

**ASX RELEASE**  
**30 January 2012**

**QUARTERLY OPERATING UPDATE**  
**31 DECEMBER 2011**

*MoxDuo<sup>®</sup> IR on track with US launch to address the \$2.5 billion acute pain market in 2012*

**Sydney, Australia & Bedminster, NJ** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced that the Company retains A\$32.9 million in cash reserves at 31 December 2011, as detailed in the Appendix 4C released today.

The Company accomplished two major milestones in the fourth quarter of 2011. The highlight of the quarter was the execution by the Company of a binding Letter of Intent (LOI) in December 2011 with Actavis Inc. for the formation of a strategic partnership to commercialise MoxDuo IR 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 underway.

The LOI followed the announcement by the Company in November 2011 that it had received written acceptance from the United States Food and Drug Administration (FDA) for review of the MoxDuo IR New Drug Application (NDA) filed earlier in the year. The letter stated that the agency had completed their NDA filing review and determined the application was sufficiently complete to permit a substantive review.

In issuing the written acceptance, the FDA set 25 June 2012 as the PDUFA (Prescription Drug User Fee Act) target date for action on the approval of the MoxDuo IR NDA. The NDA is the basis for US regulatory approval of MoxDuo IR 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.

The achievement of these two most important milestones advances the Company significantly down the path towards commercialisation.

The LOI grants Actavis exclusive rights to commercialise and further develop MoxDuo IR for the US market while assuming all costs for product launch as well as ongoing marketing and sales efforts in the US. QRxPharma, however, has retained the right to co-promote MoxDuo IR in the US and maintains all rights outside the US.

Actavis will pay QRxPharma royalties of 10% to 30% depending on net sales thresholds, except for a period starting 3 to 6 months following launch where QRxPharma will receive a 50% royalty on US\$ 150 million in cumulative sales. Under the co-promotion/profit-share right, QRxPharma can create its own sales force and provide up to 25% of the effective selling effort to US prescribers at any time following the first 12 months after product launch.

The binding LOI was also secured by a non-refundable upfront signing fee of US\$6 million, which bolstered the Company's cash position at the quarter's end. The parties expect to execute a more detailed agreement by 15 March 2012.

The QRxPharma clinical team is now focused on the development of MoxDuo Controlled Release (CR), the Company's continuous release dual opioid formulation. MoxDuo CR is intended for twice daily dosing wherein each dose provides at least 12 hours of pain relief in patients with moderate to severe chronic pain including indications such as cancer, lower back, osteoarthritis and neuropathic pain.

The Company has prepared initial formulations of MoxDuo CR and conducted a successful Phase 1 study to determine which formulations provided the optimum duration of drug levels in the blood. In 2012, QRxPharma will accelerate the MoxDuo CR tablet development, which encompasses sustained delivery technology as well as abuse deterrent and tamper resistant features. Three additional Phase 1 studies and a Phase 2 study will be conducted during CY 2012 with anticipation of MoxDuo CR undertaking Phase 3 development in 2013.

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.

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### **About MoxDuo<sup>®</sup> IR**

MoxDuo is a patented 3:2 ratio fixed dose combination of morphine and oxycodone. In head-to-head comparisons with morphine, oxycodone, Percocet<sup>®</sup> 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 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 [www.actavis.us](http://www.actavis.us).

### **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 and central nervous system (CNS) disorders. Based on a development strategy that focuses on enhancing and expanding the clinical utility of currently marketed compounds, QRxPharma'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 intends to co-promote its products in the US and seeks strategic partnerships for worldwide markets. QRxPharma's lead product candidate, immediate release MoxDuo, now awaits approval by the US Food and Drug Administration (FDA). Additionally, QRxPharma's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MoxDuo, as well as other pipeline technologies in the fields of pain management, neurodegenerative disease and venomics. 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.

# 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 December 2011

### 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 Payments for		
(a) staff costs	(848)	(1,916)
(b) advertising and marketing	-	-
(c) research and development	(2,437)	(4,835)
(d) leased assets	-	-
(e) other working capital	(708)	(1,293)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	47	80
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes refund / (paid)	-	-
1.7 Other – License fee received	5,918	5,918
Other – Gain on sale of foreign currency option contracts	-	139
<b>Net operating cash flows</b>	<b>1,972</b>	<b>(1,907)</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 (6 months) \$A'000
1.8 Net operating cash flows (carried forward)	1,972	(1,907)
<b>Cash flows related to investing activities</b>		
1.9 Payment for acquisition of:		
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	(5)	(49)
(e) other non-current assets	-	-
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	-	-
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>(5)</b>	<b>(49)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>1,967</b>	<b>(1,956)</b>
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	(7)	25,338
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>(7)</b>	<b>25,338</b>
<b>Net increase (decrease) in cash held</b>	<b>1,960</b>	<b>23,382</b>
1.21 Cash at beginning of quarter/year to date	31,968	7,291
1.22 Exchange rate adjustments to item 1.20	(1,076)	2,179
<b>1.23 Cash at end of quarter</b>	<b>32,852</b>	<b>32,852</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	\$201
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 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.

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

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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	1,057	1,150
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	31,788	30,811
<b>Total: cash at end of quarter (item 1.23)</b>		<b>32,852</b>	<b>31,968</b>

**Acquisitions and disposals of business entities**

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1	Name of entity	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: 30 January 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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