



**ASX RELEASE**  
**14 August 2014**

### **QRxPHARMA HALTS MOXDUO DEVELOPMENT**

**Sydney, Australia and Bedminster, New Jersey** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) today announced that it is halting all further development work on the Moxduo portfolio of products.

As announced on 26 May 2014, QRxPharma received a Complete Response Letter (CRL) from the United States Food and Drug Administration (FDA) regarding its Moxduo New Drug Application (NDA). Following the CRL, the Company had an End of Review (EOR) meeting with the agency on US 9 July.

The management team has since conducted a detailed review of the MoxDuo technology with particular emphasis on the EOR meeting with the FDA and made a recommendation to the Board to halt all further development of the Moxduo IR, CR and IV programs. The Board of QRxPharma has agreed with, and accepted this recommendation.

The Company believes that the Moxduo program will require a repeat Phase 2 clinical study, followed by one or more pivotal Phase 3 clinical studies. The FDA has advised that agreement on a Special Protocol Assessment (SPA) would be unlikely for these studies and given specific issues related to the design of these clinical studies, such as a primary endpoint of 90% SpO<sub>2</sub> and flexible dosing, both which have been strongly encouraged by FDA, the likelihood of success is now in considerable doubt.

The Company estimates the time and cost for such a development program to be significant and is not commercially justified given the limited residual patent life.

With immediate effect, the Company will be implementing a reduction in its overhead structure, minimizing non-essential expenditure and retaining only a small core team tasked with exploring all strategic alternatives for the Company and its assets.

The Company reported A\$10.5 million in cash reserves at 30 June 2014, however as noted in the recently filed Appendix 4C the Company has set aside in escrow A\$3.62 million to cover potential liabilities of its current employees, consultants and the former CEO arising from i) Notice entitlements, ii) Termination payments and where applicable, iii) Retention payments. In addition, the Company had been carrying as a liability excess annual leave entitlements. During July the Company paid down A\$0.43 million of this liability. Estimated free cash at 30 September 2014 will be approximately A\$3.0million

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## **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.