



ASX RELEASE

7 November 2012

2012 ANNUAL GENERAL MEETING

Sydney, Australia & Bedminster, NJ – QRxPharma (ASX: QRX and OTCQX: QRXPY), is a commercial-stage specialty pharmaceutical company focused on the development and commercialisation of new treatments for pain management, 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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For more information please contact:

John W Holaday, Ph.D.
Managing Director and Chief Executive Officer
Tel: +1 301 908 3086
Email: john.holaday@qrxpharma.com

Chris J Campbell
Chief Financial Officer and Company Secretary
Tel: +61 2 9492 8021
Email: chris.campbell@qrxpharma.com



About QRxPharma

QRxPharma Limited is a commercial-stage specialty pharmaceutical company focused on the development and commercialisation of new treatments for pain management. Based on a development strategy that focuses on enhancing and expanding the clinical utility of currently marketed compounds, 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. 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. Additionally, the Company's clinical pipeline includes an intravenous (IV) and continuous 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.



**Chairman's Address – Dr Peter Farrell
7 November 2012**

Ladies and gentlemen,

Thank you for your attendance at today's Annual General Meeting and for your ongoing support for QRxPharma. This year has brought with it a new and challenging phase in the journey towards commercialisation of MOXDUO – as I know you're all acutely aware.

At the time of last year's AGM we had recently submitted our New Drug Application (NDA) for immediate release MOXDUO – our first pain drug candidate. This was a significant milestone for the Company and the culmination of excellent clinical trial results; along with drive and commitment from the team who had worked extremely hard in the four years since our IPO to deliver this crucial milestone.

In June this year we received the disappointing news that the United States Food and Drug Administration (FDA) had issued a Complete Response Letter (CRL), advising that we were not successful with our initial NDA filing in obtaining FDA approval for MOXDUO.

While this turn of events took the Company's board and management – and shareholders – by surprise, we have since been encouraged by the outcomes of our subsequent dialogue with the FDA.

At a post-submission review meeting with the FDA in August 2012 the steps needed for approval were clarified. Importantly, it was confirmed at this meeting that there were no unexpected or problematic safety issues in any of the studies submitted as part of the MOXDUO NDA.

The FDA has requested further information regarding data filed as part of the MOXDUO NDA and additional analysis of trials completed to date, which were targeted to meet requirements for approvals in Europe and Australia. Of particular interest to the FDA were the results from Study 022, a study that compared respiratory depression for MOXDUO versus single equi-analgesic doses of morphine and oxycodone. This study indicated that MOXDUO resulted in less severe respiratory depression than either morphine or oxycodone given separately.

The next step for the Company is to refile its NDA with the additional data to address the FDA's requests, which we believe could result in a positive decision from the FDA during 2013.

Based on the dialogue that has taken place with the FDA, as part of this process, the Board and I remain confident that MOXDUO will receive approval. There is a strong precedent with drugs which receive a CRL response in the first instance and then go on to obtain approval.



Our case now rests on the merits of solid clinical results, as well as the strength of the additional data submissions, coupled with further dialogue with the FDA. Our team is singularly focused on finalising the NDA for refiling.

Between these two book-ends of initial NDA filing and CRL, the QRxPharma team has done an excellent job in preparing MOXDUO for a successful commercial launch.

In December 2011, we entered into a strategic collaboration with Actavis Inc – now owned by Watson Pharmaceuticals. Actavis is one of the world’s leading generic pharmaceutical companies and has established a branded presence in the US pain market with Kadian[®] - or morphine sulphate whose formulation was developed in Australia many years ago by F H Faulding and used for the treatment of chronic pain. Actavis is our commercialisation partner in the United States, and this collaboration is the cornerstone of our strategy for a successful commercialisation of immediate release MOXDUO in the US.

Actavis is proving to be an excellent partner, with experience in manufacturing, distribution, marketing and sales of both patented and generic opioid products. Their background and experience and the ongoing collaboration between QRxPharma and Actavis has resulted in a strong working relationship, and both parties are keen to achieve early revenues. Actavis has also confirmed support for our MOXDUO FDA strategy and are fully engaged with our efforts to address the FDA’s concerns.

Actavis was recently acquired by Watson Pharmaceuticals – a leading US pharmaceutical company listed on the New York Stock Exchange and one of the top four generic companies in the world. In our view, this development has strengthened the value of the Actavis relationship, providing further marketing muscle as we launch MOXDUO in the US branded drug marketplace.

Recently we announced a licensing agreement with Paladin Labs Inc, a Toronto Stock Exchange listed company, to commercialise immediate release MOXDUO in Canada. This is an excellent outcome that gives another vote of confidence in the global prospects for MOXDUO. Paladin is a speciality pharmaceutical company with a strong branded pain franchise. We will be working with Paladin to file a New Drug Submission during 2013 to the regulatory authorities for approval in Canada.

The Board and I are optimistic about the Company’s future and I remain confident that we are on the right path to ensure the ongoing success of QRxPharma as we develop plans to launch immediate release MOXDUO in the US in 2013.



We ended the financial year with \$23 million in cash reserves and recently closed the September quarter still with cash reserves of \$18.7 million. In the past financial year, this balance was reinforced by a successful share placement and rights issue which raised \$26.5 million during July and August 2011 and the receipt of \$5.9 million (US\$ 6 million) from Actavis on the signing of the binding Letter of Intent in December 2011. Overall our loss (after tax) of \$16 million for the year was in line with our expectations and we are very conscious of the need to conserve our cash through the upcoming year.

The team at QRX remains entirely committed to bring 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 support, which is greatly appreciated. We look forward – with cautious optimism – to announcing the successful US approval of immediate release MOXDUO in the coming year.

Thank you.



Managing Director's Address – Dr John Holaday 7 November 2012

Ladies and gentlemen,

As Peter detailed in his Chairman's Address, 2012 presented new challenges for QRxPharma. The receipt of the Complete Response Letter (CRL) in June 2012 from the US Food and Drug Administration (FDA) in response to our MOXDUO New Drug Application (NDA) was an obvious disappointment. The old saying is "if you want to make God laugh, tell him your plans". However, I want to reinforce our confidence and commitment to the successful launch of immediate release MOXDUO into the acute pain marketplace in 2013.

I draw this confidence from three areas:

- Firstly, based our interactions with the FDA since receipt of the CRL;
- Second; the ongoing support of our partners and
- Third; the strength of our technology and organisation.

As we've reported to the market previously, following the receipt of the CRL, we had a post submission review meeting with the FDA in August 2012 that confirmed that our Combination Rule Study (Study 008) satisfied efficacy requirements and there were no unexpected or problematic safety issues in any of the studies submitted as part of the MOXDUO NDA.

This is consistent with clinical data that demonstrates MOXDUO to be a safe, effective alternative to other opioids. With our science intact, the core value holds, and we continue our vigilant efforts to bring MOXDUO to approval. We are currently working through additional data to be included in a refiled NDA also including more extensive information demonstrating safety from Study 022. As Peter mentioned, the lower oxygen "desaturation" levels in patients receiving MOXDUO were in sharp contrast to the lower blood oxygen levels in patients receiving equal analgesic doses of morphine or oxycodone alone.

Oxygen desaturation is a primary indicator of respiratory depression, a medically important adverse event and the cause of death from high opioid doses. Last year, more people in the US died from drug overdoses than from traffic accidents, and 40% of those deaths were from respiratory depression caused by opioid overdoses. The analysis of our Study 022 was completed after our NDA was filed in August 2011, but early safety data from this study were included in the 120-day update filed last December. It turns out that the additional efficacy and safety information from this study was of significant interest to the FDA. We believe the results of this study provide further safety data that support the approval of MOXDUO.



Regardless of recent regulatory hurdles, our strategic partner, Actavis Inc., stands by us. We maintain open and frequent dialogue regarding product commercialisation and they are continuing to invest in the infrastructure required for MOXDUO's commercial launch in 2013. QRxPharma and Actavis are aligned in their vision that MOXDUO represents a significant opportunity for both companies, and their view has not changed since they were acquired by Watson Pharmaceuticals – a development we believe will only enhance our relationship.

There are many synergies in this strategic collaboration: immediate release MOXDUO is very well suited to the experience and expertise of Actavis' marketing and sales teams. As a leading manufacturer of branded and generic opioids, Actavis may also serve as a contract supplier for MOXDUO in the US and other global markets. Actavis also retains the option to negotiate for US marketing and sales rights to the other MOXDUO formulations - continued release (CR) for chronic pain and the hospital based intravenous (IV) formulation. In particular, the exercise of the option for MOXDUO CR by Actavis is contingent upon its achievement of certain sales milestones for immediate release MOXDUO.

The recent signing of an agreement with Paladin for the rights to immediate release MOXDUO in Canada is another strong show of support for MOXDUO from an external party. Apart from an upfront payment of US\$500,000 this agreement will be worth up to US\$25 million for QRxPharma in milestone payments, and we will receive tiered double-digit royalties on sales. Paladin also assumes responsibility for the New Drug Submission (NDS) in Canada, all product launch costs as well as ongoing marketing and sales efforts. The Company will be working with Paladin to submit the NDS to Health Canada during 2013. Paladin is an excellent partner for us to enter the Canadian market; they have extensive experience in the sector, a consistent record of growth in Canada's branded pain market and a strong balance sheet. They, too, share our confidence of the commercial prospects for MOXDUO.

While our primary focus right now is on refiling the NDA for immediate release MOXDUO, work has been done over the past year to advance the other MOXDUO formulations in our portfolio. These results reinforce the strength of our Dual Opioid[®] product portfolio.

During the year we completed two Phase I studies for MOXDUO CR. This "controlled-release" formulation is designed to provide at least 12 hours of analgesia in patients suffering from moderate to severe chronic pain including cancer, lower back, osteoarthritis and neuropathic pain. The studies were conducted in healthy volunteers to evaluate the rate at which key components of the MOXDUO CR formulation were absorbed, distributed, metabolised and eliminated by the body.



The results of these early trials exceeded our expectations. MOXDUO CR demonstrated superior bioavailability and sustained blood levels for well over 12 hours, especially in the 12 – 24 hour period when compared directly to OxyContin[®], the largest selling opioid for chronic pain. These outcomes indicate that MOXDUO CR will be effective as a once or twice a day chronic pain drug, as opposed to OxyContin which is actually prescribed three times a day to almost a third of patients – even though it is labelled for twice daily use.

The MOXDUO CR tablets used in these clinical tests also included QRxPharma's proprietary Abuse Deterrence Formulation (ADF) technology and proved to result in a limited drug recovery of less than 15% when tampered with – i.e. dissolved in water or alcohol, or crushed. Nor did the abuse deterrent features of our formulation impair bioavailability of the drug.

We continue to be vigilant in protecting our intellectual property portfolio and enhancing patent protection for MOXDUO. During 2012, the United States Patent and Trademark Office (USPTO) issued the Company US Patent No 8,182,837, expiring in 2023. This newly issued patent is directed to a pain treatment method that utilises MOXDUO's composition as a defined ratio of morphine/oxycodone (3/2). The patent covers oral administration of two Dual Opioid compositions: (1) immediate release MOXDUO for the treatment of acute pain and (2) MOXDUO CR (Controlled Release) for the treatment of chronic pain. Additional patents that are filed and under review reinforce our intellectual property portfolio that could provide protection until 2029.

Despite the obstacles we've faced this year, let's not forget the basic premise of MOXDUO and the market opportunity ahead of us. Opioids remain the gold standard for managing pain, but their use is limited by extensive side effects.

In clinical trials we have been able to demonstrate that immediate release MOXDUO delivers a 25% to 75% reduction in nausea, vomiting, dizziness, headaches and sleepiness compared to equal analgesic doses of widely prescribed acute pain opioids. The respiratory advantages of immediate release MOXDUO as demonstrated in Study 022 further indicate that MOXDUO provides a significant safety benefit with less clinical respiratory risk than either morphine or oxycodone.

The changing regulations in the US for acute pain opioids are creating even greater market opportunity for our Dual Opioid product portfolio. Because of acute liver toxicity, the FDA has ruled that all combination paracetamol (acetaminophen) / opioid acute pain products containing more than 325mg of paracetamol are to be removed from the market by January 2014, due to concerns over the safety of paracetamol. This accounts for over 100 million prescriptions for Vicodin[®] alone, the predominant acute pain opioid.



Furthermore, a potential rescheduling of Vicodin, currently the most prescribed drug in the US, from Schedule 3 to Schedule 2 (with all the other opioid drugs), will make it harder to prescribe in the US. These two factors will create a void of about 50% of the acute pain market that MOXDUO has the potential to address.

In conclusion, the strength of our organisation both here in Australia and in the United States gives me confidence that we can meet the challenges ahead and successfully commercialise MOXDUO. QRxPharma has a team with great talent and deep experience in drug development, regulatory affairs and commercialisation. Importantly it is a team that is passionate and 100% dedicated to delivering a successful outcome and delivering value to shareholders. We remain eager and have our eye firmly on the goal. We look forward to keeping you informed of our progress in the year ahead and thank you for your support and patience over this past year.

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