



ASX RELEASE
28 October 2013

QUARTERLY OPERATING UPDATE **30 SEPTEMBER 2013**

Sydney, Australia & Bedminster, NJ – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced that the Company retains A\$8.5 million in cash reserves at 30 September 2013, as detailed in the Appendix 4C released today.

During the quarter, the Company announced receipt of a Complete Response Letter (CRL) from the United States Food and Drug Administration (FDA) regarding the Company's immediate release MOXDUO New Drug Application (NDA) for the treatment of moderate to severe acute pain.

On October 3, the Company had an end-of-review meeting with the FDA in response to the CRL. At that meeting, the FDA reaffirmed that the safety and efficacy of MOXDUO are not in question, and that the Company's presentation of the totality of the respiratory safety advantages to an Advisory Committee of experts would help guide their final decision. Accordingly, the FDA encouraged QRxPharma to submit its validated data and updated NDA. The Agency will then schedule an Advisory Committee meeting preceding a Prescription Drug User Fee Act (PDUFA) date six months following NDA resubmission. The Company anticipates completing the refiling in November 2013.

The revised NDA is the basis for recommending the regulatory approval process for MOXDUO for the treatment of moderate to severe acute pain, a \$2.5 billion USD segment of the \$8 billion USD spent annually on prescription opioids in the United States. The revised NDA also serves as the regulatory foundation for submitting MOXDUO for approval in Europe, Australia, Canada and other markets in the upcoming months. Assuming approval, the Company anticipates that MOXDUO will be launched in the United States during 2014.

Also during the quarter, the Company signed a licensing agreement with an Australian subsidiary of Aspen Pharmacare Holdings Limited (JSE: APN), for the commercialisation rights to immediate release MOXDUO in Australia, New Zealand and Oceania. The agreement provided Aspen an option to enter into an additional license for the territory of South Africa which it subsequently exercised, and the license was finalised in October.

Under these licensing agreements, Aspen will assume responsibility for the regulatory filings in each country, all product launch costs, as well as all ongoing marketing and sales efforts. QRxPharma will receive up to A\$1,500,000 in regulatory approval milestones, together with double digit royalties on the sales of immediate release MOXDUO in all markets. QRxPharma retains all rights to the intravenous and controlled release formulations of MOXDUO in these territories.



Complementing our portfolio and commercial partnerships, the Company signed in July 2013 a collaboration agreement with Aesica Pharmaceuticals Limited for the worldwide promotion of QRxPharma's proprietary Stealth Beadlets® abuse deterrent technology. This technology, developed for the MOXDUO controlled release formulation, may be incorporated into almost any potentially abused drug (e.g. opioids, amphetamines, sedatives, etc.) that are sold in solid dosage forms such as tablet, sachet or capsule; they provide significant resistance against the extraction of active ingredients if crushed, solubilized or heated. Under the non-exclusive collaboration agreement, Aesica will promote QRxPharma's Stealth Beadlets technology for inclusion in their clients' existing formulations of controlled drugs.

The operating cash flow for the quarter is in accordance with the expectations of the Board of Directors and resulted primarily from the Company's continuing efforts to secure NDA approval for immediate release MOXDUO in the US and activities associated with the preparation of the regulatory filings in Europe.

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About QRxPharma

QRxPharma Limited is an Australian based, commercial-stage specialty pharmaceutical company focused on the development and commercialisation of new pain management and abuse prevention products. Based on a development strategy that focuses on enhancing the clinical utility of currently approved compounds as well as bringing new products to market, 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. In Q4 2013, the Company plans to refile with the US Food and Drug Administration a New Drug Application for its lead product candidate, immediate release MOXDUO® for the treatment of acute pain. QRxPharma has entered into strategic collaborations with Actavis Inc., Paladin Labs Inc. and Aspen Group for the commercialisation of immediate release MOXDUO in the United States, Canadian, Australian (including New Zealand and Oceania) and South African acute pain markets respectively. The Company's clinical pipeline includes an intravenous (IV) and controlled release (CR) formulation of MOXDUO. The Company has also established a collaboration agreement with Aesica Pharmaceuticals Limited, for the world-wide promotion of QRxPharma's proprietary Stealth Beadlets® abuse deterrence technology. 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.

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 September 2013

Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (3 months) \$A'000
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) staff costs	(801)	(801)
(b) advertising and marketing	-	-
(c) research and development	(1,994)	(1,994)
(d) leased assets	-	-
(e) other working capital	(634)	(634)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	9	9
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes refund / (paid)	-	-
1.7 Other – Cost recoveries received	-	-
Other – License fee received	-	-
Other – Export market development grant	-	-
Net operating cash flows	(3,420)	(3,420)

+ 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 (3 months) \$A'000
1.8 Net operating cash flows (carried forward)	(3,420)	(3,420)
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	(56)	(56)
(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)	-	-
Net investing cash flows	(56)	(56)
1.14 Total operating and investing cash flows	(3,476)	(3,476)
Cash flows related to financing activities		
1.15 Proceeds from issues of shares, options, etc.	-	-
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	-	-
Net increase (decrease) in cash held	(3,476)	(3,476)
1.21 Cash at beginning of quarter/year to date	11,960	11,960
1.22 Exchange rate adjustments to item 1.20	24	24
1.23 Cash at end of quarter	8,508	8,508

+ 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	136
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
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	916	561
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	7,585	11,392
Total: cash at end of quarter (item 1.23)		8,508	11,960

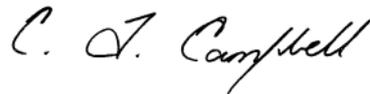
Acquisitions and disposals of business entities

	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: Date: 28 October 2013
(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.