



**ASX RELEASE**  
**13 November 2013**

## **2013 ANNUAL GENERAL MEETING**

**Sydney, Australia and Bedminster, New Jersey** - QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) is a commercial-stage speciality pharmaceutical company focused on the development and commercialisation of new pain management and abuse prevention products, is conducting its Annual General Meeting today at the offices of DibbsBarker, Lawyers, of Level 8, 123 Pitt Street, Sydney commencing at 10.00 am (Sydney time). Please find attached the addresses to be delivered by Dr Peter Farrell (Chairman) and Dr John Holaday (Managing Director and Chief Executive Officer).

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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 risk, abbreviated development paths, and improved patient outcomes. In Q4 2013, the Company plans to refile with the US Food and Drug Administration a New Drug Application for its lead product candidate, immediate release MOXDUO<sup>®</sup>, for the treatment of acute pain. QRxPharma has entered into strategic agreements with Actavis Inc., Paladin Labs Inc. and Aspen Group for the commercialisation of immediate release MOXDUO in the US, Canada, Australia (including New Zealand and Oceania) and South Africa. 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 [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.



**Chairman's Address – Dr Peter Farrell  
13 November 2013**

Ladies and gentlemen,

Thank you for your attendance at today's Annual General Meeting and for your ongoing support of QRxPharma. In the past year, our efforts have been focussed on obtaining approval from the United States Food and Drug Administration (FDA) for immediate release MOXDUO<sup>®</sup> for the treatment of moderate to severe acute pain.

As you would know, this process has been both challenging and frustrating for the Company; however, it has also generated constructive feedback. Supported by our dialogue with the FDA and further analyses of data from Study 022, management and I feel that we met the requirements which the FDA led us to believe they needed, and this month we will resubmit the New Drug Application (NDA) for their consideration. We are hopeful that both the Advisory Committee and the FDA will agree that we have ticked all the appropriate boxes needed for approval.

Let me provide you with a brief summary of where we are at the moment.

After receiving the Complete Response Letter in relation to the Company's NDA in August, the FDA arranged with the Company to conduct a formal end-of-review meeting on October 3. At that meeting, the FDA reiterated that there were no safety issues in any of the previously submitted studies, and they reaffirmed that the safety and efficacy of MOXDUO are not in question.

The FDA further encouraged the Company to submit the validated data from Study 022 and the updated NDA. The data that we will resubmit reinforce our previous conclusions that MOXDUO has a better respiratory safety profile than either morphine or oxycodone given individually. As of now, there are no opioids in the marketplace that have demonstrated a respiratory safety benefit, and respiratory depression is the cause of death from opioid overdoses. Each year, about 16,000 people die from opioid overdose in the US alone.

The Company anticipates the new Prescription Drug User Fee Act (PDUFA) date will be in Q2 CY2014 and the Agency told us they will schedule an Advisory Committee meeting ahead of the PDUFA date. This will provide the Company with an opportunity to present the totality of MOXDUO's respiratory safety advantages to an Advisory Committee of experts, who will in turn help guide the FDA's final decision.

The Company is on target to resubmit the NDA by the end of November as indicated to the market earlier. As you may appreciate, in dealing with the FDA, there are never any certainties. Nonetheless, based on the guidance we received at our meeting with the Agency in October and their suggestions we incorporated into the NDA, we remain hopeful that MOXDUO will receive FDA approval. The FDA did not request another study at this time;



however the Company is prepared to conduct another study in the future to build on the body of evidence indicating that MOXDUO has significant clinical advantages.

QRxPharma has been in close coordination with our US partner, Actavis, throughout the regulatory process and to assure that sufficient supplies of MOXDUO are available for an anticipated product launch in the US in 2014. As further endorsement of MOXDUO's product opportunity, several other important global territories have been licensed to commercialise immediate release MOXDUO.

In October 2012 Paladin Labs Inc. secured the Canadian rights. And recently we announced a strategic collaboration with Aspen Group for the Australian, New Zealand, Oceania and South African markets.

Following the resubmission of the NDA to the FDA in the US, the Company will turn its attention in Q1 2014 to finalising submissions for Europe and assisting our partners with submissions to other respective regulatory authorities outside the US.

We ended the financial year with \$12 million in cash reserves and recently closed the September quarter with cash reserves of \$8.5 million. As announced this morning the Company has successfully completed a A\$7.5 million Placement to institutional and sophisticated investors. The oversubscribed Placement was well supported primarily by existing shareholders plus some new investors. The Company also announced a Share Purchase Plan (SPP) of up to A\$2.5 million for existing shareholders to participate in this capital raise.

The issue price under the Placement and SPP of A\$0.60 per share represents a 15.5% discount to the last closing price of QRxPharma shares on 8 November 2013. The shares issued under the Placement will be issued under the Company's 15% placement capacity under ASX Listing Rule 7.1. The proceeds from the Placement and SPP will be used to fund operations through the anticipated date of the FDA decision on the approval of immediate release MOXDUO; to submit regulatory filings in Europe, Australia, New Zealand and Canada; and assuming MOXDUO is approved, provides capital for a sufficient period post approval to initiate the launch of MOXDUO.

Overall, our loss (after tax) of \$10.1 million for the year was in line with our expectations, and we remain extremely conscious of the need to conserve our cash through the upcoming year.

The QRxPharma team remains entirely committed to bringing MOXDUO to commercial launch, and I would like to take this opportunity to thank my fellow Board members, senior management and the entire QRxPharma staff in both Australia and the US for their dedication and hard work. I would also like to thank our shareholders for their ongoing patience, commitment and support, which is greatly appreciated.





**Managing Director's Address – Dr John Holaday  
13 November 2013**

Ladies and gentlemen,

First, let me thank my colleague, Chris Campbell, our CFO; our bankers, Michael Johnston and the entire Morgans team; and John Granger and David Allen of Hawkesbury Partners for their diligent and successful efforts to complete a significantly oversubscribed offering of A\$7.5 million which closed yesterday. I also want to thank Mike Quinn and Peter Campbell for their oversight as members of the Audit Committee, our Chairman, Peter Farrell, and our founder and Board member Gary Pace for their guidance and counsel.

As Peter detailed in his Chairman's Address, 2013 was indeed a challenging year for QRxPharma, but perhaps with a silver lining.

The FDA's requirements for approval of MOXDUO were clarified by our additional dialogue with them in October. Accordingly, we believe we have gained a greater understanding as to the FDA's view on important points, and this will guide our refiled NDA. We can confirm that the Agency indicated MOXDUO's potential as a safe, effective opioid formulation.

Our discussions with the FDA prompted us to further analyse Study 022 by validating data in preparation for submitting the revised NDA later this month as planned. The full audit of over 30 million data points for oxygen desaturation from Study 022 and additional analyses of the data confirmed and strengthened earlier conclusions which indicated that patients treated with MOXDUO experienced less severe respiratory depression than those treated with either morphine or oxycodone given separately.

These findings and results will be included in the refiled NDA, along with results from earlier studies, documenting MOXDUO's clinically relevant advantages in reducing nausea, vomiting, dizziness, itching, headache and sleepiness for patients treated with MOXDUO compared to those treated with other widely prescribed opioids.

Why is this so important? While opioids remain the gold standard for managing pain, their use is currently limited by these extensive side effects. As noted earlier by Peter, the primary cause of death from opioids is respiratory depression, and our results from Study 022 document MOXDUO's benefits with this important risk.

And pain management is large and growing market. Pain is the most common reason people seek medical attention in the United States, and the opioid market for treating pain is currently valued at over US\$14 billion worldwide. The acute pain market accounts for over US\$2.5 billion of the US\$8 billion spent annually on prescription opioids in the US. And, as the population ages and access to medical care improves, forecasts predict a significant rise in prescriptions for the treatment of acute and chronic pain.



Vicodin, a combination paracetamol / opioid acute pain product, is the largest selling acute pain opioid in the US, accounting for well over half of the 214 million acute opioid prescriptions last year. The FDA rules require that all Vicodin-like opioids containing more than 325 mg of paracetamol are to be removed from the market by January 2014 due to concerns over the safety of paracetamol as the leading cause of pharmacologically-induced liver failure. A few weeks ago, the Agency took further steps to restrict Vicodin availability by recommending that it be rescheduled from Schedule III to Schedule II, making Vicodin more difficult to prescribe and levelling the playing field with all other opioids. In the US, there are more than 135 million prescriptions for Vicodin alone, and losses of Vicodin prescriptions for these reasons creates a window of opportunity for new, potentially safer alternatives like MOXDUO.

For these reasons, the Company and our strategic partners are excited about the potential to launch MOXDUO into the rapidly changing acute pain market in 2014.

We are also encouraged by the recently executed licenses with Aspen for commercialising immediate release MOXDUO in Australia, New Zealand, Oceania and South Africa. Under these agreements, Aspen will assume responsibility for the regulatory filings in each country, all product launch costs, as well as all ongoing marketing and sales efforts. QRxPharma will receive up to A\$1.5 million in regulatory approval milestones, together with double digit royalties on the sales of immediate release MOXDUO in all markets. QRxPharma retains all rights to the intravenous and controlled release formulations of MOXDUO, consistent with earlier license agreements signed with Actavis, for the US rights, and Paladin for the Canadian rights to immediate release MOXDUO.

Complementing our portfolio and commercial partnerships, the Company has also recently signed a collaboration agreement with Aesica Pharmaceuticals Limited for the worldwide promotion of QRxPharma's proprietary Stealth Beadlets™ abuse deterrent technology. This technology, developed for the MOXDUO controlled release formulation for the treatment of chronic pain, may be incorporated into almost any potentially abused drug, including opioids, amphetamines and sedatives that are sold in solid dosage forms such as a tablet, sachet or capsule. They provide significant resistance against the extraction of active ingredients if crushed, solubilized or heated, and compared head-to-head with other abuse deterrent technologies, Stealth Beadlets have shown superiority. This non-exclusive agreement enables Aesica to promote this technology to their client for inclusion in their 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 of specific drugs of interest, whilst QRxPharma will negotiate license terms directly with each party.

We continue to be vigilant in protecting our intellectual property and enhancing patent protection for MOXDUO. During the year, the United States Patent and Trademark Office issued the Company US Patent number 8,462,171 which expires in 2031. The patent titled,



“Hybrid Opioid Compounds and Compositions” covers a hybrid morphine-oxycodone molecule where these two opioids are chemically linked. The patent covers the development of new chemical entities that have the potential to provide better pain relief and fewer side effects than their individual components, and forms part of a broad portfolio of patents that protect MOXDUO in various formulations up until 2029.

I would like to close by reiterating Peter’s thanks to you, our shareholders, for your continued support of QRxPharma during this regulatory process. My team and I remain committed and determined to delivering a successful outcome, and value to shareholders. The strength of our organisation both here in Australia and in the United States gives me confidence in the successful commercialisation of MOXDUO in the coming years and I look forward with great enthusiasm to the impending growth and commercial development of QRxPharma.

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