



## ASX RELEASE

26 July 2010

### QUARTERLY OPERATING UPDATE

30 JUNE 2010

*QRxPharma reports analysis of MoxDuo<sup>®</sup> IR data and completion of MoxDuo IV and MoxDuo CR studies*

**Sydney, Australia & Bedminster, NJ** – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY), announced continued progress with its three MoxDuo products currently in clinical trials, with cash reserves of A\$12.8 million at 30 June 2010 as detailed in the Appendix 4C released today.


The Company continues to closely manage its cash position while continuing to progress the development of the immediate release (IR), controlled release (CR) and intravenous (IV) formulations of MoxDuo, a family of Dual-Opioids<sup>™</sup> (morphine plus oxycodone) for the treatment of moderate to severe pain.

“Our goal is to provide physicians and patients with a variety of complementary Dual-Opioids for managing moderate to severe pain from hospital to home,” said Dr John Holaday, Managing Director and Chief Executive Officer, QRxPharma.

During the quarter, additional Phase 3 Combination Rule Study 008 data for MoxDuo IR have confirmed and reinforced both its clinical benefits and commercial potential. The study compared the efficacy and safety profiles of MoxDuo IR (12mg morphine/8mg oxycodone) against its component doses of morphine (12 mg) and oxycodone (8 mg) alone for treating moderate to severe acute pain following bunionectomy surgery. MoxDuo IR not only demonstrated statistically superior analgesic effects compared to component doses of morphine ( $p < 0.01$ ) and oxycodone ( $p < 0.01$ ) but also a favourable side effect profile despite delivering twice the opioid dose of its individual components.

In a further analysis, patients in the morphine and oxycodone control groups were 2-3 times more likely to use ibuprofen supplemental dosing than those receiving MoxDuo IR ( $p < 0.05$  to  $p < 0.01$ ). Ibuprofen is a drug widely used for minor pains, and was administered to patients who did not receive adequate pain relief from the three opioid treatment groups. These data indicate that patients were not receiving sufficient pain relief from morphine or oxycodone alone when compared to MoxDuo IR.

“While the initial Study 008 trial data demonstrated the superiority of MoxDuo IR in terms of analgesic effect, further data analysis by QRxPharma has revealed equally important findings in terms of superior overall pain relief, reduced reliance on supplemental analgesia and strong tolerability,” said Dr Holaday.



In February 2010, the Company initiated Study 009 a second pivotal Phase 3 registration trial to evaluate analgesic efficacy and safety of MoxDuo IR in patients undergoing a total knee replacement. Enrolments are progressing at a steady rate with completion of enrolment expected by end of September 2010, enabling the Company to file its NDA in Q1 2011. Depending on the time required for the FDA to review the NDA and anticipating a favourable review, the Company anticipates launch of MoxDuo IR in late 2011 or early 2012.

The Company also advanced the controlled release (MoxDuo CR) formulation of its Dual-Opioid platform during the quarter. This formulation is designed to provide 12 hours of pain relief in patients suffering from moderate to severe chronic pain including cancer, lower back, osteoarthritis and neuropathic pain, addressing a worldwide multi-billion dollar market. Following the granting of the IND by the FDA earlier in 2010, the Company successfully completed a Phase 1 trial during the quarter.


The Phase 1 trial was conducted in 14 normal healthy volunteers at one US clinical research site. This study compared the rate at which key components of the MoxDuo CR formulation were absorbed, distributed, metabolised and eliminated by the body to the pharmacokinetic profile of Oxycontin® 20 mg (sustained release oxycodone). The results were consistent with expectations for a twice-daily formulation and keeps QRxPharma on track to finalise the MoxDuo CR tablet in early 2011 and to initiate Phase 2 trials shortly thereafter.

The Company recently completed a study designed to evaluate the efficacy and safety of MoxDuo IV compared to morphine IV using patient controlled analgesia (PCA) delivery for the treatment of moderate to severe post-operative pain in patients following hip replacement surgery. The Company is now completing analysis of this 40 patient comparative proof-of-concept investigator study that was conducted in Germany.

All three MoxDuo® product candidates are now in the clinic and progressing towards commercialisation, targeting a global opioid pain market of over US\$12 billion.

“We are delighted with these outcomes which support our continuing emphasis on enhancing the value of our Dual-Opioid™ pain management asset through ongoing clinical development activities,” concluded Dr 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®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® 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 Q4 2010 and submit its New Drug Application (NDA) for MoxDuo®IR to the FDA in Q1 2011. No additional pharmacology, toxicology or long-term clinical safety studies will likely be required for regulatory submission. The Company's preclinical and clinical pipeline includes MoxDuo®IV and MoxDuo®CR, plus other technologies in the fields of 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")

30 June 2010

### Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (12 months) \$A'000
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) staff costs	(827)	(4,408)
(b) advertising and marketing	-	-
(c) research and development	(2,988)	(17,961)
(d) leased assets	-	-
(e) other working capital	(879)	(2,830)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	61	274
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>(4,633)</b>	<b>(25,364)</b>

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

	Current quarter \$A'000	Year to date (12 months) \$A'000
1.8 Net operating cash flows (carried forward)	(4,633)	(25,364)
<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	(12)	(28)
(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>(12)</b>	<b>(28)</b>
1.14 <b>Total operating and investing cash flows</b>	<b>(4,645)</b>	<b>(25,392)</b>
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	61 <sup>(i)</sup>	20,853
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>	<b>61</b>	<b>20,853</b>
<b>Net increase (decrease) in cash held</b>	<b>(4,584)</b>	<b>(4,539)</b>
1.21 Cash at beginning of quarter/year to date	16,667	17,773
1.22 Exchange rate adjustments to item 1.20	677	(474)
1.23 <b>Cash at end of quarter</b>	<b>12,760</b>	<b>12,760</b>

<sup>(i)</sup> Represents the exercise of employee share options.

**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	203
1.25	Aggregate amount of loans to the parties included in item 1.1	\$-

1.26 Explanation necessary for an understanding of the transactions

Payments include director fees, 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**  
**admitted on the basis of commitments**

**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	1,032	1,257
4.2 Deposits at call	192	2,451
4.3 Bank overdraft	-	-
4.4 Bank Accepted Commercial Bills and Term Deposits with maturity of less than 3 months	11,536	12,959
<b>Total: cash at end of quarter (item 1.23)</b>	<b>12,760</b>	<b>16,667</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		

+ 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: ..... C. J. Campbell ..... Date: ..... 26 July, 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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+ See chapter 19 for defined terms.