

Investor Update & Capital Raising

November 2009

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# **Executive Summary**

Investor update	QRxPharma is a clinical-stage specialty pharmaceutical company focused on the development and commercialisation of therapies for pain management and central nervous system (CNS) disorders
	• Study results for MoxDuo™IR have demonstrated fewer side effects than observed with morphine alone, oxycodone alone and now with Percocet ® (APAP plus oxycodone)
	• The Company has to complete two pivotal Phase 3 studies and one Phase 1 pharmacokinetic trial prior to finalising a New Drug Application filing with the US Food and Drug Administration in 2010
	Plan to commence sales 2011 into large market
Equity raising	Approximately A\$23.1 million to be raised by way of a fully underwritten Placement and Renounceable Rights Issue
Offer structure	<ul> <li>Placement of approximately 9 million new shares (12% of issued capital) final price to be determined by a bookbuild followed by a renounceable rights issue to take total raising to approximately \$23.1 million.</li> </ul>
	<ul> <li>Placement price to be determined by bookbuild (range is A\$0.80 to A\$0.95 per new share), representing a 21.0% - 33.3% discount to the last closing price of A\$1.20 per share on 10 November 2009. Rights Issue price will be the same as the Placement Price.</li> </ul>
	Rights will be traded on the ASX.
	To be fully underwritten by RBS Morgans Corporate Limited
Use of proceeds	The proceeds will be used to fund Phase 3 drug development and expenditure programme and provide additional working capital
Key Offer dates	<ul> <li>Trading Halt to undertake Placement:11 &amp; 12 November 2009; ASX announcement of Placement and Rights issue: 13 November 2009; Settlement of Placement: 18 November 2009; Placement Shares to trade on ASX: 19 November 2009; Rights Issue Record Date: 23 November 2009; Rights Issue Closing Date: 14 December 2009</li> </ul>
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### Corporate Snapshot As at 10 November 2009

### ASX Code: QRX

Last share price: \$1.20 12 month high: \$1.30 12 month low: \$0.20 Shares on issue: 75 million Market cap: \$90 million (@ \$1.20)

### Major shareholders:

Innovation Capital Group – 11.06% John Holaday (MD) – 10.06% Four Hats – 7.90% Spring Ridge Ventures I, LP – 5.64% BT Financial – 5.54% Uniquest – 5.34%

### **Register:** Top 20: 75.21%

Top 50: 84.06 % Total = 813 shareholders

### Board of Directors: Dr Peter Farrell (Chairman) Dr Gary Pace Michael Quinn Peter Campbell Dr John Holaday (Managing Director & CEO)

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## **Investment Highlights**

- Phase 3 specialty pharmaceutical company (ASX: QRX and OTCQX: QRXPY)
  - Commercialisation of Dual Opioid<sup>™</sup> products (MoxDuo<sup>™</sup>) for pain management, depth of opportunities in pain relief and brain disorders

### • Pipeline of late and early stage candidates

- Re-engineer marketed drugs to enhance and/or expand clinical and commercial value
- Abbreviated R&D paths, streamlined regulatory approvals, reduced risk of failure and renewed market value
- Target global opioid pain market of est US\$12 billion\*

<sup>6</sup> \*Source: Datamonitor 03/2009 Opening the therapeutic window for doctors and patients.

# **Investment Highlights**

- Strategic relationships
- Strong IP; broad international protection
  - Patent applications lodged which if granted are expected to extend market exclusivity through 2029; IV (intravenous), IR (immediate release) and CR (controlled release) formulations
  - Experienced board and executive team
  - Industry veterans
- Significant near term news flow

## **Experienced Board**

• Dr Peter Farrell PhD, ScD, AM (*Non-Executive Chairman*)

Chairman and founder of ResMed Inc; other directorships include Pharmaxis Limited and Nuvasive Inc.

### • Dr Gary Pace PhD (*Non-Executive* & Consultant)

Founder of QRxPharma; other directorships include ResMed Inc and Peplin Limited

• Peter Campbell FCA, FTIA (*Non-Executive*)

Other directorships include Sonic Healthcare Limited and Silex Systems Limited

### Michael Quinn MBA (Non-Executive)

Other directorships include ResMed Inc, CAP-XX Limited and Innovation Capital Group

Dr John Holaday PhD (Managing Director and Chief Executive Officer)

Co-founded Medicis Pharmaceutical Corporation (NYSE) and EntreMed Inc (NASDAQ)



# **Experienced Management Team**

Chris Campbell CA (CFO and Company Secretary)

Three decades of financial experience including "Big 4" accounting firm and as CFO of publicly traded companies

### • Dr Warren Stern PhD (*Executive VP*, *Drug Development*)

Over three decades of experience in central nervous system drug development and performing preclinical and clinical trials in psychopharmacology

### • Dr. Patricia Richards MD, PhD (*Chief Medical Officer*)

Three decades of experience as anesthesiologist/pain doctor and manager of clinical trails in pain and psychopharmacology

### • Philip Magistro MBA, MS (Chief Commercial Officer)

Marketing specialist with over 25 years experience in the pharmaceutical industry with specific expertise in product launch

### • Dr Solomon Snyder MD (Chairman of the Scientific Advisory Board)

Regarded as one of the world's leading neuroscientists, awarded the Lasker prize for identifying the opioid receptor

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# Pain Therapy Market

- Limited product innovation to date; reliance on older therapies - Opioids are the 'gold standard' in treating moderate to severe pain, but limited by side effects
- Clear need for Opioids with fewer side effects and risk factors - Nausea, vomiting, somnolence, dizziness, constipation, respiratory depression
- Complementary offering of Dual-Opioids<sup>™</sup>IV (intravenous), IR (immediate release) and CR (controlled release) formulations - Products from hospital to home in a global marketplace of est US\$12 billion, with CAGR 2004-07 in excess of 6% (volume/revenue)\*

\*Source: Datamonitor 03/2009

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# **Pain Therapy Market**

No one player "owns" the global moderate to severe pain market.

## In the US\*:

- Immediate Release (IR) US\$1.5 billion: Generic and branded led by generic Vicodin<sup>®</sup> US\$483 million together generic Percocet US\$388 million and branded Percocet<sup>®</sup> US\$135 million (Endo)
- Intravenous (IV) US\$260 million: 220 million vials dominated by generic Morphine, Fentanyl and Hydromorphone
- Controlled Release (CR) US\$4.6 billion: Branded and generic led by US\$2.2 billion OxyContin<sup>®</sup> (Purdue Pharma) followed by generic US\$0.7 billion Fentanyl

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\*Source: IMS 2008

# **Product Pipeline 2009**

PRODUCT/PROGRAM	RESEARCH	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
PAIN MANAGEMENT					
MoxDuo™ IR					
MoxDuo™ IV					
MoxDuo™ CR					
NEUROLOGIC DISEASES	,				
T9001 (DYSTONIA)					
T9001 (PARKINSON'S)					
VENOMICS					
Haemepatch™					
Textilinin					



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# MoxDuo<sup>™</sup>: Path to Market

### **Near Term Milestones:**

- FDA review of MoxDuo™IR Phase 3 Combination Rule study SPA\*
- FDA review MoxDuo™IR Phase 3 Pain (Orthopedic) study SPA\*
- File IND for MoxDuo<sup>™</sup>CR Phase 1
- Commence MoxDuo™CR Phase 1 study
- Complete dosing of MoxDuo<sup>™</sup>IV Phase 2 Investigator study
- Initiate remaining MoxDuo™IR Pivotal Phase 3 study programme

\* Irrespective of FDA review outcome the company intends to proceed with the studies

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# MoxDuo<sup>™</sup>: Path to Market

### **Targeted Milestones:**

### First Half CY 2010

- Results MoxDuo™IR Pivotal Phase 3 Combo Rule study
- Strategic Partnership(s) Europe / ROW

### Second Half CY 2010

- Results MoxDuo™IR Pivotal Phase 3 TKR study
- Lodge NDA MoxDuo™IR
- Implement strategies for bringing MoxDuo<sup>™</sup>IR to market in 2011



## What Key Opinion Leaders are saying

### ON CURRENT PAIN THERAPIES...

"Pain is poorly controlled." Pain Specialist - Atlanta

"We need a better tolerated product. Less side effects." Orthopedic Surgeon - Los Angeles

"Side effects. Constipation. The patient is spaced out, drowsy, itching. Most are not happy or comfortable." Pain Specialist - Los Angeles

### ON MOXDUO™...

"Fascinating. I've never seen a combination of two narcotics. I've seen it combined with anti-inflammatories. This is great. Requires a smaller amount and it's symbiotic." Orthopedic Surgeon - Atlanta

> "It has real advantages. The same pain relief but less side effects. Increases safety of the patient." Pain Specialist - Atlanta

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"I like it. A reduction in all the side effects [we mentioned]. Low potential for sedation. Absolutely key for the elderly. No increase in side effects if you increase the dose. It's better." Podiatrist - Los Angeles

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# **MoxDuo™: Key Differentiators**

- MoxDuo<sup>™</sup>IR opens the therapeutic window for acute pain relief
  - Fewer moderate to severe side effects than equianalgesic doses of morphine, oxycodone and Percocet<sup>®</sup> in two distinctly different types of pain

### Streamlined route to approval

- 505(b)(2) regulatory path
- Anticipate NDA filing of MoxDuo<sup>™</sup>IR with the FDA in 2010
- Broad spectrum platform technology
  - Immediate release, intravenous, and controlled release product formulations give doctors more options in successfully treating pain

### MoxDuo<sup>™</sup> is a patented product

- IP covers composition of matter, mechanism of action and new formulations
  - No patented combination product contains 2 opioids
- Issued patents protect against similar opioid combinations
- Patent applications lodged which if granted are expected to extend market exclusivity through 2029; IV (intravenous), IR (immediate release) and CR (controlled release) formulations
  - North America and other major markets

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# **New Platform Technology**

- Broader selection of complementary analgesic options to pain specialists
  - MoxDuo<sup>™</sup> Immediate Release (IR) oral capsules
    - Target: Moderate to severe acute pain
    - Phase 3 studies
  - MoxDuo<sup>™</sup> IV liquid formulation
    - Target: Hospital-based pain
    - Phase 2 and concurrent formulation development
  - MoxDuo<sup>™</sup> Controlled Release (CR) oral tablets
    - Twice daily dosing; abuse-deterrent technology
    - Targets: Chronic pain (mainly moderate to severe osteoarthritis and lower back pain), neuropathic pain, cancer pain

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Phase 1 scheduled to start January 2010



## Study 021: Purpose and Key Results Acute Pain after Bunionectomy

- FDA requires combination Rule Phase 3 Study (MoxDuo™IR vs. component doses of morphine and oxycodone alone):
  - Efficacy already confirmed in 2009 dose-response study
  - Estimate the number of patients to power a successful pivotal Phase 3 study for use in filing of New Drug Application (NDA) with the FDA
- MoxDuo™IR (12mg/8mg) provided significantly more pain relief than component doses of morphine (12mg) and oxycodone (8mg)
  - Frequency of moderate to severe nausea, vomiting and dizziness 50% to 75% lower than morphine or oxycodone alone
- Demonstrated Enhanced Tolerability of MoxDuo<sup>™</sup>IR (pain relief with fewer side effects) compared to equianalgesic doses of morphine and oxycodone

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## Study 020: Purpose and Key Results Pilot Total Knee Replacement (TKR)

- Compare MoxDuo<sup>™</sup>IR vs. Percocet<sup>®</sup>, a widely prescribed opioid
  - Addresses FDA requirement to show efficacy in second pain model
  - Select a control group of MoxDuo<sup>™</sup>IR fixed low dose (3/2mg) for the pivotal Phase 3 TKR study (009)
  - Estimate the number of patients to power successful pivotal Phase 3 study for use in filing of New Drug Application (NDA) with the FDA
  - Open label, randomized comparison of MoxDuo<sup>™</sup>IR 12/8mg (flexible regimen) and versus Percocet<sup>®</sup> given as standard of care.
- Demonstrated Enhanced Tolerability of MoxDuo<sup>™</sup>IR (pain relief with less nausea, vomiting, hypotension and constipation) compared to equianalgesic dose of Percocet<sup>®</sup>

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## **Financial Overview**

	*Audited	**Unaudited			ProForma Balance
	Balance Sheet 30 Jun 2009	Balance Sheet		Adjustments	Sheet
	AUD \$'000	30 Sep 2009 AUD \$'000	(i) AUD \$'000	(ii) AUD \$'000	30 Sep 2009 AUD \$'000
ASSETS	A0D \$ 000				
Current Assets					
Cash & cash equivalents	17,773	12,911	579	21,548	35,038
Trade & other receivables	66	31		,	31
Other current assets	566	336			336
Total	18,405	13,278		-	35,405
Non-current Assets					
Other financial assets	0	0	407		407
Property, plant & equipment	274	265			265
Intangible assets	0	0		_	0
Total	274	265		_	672
Total Assets	18,679	13,543		_	36,077
LIABILITIES					
Current Liabilities					
Trade & other payables	(1,684)	(1,617)		_	(1,617)
Total Liabilities	(1,684)	(1,617)		_	(1,617)
Net Assets	16,995	11,926		_	34,460
EQUITY				_	
Contributed equity	79,694	7 <mark>9,694</mark>		21,548	101,2 <mark>42</mark>
Reserves	5,737	5,782	986		6,768
Outside Equity Interest	0	0			0
Accumulated losses	(68,436)	(73,550)		_	(73,550)
Total equity	16,995	11,926		_	34,460

Notes:

(i) Issue of equity to outside parties in Venomics Pty Ltd and recognition of gain associated with investment by

Nuokong Medicines Co Ltd in Venomics Hong Kong Ltd

(ii) Net proceeds of offering

\* The Audited Balance Sheet should be read in conjunction with the information, disclosures and accounting policies contained within the annual report for year ended 30 June 2009

\*\* The Unaudited Balance Sheet has been prepared with policies that are consistent with those published in the annual report 30 June 2009 20

## **Offer Details**

Pricing	
Closing price on 10 November 2009	\$1.20
Equity raising (bookbuild range):	\$0.80 - \$0.9 <mark>5</mark>
Discount range to closing price of \$1.20	21.0% - 33.3%

### Equity raising details

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Placement	
Placement (12% of issued capital)	9m shares
Placement proceeds	\$7.2m - \$8.6m
Entitlement offer	
Entitlement offer proceeds <sup>1</sup>	\$15.9m - \$14.5m
Total equity raised	\$23.1m

1. Rights issue ratio to be determined based on Final Bookbuild Price

### **Offer Structure & size**

Placement

Followed by a fully underwritten renounceable rights issue (new placement shares to participate in rights issue)

Rights may be traded on the ASX

Shareholders are able to apply for additional shares in excess of their rights

### Ranking

Shares issued under the placement and rights issue will rank equally in all respects with existing ordinary shares from allotment

### Underwriting

Placement & Rights issue to be fully underwritten by RBS Morgans Corporate Limited



# **Use of Funds**

FX Rate USD: AUI	\$0.9100
	AUD\$000
Source of Funds	
Proceeds of Placement and Rights Issue	\$23,063
Expenses of the Offer	(\$1,514)
Net proceeds of the Offer	\$21,548
Use of Funds	
Drug development expenditure programme - external costs	
Phase 3 clinical trials and submission of an NDA for MoxDuo™IR	\$15,549
Additional working capital for drug expenditure programme, business development and G & A	\$5,999
Total	\$21,548

	AUD\$000
Proforma Cash Balance 30 September 2009	\$35,038
Drug development expenditure programme	
Phase 3 clinical trials, CMC & Packaging, NDA for MoxDuo™IR inclusive of headcount and overhead	
to support clinical programme	\$25,140
Advancement of clinical programme for MoxDuo™IV & CR	\$2,310
Research and development of other preclinical drugs	\$666
Other working capital to support business development and G & A	\$6,922
Total	\$35,038

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## **Timetable**

Event	Dates
Trading Halt and Placement	Wednesday 11 November to Thursday 12 November 2009
Announcement Date - 708AA Cleansing Notice, Rights Issue Offer Document and Appendix 3B lodged with ASX	Friday 13 November 2009
Settlement of Placement and Allotment of Placement Shares	Wednesday 18 November 2009
Placement Shares trade on ASX	Thursday 19 November 2009
Rights begin trading and Shares quoted ex-rights	Tuesday 17 November 2009
Record Date for the Rights Issue	7pm (Sydney time) Monday 23 November 2009
Rights trading ends	Tuesday 7 December 2009
Deferred settlement trading	Wednesday 8 December 2009
Rights Issue closes	Monday 14 December 2009
ASX notified of under-subscriptions	Thursday 17 December 2009
Despatch date (deferred settlement trading ends)	Friday 18 December 2009
Normal trading commences	Monday 21 December 2009

The above timetable is indicative only and subject to change without notice.

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### **QRX** *Pharma*

# **Ineligible Shareholders**

- Ineligible Shareholders are those Shareholders with registered addresses outside of Australia, New Zealand and United States of America (USA)\* as at the Record Date. QRxPharma have decided not to make an offer to these Shareholders in accordance with the ASX Listing Rules. Entitlement and Acceptance Forms are not being sent to Ineligible Shareholders.
- QRxPharma will appoint a nominee for Ineligible Shareholders.
- QRxPharma will issue the nominee with the Entitlements that would have been available for subscription by Ineligible Shareholders had they been eligible to participate in the Rights Issue.
- The nominee will endeavour to sell the Entitlements of these Ineligible Shareholders to purchasers that are sophisticated investors for the purposes of s708(8) of the Corporations Act or professional investors for the purposes of s708(11) of the Corporations Act.
- QRxPharma will remit the proceeds of any such sales (net of expenses) proportionately to Ineligible Shareholders.
  - \* Non Accredited Investors in the USA are ineligible.

# The Opportunity . . .

- Compelling data as part of its Phase 3 programme in est US\$12 billion global opioid pain market\*
- Late and early stage clinical pipeline commercialisation of first product MoxDuo™IR in 2011

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- Strategic partnerships in negotiations
- Portfolio of early and late products
- Experienced management and board





An investment in QRxPharma will be accompanied by various risks and should be considered speculative in nature. Some of these risks are specific to the Company while others relate to investing in shares in general. It is for this reason that none of QRxPharma nor its Directors or advisors provide any guarantee with respect to market value or that profitability will be achieved or dividends will be paid.

This section describes a range of risks associated with an investment in QRxPharma. The risks outlined should not be considered exhaustive of the risks faced by QRxPharma and its investors but these and other risks could have a material impact on the financial performance of the company and the value of the Shares offered under the Placement and the Rights Issue.

Before making a decision, investors should consider each of the risks described in this section, as well as other information in the Rights Issue Booklet and QRxPharma's periodic and continuous disclosure announcements lodged with the ASX. Investors should carefully consider these factors in light of their investment objectives and financial circumstances. If investors are in any doubt regarding the terms and conditions of the Rights Issue Booklet they should seek professional advice from their stockbroker, solicitor, accountant, or other qualified professional financial advisor.

### **General Risks**

### **Share Market Risks**

Potential investors should recognise that there are risks associated with any investment in shares. On completion of the Placement and Rights Issue, the Shares may trade on the ASX at higher or lower prices than the offer price. The price at which the Shares trade on the ASX may vary as a result of QRxPharma's financial performance and as a result of external factors which are not under the control of the Company and the Directors. The share price will be subject to changes in overall market conditions and investor perspectives of the specialty pharmaceutical industry. The share prices of specialty pharmaceutical companies can be volatile and there can be no guarantee that the price of the Shares will increase after the Placement and Rights Issue.

### Liquidity and Realisation Risk

There is no guarantee that an active market in the Company's Shares will develop. There may be relatively many or few buyers or sellers of the Shares trading on the ASX at any given time which may increase share price volatility.

### **General Economic Conditions and Currency Fluctuations**

There are a wide range of macro-economic and political factors, both in Australia and internationally, which are beyond the Company's control and which may affect the Company's operating and financial performance. These may include factors such as economic growth, inflation, exchange rates, interest rates, consumer spending and government fiscal, monetary and regulatory policies. There is also the risk of terrorist and other activities which may adversely impact the global economy and share market conditions in general.

A significant proportion of QRxPharma's revenues and expenses is expected to be denominated in currencies other than Australian dollars, in particular US dollars. The Company expects approximately 90% of the Rights Issue and Placement proceeds will be exposed to fluctuations between the Australian dollar and the US dollar. As a result, if proper hedging is not in place, exchange rate movements could have an adverse impact on the Company's financial results.

### Tax Risk

Any change to the rate of company income tax in the jurisdictions in which QRxPharma operates will impact on financial performance, cash flows the share price and shareholder returns. Any changes to the rates of income tax applying to individuals or trusts will also impact shareholder returns. Additionally, any change to the tax arrangements between Australia and other jurisdictions could adversely impact the Company's future earnings and the level of dividend franking.

### Legislative and Regulatory Changes

Changes to laws and regulations or accounting standards which apply to QRxPharma could have an adverse impact on the Company's financial performance. Some legislative and regulatory changes that could have an adverse impact on the Company include changes to regulatory requirements for the commercialisation of the Company's pipeline products.

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## **Specific Risks to QRxPharma**

### **Clinical Development**

QRxPharma is in late stage clinical development for its lead product and has additional products at an earlier stage of development. There are inherent risks involved with the development of pharmaceutical products including failure during clinical trials or failure to achieve sufficient robustness and reliability. QRxPharma is yet to commercialise any products from its development programmes and cannot guarantee that its research and development activities will lead to the development and successful commercialisation of its products. There is also no guarantee that QRxPharma will succeed in bringing its products to market at a time that allows it to capture market opportunities.

### **Regulatory Risks**

To obtain regulatory approval for the commercial sale of any one of its products, QRxPharma must prove that its products are both safe and effective for use in each proposed indication. There can be no guarantees that large scale clinical trials will reinforce the findings of earlier clinical research or prove the products to be safe and effective in any event. FDA approval to conduct Phase 3 trials for MoxDuo<sup>™</sup>IR does not mean NDA approval from the FDA to sell MoxDuo<sup>™</sup>IR will be forthcoming. Unexpected delays to regulatory approval and commercialisation may therefore occur.

As with any company involved in developing pharmaceutical products, QRxPharma must comply with the regulatory framework in any country in which it intends to market the product in question. These requirements vary depending on the relevant product and the nature of approvals or changes being considered. In general, established agents which have less significant proposed changes will face less substantial requirements for demonstration of safety and efficacy. Consequently, regulatory requirements may vary depending on the product in question.

Equally, FDA approval of MoxDuo<sup>TM</sup>IR does not necessarily mean that approval will automatically be obtained for MoxDuo<sup>TM</sup>IV or MoxDuo<sup>TM</sup>CR.

The Company has submitted Special Protocal Assessments (SPAs) however approval is not certain and even if obtained final regulatory approval is not guaranteed.

#### **Future Funding Requirements**

The Directors believe that QRxPharma will have sufficient cash reserves to fund its activities through to completion of Phase 3 trials and submission of a NDA for FDA regulatory approval of MoxDuo<sup>TM</sup>IR. However, QRxPharma may need to raise additional funds from time to time to meet its future funding requirements. The Company may not be successful in raising adequate funds on favourable terms and this could have a material adverse impact on QRxPharma's prospects.

### **Reliance on Partners and Commercial Agreements**

QRxPharma does not have and does not intend to obtain facilities capable of manufacturing its proposed products in commercial quantities. QRxPharma will be dependent on third parties to manufacture any products (or constituent parts) that it develops. There can be no assurance that the Company will succeed in establishing a supply chain through contract manufacturing and supply arrangements on favourable terms or that such a supply chain would remain uninterrupted. This exposes QRxPharma to potential delay and pricing issues.

The success of QRxPharma's product development and commercialisation is in part dependant on its technology and discovery relationships. These relationships expose the Company to some risks - its collaborators may disrupt the manufacturing or distribution of the Company's products, terminate or fail to renew agreements with the Company, experience financial difficulty, become insolvent or enter into partnerships with the Company's competitors.

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## **Specific Risks to QRxPharma**

### **Reliance on Key Personnel**

QRxPharma has a number of key personnel at the Board, executive and scientific/operational level. While QRxPharma is committed to providing attractive employment conditions and prospects, there can be no guarantee that the Company can retain these key personnel. The loss of the services of any of these individuals could have a material adverse impact on the Company's research, product development and commercialisation success.

There can be no assurance that QRxPharma will be able to attract and retain the services of additional scientific, technical, manufacturing, sales and managerial staff as the need arises. This is due to the specialised and competitive nature of the specialty pharmaceuticals industry and it may also have a material adverse impact on QRxPharma's success.

#### Protection of Proprietary Technology and Trade Secrets

The commercial success of QRxPharma partly depends on its ability to obtain patent protection of its products and technologies in its main markets and to protect its trade secrets. There can be no guarantee that technologies or products developed by the Company will be patentable, that patents will be granted for products currently in development or that its patents will be sufficient to protect QRxPharma from competition from third parties with similar technology.

#### **Current Patents**

It is possible that third parties may assert IP claims against the Company under copyright, trade secret, patent or other laws. The Company is not aware of any such claims in relation to the IP rights in which it has interest. If such claims were to arise, there may be an adverse effect on the Company's business, including costly litigation and the diversion of Management attention, which could occur regardless of the outcome of any proceedings.

#### Litigation

QRxPharma is exposed to the risk of actual or threatened litigation or legal disputes in the form of customer claims, personal injury claims or employee claims. If any claim was successfully pursued it may adversely impact the financial performance, financial position, cash flow and share price of the Company. An employee has recently made a claim against QRxPharma. However, the Board: (a) does not consider that the claim is valid; and (b) considers that if the claim was upheld, it would not have a material effect on the financial performance, financial position, cash flow or share price of the Company. QRxPharma has had no other actual or threatened litigation or legal disputes.

#### Use of Net Proceeds of the Offer

QRxPharma has indicated the current anticipated use of net proceeds of the Placement and Rights Issue proceeds earlier in this presentation. However, the Board will have total discretion in the allocation of the funds. A failure to apply the funds effectively could have an adverse impact on the business.

### Dividends

The ability of QRxPharma to pay dividends in the future will depend on the success of its clinical trials and its ability to commercialise its products in development. In addition, considerations such as future capital requirements and the Company's financial position will impact the amount, timing and payment of any dividend. There may also be factors outside of QRxPharma's control which affect the ability of the Company to pay dividends and as such the Directors are unable to give any guarantee regarding the payment of dividends in the future.

#### Competition

QRxPharma competes with several large organisations, some of which are multi-national and have worldwide distribution networks. The Company believes that the major competitors in the drug market for the treatment of moderate to severe pain include Endo Pharmaceuticals, Abbott, Purdue Pharma, Mundipharma, Cephalon, King Pharmaceuticals and Johnson & Johnson. Compared to QRxPharma the Directors believe that several of these firms have substantially greater financial resources and greater technical and market strength. Companies that would be likely to lose market share may develop strategies to resist the introduction and sales growth of QRxPharma's products.

In addition, there can be no guarantee that the Company's competitors will not be successful in developing technologies and products that are more effective or cost efficient than those technologies and products that the Company is currently developing. As a result, the Company's products may become uncompetitive and the business would suffer.

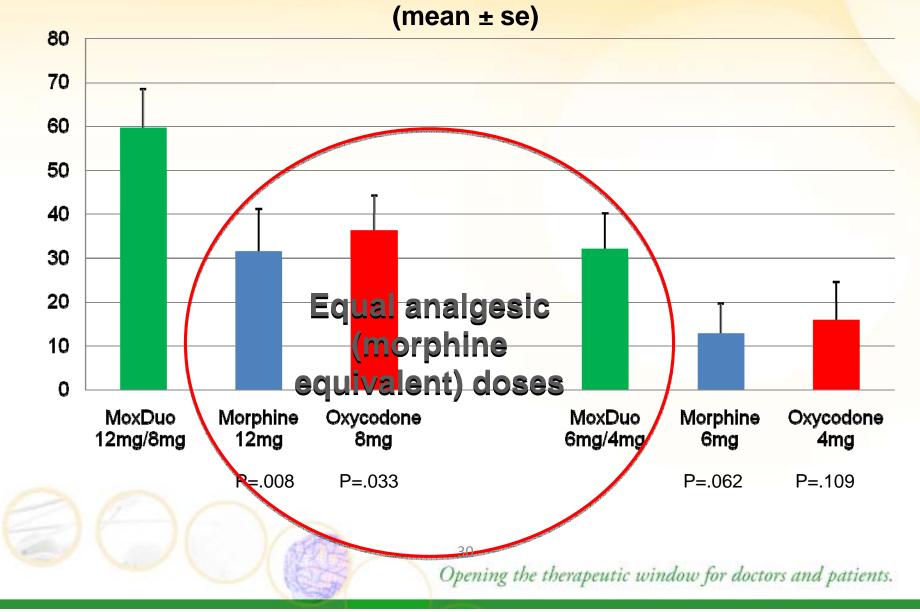
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# Appendix: Clinical Data and CNS Programme

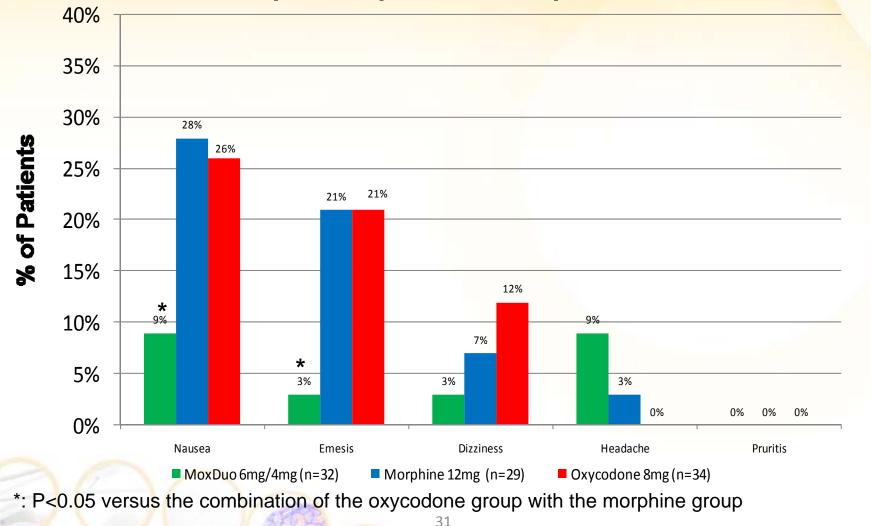
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## Study 021: Summary of SPID 2 4 Score by Treatment



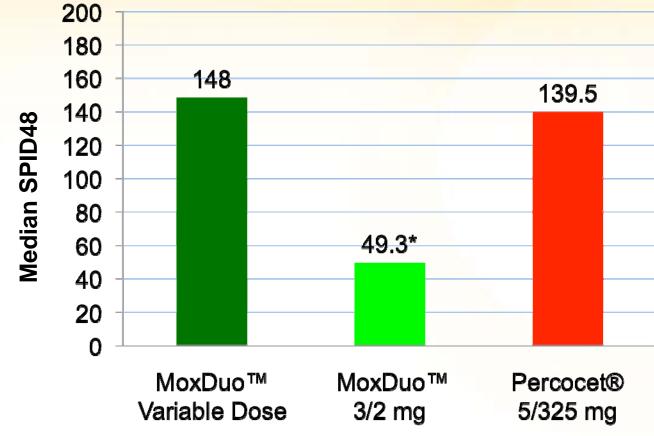
## Study 021: Opioid Moderate-Severe Adverse Events

**Morphine Equivalent Comparisons** 



# Pilot TKR – Study 20

Efficacy (SPID48)



\* P<0.048 Compared to MoxDuo<sup>™</sup> variable dose

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# Pilot TKR – Study 20

### **Moderate-Severe Adverse Events**

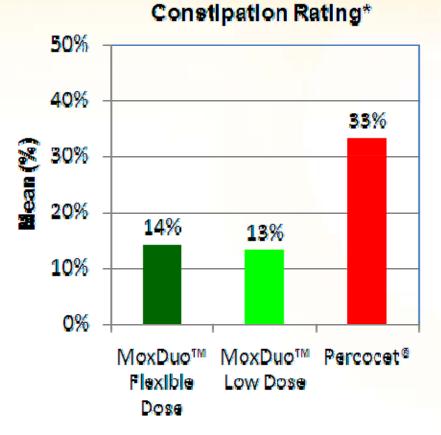
Adverse Event	MoxDuo™	Percocet®
	N=14	N=15
Any GI AE	14%	47%
Nausea	0%	27%
Emesis	0%	20%
Constipation	7%	13%
Hypotension	0%	13%
O2 Desaturation	0%	0%
Somnolence	0%	0%
Headache	0%	0%
Dizziness	0%	0%

Lower percentage of patients with moderate-severe AEs in the MoxDuo<sup>™</sup> arm than in the Percocet arm, despite receiving higher morphine equivalent total doses (202mg vs. 79.5mg, respectively)

<sup>33</sup> 

# Pilot TKR – Study 20

### **Bowel Function Measures**

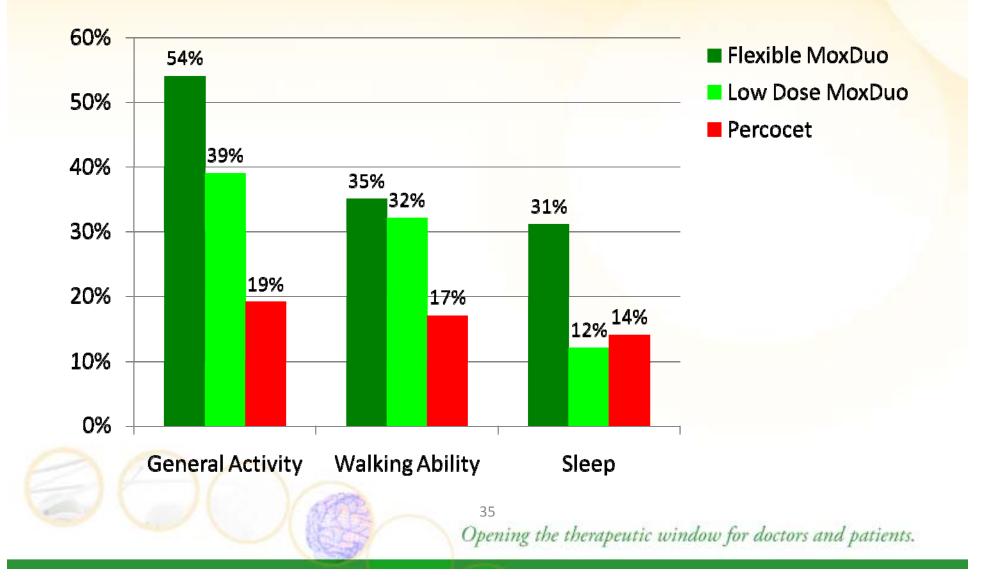


\* Percent of Patients with Somewhat–Very Bothersome Ratings

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# Study 020: Brief Pain Inventory

Mean % Improvement from Baseline to End of Treatment



# **Central Nervous System Programme**

- Focus on reducing protein misfolding linked to neurodegenerative diseases
  - Dystonia, Huntington's, Parkinson's and Alzheimer's
- Treat at causative level; not provide temporary symptomatic relief
  - Exclusive rights to novel IP; sponsored research agreement with the University of Alabama
  - Drug targets to increase activity of normal Torsin A
- Development approach
  - NCE discovery
  - Fast-track repositioning of known chemical entities because the FDA already knows these drugs