



ASX RELEASE
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Initiation of NDA Filing Caps Off Another Successful Year for MoxDuo[®] Pain Therapy Development

Company moves significantly closer to entering the \$2.5 billion acute pain market in US


Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced during the financial year ended 30 June 2011 significant progress on its' Phase 3 development programme for MoxDuo[®] IR, culminating in the achievement of a significant milestone in July 2011 with the initiation of the filing of its New Drug Application (NDA) with the United States Food and Drug Administration (FDA). This NDA submission moves the Company significantly closer to entering the \$2.5 billion market for prescription opioids to treat moderate to severe acute pain, a segment of the \$8 billion spent annually on prescription opioids in the US.

Financial results released today reported the Company retaining \$7.3 million in cash reserves at 30 June 2011. The cash balance on hand at 30 June 2011 has been significantly increased subsequent to the financial year end, with an oversubscribed Placement to institutions and professional investors, raising \$25 million as announced to the ASX on 22 July 2011. The Company has also launched a 1 for 20 non-renounceable rights issue to raise up to an additional \$10.4 million. The combined Placement and Rights Issue (if fully subscribed) will raise gross proceeds of up to \$35.4 million. Post the Placement and Rights Issue (if fully subscribed), the Company's pro-forma net cash position (after expenses of the capital raising) at 30 June 2011 would be approximately \$41 million.

QRxPharma intends to use the proceeds from the Placement and Rights Issue to progress MoxDuo IR through FDA approval and commercialisation leading to product launch expected in 2012, to progress the development of MoxDuo controlled release (CR) and to provide additional working capital. The capital raising also puts the Company in a strong financial position as it negotiates with potential partners.

The net loss for the year ended 30 June 2011 from ordinary activities of \$25.6 million (2010: net loss \$27.3 million) was in line with expectations of the Board of Directors, and resulted from fulfilling research and development activities in the progression of the Company's clinical pipeline candidates and preclinical stage drugs.

"Lodgement of the NDA is a significant achievement for the Company and to our best knowledge QRxPharma's NDA is only the second NDA filing with the FDA by a standalone Australian therapeutics company within the last decade. I am extremely proud of the progress we have made during the financial year ended 30 June 2011, and excited by the prospect of product approval and potential product sales in 2012," said Dr. John Holaday, Managing Director and CEO.



To date, nearly 800 patients have been treated with MoxDuo IR in clinical trials, and these studies have shown patients who received MoxDuo IR were 25-75% less likely to experience the range of serious side effects including nausea, vomiting, dizziness, sleepiness, or constipation. A more recent study has also demonstrated a further safety advantage with significantly less respiratory depression as measured by oxygen desaturations with MoxDuo IR when directly compared to morphine or oxycodone at equianalgesic doses.

The initiation of the NDA comes on the back of a number of achievements over the last 12 months including the following:

MoxDuo IR


In February 2011 the Company announced the successful completion of its third pivotal Phase 3 registration trial (Study 009) for this lead product candidate using a second pain model. The objective was to evaluate the analgesic efficacy and safety of MoxDuo IR comparing a flexible dose against a fixed low dose regimen for managing moderate to severe pain following a total knee replacement surgery. Analysis of data indicated that patients in the flexible dose treatment group achieved statistically superior pain reduction ($p < 0.02$) compared to those receiving the lower dose.

In June 2011 the Company completed a comparative safety study (Study 022) comparing the tolerability and safety profile of MoxDuo IR to equianalgesic doses of either morphine or oxycodone alone. The primary endpoint of respiratory depression as measured by oxygen desaturations, which were less severe and of shorter duration in patients receiving MoxDuo compared to those receiving equianalgesic doses of either morphine or oxycodone alone, was met. This study will be submitted to the FDA as part of a 2011 NDA update filing and will also be supportive of the European Marketing Authorisation Application (MAA) scheduled for submission in the first half of 2012.

MoxDuo IV

In August 2010 the Company announced positive results of its Phase 2 comparative proof-of-concept study to evaluate the efficacy and safety of its IV (intravenous) formulation of morphine plus oxycodone versus IV morphine alone for the treatment of moderate to severe post-operative pain in patients following hip replacement surgery. The main findings demonstrated that the combination morphine/oxycodone formulation resulted in fewer side effects and offered better pain relief than morphine alone.

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About QRxPharma

QRxPharma Limited (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. 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 U.S. and seeks strategic partnerships for worldwide markets. QRxPharma's lead product candidate, immediate release MoxDuo, successfully completed pivotal Phase 3 studies and the Company has filed its New Drug Application (NDA) with the US Food and Drug Administration (FDA). The Company's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MoxDuo, as well as other 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.