

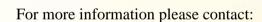
#### **ASX RELEASE**

16 November 2011

## 2011 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 and central nervous system (CNS) disorders, is conducting its Annual General Meeting today at the offices of Dibbs Barker, 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 (ASX: QRX and OTCQX: QRXPY) is a commercial-stage specialty pharmaceutical company focused on the development and commercialisation of new treatments for pain management and central nervous system (CNS) disorders. 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. The Company intends to co-promote its products in the US and seeks strategic partnerships for worldwide markets. QRxPharma's lead product candidate, immediate release MoxDuo, now awaits approval by the US Food and Drug Administration (FDA). Additionally, the Company's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MoxDuo, as well as other pipeline technologies in the fields of pain management, neurodegenerative disease and venomics. 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 16 November 2011

Ladies and gentlemen,

It gives me pleasure to report to you on the progress that QRxPharma has made over the past 12 months. Most significantly, after completing all pivotal Phase 3 registration studies for MoxDuo IR, for the treatment of moderate to severe acute pain, we have submitted the New Drug Application (NDA) to the United States Food and Drug Administration (FDA) – a significant achievement for any therapeutics company. Last week we received from the FDA our PDUFA date of 25 June 2012 as the target date for action on the approval of the MoxDuo IR NDA. We are proud of this accomplishment as the submission of the NDA has been completed just four years after the Company's Initial Public Offering.

We are now finalising plans to launch MoxDuo IR into the \$2.5 billion US prescription opioids market for the treatment of moderate to severe acute pain in 2012, and anticipate regulatory approvals in Europe, Canada and Australia to follow a year later.

Pain is cited as the most common reason for visiting the doctor in the United States, but the world has offered little innovation in this area. Morphine has been in use since 1805 and oxycodone since 1916 and these still remain among the most commonly prescribed pain dugs. Up to now, there has not been a new opioid launched into the acute pain marketplace where direct comparisons with existing opioids have been made. We are optimistic for the future of MoxDuo IR having treated over 700 post-surgical patients experiencing moderate to severe pain with MoxDuo IR in clinical trials which consistently demonstrated significant analgesia and safety advantages over existing opioids that are current standards of care. Our studies have shown patients who received MoxDuo IR were 25 to 75% less likely to experience the range of serious side effects including nausea, vomiting, dizziness, sleepiness or constipation.

In addition to MoxDuo's established advantages over other opioids, we believe QRxPharma's commercial position has also been strengthened by recent FDA actions regarding paracetamol (acetaminophen) / opioid combination products. Due to concerns over the safety of paracetamol, combination products containing more than 325mg of paracetamol must be removed from the market by January of 2014. This mandate affects over 100 million prescriptions per year in the US, including the most widely prescribed drug, Vicodin<sup>®</sup>. In addition, widespread abuse of Vicodin has prompted the US Congress to propose legislation to change the product's prescription category from Schedule 3, a more easily prescribed category of drugs, to Schedule 2 with all other opioids (including MoxDuo). This confluence of events increases the opportunity for MoxDuo IR as an advantaged product in a wide-open marketplace.

We ended the financial year with cash reserves of \$7.3 million, and closed the September quarter with cash on hand of \$32.0 million following our well supported recent capital raising which included a Placement to institutions and professional investors, and a Rights Issue that together raised a total of \$26.5 million before expenses.



We recorded a net loss for the year of \$25.6 million which compares to a loss of \$27.5 million for the previous year. This was in line with our expectations as we continue to fund research and development and the timely progression of our product pipeline.

The Company intends to use the recently raised funds to advance MoxDuo IR through FDA approval and commercialisation as well as to progress the development of MoxDuo CR, our continuous release Dual Opioid formulation, which is designed to provide 12 hours of pain relief in patients with moderate to severe chronic pain. MoxDuo CR represents a significant market opportunity with over \$5.6 billion spent annually on opioids in the US for the treatment of chronic pain. The improved tolerability profile of MoxDuo may make it a strong offering for patients suffering from chronic disease as they are often saddled with managing an array of side effects from their medications. The funds also give the Company a firm foundation to negotiate the best strategic partnership to augment our commercialisation strategy, all of which is a work in progress.

### Conclusion

Ladies and gentlemen, I would like to take this opportunity to thank all of you for your ongoing support - 2012 looks to be a truly transformational year for the Company. Your management team and Board of Directors remain focused on our goal to market MoxDuo IR in the US in 2012, thus transitioning from a product development company to a fully integrated commercial organization. I look forward to reporting further clinical, regulatory and commercial developments over the year ahead.

Thank you.



# Managing Director's Address – Dr John Holaday 16 November 2011

Thank you, Peter

I could not be more pleased to stand before you this morning to review our accomplishments over the past year and highlight our plans going forward. Firstly, I would also like to reiterate Peter's comments and thank you, our shareholders, for your ongoing support most apparently demonstrated by our recent capital raising.

As Peter highlighted - the filing of the NDA for MoxDuo IR is a significant achievement for the Company and one of which we are proud. The NDA was submitted under 505(b)(2) regulations wherein approval for a new drug may be based in part on the historical published evidence supporting each of MoxDuo's already approved components to supplement the data derived from the robust QRxPharma development program. A 505(b)(2) approval also provides commercial benefits because, in parallel to patents which cover MoxDuo until 2029, it affords additional regulatory market exclusivity to the Company.

Later this year, the Company will augment its NDA filing with additional safety information derived from the recently completed Study 022. This Phase 3 study compared the tolerability and safety profile of MoxDuo IR to equi-analgesic doses of either morphine or oxycodone alone. The primary endpoint was respiratory depression as measured by oxygen desaturations in the blood. Respiratory depression is the leading cause of death from high doses of opioids. Clinical data indicate that MoxDuo provides a significant safety benefit with less clinical respiratory risk than either morphine or oxycodone. No other opioid has ever demonstrated a lower incidence of respiratory depression while offering the same or better pain relief.

These findings reinforce MoxDuo's well-established safety profile with earlier trials demonstrating a 25% to 75% reduction in nausea, vomiting, dizziness, sleepiness and constipation compared to other widely prescribed opioids. We also believe the significant respiratory advantages of MoxDuo IR demonstrated in Study 022 will be attractive to strategic partners, regulators and prescribers as well as support the European Marketing Authorisation Application (MAA) scheduled for submission in mid-2012.

Following the NDA lodgement for our acute pain product, the QRxPharma clinical team has shifted its focus to the development of MoxDuo CR, our continuous release dual opioid formulation intended for twice daily dosing wherein each dose provides at least 12 hours of pain relief in patients with moderate to severe chronic pain including cancer, lower back, osteoarthritis and neuropathic pain. Chronic pain is the largest opioid market, with over \$5.6 billion in US sales alone. Last year, QRxPharma prepared initial formulations of MoxDuo CR and conducted a successful Phase I study to determine which formulations provided the optimum duration of drug levels in blood. This provided critical information about the rate at which key components of the MoxDuo CR formulation were absorbed, distributed, metabolised and eliminated by the body compared to the pharmacokinetic profile of Oxycontin® 20 mg (sustained release oxycodone). The results were consistent with expectations for a twice daily formulation.



During the coming year, the Company will accelerate the MoxDuo CR tablet development that encompasses sustained delivery technology as well as abuse deterrent and tamper resistant features. We have designed additional Phase 1 and 2 studies for submission to the FDA and will initiate these clinical trials in the coming year as we move MoxDuo CR towards NDA submission.

Financially, QRxPharma is in a strong position as we embark on the challenges of the year ahead. We continue to be very pleased by the level of support we have received from investors, noting that our recent Placement was very well supported by both existing and new investors, with the Company welcoming a number of new Australian, US and UK based fund managers to the share register. We are working to complete partnering efforts as we strive to negotiate the best deal for our shareholders.

I would like to close by again thanking all of the employees, our Board of Directors and our shareholders for your support. Time and time again, in the management of moderate to severe pain following multiple surgical procedures, formulations, and doses, MoxDuo has continued to demonstrate better pain control with a significant reduction of clinically meaningful adverse events. The next 12 months promises to be an extremely exciting time for the company as we transition from a clinical stage entity to a commercial company and launch MoxDuo IR into a multi-billion dollar global market.

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