



**ASX RELEASE**  
**26 October 2012**

## **QUARTERLY OPERATING UPDATE** **30 SEPTEMBER 2012**

**Sydney, Australia & Bedminster, NJ** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced that the Company retains A\$18.7 million in cash reserves at 30 September 2012, as detailed in the Appendix 4C released today.

The activities for the quarter ended 30 September 2012 have focused on addressing the Complete Response Letter (CRL) received from the United States Food and Drug Administration (FDA) in late June 2012 with respect to the Company's immediate release MOXDUO® New Drug Application (NDA) filing.

Following a review with the FDA in mid-August 2012 where the steps required for approval of immediate release MOXDUO were clarified, the Company believes that analysis of the additional data requested by the Agency and subsequent re-filing of the NDA could result in a positive decision from the FDA around mid-2013. Importantly, at the August 2012 meeting, the FDA confirmed that there were no unexpected or problematic safety issues in any of the studies submitted as part of the NDA.

The FDA requested further information regarding data filed as part of the MOXDUO NDA and additional analysis of trials completed to date, including Study 022 which evaluated oxygen desaturation levels in patients receiving MOXDUO compared to those administered morphine or oxycodone alone at equi-analgesic doses. Study 022, involving 375 patients, demonstrated that patients receiving MOXDUO had an appreciably lower risk of experiencing medically significant oxygen desaturations than patients receiving equi-analgesic doses of morphine or oxycodone. Oxygen desaturation is a medically important adverse event and a leading cause of death from high doses of opioids.

Following the close of the quarter, the Company announced the execution of a licensing agreement with Paladin Labs Inc. ("Paladin") (TSX: PLB), a leading Canadian specialty pharmaceutical company, for the Canadian commercialisation rights to immediate release MOXDUO.

Under the License Agreement, Paladin receives exclusive rights to commercialise immediate release MOXDUO in Canada and assumes responsibility for the New Drug Submission (NDS), all product launch costs as well as on-going marketing and sales efforts. Upon the signing in October, QRxPharma received a non-refundable, non-creditable up-front payment of US\$500,000.



In addition, QRxPharma will receive tiered double-digit royalties and up to US\$25 million in milestone payments on achievement of specific sales, regulatory and reimbursement targets. QRxPharma retains the Canadian rights to the intravenous and controlled release formulations of MOXDUO, which are in clinical development.

The operating cash outflow for the quarter is in accordance with the expectations of the Board of Directors and resulted primarily from continuing research and development activities in the progression of the Company's pipeline candidates.

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#### **About QRxPharma**

QRxPharma Limited is a commercial-stage specialty pharmaceutical company focused on the development and commercialisation of new treatments for pain management. Based on a development strategy that 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. QRxPharma entered into strategic collaborations with Actavis Inc. in December 2011 and Paladin Labs Inc. in October 2012 for the commercialisation of immediate release MOXDUO® in the US and Canadian acute pain markets respectively. Additionally, the Company's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MOXDUO. For more information, visit [www.qrxpharma.com](http://www.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.

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# 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 September 2012

### Consolidated statement of cash flows

| Cash flows related to operating activities                | Current quarter<br>\$A'000 | Year to date<br>(3 months)<br>\$A'000 |
|---|----------------------------|---------------------------------------|
| 1.1 Receipts from customers                               |                            |                                       |
| 1.2 Payments for (a) staff costs                          | (1,158)                    | (1,158)                               |
| (b) advertising and marketing                             | -                          | -                                     |
| (c) research and development                              | (2,279)                    | (2,279)                               |
| (d) leased assets   | -                          | -                                     |
| (e) other working capital                                 | (764)                      | (764)                                 |
| 1.3 Dividends received                                    | -                          | -                                     |
| 1.4 Interest and other items of a similar nature received | 26                         | 26                                    |
| 1.5 Interest and other costs of finance paid              | -                          | -                                     |
| 1.6 Income taxes refund / (paid)                          | -                          | -                                     |
| 1.7 Other – Cost recoveries received                      | 382                        | 382                                   |
| <b>Net operating cash flows</b>                           | <b>(3,793)</b>             | <b>(3,793)</b>                        |

+ See chapter 19 for defined terms.

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

|  | Current quarter<br>\$A'000 | Year to date<br>(3 months)<br>\$A'000 |
|--|----------------------------|---------------------------------------|
| 1.8 Net operating cash flows (carried forward)   | (3,793)                    | (3,793)                               |
| <b>1.9 Cash flows related to investing activities</b>  |                            |                                       |
| Payment for acquisition of:  |                            |                                       |
| (a) businesses (item 5)  | -                          | -                                     |
| (b) equity investments   | -                          | -                                     |
| (c) intellectual property  | -                          | -                                     |
| (d) physical non-current assets  | (6)                        | (6)                                   |
| (e) other non-current assets   | -                          | -                                     |
| <b>1.10 Proceeds from disposal of:</b>   |                            |                                       |
| (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 Term Deposit with maturity greater than 3 months) | -                          | -                                     |
| <b>Net investing cash flows</b>  | <b>(6)</b>                 | <b>(6)</b>                            |
| <b>1.14 Total operating and investing cash flows</b>   | <b>(3,799)</b>             | <b>(3,799)</b>                        |
| <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   | -                          | -                                     |
| <b>Net financing cash flows</b>  | <b>-</b>                   | <b>-</b>                              |
| <b>Net increase (decrease) in cash held</b>  | <b>(3,799)</b>             | <b>(3,799)</b>                        |
| 1.21 Cash at beginning of quarter/year to date   | 22,950                     | 22,950                                |
| 1.22 Exchange rate adjustments to item 1.20  | (426)                      | (426)                                 |
| <b>1.23 Cash at end of quarter</b>   | <b>18,725</b>              | <b>18,725</b>                         |

+ 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 | \$118                      |
| 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 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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**Appendix 4C**  
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**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   | 1,264                      | 789                         |
| 4.2   | Deposits at call   | 7                          | 7                           |
| 4.3   | Bank overdraft   | -                          | -                           |
| 4.4   | Bank Accepted Commercial Bills and Term Deposits with maturity of less than 3 months | 17,454                     | 22,154                      |
| <b>Total: cash at end of quarter (item 1.23)</b>  |  | <b>18,725</b>              | <b>22,950</b>               |

**Acquisitions and disposals of business entities**

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

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+ See chapter 19 for defined terms.

## Compliance statement

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.



Sign here: ..... Date: 26 October 2012  
(Company Secretary)

Print name: Chris J Campbell

## Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 1026: Statement of Cash Flows* apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 - reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 - itemised disclosure relating to acquisitions
  - 9.4 - itemised disclosure relating to disposals
  - 12.1(a) - policy for classification of cash items
  - 12.3 - disclosure of restrictions on use of cash
  - 13.1 - comparative information
3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

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