



**ASX RELEASE**

18 July 2011

## **QRxPharma Announces NDA Filing for MoxDuo<sup>®</sup> IR**

*Successful pivotal Phase 3 studies enable achievement of this significant milestone*

**Sydney, Australia and Bedminster, New Jersey** -- QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today initiation of the New Drug Application (NDA) approval process for MoxDuo IR with the United States Food and Drug Administration (FDA). This NDA submission sets the stage for the regulatory approval process for MoxDuo IR for the treatment of moderate to severe acute pain, a \$2.5 billion segment of the \$8 billion spent annually on prescription opioids in the US. MoxDuo IR, an immediate-release Dual Opioid<sup>®</sup> pain therapy, is a patented 3:2 fixed ratio combination of morphine and oxycodone.

“In just four years, we have successfully moved MoxDuo IR through clinical trials and NDA submission by demonstrating its effectiveness and safety. Achievement of this milestone clearly establishes the value of this Dual Opioid product to patients and prescribers as well as potential partners,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “The timeframe and capital efficient manner in which these milestones were achieved are impressive accomplishments compared to conventional industry development and cost benchmarks.”

This NDA submission is based on a full clinical and manufacturing program for MoxDuo IR. As agreed with the FDA, the NDA for MoxDuo IR is being submitted under 505(b)(2) regulations wherein approval for a new drug may be obtained more efficiently because the approval process can rely upon historical data regarding its’ already approved components. A 505(b)(2) approval also provides commercial benefits because, in parallel to patents which cover MoxDuo until 2029, it affords to the sponsor additional regulatory market exclusivity, allowing companies to develop a marketing strategy with a brand consumers recognize and may prefer in a potentially wide-open market.

As agreed with the FDA during its pre-NDA meeting with the Company in March, 2011, the NDA manufacturing section filing initiated the NDA review and is classified as an ‘early submission’, enabling sponsors like QRxPharma to obtain a head-start on the overall review process, with the remaining technical documentation to follow in August. Approval of an NDA typically takes 10-12 months from submission. Later this year, the Company will augment the filing with additional safety information derived from the recently completed Study 022.





### **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.