

QRx  
Pharma

**MoxDuo™**  
A Novel Opioid for  
Moderate to Severe Pain Management

August 2009

# Disclaimer

This presentation, including information contained in this disclaimer, is given to you in strict confidence. By attending the presentation, you agree that no part of this presentation or disclaimer may be disclosed, distributed or reproduced to any third party without the consent of QRxPharma Limited (“QRxPharma”).

This presentation is being provided for the sole purpose of providing the recipients with background information about QRxPharma’s business. This presentation, including the information contained in this disclaimer, does not constitute an offer, invitation or recommendation to subscribe for or purchase any security and neither the presentation, disclaimer nor anything contained in them forms the basis of any contract or commitment.

No representation, express or implied, is made as to the fairness, accuracy, completeness or correctness of information contained in this presentation, including the accuracy, likelihood of achievement or reasonableness of any forecasts, prospects, returns or statements in relation to future matters contained in the presentation (“forward-looking statements”). Such forward-looking statements are by their nature subject to significant uncertainties and contingencies and are based on a number of estimates and assumptions that are subject to change (and in many cases are outside the control of QRxPharma and its Directors) which may cause the actual results or performance of QRxPharma to be materially different from any future results or performance expressed or implied by such forward-looking statements.

To the maximum extent permitted by law, neither QRxPharma nor its related corporations, directors, employees or agents, nor any other person, accepts any liability, including, without limitation, any liability arising from fault or negligence, for any loss arising from the use of this presentation or its contents or otherwise arising in connection with it.

You represent and confirm by attending and/or retaining this presentation, that you accept the above conditions.

# Who is QRxPharma Limited?

- **Phase 3 specialty pharmaceutical company (ASX: QRX and OTCQX: QRXPY)**
  - Commercialisation of Dual Opioid products 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 opioid global market of over US\$15 billion**

# Building Sustainable Value

- **Late and early stage clinical pipeline**
  - Commercialisation first product 2011
- **Strategic relationships**
  - Active in building strategic relationships to accelerate commercialisation of products
- **Strong IP; broad international protection**
- **Low burn rate, cash runway into FY2011 with A\$17.8 million COH (30 June 2009)**
- **Experienced board and executive team**

# Product Pipeline 2009

PRODUCT/PROGRAM	RESEARCH	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
<b>PAIN MANAGEMENT</b>					
MoxDuo™ IR	██████████	██████████	██████████	██████████	██████████
MoxDuo™ IV	██████████	██████████	██████████	██████████	
MoxDuo™ CR	██████████	██████████			
<b>CNS</b>					
T9001 (DYSTONIA)	██████████	██████████	██████████		
T9001 (PARKINSON'S)	██████████	██████████			
<b>VENOMICS</b>					
Q8010	██████████				
Q8008	██████████				

# Pain Therapy Market

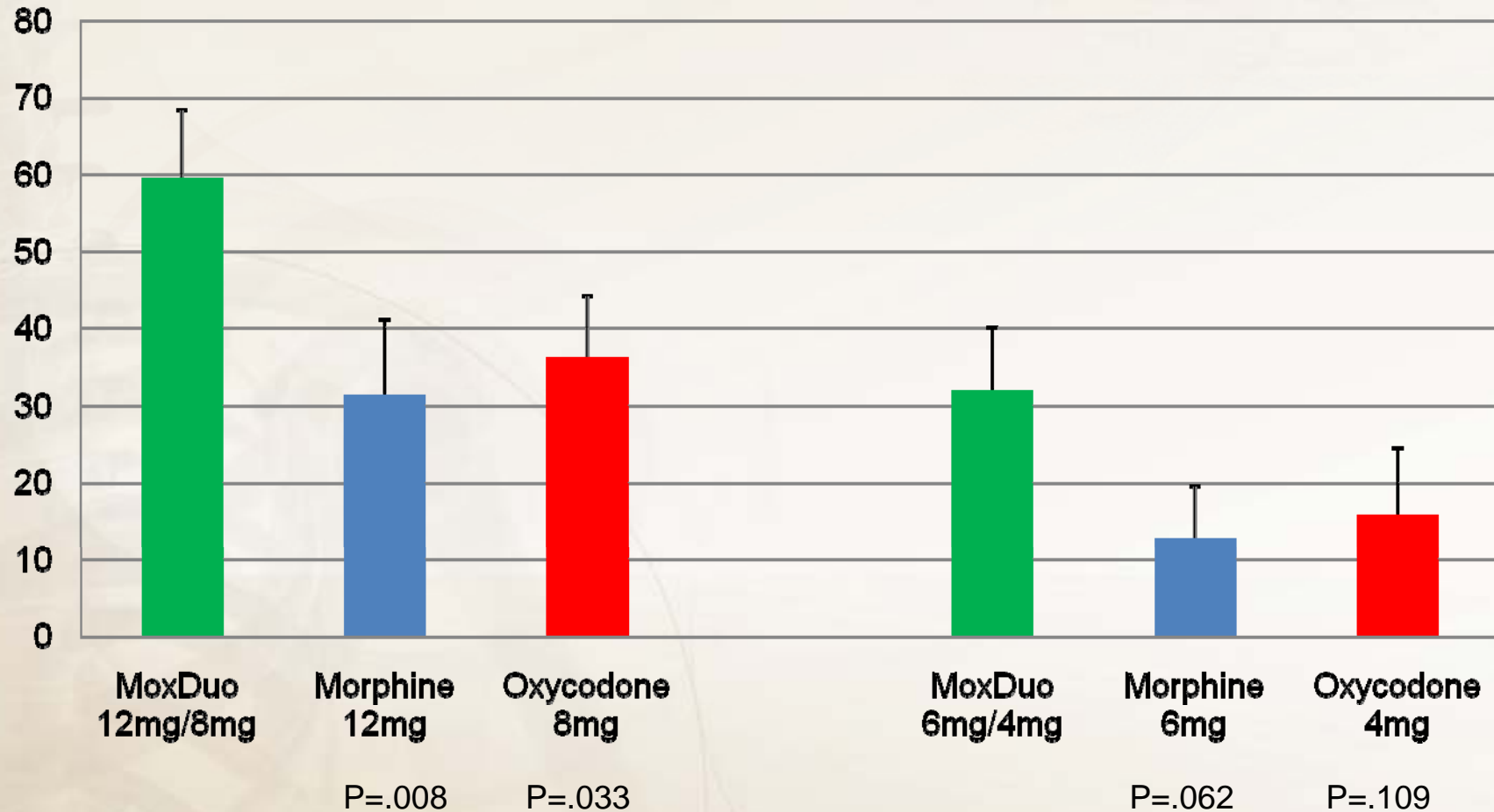
- **Limited product innovation to date; reliance on older therapies** - Opioids are the “gold standard” in treating moderate to severe pain, but limited by side effects
- **Clear need for Opioids with fewer side effects and risk factors** – Respiratory depression, constipation, nausea, vomiting, somnolence, dizziness
- **Complementary offering of Dual Opioids IV, IR and CR formulations** – Products from hospital to home in a global marketplace of over US\$15 billion, growing at 15% annually

# Key Clinical Results

## Study 21 (Acute Pain after Bunionectomy)

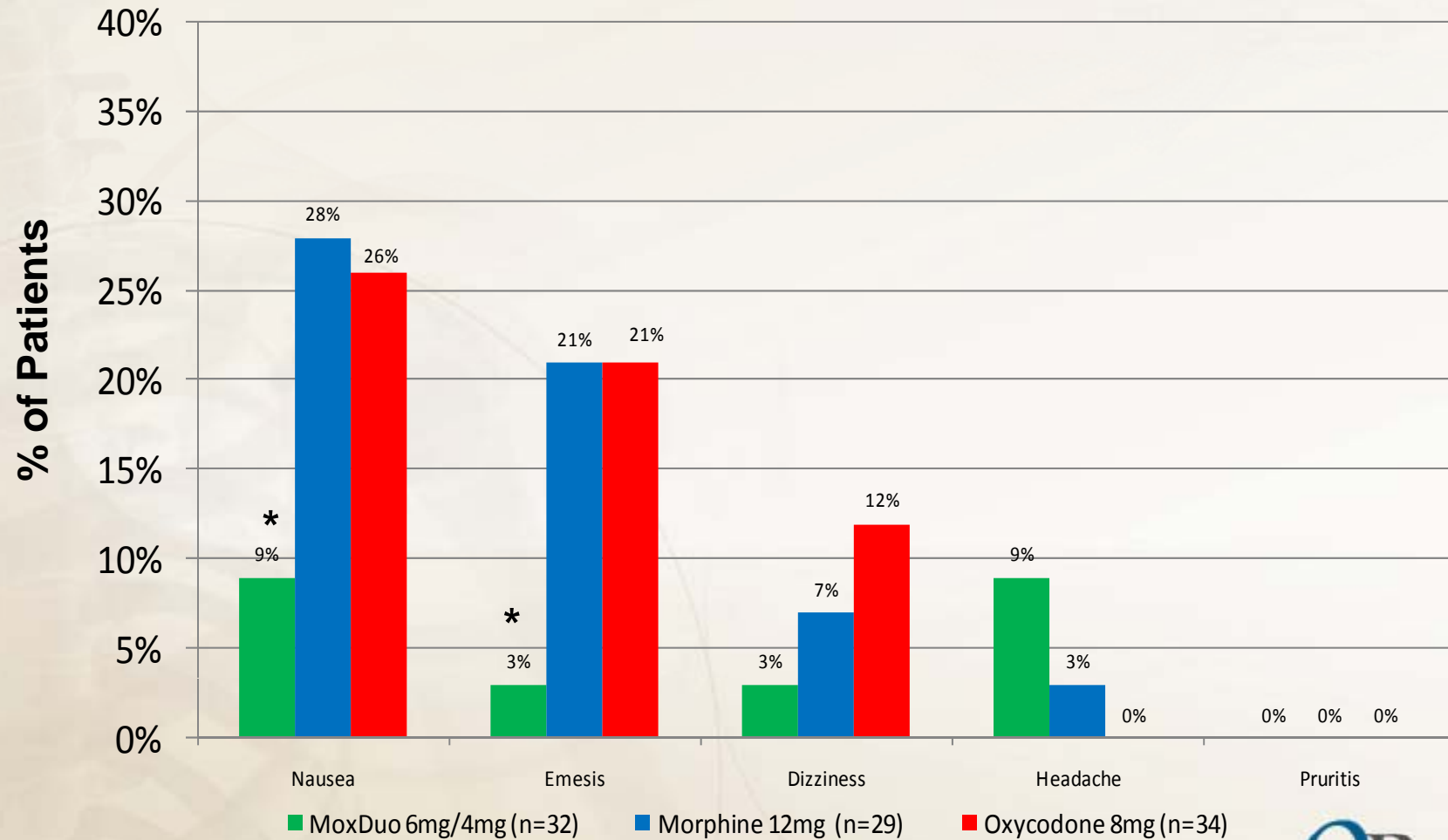
- **Combination Rule Phase 3 Study (MoxDuo™ vs. components) will be successful:**
  - Efficacy already confirmed in QRxPharma's Phase 3 program
  - Established sample size in this pilot study
- **Demonstrated Enhanced Tolerability of MoxDuo™ IR at equi-analgesic doses in Study 21**
  - **Tolerability means better pain relief with fewer side effects**
  - MoxDuo™ 6mg/4mg vs. morphine 12mg and vs. oxycodone 8mg
  - Frequency of moderate to severe nausea, vomiting and dizziness 50% to 75% lower than morphine or oxycodone alone

# Summary of SPID<sub>24</sub> Score by Treatment (mean ± se)





# Opioid Moderate-Severe Adverse Events: Morphine Equivalent Comparisons



\*: P<0.05 versus the combination of the oxycodone group with the morphine group

# Pilot Total Knee Replacement (TKR) Study 20 - Objectives & Design

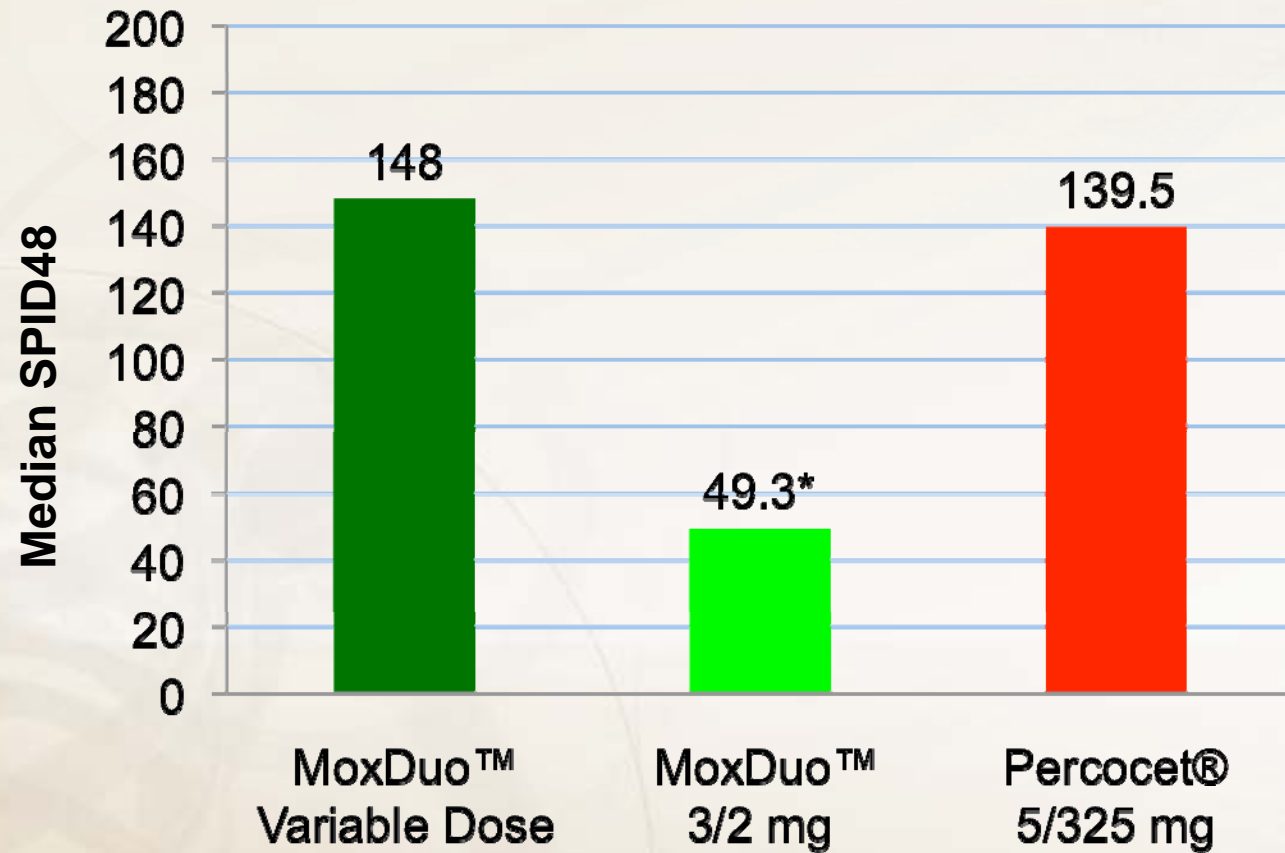
- **Objectives:**

- Compare MoxDuo™ IR vs. Percocet®, the most widely prescribed opioid in these patients
- Select a control group for the pivotal Phase 3 TKR study (009)
- Determine number of patients to assure successful filing of New Drug Application (NDA) with the FDA

- **Design:**

- Open label, randomized comparison of MoxDuo™IR 12/8mg (flexible regimen) and MoxDuo™IR low dose (3/2mg) versus Percocet® given at standard of care.
- Multicenter in patients following TKR

# Pilot TKR - Study 20 Efficacy (SPID48)



\* P<0.048 Compared to MoxDuo™ variable dose

# Pilot TKR – Study 20

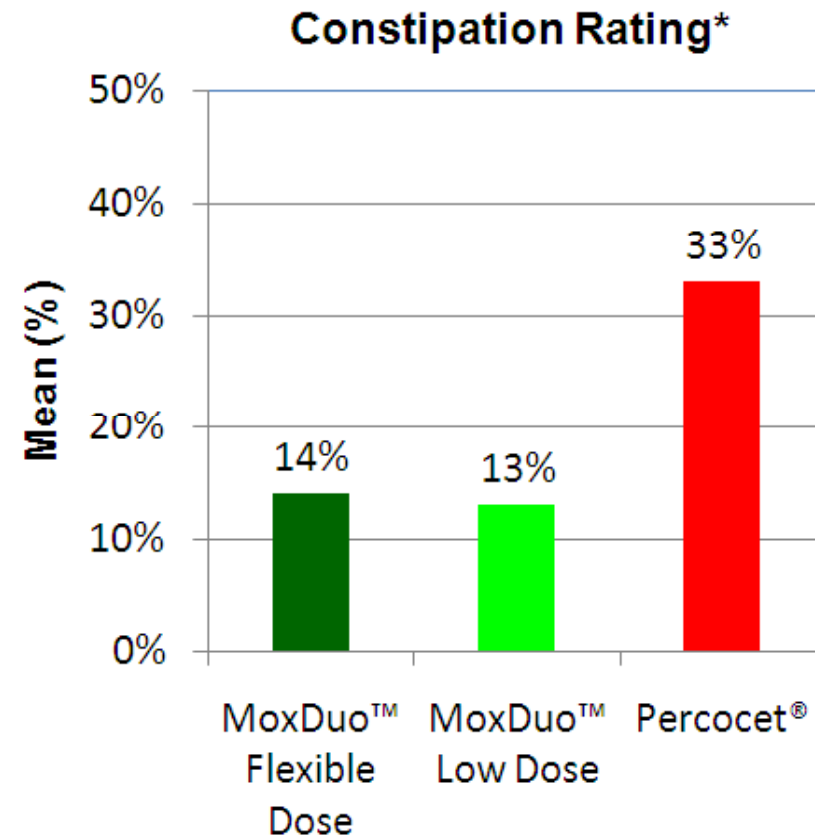
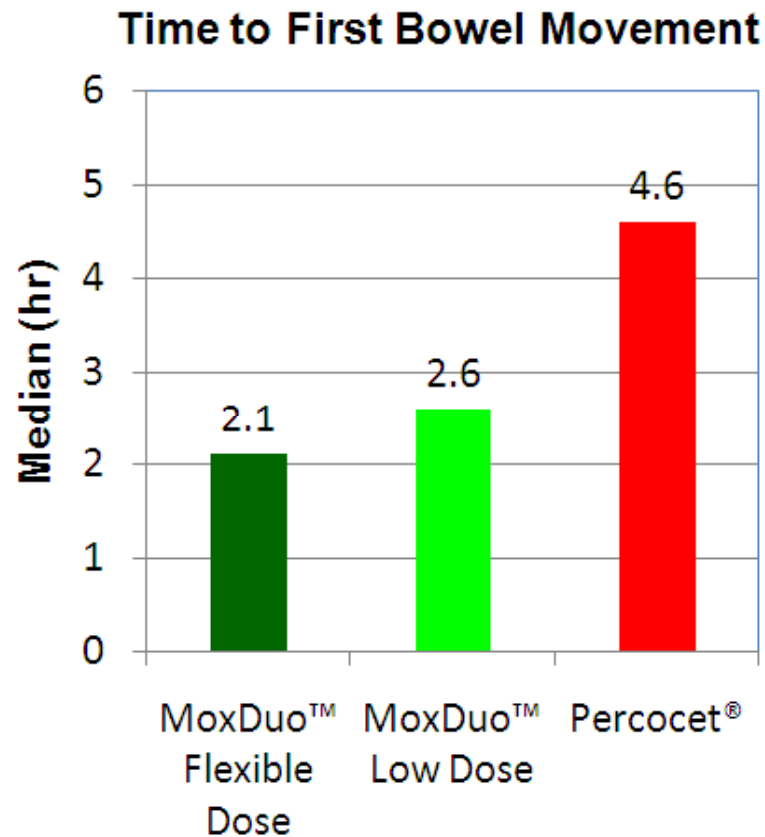
## Moderate-Severe Adverse Events

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

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

# Pilot TKR – Study 20

## Bowel Function Measures



\*Percent of patients with somewhat-very bothersomeness ratings

# MoxDuo™ Key Differentiators

- **MoxDuo™ IR opens the therapeutic window for acute pain relief**
  - Fewer side effects than morphine, oxycodone and Percocet® in two distinctly different types of pain
- **Streamlined route to approval**
  - 505(b)(2) regulatory path and SPA filing
  - Anticipate NDA filing of MoxDuo™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

# New Platform Technology

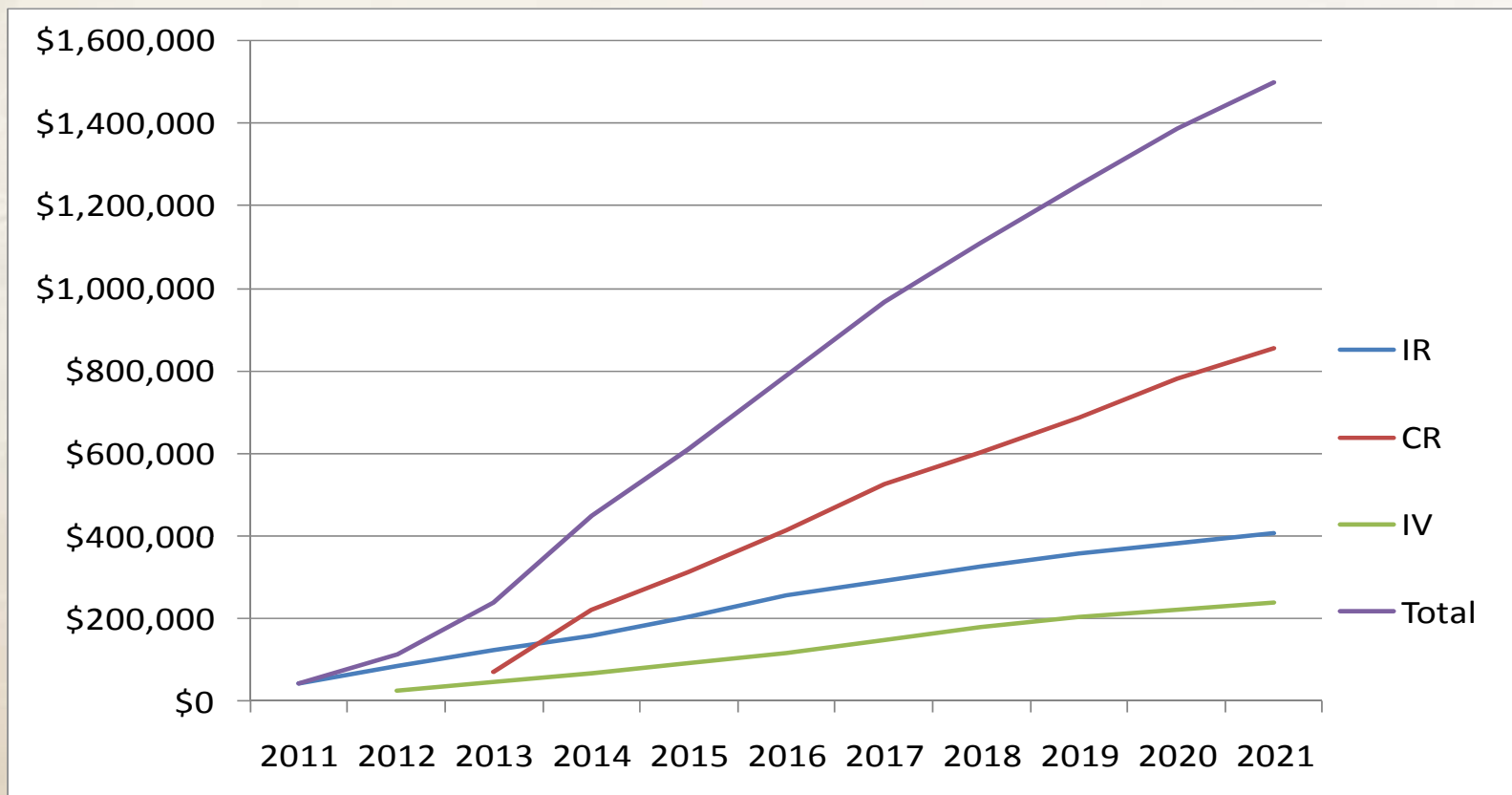
- **Broader selection of complementary analgesic options to pain specialists**
  - MoxDuo™ Immediate Release (IR) oral capsules
    - Target: Acute pain
    - Phase 3 studies
  - MoxDuo™ IV liquid formulation
    - Target: Hospital-based pain
    - Phase 2 and concurrent formulation development

# New Platform Technology

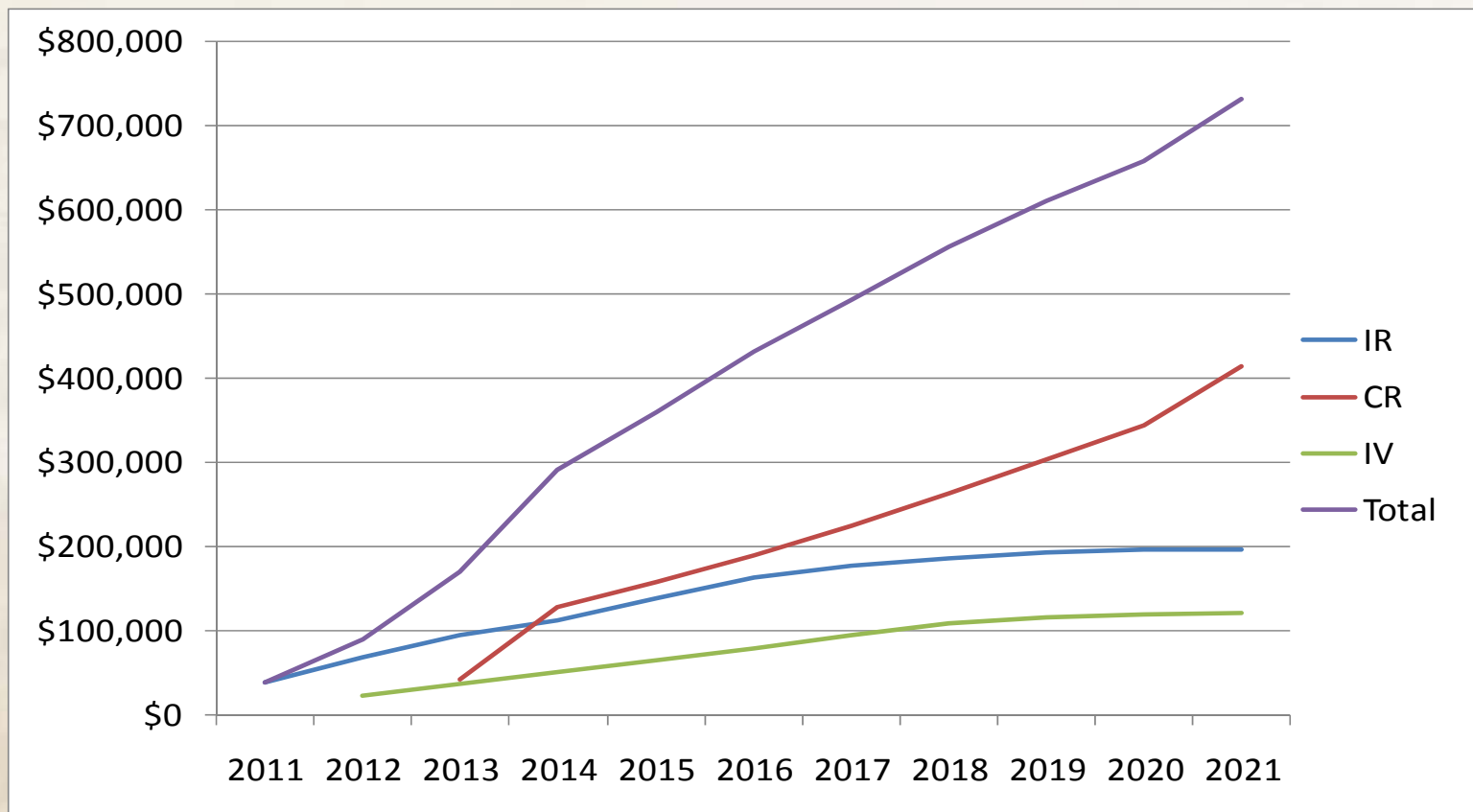
- **Broader selection of complementary analgesic options to pain specialists**
  - MoxDuo™ Controlled Release (CR) oral capsules
    - 12-hour in vitro release profile; abuse-deterrent technology
    - Target: Neuropathic pain, cancer, back pain, osteo-arthritis
    - Phase 1 scheduled for 2009



# MoxDuo™ US Forecast (US\$000)



# MoxDuo™ EU Forecast (US\$000)



# MoxDuo™ 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**
- **Expected market exclusivity through 2029; all formulations**
  - North America and all other major markets

# CNS Program

- **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 UA
  - 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

# Newsflow (Calendar Year)

- **Q3 2009**

- Comparative study data MoxDuo™ IR versus Percocet®
- FDA review of MoxDuo™ IR Phase 3 Combination Rule study SPA

- **Q4 2009**

- FDA review MoxDuo™ IR Pain (Orthopedic) study SPA
- Commence MoxDuo™ CR Phase 1 study
- Complete dosing of MoxDuo™ IV Phase 2 Investigator study
- Initial strategic partnership

# Experienced Board and Management Team

## Board:

- Peter Farrell (ResMed)
- Michael Quinn (Innovation Capital)
- Peter Campbell (Sonic Healthcare)
- Gary Pace (ResMed, founder QRxPharma)
- John Holaday (MD and CEO)

## Management:

- John Holaday, (MD and CEO)
- Chris Campbell (CFO)
- Warren Stern (Exec. VP, Drug Development)