



**ASX RELEASE**

**29 April 2013**

## **QUARTERLY OPERATING UPDATE 31 MARCH 2013**

**Sydney, Australia & Bedminster, NJ** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced that the Company retains A\$13.9 million in cash reserves at 31 March 2013, as detailed in the Appendix 4C released today.

During the quarter the Company resubmitted its MOXDUO<sup>®</sup> New Drug Application (NDA) with the US Food and Drug Administration (FDA). Subsequently the Agency advised the Company that it had formally accepted the resubmission and set 26 August 2013 as the Prescription Drug User Fee Act (PDUFA) date for action.

“We are delighted the FDA has formally accepted our resubmission,” said QRxPharma Managing Director and Chief Executive Officer, Dr John Holaday. “Assuming approval, we anticipate product launch with our US commercialisation partner, Actavis, before the end of this calendar year” added Holaday.

The NDA is the basis for recommencing the regulatory approval process for MOXDUO 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, an immediate release Dual Opioid<sup>®</sup> pain therapy, is a patented 3:2 fixed ratio combination of morphine and oxycodone.

The resubmitted NDA included a comprehensive analysis of Study 022 which demonstrated the lower risks of respiratory depression for MOXDUO when compared to either morphine or oxycodone. QRxPharma believes the resubmitted clinical data demonstrate safety advantages of MOXDUO over its components, morphine and oxycodone, and that MOXDUO provides as good or better analgesia as indicated by past studies involving more than 1,600 patients experiencing moderate to severe acute post-operative pain.

The revised NDA also includes the results of five other Phase 2 and 3 clinical trials conducted by the Company over the past six years showing less nausea, vomiting, itching and headache in patients treated with MOXDUO.

As previously reported, despite the Agency confirming that there were no efficacy or safety issues in any of the studies that were part of the original NDA, the resubmitted application will undergo an Advisory Committee review which is expected to be scheduled between late June and late July and the Company will update shareholders once formal notification has been received.



The operating cash flow for the quarter is in accordance with the expectations of the Board of Directors and resulted primarily from the Company's continuing efforts to secure NDA approval for MOXDUO in the US and activities associated with the preparation of the regulatory filings in Canada, Europe and Australia.

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#### **About QRxPharma**

QRxPharma Limited is an Australian based, commercial-stage specialty pharmaceutical company focused on the development and commercialisation of new treatments for pain management. 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's lead product candidate, immediate release MOXDUO<sup>®</sup> for the treatment of acute pain, is presently under review at the US Food and Drug Administration. 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<sup>®</sup> 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")

31 March 2013

### Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (9 months) \$A'000
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) staff costs	(660)	(2,731)
(b) advertising and marketing	-	-
(c) research and development	(1,293)	(5,730)
(d) leased assets	-	-
(e) other working capital	(698)	(2,382)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	10	48
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes refund / (paid)	-	-
1.7 Other – Cost recoveries received	-	1,634
Other – License fee received	-	485
<b>Net operating cash flows</b>	<b>(2,641)</b>	<b>(8,676)</b>

+ See chapter 19 for defined terms.

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

	Current quarter \$A'000	Year to date (9 months) \$A'000
1.8 Net operating cash flows (carried forward)	(2,641)	(8,676)
<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	(4)	(13)
(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>(4)</b>	<b>(13)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(2,645)</b>	<b>(8,689)</b>
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	18	26
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>18</b>	<b>26</b>
<b>Net increase (decrease) in cash held</b>	<b>(2,627)</b>	<b>(8,663)</b>
1.21 Cash at beginning of quarter/year to date	16,598	22,950
1.22 Exchange rate adjustments to item 1.20	(92)	(408)
<b>1.23 Cash at end of quarter</b>	<b>13,879</b>	<b>13,879</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 \$A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	\$119
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 \$A'000	Amount used \$A'000
3.1	Loan facilities	-	-
3.2	Credit standby arrangements	-	-

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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 \$A'000	Previous quarter \$A'000
4.1	Cash on hand and at bank	861	1,740
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	13,011	14,851
<b>Total: cash at end of quarter (item 1.23)</b>		<b>13,879</b>	<b>16,598</b>

**Acquisitions and disposals of business entities**

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
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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## 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.

*C. J. Campbell*

Sign here: ..... Date: 29 April 2013  
(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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