

ASX RELEASE 25 February 2014

## INTERIM REPORT FOR THE HALF YEAR ENDED 31 DECEMBER 2013

**Sydney, Australia and Bedminster, New Jersey** - QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) today reported a net loss for the half-year ended 31 December 2013 from ordinary activities of \$5.1 million (compared to a net loss of \$5.2 million for the half-year ended 31 December 2012) with the Company retaining cash reserves of \$17.2 million (compared to \$12.0 million at 30 June 2013), as detailed in the Appendix 4D released today. The Company's cash position was bolstered during the half-year with the closing of a capital raising which included a Share Placement to institutional and sophisticated investors, and a Share Purchase Plan (SPP) that together raised a total of A\$11.6 million before expenses.

The net loss for the period of \$5.1 million (2012: net loss \$5.2 million) from ordinary activities resulted from the Company's continuing efforts to secure approval for immediate release Moxduo<sup>®</sup>. This included efforts to obtain approval from the United States Food and Drug Administration (FDA) of a New Drug Application (NDA) in the United States (US), and activities associated with the preparation of the regulatory filings in Europe, Australia and Canada.

During the half-year the Company announced the resubmission of its NDA with the FDA for immediate release Moxduo. The FDA has established 25 May 2014 as the new Prescription Drug User Fee Act (PDUFA) date for action, and the Company expects the FDA to schedule an Advisory Committee meeting in April, 2014.

Assuming approval by the FDA in May 2014, the Company intends to launch immediate release Moxduo with Actavis, its US commercialisation collaborator, into the US\$2.6 billion acute pain prescription opioid market in the United States in the second half of CY2014. Under the strategic agreement, Actavis provides for the launch costs and sales force, whilst the Company co-ordinates regulatory and manufacturing efforts.

The data in the revised NDA which QRxPharma believe demonstrates the respiratory safety advantages of Moxduo will also provide the basis for the regulatory submissions for Moxduo in Europe, Australia, and Canada planned for the coming months by either the Company or its strategic collaborators.

Also during the half-year, the Company announced execution of a licensing agreement with Aspen for the commercialisation rights to immediate release Moxduo in Australia (including New Zealand and Oceania) and South Africa as well as the execution of a licensing agreement with ABIC Marketing, the Israeli domestic subsidiary of Teva Pharmaceutical Industries Limited, for the commercialisation rights to immediate release Moxduo in Israel. In addition, the Company signed a collaboration agreement with Aesica Formulation Development Limited for the world-wide promotion of the Company's proprietary Stealth Beadlets<sup>TM</sup> abuse deterrent technology.

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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 refiled New Drug Application for its lead product candidate immediate release Moxduo<sup>®</sup> for the treatment of acute pain, is presently under review at the US Food and Drug Administration. 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<sup>™</sup> abuse deterrence technology. For more information, visit <u>www.qrxpharma.com</u>.

## **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.