



FOR IMMEDIATE RELEASE

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FDA Accepts Streamlined Phase 3 Development Plan for Q8003IR “Dual Opioid” Pain Therapy

No Long Term Safety Data Required; Only Two Additional Phase 3 Studies for NDA Submission

Sydney, Australia & Bedminster, NJ – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY), a clinical-stage specialty pharmaceutical company focused on the development and commercialization of therapies for pain and central nervous system (CNS) disorders, announced today that the US Food and Drug Administration (FDA) accepted its proposed Phase 3 protocol designs and statistical analyses to demonstrate the efficacy and safety of Q8003IR, an immediate release dual-opioid (morphine plus oxycodone) product intended for the management of moderate to severe acute pain. Pending incorporation of the FDA’s recommended modifications, only two Phase 3 trials will be required for NDA filing. Under this streamlined clinical development program, no additional pharmacology, toxicology or long-term clinical safety studies will be required for regulatory submission and market approval.

“This is a significant and positive outcome,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma, commenting on the FDA review meeting. “Acceptance of QRxPharma’s streamlined development plan for Q8003IR is a measure of success in terms of reduced risk, resource efficiencies, and potential value of dual opioids. We believe this outcome serves to reinforce the soundness of our business strategy – to expand the clinical utility of existing compounds and deliver new treatments for targeted indications with well-defined paths to regulatory approval and sales.”

Following QRxPharma’s FDA meeting on July 21, 2008, the Company reported the Agency had determined no new animal safety studies were needed; accepted the design of the proposed combination rule study with minimal modifications; and found the proposed number of patients receiving Q8003IR, as well as the duration of dosing, sufficient for regulatory submission of a 505(b)2 NDA.

“No additional clinical studies or measures of safety and efficacy beyond those proposed by QRxPharma were requested,” said Dr. Warren Stern, Executive Vice President, Drug Development, QRxPharma. “Having successfully completed an initial Phase 3 trial in April 2008, QRxPharma continues to satisfy FDA requirements and demonstrate the potential of Q8003IR to provide equal or better analgesia with a reduction of total opioid dose and improved tolerability.”

Final Phase 3 studies for Q8003IR will include a combination rule study in patients experiencing post-surgery (bunionectomy) pain and placebo controlled study in patients following total knee replacement.

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Forward Looking Statements

This press 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 commercialization of the Company's proposed products.

About QRxPharma

QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) is a clinical-stage specialty pharmaceutical company focused on the development and commercialization of new treatments for pain management and central nervous system (CNS) disorders. Based on a business strategy to expand the clinical utility and commercial value of marketed and/or existing compounds, the Company's product portfolio includes both late and early stage clinical drug candidates with well-defined paths to regulatory approval and sales. QRxPharma intends to directly commercialize its products in the US and seek strategic partnerships abroad. QRxPharma's lead compound, Q8003IR, completed its first Phase 3 clinical trial in April 2008, having met all primary and secondary endpoints. The Company's preclinical and clinical pipeline includes other technologies in the fields of pain management, neurodegenerative disease and venomics. For more information: www.QRxPharma.com.