



## ASX RELEASE

28 July 2009

### FOURTH QUARTER OPERATING UPDATE

#### *Data Demonstrate MoxDuo™ IR Provides Better Tolerability Than Morphine and Oxycodone Alone*

**Sydney, Australia & Bedminster, NJ** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY), announced that the Company retains A\$17.8 million in cash reserves at 30 June 2009, as detailed in the Appendix 4C released today.

“Whilst the Company continues to pursue business development opportunities, management remains committed to closely managing the cash burn whilst undertaking necessary value added development work to support commercial discussions” said Dr. John Holaday, Managing Director and CEO of QRxPharma.

“The Company was delighted with the successful completion of a Phase 3 program pilot study comparing the efficacy and safety profile of MoxDuo™ IR against component doses of morphine and oxycodone announced during the quarter” added Holaday. Patient data demonstrated that MoxDuo™ IR reduces pain significantly more than its component doses; further, when compared to equianalgesic doses of morphine and oxycodone, MoxDuo™ IR produced fewer and less intense side effects.

The results of the above study were incorporated into an updated version of the Company’s “combination rule” Phase 3 study protocol for MoxDuo™ IR submitted in June 2009 to the US Food and Drug Administration (FDA) for Special Protocol Assessment (SPA) approval. The SPA process provides a mechanism by which the Company can achieve a binding agreement with the FDA regarding the acceptability of the study design and proposed statistical analysis plan prior to implementation of the clinical trial. The Company expects a response from the FDA on this latest SPA submission by the end of August 2009.

“The clinical activity for the quarter focused on a comparative 3-arm pilot study to evaluate the analgesic efficacy and safety profile of MoxDuo™ IR capsules in patients who underwent joint replacement surgery. I am pleased to report that the Company completed this study in mid July, and we anticipate that analysis of results over the coming weeks will augment current business development discussions” said Holaday.

Data from this study will further enhance knowledge about how to optimize the design and implementation of a pending pivotal Phase 3 study, a double-blind, controlled trial in patients following joint replacement surgery. The Company also intends to use this

knowledge to complete the filing of a second SPA with the FDA in respect to the planned Phase 3 pivotal trial.

The Company also announced on 23 July 2009 the initial patient was dosed in Germany as part of the first Phase 2 study evaluating the efficacy and safety of its Dual-Opioid™ as an intravenous morphine plus oxycodone formulation compared against IV morphine alone, for the treatment of moderate to severe post-operative pain in patients following hip replacement surgery. Data from this study will serve as a significant predictor of MoxDuo™ IV's clinical benefits and provide guidance for the design of further clinical trials leading to an Investigational New Drug (IND) submission to the FDA in 2010.

The study which will involve 40 patients recovering from hip replacement surgery is being conducted at the Cologne-Merheim Medical Center, a part of Witten/Herdecke University, and Cologne University Hospital, both in Cologne, Germany. The Company expects the study to be completed before the end of 2009.

MoxDuo™ CR, a continuous release formulation of QRxPharma's Dual-Opioid™ designed to provide 12 hours of pain relief in patients with moderate to severe pain, continues on track to initiate Phase I studies by the end of 2009. This proprietary formulation encompasses not only sustained delivery technology, but also technologies to deter abuse and tampering.

QRxPharma also confirms quarterly progress relating to its other clinical pipeline candidates and preclinical stage drugs:

- Development efforts with the Company's Dystonia, Parkinson's Disease and Alzheimer's Disease programme (Torsin) with a family of small molecules continues under a collaborative research agreement at the University of Alabama (Caldwell Labs) to confirm the preclinical efficacy of its lead molecules. Preclinical trials supported in part by the Michael J. Fox Foundation are presently underway to evaluate QRxPharma's lead drug candidates in models of Parkinson's Disease.
- Business development efforts also continue to proceed with QRxPharma's venomics platform to secure strategic relationships for the clinical and commercial development of these venom-derived coagulants and anti-coagulants.

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## **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 abroad.

QRxPharma's lead compound, MoxDuo™ IR, the first combination opioid product for the improved control of moderate to severe pain, successfully completed a Phase 3 study and a pilot Combination Rule study and met 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).

# Appendix 4C

## Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001, 24/10/2005.

Name of entity

QRxPharma Limited

ABN

16 102 254 151

Quarter ended ("current quarter")

30 June 2009

### Consolidated statement of cash flows

#### Cash flows related to operating activities

|     |   |                |                 |
|-----|---|----------------|-----------------|
| 1.1 | Receipts from customers                               | -              | -               |
| 1.2 | Payments for  |                |                 |
|     | (a) staff costs                                       | (888)          | (3,749)         |
|     | (b) advertising and marketing                         | -              | -               |
|     | (c) research and development                          | (3,123)        | (12,342)        |
|     | (d) leased assets                                     | -              | -               |
|     | (e) other working capital                             | (774)          | (1,860)         |
| 1.3 | Dividends received                                    | -              | -               |
| 1.4 | Interest and other items of a similar nature received | 28             | 813             |
| 1.5 | Interest and other costs of finance paid              | -              | -               |
| 1.6 | Income taxes refund / (paid)                          | -              | -               |
| 1.7 | Other (provide details if material)*                  | 150            | 150             |
|     | <b>Net operating cash flows</b>                       | <b>(4,607)</b> | <b>(16,988)</b> |

| Current quarter<br>\$A'000 | Year to date<br>(12 months)<br>\$A'000 |
|----------------------------|--|
| -                          | -                                      |
| (888)                      | (3,749)                                |
| -                          | -                                      |
| (3,123)                    | (12,342)                               |
| -                          | -                                      |
| (774)                      | (1,860)                                |
| -                          | -                                      |
| 28                         | 813                                    |
| -                          | -                                      |
| -                          | -                                      |
| 150                        | 150                                    |
| (4,607)                    | (16,988)                               |

\* The entity received an Export Market Development Grant of \$150,000 during the quarter.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

|  | Current quarter<br>\$A'000 | Year to date<br>(12 months)<br>\$A'000 |
|--|----------------------------|--|
| 1.8 Net operating cash flows (carried forward)   | (4,607)                    | (16,988)                               |
| <b>Cash flows related to investing activities</b>  |                            |  |
| 1.9 Payment for acquisition of:  |                            |  |
| (a) businesses (item 5)  | -                          | -                                      |
| (b) equity investments   | -                          | -                                      |
| (c) intellectual property  | -                          | -                                      |
| (d) physical non-current assets  | (125)                      | (229)                                  |
| (e) other non-current assets   | -                          | -                                      |
| 1.10 Proceeds from disposal of:  |                            |  |
| (a) businesses (item 5)  | -                          | -                                      |
| (b) equity investments   | -                          | -                                      |
| (c) intellectual property  | -                          | -                                      |
| (d) physical non-current assets  | -                          | -                                      |
| (e) other non-current assets   | -                          | -                                      |
| 1.11 Loans to other entities   | -                          | -                                      |
| 1.12 Loans repaid by other entities  | -                          | -                                      |
| 1.13 Other (Bank Accepted Commercial bills and<br>Term Deposit with maturity greater than 3<br>months) | -                          | -                                      |
| <b>Net investing cash flows</b>  | (125)                      | (229)                                  |
| <b>1.14 Total operating and investing cash flows</b>   | (4,732)                    | (17,217)                               |
| <b>Cash flows related to financing activities</b>  |                            |  |
| 1.15 Proceeds from issues of shares, options, etc.   | -                          | -                                      |
| 1.16 Proceeds from sale of forfeited shares  | -                          | -                                      |
| 1.17 Proceeds from borrowings  | -                          | -                                      |
| 1.18 Repayment of borrowings   | -                          | -                                      |
| 1.19 Dividends paid  | -                          | -                                      |
| 1.20 Other (provide details if material)   | -                          | -                                      |
| <b>Net financing cash flows</b>  | -                          | -                                      |
| <b>Net increase (decrease) in cash held</b>  | (4,732)                    | (17,217)                               |
| 1.21 Cash at beginning of quarter/year to date   | 25,410                     | 29,672                                 |
| 1.22 Exchange rate adjustments to item 1.20  | (2,905)                    | 5,318                                  |
| 1.23 <b>Cash at end of quarter</b>   | 17,773                     | 17,773                                 |

+ See chapter 19 for defined terms.

**Payments to directors of the entity and associates of the directors**

**Payments to related entities of the entity and associates of the related entities**

|      |  | Current quarter<br>\$A'000 |
|------|--|----------------------------|
| 1.24 | Aggregate amount of payments to the parties included in item 1.2 | 217                        |
| 1.25 | Aggregate amount of loans to the parties included in item 1.11   | -                          |

1.26 Explanation necessary for an understanding of the transactions

Payments include salary and wages, director fees, and consultancy fees on normal commercial terms.

**Non-cash financing and investing activities**

2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

Nil

2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

Nil

**Financing facilities available**

*Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).*

|     |                             | Amount available<br>\$A'000 | Amount used<br>\$A'000 |
|-----|-----------------------------|-----------------------------|------------------------|
| 3.1 | Loan facilities             | -                           | -                      |
| 3.2 | Credit standby arrangements | -                           | -                      |

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+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

**Reconciliation of cash**

| Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows. |  | Current quarter<br>\$A'000 | Previous quarter<br>\$A'000 |
|---|--|----------------------------|-----------------------------|
| 4.1   | Cash on hand and at bank   | 527                        | 2,164                       |
| 4.2   | Deposits at call   | -                          | -                           |
| 4.3   | Bank overdraft   | -                          | -                           |
| 4.4   | Bank Accepted Commercial Bills and Term Deposits with maturity of less than 3 months | 17,246                     | 23,246                      |
| <b>Total: cash at end of quarter (item 1.23)</b>  |  | <b>17,773</b>              | <b>25,410</b>               |

**Acquisitions and disposals of business entities**

|     | Acquisitions<br>(Item 1.9(a))             | Disposals<br>(Item 1.10(a)) |
|-----|---|-----------------------------|
| 5.1 | Name of entity                            | Nil                         |
| 5.2 | Place of incorporation or registration    | Nil                         |
| 5.3 | Consideration for acquisition or disposal |                             |
| 5.4 | Total net assets                          |                             |
| 5.5 | Nature of business                        |                             |

+ See chapter 19 for defined terms.

