



ASX RELEASE
29 August 2013

PRELIMINARY FINANCIAL RESULTS YEAR ENDED 30 JUNE 2013

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) today reported a net loss for the year ended 30 June 2013 from ordinary activities of \$10.1 million (compared to a net loss of \$16 million in 2012) with the Company retaining cash reserves of \$12 million (compared to \$23 million in 2012). The operating results for the year ended 30 June 2013 are reflective of the Company's efforts to secure approval from the United States Food and Drug Administration (FDA) for its lead compound, immediate release MOXDUO® in the US, while continuing to advance regulatory filings in Canada, Europe, and Australia.

Regulatory

QRxPharma remains committed to launching immediate release MOXDUO into the \$2.5 billion US acute pain marketplace. Having been denied in June 2012 a first cycle approval by the FDA of its New Drug Application (NDA), the Company continued to progress towards an approval during the financial year. The FDA had previously set 26 August 2013 as the Prescription Drug User Fee Act (PDUFA) date for action on the Company's resubmitted NDA and 17 July 2013 as the date for an FDA Advisory Committee meeting.

During preparation for the Advisory Committee Meeting, the Company found timing misalignments in the oxygen desaturation data from one trial site. To allow the Company and the FDA time to fully consider results of recent findings for Study 022, the Advisory Committee Meeting was delayed.

In August 2013, the FDA issued the Company a Complete Response Letter (CRL) regarding the Company's MOXDUO NDA to allow time to submit and evaluate further information required for the FDA to fully consider the respiratory safety advantages of MOXDUO from Study 022. The Company plans to complete a refiling of its NDA in Q4 2013, inclusive of additional information and analysis as requested by the FDA and anticipates a new PDUFA date in Q2 2014, preceded by an Advisory Committee Meeting.

"We remain confident in MOXDUO as a potential therapeutic option for the millions of patients suffering from moderate to severe acute pain and will continue our efforts to bring this therapy to market," said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma.



Commercialisation

During the year QRxPharma entered into a strategic collaboration with Paladin Labs Inc (Paladin). Paladin has exclusive rights to commercialise immediate release MOXDUO for the Canadian market, is responsible for the New Drug Submission (NDS), all product launch costs, as well as ongoing marketing and sales efforts. QRxPharma will receive tiered double digit royalties and up to US\$25 million in milestone payments on achievement of specific sales, regulatory and reimbursement targets.

In July 2013 the Company signed a Collaboration Agreement with Aesica Formulation Development Limited (Aesica) for the world-wide promotion of the Company's proprietary Stealth Beadlets® abuse deterrent technology. Aesica supplies pharmaceutical contract development and manufacturing services globally and operates six manufacturing sites across the UK, Germany and Italy. Under the non-exclusive Collaboration Agreement, Aesica will promote QRxPharma's Stealth Beadlets technology for inclusion in their clients' existing formulations of controlled drugs. Aesica will enter into fee-for-service contracts with such third parties for the development of the new Abuse Deterrent Formulations (ADF) of specific drugs of interest, whilst QRxPharma will negotiate license terms directly with each party.

Intellectual Property

During the year, the Company further strengthened its' intellectual property portfolio with the announcement in June 2013, that the United States Patent and Trademark Office (USPTO) issued the Company US Patent No 8,461,171 expiring in 2031. This patent covers a hybrid morphine-oxycodone molecule where these two different opioids are chemically linked.

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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 treatments for pain management. The Company's product portfolio includes both late and early stage clinical drug candidates with the potential for reduced risk, abbreviated development paths, and improved patient outcomes. The Company's lead product candidate, immediate release MOXDUO® for the treatment of acute pain, is presently under review at the US Food and Drug Administration. QRxPharma entered into strategic collaborations with Actavis Inc. in December 2011 and Paladin Labs Inc. in October 2012 for the commercialisation of immediate release MOXDUO® in the US and Canadian acute pain markets respectively. In July 2013, QRxPharma announced a collaboration agreement with Aesica Formulation Development Limited, for the world-wide promotion of QRxPharma's proprietary Stealth Beadlets® abuse deterrence technology. Additionally, the Company's clinical pipeline includes an intravenous (IV) and controlled release (CR) formulation of MOXDUO. 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.