

ASX RELEASE 24 January 2013

## QUARTERLY OPERATING UPDATE 31 DECEMBER 2012

**Sydney, Australia & Bedminster, NJ** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced that the Company retains A\$16.6 million in cash reserves at 31 December 2012, as detailed in the Appendix 4C released today.

The activities for the quarter ended 31 December 2012 continued to focus 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 the close of the quarter, the Company announced on 16 January 2013 that the steps necessary for approval of MOXDUO have been clarified with the FDA. QRxPharma will resubmit its MOXDUO NDA this quarter, with an expected new PDUFA date to be set for Q3 2013.

During the Company's most recent FDA review meeting, QRxPharma presented a position that although the Combination Rule does not require a demonstration of greater efficacy or safety, the data submitted to date indicate a safety advantage for MOXDUO compared to either morphine or oxycodone alone. Results from Study 022, which demonstrated that oxygen desaturation was less severe with MOXDUO than with oxycodone or morphine, were presented to the full review committee and noted with interest. The FDA recommended the Company provide a more extensive analysis of Study 022 when the revised MOXDUO NDA is resubmitted.

The FDA also voiced for the first time that no precedent exists for their review of combination products where two drugs in the same category are combined (e.g. morphine and oxycodone as "opioids"). Therefore, despite the Agency previously confirming that there were no safety issues in any of the studies that were part of the original NDA, the resubmitted application, including new results from Study 022, will likely undergo review by an Advisory Committee in late Q2 2013. The Advisory Committee will evaluate the approvability of MOXDUO in the management of acute pain. The reliance on Advisory Committees has been made more common or compulsory since the FDA Amendments Act of 2007.

Whilst the US approval of MOXDUO remains the priority, the Company has also continued work on the preparation of the regulatory filings in Canada, Europe and Australia and expect



that these regulatory filings will be submitted before the end of Q2 2013. In December 2012 the Company and Aoxing Pharmaceutical Company, Inc (NYSE AMEX: AXN) mutually agreed to terminate their strategic alliance in China. All related intellectual property rights reverted to QRxPharma and both parties are free to pursue alternative opportunities in the Chinese pain management market.

During the quarter the Company received \$1.3 million from Actavis Inc. in respect to cost recoveries billed under the licence arrangements between the respective companies. In addition, \$0.5 million was received from Paladin Inc. following the October 2012 signing of the previously reported License Agreement with Paladin Inc. to commercialise immediate release MOXDUO in Canada.

The operating cash flow 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 ORxPharma**

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® 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® 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.

#### **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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Rule 4.7B

# **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	Quarter ended ("current quarter")
16 102 254 151	31 December 2012

## Consolidated statement of cash flows

Cash flows related to operating activities		Current quarter \$A'000	Year to date (6 months) \$A'000
1.1	Receipts from customers	-	-
1.2	(b) advertising and marketing (c) research and development (d) leased assets (e) other working capital  Dividends received Interest and other items of a similar nature received Interest and other costs of finance paid Income taxes refund / (paid)	(912) - (2,158) - (921)	(2,071) - (4,437) - (1,684)
1.3 1.4		- 12	38
1.5 1.6 1.7		- 1,252 485	- - 1,634 485
	Net operating cash flows	(2,242)	(6,035)

24/10/2005

<sup>+</sup> See chapter 19 for defined terms.

		Current quarter \$A'000	Year to date (6 months) \$A'000
1.8	Net operating cash flows (carried forward)	(2,242)	(6,035)
1.9	Cash flows related to investing activities Payment for acquisition of:		
	<ul><li>(a) businesses (item 5)</li><li>(b) equity investments</li></ul>	-	-
	(c) intellectual property	-	-
	(d) physical non-current assets	(3)	(9)
	(e) other non-current assets		
1.10	Proceeds from disposal of:		
	<ul><li>(a) businesses (item 5)</li><li>(b) equity investments</li></ul>	-	-
	(c) intellectual property	-	-
	(d) physical non-current assets	-	-
1.11	(e) other non-current assets 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)	-	-
	Net investing cash flows	(3)	(9)
1.14	Total operating and investing cash flows	(2,245)	(6,044)
	Cash flows related to financing activities		
1.15	Proceeds from issues of shares, options, etc.	8	8
1.16	Proceeds from sale of forfeited shares	-	-
1.17	Proceeds from borrowings	-	-
1.18 1.19	Repayment of borrowings Dividends paid	-	-
1.20	Other	-	-
	Net financing cash flows	8	8
	Net increase (decrease) in cash held	(2,237)	(6,036)
1.21	Cash at beginning of quarter/year to date	18,725	22,950
1.22	Exchange rate adjustments to item 1.20	110	(316)
1.23	Cash at end of quarter	16,598	16,598

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<sup>+</sup> 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	\$210	
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, directors' fees and consultancy fees terms.	s on normal commercial	
No	on-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	-	-

<sup>+</sup> See chapter 19 for defined terms.

## Reconciliation of cash

show	nciliation of cash at the end of the quarter (as n in the consolidated statement of cash flows) e related items in the accounts is as follows.	Current quarter \$A'000	Previous quarter \$A'000
4.1	Cash on hand and at bank	1,740	1,264
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	14,851	17,454
	Total: cash at end of quarter (item 1.23)	16,598	18,725

# 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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<sup>+</sup> See chapter 19 for defined terms.

## **Compliance statement**

- 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. A. Camfbell		
Sign here:		Date:	24 January 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.

<sup>+</sup> See chapter 19 for defined terms.