



**ASX RELEASE**

27 April 2010

**QUARTERLY OPERATING UPDATE  
31 MARCH 2010**

*QRxPharma Successfully Completes Pivotal Phase 3 Combination Rule Study for MoxDuo<sup>®</sup> IR in Patients with Post-Surgical Pain*


**Sydney, Australia & Bedminster, NJ** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY), announced that the Company retains A\$16.7 million in cash reserves at 31 March 2010, as detailed in the Appendix 4C released today.

“The highlight of this quarter was the successful completion of the first of two pivotal Phase 3 studies for MoxDuo<sup>®</sup> IR, an immediate-release Dual-Opioid<sup>™</sup> pain therapy” said Dr. John Holaday, Managing Director and CEO of QRxPharma. With the successful completion of this pivotal trial, the Company can better demonstrate the value of this product to potential partners, prescribers and patients. “We were delighted with the outcome of this study which supports our continuing emphasis on enhancing the value of our Dual-Opioid<sup>™</sup> pain management asset through ongoing development activities” added Holaday.

Required for the submission of a New Drug Application (NDA) with the United States Food and Drug Administration (FDA), this pivotal Phase 3 study which is expected to satisfy what is known as the “combination rule”, compared the efficacy and safety profiles of MoxDuo<sup>®</sup> IR against its component doses of morphine and oxycodone alone. The study achieved its primary endpoint demonstrating that MoxDuo<sup>®</sup> IR reduced moderate to severe pain following bunionectomy surgery significantly better than its individual components. Initiated in December 2009, the Company dosed 522 patients at six US clinical research sites in the conduct of this “combination rule” study.

In February 2010, the Company initiated a second pivotal Phase 3 registration trial to evaluate analgesic efficacy and safety of MoxDuo<sup>®</sup> IR. This two-arm study compares the effectiveness of a flexible dosing regimen vs a fixed low dose of MoxDuo<sup>®</sup> IR in 140 patients following total knee replacement surgery with results of this study expected during Q3 CY2010. Based on earlier pilot study data, the Company believes the second pivotal trial will also yield statistically significant results, enabling the Company to file its NDA by end 2010 with launch by end 2011.

The Company’s MoxDuo<sup>®</sup> product portfolio also includes intravenous (IV) and controlled release (CR) formulations and the development of these formulations also took significant steps forward during the quarter.



In late February 2010, the Company announced a strategic alliance with Aoxing Pharmaceutical Company, Inc (NYSE AMEX: AXN) (“Aoxing”) to collaborate in the development of MoxDuo<sup>®</sup> IV. Aoxing will fund the development of MoxDuo<sup>®</sup> IV for the China market in exchange for exclusive marketing rights in China. QRxPharma will retain ownership of MoxDuo<sup>®</sup> IV and may use the clinical work completed by Aoxing for product registration purposes outside of China. In addition, Aoxing also licensed the rights to the China market for MoxDuo<sup>®</sup> IR.

The Company expects to complete enrolment by 30 April 2010 of a 40 patient comparative proof-of-concept investigator study being conducted in Germany, evaluating the efficacy and safety of MoxDuo<sup>®</sup> IV versus IV morphine alone for the treatment of moderate to severe post-operative pain in patients following hip replacement surgery. It is anticipated that the results of this study will be available before the end of Q2 CY2010.

Finally, in late March 2010, the Company announced the granting by the FDA of an IND for MoxDuo<sup>®</sup> CR, and the initiation of the first Phase 1 trial to evaluate the pharmacokinetic (PK) profiles of experimental CR morphine and oxycodone formulations that will be incorporated into MoxDuo<sup>®</sup> CR. The vision for the MoxDuo<sup>®</sup> CR tablet is to provide 12 hours of relief (enabling twice daily dosing) in patients with moderate to severe chronic pain including cancer, lower back and osteoarthritis pain.

With the initiation of this trial, all three MoxDuo<sup>®</sup> product candidates are now in the clinic and progressing towards commercialisation, targeting a global opioid pain market of over US\$12 billion.

The operating cash outflow for the quarter is aligned with prior expectations. “We continue to closely manage our cash position while progressing the Phase 3 development programme for lead candidate MoxDuo<sup>®</sup> IR, a Dual Opioid™ (morphine plus oxycodone) product for the treatment of moderate to severe acute pain” said Holaday.

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## 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.

## About QRxPharma

QRxPharma (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 which 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 directly commercialise its products in the US and seek strategic partnerships for worldwide markets. QRxPharma's lead product candidate, MoxDuo<sup>®</sup> IR, is in Phase 3 clinical development and has successfully completed multiple comparative studies evaluating its efficacy and safety against equianalgesic doses of morphine, oxycodone and Percocet<sup>®</sup> for the treatment of acute pain. Data collected from these studies provided additional guidance for optimising the design and initiation of two pivotal Phase 3 studies required for New Drug Application (NDA) filings with the US Food and Drug Administration (FDA). QRxPharma expects to complete its Phase 3 program Q3 CY2010 and file its NDA for MoxDuo<sup>®</sup> IR in Q4 CY2010. The Company's preclinical and clinical pipeline includes other technologies in the fields of pain management, neurodegenerative disease and venomics. For more information, visit [www.qrxpharma.com](http://www.qrxpharma.com).

# 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 2010

### 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	(811)	(3,581)
(b) advertising and marketing	-	-
(c) research and development	(9,147)	(14,973)
(d) leased assets	-	-
(e) other working capital	(471)	(1,952)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	150	213
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes refund / (paid)	-	-
1.7 Other - Foreign Currency Option Premium	-	(439)
<b>Net operating cash flows</b>	<b>(10,279)</b>	<b>(20,732)</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)	(10,279)	(20,732)
<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	(2)	(16)
(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>1.14 Total operating and investing cash flows</b>	(10,281)	(20,748)
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	(113) <sup>(i)</sup>	20,792
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 (provide details if material)	-	-
<b>Net financing cash flows</b>	(113)	20,792
<b>Net increase (decrease) in cash held</b>	(10,394)	44
1.21 Cash at beginning of quarter/year to date	27,173	17,773
1.22 Exchange rate adjustments to item 1.20	(112)	(1,150)
<b>1.23 Cash at end of quarter</b>	16,667	16,667

<sup>(i)</sup> Represents the balance of costs incurred with respect to the Placement and Rights Issue which the Company completed during the quarter ended December 2009.

**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	109
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	-	-

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
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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	1,257	1,726
4.2 Deposits at call	2,451	2,500
4.3 Bank overdraft	-	-
4.4 Bank Accepted Commercial Bills and Term Deposits with maturity of less than 3 months	12,959	22,947
<b>Total: cash at end of quarter (item 1.23)</b>	<b>16,667</b>	<b>27,173</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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+ 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: 27 April 2010.  
(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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