



## ASX RELEASE

26 July 2010

### **QRxPHARMA RECEIVES POSITIVE FEEDBACK FROM SCIENTIFIC ADVICE MEETINGS IN EUROPE ON MOXDuo<sup>®</sup> IR DEVELOPMENT AND REGISTRATION**

*Company Plans for Global Registration Following US NDA Filing*


**Sydney, Australia and Bedminster, New Jersey** – QRxPharma (ASX:QRX and OTCQX:QRXPY) reported today positive outcomes of its European Scientific Advice meetings on the development and registration of MoxDuo IR, an immediate release Dual-Opioid™ pain therapy. The Company is currently completing pivotal Phase 3 trials required for filing a New Drug Application (NDA) for MoxDuo IR with the United States Food and Drug Administration (FDA). QRxPharma intends to submit a Marketing Authorisation Application (MAA) in Europe, the second largest market (approximately US\$3.5 billion) in the world for opioid analgesics. In support of these registration activities, the Company held Scientific Advice meetings in Germany and the United Kingdom in May 2010. Based on the positive responses in the official minutes of these meetings, QRxPharma intends to select Germany as the lead Agency for European MAA review, and will submit the application in 2011.

“Similar to the FDA’s acceptance of our streamlined development plan for MoxDuo IR, feedback and guidance from the European Agencies regarding the suitability of our data package for MAA submission is also positive,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “Our objective is to launch MoxDuo IR globally in 2012, and this feedback clears a significant hurdle and facilitates our European regulatory and commercialisation strategy.”

In reply to questions posed by QRxPharma to the German Federal Institute for Drugs and Medical Devices (BfArM), the data package available from the US studies was considered acceptable for MAA submission in Europe with the addition of a Phase 3 study in bunionectomy patients comparing the adverse event profile of MoxDuo IR to equi-analgesic doses of morphine and of oxycodone (total n=300). This study will include the proposed primary safety endpoints of the occurrence rate of moderate-severe nausea, emesis or dizziness, with an improvement for MoxDuo IR compared to morphine and oxycodone treatments being defined as a clinically relevant effect.

Assuming a positive outcome of this additional study and pending review of the MAA, such differences may be cited in the product package labelling in Europe and will further augment data for label claim submission with the FDA in the US.

QRxPharma successfully completed a pivotal Phase 3 “combination rule” study in April 2010 and announced that primary and secondary endpoints were achieved. In this study, MoxDuo IR



demonstrated both a statistically superior analgesic effect compared to morphine and oxycodone alone as well as a favourable side effect profile despite delivering twice the opioid dose of its individual components. These findings complement earlier clinical trials demonstrating that MoxDuo IR opens the therapeutic window by providing significant acute pain relief while reducing side effects.

**About Scientific Advice:**

The Scientific Advice process provides QRxPharma a forum to discuss the adequacy of its MoxDuo IR development plan as well as the results obtained to date for product registration purposes. The responses given by the Agencies are based on the questions and documentation submitted for discussion and cannot account for future changes or developments in scientific knowledge or regulatory requirements. Scientific Advice given is not legally binding with regard to any future application for the product concerned.

###


For more information please contact:

Dr John W Holaday  
Managing Director and Chief Executive Officer  
Tel: +1 301 908 3086  
Email: [john.holaday@qrxpharma.com](mailto:john.holaday@qrxpharma.com)

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

### **About QRxPharma**

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. 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 directly commercialise its products in the US and seek 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 equianalgesic doses of morphine, oxycodone and Percocet® for the treatment of acute pain. Data collected from these studies provided additional guidance for optimising the design and initiation of two pivotal Phase 3 studies required for New Drug Application (NDA) filings with the US Food and Drug Administration (FDA). QRxPharma expects to complete its Phase 3 program Q4 2010 and submit its New Drug Application (NDA) for MoxDuo®IR to the FDA in Q1 2011. No additional pharmacology, toxicology or long-term clinical safety studies will likely be required for regulatory submission. The Company's preclinical and clinical pipeline includes MoxDuo®IV and MoxDuo®CR, plus other technologies in the fields of neurodegenerative disease and venomics. For more information, visit [www.qrxpharma.com](http://www.qrxpharma.com).

