

# ASX RELEASE

8 November 2010

# **2010 ANNUAL GENERAL MEETING**

Sydney, Australia & Bedminster, NJ – QRxPharma (ASX: QRX and OTCQX: QRXPY) is a clinical-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 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 Limited**

ORxPharma Limited (ASX: ORX and OTCOX: ORXPY) is a clinical-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 which 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 U.S. and seeks strategic partnerships for worldwide markets. QRxPharma's lead product candidate, MoxDuo IR, is in Phase 3 clinical development and has successfully completed multiple comparative studies evaluating its efficacy and safety against equi-analgesic doses of morphine, oxycodone and Percocet<sup>®</sup> for the treatment of acute pain. QRxPharma expects to complete its Phase 3 program in Q4 CY2010 and file its New Drug Application (NDA) with the US Food and Drug Administration (FDA) for MoxDuo IR in the first half of CY2011. The Company's preclinical and clinical pipeline includes other technologies in the fields of pain management, neurodegenerative disease and venomics. For more information, visit www.grxpharma.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; 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 8 November 2010

Ladies and gentlemen,

It is with pleasure that I report to you the excellent progress that QRxPharma has made over the past 12 months. The Company is heading towards commercialisation of its lead asset, MoxDuo<sup>®</sup> IR, the immediate release morphine/oxycodone formulation, and, subject to the approval of our shareholders, we secured an additional A\$14 million in funding through a Share Placement, plus an ongoing Share Purchase Plan, that will add to this amount. These additional funds will allow us to complete our studies for MoxDuo IR, file our New Drug Application, or NDA, with the U.S. Food and Drug Administration (FDA) in 2011, as well as advance our other programs. We continue to work to bring these pain management drugs to market with the goal of making a significant difference in the lives of patients while continuing to build shareholder value.

# MoxDuo

The major reason why moderate to severe pain relief is not properly managed by opioid drugs is due to the significant side effects they produce, which include nausea, vomiting, dizziness, constipation, sedation and respiratory depression. According to data from our clinical trials, QRxPharma's Dual-Opioid<sup>®</sup> drugs, which combine a fixed-ratio of morphine and oxycodone, provide as good or better pain relief than existing opioids concomitant with a 50-75% reduction in these side effects.

We are excited about the progress that has been made over the past year with our MoxDuo product candidates, based on this Dual Opioid<sup>®</sup> platform technology. The Company's portfolio includes three complementary products to treat moderate to severe pain from hospital to home: MoxDuo IR, an immediate-release oral tablet for acute pain; MoxDuo IV, an intravenous formulation for hospital-based pain; and MoxDuo CR, a controlled-release oral tablet with abuse deterrent and tamper resistant technologies for treating chronic pain.

The status of the Company's lead asset, MoxDuo IR, has remained on track and is heading towards commercialization in the next 18 months. The market for opioids globally is over \$12 billion, including a significant market for MoxDuo IR for acute pain, with over 1.9 million prescriptions annually in the US alone. This is the largest category of drug sales in the US, far exceeding other well-known drugs, such as Statins which lower cholesterol levels in the blood.

Over the past year, clinical progress has been steady and consistent. Our meetings with the FDA have provided guidelines which we are successfully addressing within our clinical program. One of our required Phase 3 trials is completed, and the results of the second Phase 3 study are expected by the end of this calendar year. To date, over 600 patients have been treated in various trials with MoxDuo IR, and all have demonstrated consistent results: the same or better pain relief with a 50-75% reduction in side effects over current standards of care. We plan to complete the clinical portion of this program, with one additional trial comparing adverse events, to support our regulatory filing in Europe and our proposed labelling claims in the U.S. As a result, we believe we have a very robust package to take to both the U.S. and European regulatory agencies in 2011. With a favourable review, we expect to be able to launch the product and offer it to US patients in early 2012.

We have also significantly advanced our other MoxDuo programs. For the IV formulation, a Phase 2 investigator sponsored trial was completed in Germany and demonstrated superior pain relief with significantly fewer side effects. This year, the Company also formed a strategic alliance with China-based Aoxing Pharmaceuticals to support development efforts for MoxDuo IV in China while QRxPharma retains rights for the rest of the world.

For MoxDuo CR, a continuous release Dual Opioid for the treatment of chronic pain, the Company had an Investigational New Drug application approved in the U.S. and subsequently completed a successful Phase 1 trial for the compound, demonstrating results consistent with a 12-14 hour pain relief profile.

#### **Other Development Programs**

In addition to the pain management programs, we have also continued development on our other pipeline programs including promising drug candidates for the treatment of dystonia, Parkinson's, and Alzheimer's diseases. These programs are advanced in collaboration with our partners at the University of Alabama and the Michael J. Fox Foundation. During the fiscal year, the Company also secured a strategic alliance with Liaoning Nuokang Medicines Co., the China based subsidiary of China Nuokang Biopharmaceuticals, for the development and commercialization of our venomics assets in China. These product candidates offer significant promise in treating problems arising from insufficient blood coagulation. As a result of these strategic alliances, QRxPharma has significantly leveraged our development opportunities to advance our non-pain assets.

## **Financial Report**

We remain focused on the clinical advancement, regulatory approval, and commercialisation of our core MoxDuo product candidates for the treatment of moderate to severe pain. QRxPharma remains fiscally conservative and closely monitors its cash spend, ending the financial year with cash reserves of \$12.8 million. We continue to make progress in partnering our MoxDuo products as we strive to enter the commercial marketplace in 2012. Together with the net proceeds of the share placement and current SPP, we anticipate that we have sufficient funding to complete the remaining clinical trials and lodge the NDA with the FDA for MoxDuo IR. Funds will also be used to progress the development of the intravenous and controlled release formulations of MoxDuo, as well as provide minimal support for the non-pain assets. For the financial year ended 30 June 2010, the Company reported a net loss of \$27.5 million – that compares to a loss of \$13.5 million the year before. This was in line with our expectations as we continue to fund research and development and the timely progression of our product pipeline.

#### Conclusion

Ladies and gentlemen, I would like to take this opportunity to thank all of you for your ongoing support. 2011 will be a transformational year for the Company with the filing of our first NDA. Your management team and Board of Directors remain focused on our goal to market MoxDuo IR in the U.S. in 2012, thus transitioning from a product development company to a fully integrated commercial organisation. I look forward to reporting further clinical, regulatory and commercial developments during this fiscal year and beyond. Ladies and gentlemen, QRxPharma is at a key phase of its clinical and commercial development.

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Thank you

# Managing Director's Address – Dr John Holaday 8 November 2010

Thank you, Peter

I could not be more pleased to stand before you today to review our accomplishments over the past year and highlight our plans going forward. First, I would also like to reiterate Peter's comments and thank you, our shareholders, for your ongoing support most recently demonstrated by our capital raising. We now have the funding to complete all the necessary trials for our MoxDuo IR and file the appropriate documentation with the regulatory authorities in both the U.S. and Europe next year.

Furthermore, we have also recently been awarded grant funding totalling US\$733,437 through the Qualifying Therapeutic Discovery project programme offered by the US Government's Department of Treasury for our MoxDuo IR, MoxDuo CR and Torsin development programmes. This non-dilutive funding will supplement and support our late stage clinical activities of MoxDuo IR, as well as assisting to fund our Phase 1 and 2 development programme of MoxDuo CR and further our Torsin development work.

## **2010** Achievements

While Peter highlighted our general success with our MoxDuo platform, I would like to provide you with a bit more detail on the exciting clinical results we saw over the past year in each of our trials focused on MoxDuo's management of moderate to severe pain.

Since this time a year ago, the Company has initiated the two Phase 3 trials for MoxDuo IR required for NDA submission with the U.S. FDA. The first Phase 3 trial was completed in April 2010 and we expect data to satisfy the FDA's "combination rule" requirement comparing the efficacy and safety profiles of MoxDuo IR against component doses of morphine and oxycodone alone for post-operative pain following bunionectomy surgery. The trial enrolled 522 patients at 6 US clinical research sites and met its primary endpoint comparing MoxDuo IR versus its milligram components as measured by the sum of pain intensity differences for each patient from baseline over the 48-hour treatment period, known as SPID48. MoxDuo IR demonstrated both a statistically superior analgesic effect compared to component doses of morphine and oxycodone, as well as a favourable side effect profile.

In February 2010, the Company initiated our second pivotal Phase 3 registration trial comparing the effectiveness and safety of a flexible MoxDuo IR dose regimen to a fixed

low dose for patients who have undergone total knee replacement surgery. The primary endpoint for evaluating the efficacy of flexible dose versus low dose MoxDuo IR is once again the difference in pain relief scores. The trial will also track secondary endpoints that include: efficacy relating to the time to onset of analgesia and total pain relief, the amount of supplemental analgesia used throughout the treatment period, and safety as measured by incidence and intensity of opioid-related adverse effects. The study is targeted to enrol 140 patients at 10 U.S. clinical sites, and a recent interim analysis at the half way point revealed that the study is likely to reach statistical significance without the addition of more patients. We expect to complete patient dosing and report results by the end of this calendar year.

According to our meetings with the FDA, these two pivotal studies should satisfy the requirements for regulatory submission and market approval and are sufficient for the Company to file an NDA with no further pharmacology, toxicology or long-term clinical safety studies. As Peter mentioned, we look forward to filing this NDA in 2011 with targeted commercial launch of MoxDuo IR in 2012.

Over the past year, we have also conducted several positive meetings with the European regulatory agencies in Germany and the United Kingdom. We agreed with their recommendation for an additional comparative study to further distinguish MoxDuo IR from morphine and oxycodone. We expect to initiate this trial in the U.S. before the end of this calendar year, and anticipate it taking approximately three months to complete. Positive results from this study could also enable labelling claims of side effect superiority of MoxDuo IR to morphine and oxycodone both in the EU and the U.S.

While we remain focused on the completion of our pivotal trials and regulatory submission for MoxDuo IR, we continue to advance our other pain programs. The Company successfully completed a Phase 2 study for MoxDuo IV in August of this year. This comparative, proof-of-concept study evaluated the efficacy and safety of intravenous morphine and oxycodone versus IV morphine alone for the treatment of pain in patients following hip replacement surgery. The Investigator Sponsored Trial enrolled 40 patients and was conducted in Germany in collaboration with QRxPharma. During the initial evaluation period, data indicated patients receiving the Dual Opioid IV compared to those receiving morphine alone experienced the following results: 50% better pain relief; 67% of patients reported good to very good pain relief compared to 53% of those receiving morphine alone; higher SPID48 scores; ability to achieve better pain relief faster and with less drug; and, a lesser incidence of nausea and vomiting. The final product in the MoxDuo portfolio is the continued release, or CR formulation designed to provide at least 12 hours of pain relief per dose in patients suffering from chronic pain including cancer, lower back, osteoarthritis and neuropathic pain. In October 2009, QRxPharma announced a contractual agreement with Patheon to manufacture clinical supplies of MoxDuo CR. Patheon is a well-known manufacturing organisation with proven ability to develop novel formulations of drugs and we believe is the ideal partner for this product candidate that will include abuse deterrent and tamper resistant features. The Company was granted an IND and successfully completed a Phase I trial designed to determine which of the various experimental formulations provided the optimum duration of drug levels in the blood. The results were consistent with expectations for a twice-daily formulation and keeps QRxPharma on track to finalise the MoxDuo CR tablet formulation in 2011 and initiate Phase 2 trials shortly thereafter.

Over the course of the Company's fiscal year, QRxPharma also secured two key partnership and licensing deals. In February 2010, the Company and Aoxing Pharmaceutical Company announced collaboration in the development of MoxDuo IV that allows for development and marketing rights for the product candidate in China. QRxPharma retains ownership of the asset and may use the development work completed by our partner for future licensing, product registration, and commercialization outside of China. In addition, Aoxing also licensed the rights to the China market for MoxDuo IR. In October 2009, the Company licensed QRxPharma's venomics assets to Liaoning Nuokang Medicines Co, the China based subsidiary of China Nuokang Biopharmaceuticals Inc. Data generated through the development of these products in China will support partnering activities in other territories, the rights of which have been retained by QRxPharma's subsidiary, Venomics Pty Limited.

## Conclusion

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 file our first NDA and prepare to commercialize and launch MoxDuo IR into a multi-billion dollar global market.

Thank you.

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