

ASX RELEASE 16 April 2012

QUARTERLY OPERATING UPDATE 31 MARCH 2012

MoxDuo[®] IR PDUFA date approaching

Sydney, Australia & Bedminster, NJ – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced that the Company retains A\$27.3 million in cash reserves at 31 March 2012, as detailed in the Appendix 4C released today.



The highlight of the quarter was the execution by the Company of the License and Option Agreement (LOA) in March with Actavis, Inc. for the formation of a strategic partnership to commercialise MoxDuo IR, an immediate-release Dual-Opioid[®] utilising a 3:2 ratio of morphine and oxycodone, in the US acute pain marketplace. The launch of MoxDuo IR in the US is projected to occur in Q3 CY 2012 and pre-launch preparations are well underway. The LOA followed a 20 December 2011 signing of a binding Letter of Intent (LOI) secured by a US\$6 million non-refundable upfront signing fee to QRxPharma.

"With the finalisation of the LOA with Actavis we now await our 25 June 2012 PDUFA date when the MoxDuo IR New Drug Application review by the FDA will be completed," said Dr. John Holaday, Managing Director and Chief Executive Officer of QRxPharma. "We are also working to advance our MoxDuo CR formulation into Phase 2 proof-of-concept studies around mid-year."

The US Food and Drug Administration (FDA) set 25 June 2012 as the PDUFA (Prescription Drug User Fee Act) target date for action on the approval of the MoxDuo IR New Drug Application (NDA). The NDA is the basis for US regulatory approval of MoxDuo IR for the treatment of moderate to severe acute pain. MoxDuo IR will be targeting a \$2.5 billion segment of the \$8+ billion spent annually on prescription opioids in the US.

During the quarter the Company also successfully undertook two Phase 1 studies in healthy volunteers for MoxDuo CR, a controlled-release Dual-Opioid utilising the same 3:2 ratio of morphine and oxycodone. The proprietary MoxDuo CR formulation is designed to provide at least 12 hours of analgesia in patients suffering from moderate to severe chronic pain

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including cancer, lower back, osteoarthritis and neuropathic pain. MoxDuo CR encompasses both sustained delivery technology as well as abuse deterrent and tamper resistant features which are essential for this product formulation.

The successful completion of these MoxDuo CR Phase 1 trials confirmed the advantages of this formulation and will enable the Company to proceed with Phase 2 Proof-of-Concept clinical studies mid-year 2012. The results of these Phase 1 studies as announced on 11 April 2012 suggest that MoxDuo CR may be positioned as a once or twice per day formulation for treating chronic pain, with the potential advantage of significantly reduced side effects as witnessed with immediate release MoxDuo. In the US alone, the chronic opioid pain market is a \$6 billion a year opportunity. MoxDuo CR is expected to launch into the US chronic pain market in 2015.

In February the Company announced the appointment of Edward Rudnic, PhD, as Chief Operating Officer (COO). Dr. Rudnic brings more than 30 years of senior management and product commercialisation experience to QRxPharma through his career as an executive in the life sciences industry. Dr. Rudnic is a recognised leader in the development and commercialisation of pharmaceutical products and drug delivery technologies. His primary role will be to coordinate the Company's commercialisation plans with our strategic partner, Actavis Inc., for our intended launch of MoxDuo IR.

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 clinical pipeline candidates and preclinical stage assets.

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About MoxDuo IR

MoxDuo IR (immediate release) is a patented 3:2 ratio fixed dose combination of morphine and oxycodone. In head-to-head comparisons with morphine, oxycodone, Percocet[®] and placebo, more than 700 patients have been treated with MoxDuo IR in seven clinical trials over QRxPharma's successful Phase 3 development programme.

About MoxDuo CR

MoxDuo CR (controlled release) is a patented 3:2 ratio fixed dose combination of morphine and oxycodone designed to relieve moderate to severe chronic pain as a once- to twice-a-day formulation. The MoxDuo CR formulation contains proprietary technology to limit tampering or abuse by inhalation or solubilisation in water or alcohol.

About Actavis

Actavis Inc. is the US subsidiary of Actavis Group hf. Approximately one third of Actavis Group hf's sales are generated in North America, Actavis' single largest market. Actavis, Inc. has been manufacturing Kadian[®] for 15 years, and US sales for that product have grown 50% in the last 5 years to approximately \$275 million for the 12 months ending September 30, 2011, according to IMS Health. Based in Morristown, NJ, Actavis, Inc. has manufacturing facilities in Elizabeth, NJ and Lincolnton, NC. Actavis also has research and development facilities in Elizabeth, NJ, Owings Mills, MD and Sunrise, FL. Actavis Group



is one of the world's leading generic pharmaceutical companies specialising in the development, manufacture and sale of generic pharmaceuticals. Actavis has operations in 40 countries, with 10,000 employees. For more information, visit <u>www.actavis.us</u>.

About QRxPharma

QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) 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's lead product candidate, immediate release MoxDuo, has a Prescription Drug User Fee Act (PDUFA) date of 25 June 2012 when the New Drug Application review by the US Food and Drug Administration (FDA) will be completed. The Company recently signed a strategic partnership agreement with Actavis, Inc. to commercialise MoxDuo IR in the US acute pain market, with product launch anticipated in 3Q, CY2012. QRxPharma may co-promote its products in the US and plans to seek strategic partnerships for worldwide markets. 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 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

16 102 254 151

Quarter ended ("current quarter")

31 March 2012

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 1.3 1.4 1.5 1.6 1.7	Payments for (a) staff costs (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) Other – License fee received Other – Gain on sale of foreign currency option contracts	(1,434) (2,849) (728) - 25 - - -	(3,350) (7,685) (2,021) - 106 - 5,918 139
_	Net operating cash flows	(4,986)	(6,893)

⁺ 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)	(4,986)	(6,893)
1.9	Cash flows related to investing activities Payment for acquisition of:		
	(a) businesses (item 5)(b) equity investments	-	-
	(c) intellectual property(d) physical non-current assets(e) other non-current assets	- (10) -	(59)
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 Loans to other entities		
1.11		-	-
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	(10)	(59)
1.14	Total operating and investing cash flows	(4,996)	(6,952)
	Cash flows related to financing activities		
1.15	Proceeds from issues of shares, options, etc.	85	25,423
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	85	25,423
	Net increase (decrease) in cash held	(4,911)	18,471
1.21	Cash at beginning of quarter/year to date	32,852	7,291
1.22	Exchange rate adjustments to item 1.20	(618)	1,561
1.23	Cash at end of quarter	27,323	27,323

⁺ 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	\$191
1.25	Aggregate amount of loans to the parties included in item 1.11	\$-
	Evaluation possess for an understanding of the transactions	

 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	-	-

⁺ 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	1,771	1,057
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	25,545	31,788
	Total: cash at end of quarter (item 1.23)	27,323	32,852

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		

⁺ 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.

C. J. Campbell

Sign here:

nere: Date: 16 April 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.

⁺ See chapter 19 for defined terms.