

ASX RELEASE 28 April 2011

## QUARTERLY OPERATING UPDATE 31 MARCH 2011

MoxDuo<sup>®</sup> IR New Drug Application on track for mid-year 2011 submission

Sydney, Australia & Bedminster, NJ – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced that the Company retains A\$14.9 million in cash reserves at 31 March 2011, as detailed in the Appendix 4C released today.

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

During the quarter the Company meet a major milestone with completion of a pre-New Drug Application (NDA) meeting with the United States Food and Drug Administration (FDA) for its MoxDuo Immediate Release formulation, a patented 3:2 ratio fixed dose combination of morphine and oxycodone, for managing moderate to severe acute pain. Clinical trials conducted to date have consistently demonstrated the benefits of MoxDuo, achieving as good or better pain relief with fewer incidences of moderate to severe side effects compared to current standards of care.

The pre-NDA meeting considered QRxPharma's regulatory strategy, and the FDA provided constructive feedback on specific sections of the planned NDA. The Company is on track to submit a NDA for MoxDuo IR mid-year 2011 once the comprehensive data analysis is complete.

In late January 2011 the Company initiated a further Phase 3 trial, Study 022, and was pleased to announce only yesterday that the dosing of 375 patients is complete with top line results expected in June. The study was designed to compare the tolerability and safety profile of MoxDuo IR to equi-analgesic doses of either morphine or oxycodone alone. The results of the trial will support the pathway for safety labelling in Europe and the US with projected commercial launch of MoxDuo IR in the US in 2012 and in Europe in 2013.

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In February 2011 the Company reported the successful completion of its Phase 3 registrational trial programme with the finalisation of Study 009 which was designed to evaluate the analgesic efficacy and safety of MoxDuo, comparing a flexible dose against a fixed low-dose regimen for managing moderate to severe pain following total knee replacement surgery (TKR).

Subsequent to the close of the quarter the Company announced that the United States Patent and Trademark Office (USPTO) issued the Company a new patent, U.S. Patent #7,923,453, which expires in 2029. This patent covers a proprietary dosing algorithm for converting patients from intravenous opioid administration to orally administered MoxDuo IR, thereby more effectively and safely managing acute pain following surgery.

This is the first of several patent applications filed by the Company to be approved which extend global exclusivity of the MoxDuo Dual Opioid<sup>®</sup> product line.

MoxDuo is being developed by QRxPharma in three presentations: oral immediate release (MoxDuo IR), intravenous (MoxDuo IV) and controlled release (MoxDuo CR). These three product candidates are staged to address the \$12 billion global market for the treatment of moderate to severe pain. MoxDuo IR targets the acute pain market, a \$2.5 billion segment of the \$7 billion spent annually on prescription opioids in the US.

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#### **About QRxPharma Limited**

QRxPharma Limited (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 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. The Company intends to co-promote its products in the U.S. and seeks strategic partnerships for worldwide markets. QRxPharma's lead product candidate, immediate release MoxDuo, has successfully completed pivotal Phase 3 studies and the Company expects to file its New Drug Application (NDA) with the US Food and Drug Administration (FDA) in mid-2011. The Company's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MoxDuo, as well as other technologies in the fields of pain management, neurodegenerative disease and venomics. 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.

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

16 102 254 151

Quarter ended ("current quarter")

31 March 2011

## 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 (b) advertising and marketing (c) research and development (d) leased assets (e) other working capital	(1,192) - (3,968) - (743)	(3,346) (9,977) (2,379)
1.3 1.4	Dividends received Interest and other items of a similar nature	33	152
1.5 1.6 1.7	received Interest and other costs of finance paid Income taxes refund / (paid) Other – Foreign Currency Option Premium - Qualifying Therapeutic Discovery Grant	- - -	- (204) 749
	Net operating cash flows	(5,870)	(15,005)

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

		Current quarter \$A'000	Year to date (9 months) \$A'000
1.8	Net operating cash flows (carried forward)	(5,870)	(15,005)
1.9	<b>Cash flows related to investing activities</b> Payment for acquisition of:		
	<ul><li>(a) businesses (item 5)</li><li>(b) equity investments</li></ul>	-	-
	<ul><li>(c) intellectual property</li><li>(d) physical non-current assets</li></ul>	- (4)	(23)
	(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	-	-
	(e) other non-current assets	-	-
1.11	Loans to other entities	-	-
1.12	Loans repaid by other entities Other (Bank Accepted Commercial bills and	-	-
1.13	Term Deposit with maturity greater than 3 months)	-	-
	Net investing cash flows	(4)	(23)
1.14	Total operating and investing cash flows	(5,874)	(15,028)
	Cash flows related to financing activities		
1.15	Proceeds from issues of shares, options, etc.	-	18,809
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	-	-
	Net financing cash flows	-	18,809
	Net increase (decrease) in cash held	(5,874)	3,781
1.21	Cash at beginning of quarter/year to date	21,096	12,760
1.22	Exchange rate adjustments to item 1.20	(309)	(1,628)
1.23	Cash at end of quarter	14,913	14,913

<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	\$193
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	-	-

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

## **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	2,207	1,953
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	12,699	19,136
	Total: cash at end of quarter (item 1.23)	14,913	21,096

## 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		

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

#### **Compliance statement**

- <sup>1</sup> 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: 28 April 2011 (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.