The Agency indicated clinical information demonstrating a clear benefit over oxycodone and morphine alone, either by efficacy, or safety, in an appropriate patient population, is needed.

The Company is presently reviewing the Agency's feedback and will request a meeting with the FDA to clarify the steps required for approval.

"We will work with FDA to develop a clinical program that addresses the Agency's feedback and ensure that the completed program will clearly demonstrate Moxduo's benefit," said Dr. Edward Rudnic, Chief Executive Officer, QRxPharma.

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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. The Company's product portfolio includes both late and early stage clinical drug candidates with the potential for reduced risks and improved patient outcomes. QRxPharma has entered into strategic agreements with Actavis Inc., Paladin Labs Inc., Aspen Group and Teva Pharmaceuticals 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](http://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.