

## **QRxPharma Limited** ABN 16 102 254 151

## ASX Half year report – 31 December 2009

## Lodged with the ASX under Listing Rule 4.2A

This report is to be read in conjunction with the financial statements for the year ended 30 June 2009 and any public announcements made by QRxPharma Limited during the interim reporting period in accordance with the continuous disclosure requirements of the Corporations Act 2001.

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## **QRxPharma** Limited

ABN 16 102 254 151

## Reporting period: Half year ended 31 December 2009 (Previous corresponding period: Half year ended 31 December 2008)

### **Results for announcement to the market**

				<u>A\$'000</u>
<b>Revenue</b> from ordinary activities	Down	92%	to	50
<b>Net loss</b> from ordinary activities after tax	Down	2044%	to	11,823
<b>Net loss</b> for the half year attributable to members	Down	2034%	to	11,761

### Note:

- 1. Revenue from ordinary activities is represented by interest income earned on cash reserves. At 31 December 2009, following a successful capital raising of \$21.6 million before offering expenses, the Group retains \$27.2 million (30 June 2009 \$17.8 million) in cash and cash equivalents. At 31 December 2008, the Group had \$29.9 million in cash and cash equivalents.
- 2. The Group's result for the period ended 31 December 2009 is reflective of the continuation of the Phase 3 clinical trial program for the lead compound MoxDuo<sup>TM</sup> IR and the continued progression of other clinical pipeline candidates and preclinical stage drugs in line with forecast development plans. The result includes an unrealised foreign exchange loss of \$1.0 million (2008: gain \$7.3 million).

### Dividends

It is not proposed to pay a dividend.

## **Other Appendix 4D information**

	<u>31 December</u> 2009	<u>31 December</u> <u>2008</u>
Net tangible assets per ordinary share	\$0.26	\$0.41

# **QRxPharma Limited** ABN 16 102 254 151

## Interim report for the half-year ended 31 December 2009

## QRxPharma Limited ABN 16 102 254 151 Interim report – 31 December 2009

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This half-year report covers the consolidated entity consisting of QRxPharma Limited and its subsidiaries. The financial report is presented in the Australian currency.

QRxPharma Limited is a company limited by shares, incorporated and domiciled in Australia. Its registered office and principal place of business is:

QRxPharma Limited Level 1 194 Miller Street North Sydney NSW 2060

This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2009 and any public announcements made by QRxPharma Limited during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

A description of the nature of the consolidated entity's operations and its principal activities is included in the directors' report which is not part of this financial report.

The half-year report was authorised for issue by the directors on 17 February 2010. The company has the power to amend and reissue the financial report.

Through the use of the internet, we have ensured that our corporate reporting is timely, complete, and available globally at minimum cost to the company. All press releases, financial reports and other information are available on our website: www.qrxpharma.com.

#### **Directors' report**

Your directors present their report on the consolidated entity (referred to hereafter as the Group) consisting of QRxPharma Limited (referred to hereafter as the Company) and the entities it controlled at the end of, or during, the half- year ended 31 December 2009.

#### Directors

The following persons were directors of QRxPharma Limited during the whole of the half-year and up to the date of this report:

Peter C Farrell John W Holaday R Peter Campbell Gary W Pace Michael A Quinn

#### **Review of operations**

The consolidated entity has made a loss from ordinary activities after income tax of \$11.8 million (2008: profit \$0.6 million) for the half-year.

	Half-year 31 Dec 2009 \$'000	Half-year 31 Dec 2008 \$'000
Interest income Other income Research and development expenditure General and administration Business development Employee salary benefits Depreciation and amortisation Net foreign exchange (loss)/gain	50 444 (5,956) (1,058) (494) (3,737) (32) (1,040)	609 569 (4,118) (793) (99) (2,840) (13) 7,293
(Loss) / profit for the half-year Non controlling interest Loss attributable to owners of QRxPharma Limited	(11,823) <u>62</u> (11,761) 2009 Cents	608 608 2008 Cents

Basic and diluted profit (loss) per share

The consolidated financial statements incorporate the assets and liabilities of QRxPharma Limited and its controlled subsidiaries, QRxPharma Inc, Venomics Pty Limited, The Lynx Project Pty Limited and Haempatch Pty Limited as at 31 December 2009 and the results of QRxPharma Limited and its subsidiaries for the half-year ended 31 December 2009.

(15.1)

0.8

The Group's expenditure for the period ended 31 December 2009 reflects the continuation of the Group's Phase 3 development programme for its lead product candidate MoxDuo<sup>TM</sup>IR (Q8003IR), an immediate release Dual Opioid<sup>TM</sup> (morphine plus oxycodone) product for the treatment of moderate to severe pain, and the continued development of its other clinical pipeline candidates and preclinical stage drugs in line with forecast development plans.

QRxPharma Limited Directors' Report 31 December 2009 (continued)

#### **Review of Operations (continued)**

During the half-year, the Company completed its second pilot study for MoxDuo™IR, which was conducted on patients following total knee replacement surgery. The study demonstrated that when compared at equianalgesic doses with Percocet, MoxDuo<sup>™</sup>IR demonstrated great overall tolerability with substantially fewer incidences of moderate to severe nausea, vomiting, constipation and hypotension than Percocet®.

Also during the half-year, QRxPharma initiated the first of two MoxDuo<sup>TM</sup>IR registrational studies required for lodgement of a new drug application (NDA) with the US Food and Drug Administration (FDA). The study compares the efficacy and safety profiles of MoxDuo<sup>TM</sup>IR against component doses of morphine and oxycodone alone for the management of moderate to severe post-operative pain following bunionectomy surgery. The second Phase 3 registrational trial, which was initiated in February 2010, is a double-blind controlled study to evaluate the effectiveness of MoxDuo<sup>TM</sup>IR in patients following total knee replacement surgery.

With respect to other clinical pipeline candidates and preclinical stage drugs, the Group through this half-year has:

- Initiated a comparative proof-of-concept study to evaluate the efficacy and safety of MoxDuo<sup>TM</sup>IV versus IV (intravenous) morphine alone for the treatment of moderate to severe post-operative pain in patients following hip replacement surgery.
- Signed a contractual agreement with Patheon to manufacture clinical supplies of QRxPharma's controlled release Dual Opioid ™ formulation, designed to provide 12 hours of pain relief in patients with moderate to severe pain.
- Finalised a deal with Liaoning Nuokang Medicines Co Ltd, a Chinese biopharmaceutical company based in Shenyang, China to develop and commercialise QRxPharma's venomics assets for the Chinese market.
- Progressed QRxPharma's Dystonia and Parkinson's disease development program (Torsin) under a collaborative research agreement at the University of Alabama (Caldwell Labs) to confirm the preclinical efficacy of its lead molecules.

The Group retains \$27.2 million in cash reserves at 31 December 2009 after conducting a successful \$21.6 million (before expenses) fully underwritten capital raising during the final quarter of 2009. These funds will be used to fund the two pivotal Phase 3 registrational studies and to file the NDA with the FDA for MoxDuo<sup>TM</sup>IR as well as funding the continuation of the development of MoxDuo<sup>TM</sup>IV and MoxDuo<sup>TM</sup>CR as part of the Group's product portfolio, to address pain management from hospital to home.

#### Auditor's independence declaration

A copy of the auditor's independence declaration as required under section 307C of the *Corporations Act 2001* is set out on page 3.

#### Rounding of amounts

The Company is of a kind referred to in Class Order 98/100, issued by the Australian Securities and Investment Commission, relating to the "rounding off" of amounts in the directors' report and financial report. Amounts in the directors' report and financial report have been rounded off to the nearest thousand dollars in accordance with that Class Order.

This report is made in accordance with a resolution of directors.

Farla

Peter C Farrell Director

Sydney Date: 17 February 2010

## PriceWATerhouseCoopers 🛛

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#### Auditor's Independence Declaration

As lead auditor for the review of QRxPharma Limited for the half year ended 31 December 2009, I declare that to the best of my knowledge and belief, there have been:

- a) no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the review; and
- b) no contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of QRxPharma Limited and the entities it controlled during the period.

Manoj Santiago Partner PricewaterhouseCoopers

Sydney 17 February 2010

#### **QRxPharma Limited Consolidated statement of comprehensive income** For the half-year ended 31 December 2009

	Note	Half - yea	ar
		2009	2008
		\$'000	\$'000
Revenue from continuing operations		50	609
Other income Employee benefits expense	3	444	7,862
- employee salary benefits		(2,700)	(2,068)
<ul> <li>defined contribution superannuation</li> </ul>		(36)	(20)
<ul> <li>share based payments</li> </ul>		(1,001)	(752)
Research and development		(5,956)	(4,118)
Business development		(494)	(99)
General and administration		(1,058)	(793)
Net foreign exchange loss		(1,040)	-
Depreciation and amortisation		(32)	(13)
Profit / (loss) before income tax		(11,823)	608
Income tax benefit			
(Loss) / profit from continuing operations		(11,823)	608
(Loss) / profit for the half-year		(11,823)	608
Total comprehensive (loss) / income for the half-year		(11,823)	608
Loss is attributable to: Owners of QRxPharma Limited		(11,761)	608
Non controlling interest		(62) (11,823)	608
		(11,623)	008
Earnings per share for loss attributable to the ordinary equity holders of the company:		Cents	Cents
Basic (loss) / profit per share Diluted (loss) / profit per share		(15.1) (15.1)	0.8 0.8

The above consolidated statement of comprehensive income should be read in conjunction with the accompanying notes.

#### QRxPharma Limited Consolidated balance sheet As at 31 December 2009

ASSETS Current assets	Note	31 December 2009 \$'000	30 June 2009 \$'000
Cash and cash equivalents Trade and other receivables Derivative financial instruments Other current assets Total current assets	4 5	27,173 41 476 <u>1,123</u> 28,813	17,773 66 <u>566</u> 18,405
<b>Non-current assets</b> Property, plant and equipment Available for sale financial assets Total non-current assets	6	261 407 668	274
Total assets		29,481	18,679
LIABILITIES Current Liabilities Trade and other payables Total current liabilities Total liabilities Net assets		<u>2,578</u> 2,578 2,578 2,578 26,903	<u> </u>
<b>EQUITY</b> Contributed equity Reserves Accumulated losses Capital and reserves attributable to the owners of QRxPharma Limited Non controlling interest	7	100,022 6,908 (80,197) 26,733 170 26,903	79,694 5,737 (68,436) 16,995 

The above consolidated balance sheet should be read in conjunction with the accompanying notes.

### QRxPharma Limited Consolidated statement of changes in equity For the half-year ended 31 December 2009

Attributable to owners of QRxPharma Limited					
Contributed I equity \$'000	Reserves \$'000	Retained earnings \$'000	Total \$'000	Non- controlling interest \$'000	Total equity \$'000
79,694	3,584	(54,941)	28,337	· -	28,337
-	۔ 1,801	608 -			608 1,801
79,694	5,385	(54,333)	30,746		30,746
79,694	5,737	(68,436)	16,995	; <u> </u>	16,995
-	-	(11,761)	(11,761)	(62)	(11,823)
20,328	-	-	20,328	; -	20,328
-	(178)	-			(178)
-	886 463	-	- + +		.,
100,022	6,908	(80,197)	26,733	170	26,903
	Contributed I equity \$'000 79,694 - - 79,694 79,694 - 20,328 - -	Contributed Reserves equity \$'000 \$'000 79,694 3,584 1,801 79,694 5,385 79,694 5,737  20,328 - (178) - 886 - 463	Contributed Reserves equity \$'000         Retained earnings \$'000           79,694         3,584         (54,941)           -         -         608           -         1,801         -           79,694         5,385         (54,333)           79,694         5,385         (54,333)           79,694         5,737         (68,436)           -         -         (11,761)           20,328         -         -           -         (178)         -           -         886         -           -         463         -	Contributed Reserves equity         Retained earnings         Total earnings           \$'000         \$'000         \$'000         \$'000           79,694         3,584         (54,941)         28,337           -         -         608         608           -         1,801         -         1,801           79,694         5,385         (54,333)         30,746           79,694         5,737         (68,436)         16,995           -         -         (11,761)         (11,761)           20,328         -         -         20,328           -         (178)         -         (178)           -         886         -         886           -         463         -         463	Contributed Reserves equity \$'000         Retained earnings \$'000         Total \$'000         Non- controlling interest \$'000           79,694         3,584         (54,941)         28,337         -           -         -         608         608         -           -         -         608         608         -           -         1,801         -         1,801         -           79,694         5,385         (54,333)         30,746         -           79,694         5,737         (68,436)         16,995         -           -         -         (11,761)         (11,761)         (62)           20,328         -         -         20,328         -           -         (178)         -         (178)         -           -         886         -         886         116           -         463         -         463         116

The above consolidated statement of changes in equity should be read in conjunction with the accompanying notes.

#### **QRxPharma Limited Consolidated cash flow statement** )9

For	the	half-\	/ear	ended	31	Decembe	er 200	ç
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		Half-year	
	Note	2009 \$'000	2008 \$'000
	NULE	φ <b>000</b>	\$ 000
Cash flows from operating activities Payments to suppliers and employees (inclusive of			
goods and services tax)		(10,084)	(7,220)
Payments for patents Interest received		(434)	(396)
Interest received		63	616
Net cash inflow / (outflow) from operating activities		(10,455)	(7,000)
Cash flows from investing activities		(4.4)	(00)
Payments for property, plant and equipment		<u>    (14)</u>	(28)
Net cash inflow/(outflow) from investing activities		(14)	(28)
Cash flows from financing activities			
Proceeds from share placement and rights issue	7	21,600	-
Proceeds from share issue in subsidiary	-7	579	-
Payments made in relation to capital raising	7	(1,272)	
Net cash inflow/(outflow) from financing activities		20,907	
Net increase/(decrease) in cash and cash equivalents		10,438	(7,028)
Cash and cash equivalents at the beginning of the			
Financial year		17,773	29,672
Effects of exchange rate changes on cash and			
cash equivalents		(1,038)	7,296
Cash and cash equivalents at end of half-year		27,173	29,940

The above consolidated cash flow statement should be read in conjunction with the accompanying notes.

#### 1 Basis of preparation of half-year report

This general purpose financial report for the interim half-year reporting period ended 31 December 2009 has been prepared in accordance with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Act 2001*.

This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2009 and any public announcements made by QRxPharma Limited during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

#### Financial statement presentation

The Group has applied the revised AASB 101 *Presentation of Financial Statements* which became effective on 1 July 2009. The revised standard requires the separate presentation of a statement of comprehensive income and a statement of changes in equity. All non-owner changes in equity must now be presented in the statement of comprehensive income. As a consequence, the Group had to change the presentation of its financial statements. Comparative information has been re-presented so that it is also in conformity with the revised standard.

#### Change in accounting policy

The Group has adopted AASB 8 *Operating Segments* from 1 July 2009. AASB 8 replaces AASB 114 *Segment Reporting*. The new standard requires a 'management approach', under which segment information is presented on the same basis as that used for internal reporting purposes

#### Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to senior management and the Board of Director of QRxPharma Limited.

Other than mentioned above, the accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period.

#### 2 Segment information

The Board of Directors of QRxPharma Limited monitors the performance of the Group at a consolidated level. Segment results and total assets and liabilities are represented by the consolidated statements of comprehensive income and consolidated balance sheet.

#### QRxPharma Limited Notes to the consolidated financial statements 31 December 2009

#### 3 Other income

	Note	Half-ye	ear
		2009 \$'000	2008 \$'000
Gain on loss of control of subsidiary Net foreign exchange gain Fair value gain on derivative financial instrument		407 <u>37</u>	- 7,293 <u>569</u>
		444	7,862

#### 4 Fair value gain on derivative financial instrument

During the half year ended 31 December 2009, the Group entered into a series of Flexible Forward foreign exchange contracts to protect against adverse foreign exchange movements between the AU\$ and US\$. Each contract stands alone and all mature within 6 months of 31 December 2009. Each contract has a floor rate of US\$0.91 and a ceiling of US\$0.98. On the maturity of each contract, if the spot rate is below the floor rate, the Company is obligated to buy the contracted amount of US dollars from the bank at US\$0.91. If the spot rate is above the ceiling rate on contract maturity, the Company is obligated to buy the contracted amount of US\$0.91 and US\$0.98. If the spot rate is between US\$0.91 and US\$0.98, there is no obligation by either the bank or the company.

At 31 December 2009, a fair value of AU\$476,557 has been recognised in relation to these contracts.

#### 5 Other current assets

	Half-ye	Half-year		
	2009 \$'000	2008 \$'000		
Prepayments	1,123	566		

Prepayments relate predominantly to advance payments of clinical trial expenditure.

#### 6 Available for sale financial assets

During the half year, Liaoning Nuokang Medicines Co. Ltd., a Chinese biopharmaceutical company based in Shenyang, China, invested US\$5 million for a controlling interest in Venomics Hong Kong Limited a company established to develop and commercialise the Group's venomics assets, Textilinin and Haempatch<sup>™</sup>, for the Chinese market. Venomics Pty Limited, which is a majority owned subsidiary of QRxPharma Limited and holds all of the venomics assets of the Group, maintains a minority interest in Venomics Hong Kong Limited. Data generated through the development of these products in China will support partnering activities in other territories, the rights of which have been retained by Venomics Pty Limited. The available for sale financial asset recognises the Group's investment in Venomics Hong Kong Limited.

#### 7 Equity securities issued

	Number of shares	lssue price	\$'000
1 July 2009Balance19 November 2009Share placement23 December 2009Rights issueLess: transaction costs arising on issue of shares21 December 2000	75,000,000 10,000,000 17,000,000	0.80 0.80	79,694 8,000 13,600 (1,272)
31 December 2009 Balance	<u>102,000,000</u>		100,022

During the half year, QRxPharma Limited successfully raised \$21.6 million (before expenses) as a result of a fully underwritten institutional placement raising \$8 million and a fully underwritten 1 for 5 renounceable rights issue raising a further \$13.6 million. The issue price under the placement and rights Issue was \$0.80 per share resulting in the issue of 27 million new ordinary shares.

#### 8 Subsidiaries

The consolidated financial statements incorporate the assets, liabilities and results of the following subsidiaries:

Name of entity	Country of incorporation	Class of shares	31 Dec 2009 %	30 June 2009 %
The Lynx Project Pty Limited	Australia	Ordinary	100	100
Haempatch Pty Limited	Australia	Ordinary/Preference	100	100
QRxPharma, Inc.	USA	Ordinary	100	100
Venomics Pty Limited	Australia	Ordinary	80	100
Venomics Hong Kong Limited	Hong Kong	Ordinary	6.98	100

#### 9 Contingent liabilities

There have been no other changes in the company's contingent liabilities reported as at 30 June 2009.

#### 10 Events occurring after the balance sheet date

No significant events have occurred after the balance sheet date which would have a material impact on the financial results of the Group.

In the directors' opinion:

- the financial statements and notes set out on pages 4 to 10 are in accordance with the Corporations (a) Act 2001, including:
  - complying with Accounting Standards, the Corporations Regulations 2001 and other (i)
  - mandatory professional reporting requirements; and giving a true and fair view of the consolidated entity's financial position as at 31 December (ii) 2009 and of its performance for the half-year ended on that date; and
- (b) there are reasonable grounds to believe that QRxPharma Limited will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the directors.

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Peter C Farrell Director

Sydney Date: 17 February 2010

## PriceWATerhouseCoopers 🛛

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## Independent auditor's review report to the members of QRxPharma Limited

#### **Report on the Half-Year Financial Report**

We have reviewed the accompanying half-year financial statements of QRxPharma Limited, which comprise the statement of financial position as at 31 December 2009, and the statement of comprehensive income, statement of changes in equity and statement of cash flows for the half-year ended on that date, other selected explanatory notes and the directors' declaration for the QRxPharma Limited Group (the consolidated entity). The consolidated entity comprises both QRxPharma Limited (the company) and the entities it controlled during that half-year.

#### Directors' responsibility for the half-year financial report

The directors of the company are responsible for the preparation and fair presentation of the halfyear financial report in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Act 2001*. This responsibility includes establishing and maintaining internal control relevant to the preparation and fair presentation of the half-year financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

#### Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of an Interim Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the financial report is not in accordance with the *Corporations Act 2001* including: giving a true and fair view of the consolidated entity's financial position as at 31 December 2009 and its performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As the auditor of QRxPharma Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. It also includes reading the other information included with the financial report to determine whether it contains any material inconsistencies with the financial report. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

While we considered the effectiveness of management's internal controls over financial reporting when determining the nature and extent of our procedures, our review was not designed to provide assurance on internal controls.



## Independent auditor's review report to the members of QRxPharma Limited (continued)

Our review did not involve an analysis of the prudence of business decisions made by directors or management.

#### Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001.* 

#### Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of QRxPharma Limited is not in accordance with the *Corporations Act 2001* including:

- (a) giving a true and fair view of the consolidated entity's financial position as at 31 December 2009 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 Interim Financial Reporting and Corporations Regulations 2001.



PricewaterhouseCoopers

Manoj Santiago Partner

Sydney 17 February 2010