



**FOR IMMEDIATE RELEASE**

August 21, 2008

**QRxPHARMA ON TRACK WITH SUCCESSFUL COMPLETION DURING THE YEAR OF INITIAL PHASE 3 TRIALS FOR ITS LEAD DUAL-OPIOID® Q8003IR**

*The Company retains A\$29.7 million in cash reserves.*

**Sydney, Australia & Bedminster, NJ** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY), released its financial results for the year ended 30 June 2008 today with the Company retaining A\$29.7 million in cash reserves, after a successful year with the initiation of its Phase 3 clinical trial program for the lead compound Q8003IR and the continued progression of its other development projects.

Dr. John Holaday, QRxPharma's Managing Director and CEO, noted that the operating result reflects the Company's emphasis on the successful completion of its first Phase 3 clinical trial with Q8003IR, the immediate release formulation of our patented dual-opioid® oral analgesic. The Company continues with efforts to conserve cash while maintaining positive momentum for its lead product launch as early as 2010.

"In late November, 2007, we started our first Phase 3 study with the primary objective of determining the best dosage for pain relief in post-surgical patients; secondary objectives included patient ratings and side effect profiles. Ahead of schedule and under budget, in early May of this year we announced completion of this Phase 3 study that established a 12mg/8mg morphine and oxycodone combination of Q8003IR as the preferred dose for optimal efficacy and tolerability, with rapid onset of pain relief and a duration of action in excess of six hours," Dr. Holaday said.

"Capping off a successful year of development activity for the Q8003IR programme was our meeting with the US Food and Drug Administration (FDA) in July, 2008. The purpose of this meeting was to review all of our clinical data with Q8003IR, including efficacy, safety, side effects and tolerability, and to assess the sufficiency of our further clinical plans, leading to a New Drug Application (NDA). Pending incorporation of the FDA's recommended modifications, only two more Phase 3 trials will be required for NDA filing. Under this streamlined clinical development programme, no additional pharmacology, toxicology or long-term clinical safety studies will be required for regulatory submission. The Company is however considering additional studies that may provide data that will enhance market entry," Dr. Holaday said.

QRxPharma's second dual opioid, Q8011CR, is being formulated and it is anticipated that Phase 1 studies will be initiated within a year. This controlled release drug targets the chronic pain market via a formulation designed to provide twelve hours of pain relief, with the potential for abuse prevention technology to be incorporated into the final product.

"Our objective is to extend earlier preclinical and clinical science indicating that our portfolio of dual-opioid® combinations of morphine and oxycodone provide superior pain relief while



minimising side effects. This portfolio of product candidates includes an immediate release formulation (Q8003IR), a continuous release formulation (Q8011CR) and an intravenous formulation (Q8011IV). These complementary products together cover both the acute and chronic pain markets (A\$12 billion global marketplace) and will give the prescribing physician more choices in managing moderate to severe pain with improved pain relief and minimal side effects” Dr. Holaday said.

“We have also continued our close association with both the University of Alabama and the University of Queensland, progressing our preclinical stage pipeline in the areas of neurodegenerative disease and venomics respectively,” added Dr. Holaday.

“We see a clear need to broaden our shareholder base in order to recognise the value of our growing assets. To that end, with JP Morgan, we initiated an American Depository Receipt (ADR) program for US listing, and then recently joined the OTCQX (QRXPY) with the help of our Principal American Liaison (PAL), Merriman Curhan and Ford. This initiative is part of a broad strategy to maximize value, provide access to U.S. investors, and increase liquidity,” said Dr. Holaday.

A loss of \$36.6 million for the year ended 30 June 2008 was recorded. This loss includes non cash charges of \$18.1 million relating to an impairment charge to the Torsin intellectual property licensed from the University of Alabama of \$14.6 million, determined in accordance with Accounting Standard AASB136 “Impairment of Assets”, and share based payments charges of \$3.5 million. Excluding these charges the loss was in line with expectations in fulfilling research and development efforts, in the progression of the Company’s clinical pipeline candidates and preclinical stage drugs.

“I am proud of what we have accomplished over the past year. During the coming year, we will conserve our cash, continue our comprehensive clinical trial program, focus on adding global shareholders and emphasize business development to establish appropriate strategic partnerships for accelerating commercialisation of our product portfolio,” said Dr. Holaday.

“We remain confident that our business plan will create long term value for shareholders as we bring new drugs into the market for the treatment of pain and central nervous system diseases,” Dr. Holaday concluded.

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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](http://www.QRxPharma.com).