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# Corporate Overview

- Develop and commercialize therapies for pain management and CNS disorders
  - Global footprint: Sydney, AU and New Jersey, US
  - Listed on the ASX: QRX and OTCQX: QRXPY
- MoxDuo<sup>®</sup> product portfolio catalyst for growth
  - Proprietary combination of morphine and oxycodone
  - MoxDuo<sup>®</sup>IR: lead product; Phase 3 (acute pain)
- Strategic relationships
  - Aoxing (NYSE AMEX:AXN) collaboration in China

# Treatment Landscape: MoxDuo<sup>®</sup> Relevance

- Large specialty pharma opportunity
  - US\$12 billion globally; US\$7+ billion in US alone\*
- Limited innovation with reliance on old therapies
  - Opioids are the “gold standard” in treating pain
- 150 million people in major markets suffer from acute pain
  - Most common reason people seek medical attention
  - 75 million Americans experience acute pain each year due to injuries and/or surgery
- Need for better pain relief with fewer side effects
  - Respiratory depression, sedation, constipation, nausea, vomiting

# Product Line Impact: Hospital to Home

- **MoxDuo<sup>®</sup>IR** (Immediate Release): oral capsules
  - Target: Moderate to severe acute pain
  - Status: Phase 3 program nearing completion
    - Positive bunionectomy results; total knee replacement trial ongoing
  - Anticipate NDA filing with the FDA in Q1, 2011
- **MoxDuo<sup>®</sup>IV** (Intravenous): liquid formulation
  - Target: Hospital-based pain
  - Status: Phase 2 and concurrent formulation development
- **MoxDuo<sup>®</sup>CR** (Controlled Release): oral capsules
  - Target: Chronic pain (i.e. osteo-arthritis, back, neuropathic)
  - Status: Phase 1

# Product Pipeline


PRODUCT/PROGRAM	RESEARCH	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
<b>PAIN MANAGEMENT</b>					
MoxDuo® IR	[Progress bar spanning Research, Pre-clinical, Phase I, Phase II, and Phase III]				
MoxDuo® IV	[Progress bar spanning Research, Pre-clinical, Phase I, and Phase II]				
MoxDuo® CR	[Progress bar spanning Research and Pre-clinical]				
<b>NEUROLOGIC DISEASES</b>					
T9001 (DYSTONIA)	[Progress bar spanning Research and Pre-clinical]				
T9001 (PARKINSON'S)	[Progress bar spanning Research and Pre-clinical]				
<b>VENOMICS</b>					
Haemepatch™	[Progress bar spanning Research and Pre-clinical]				
Textilinin	[Progress bar spanning Research and Pre-clinical]				

# Opportunity Snapshot

- Three formulations address spectrum of therapeutic needs
  - Led by MoxDuo IR commercialization expected early 2012
- Represent key advantages over current treatment options
  - Widen therapeutic window for acute pain relief
  - As good or better pain relief with fewer side effects than morphine, oxycodone and Percocet<sup>®</sup>
- Economic Impact to healthcare system
  - Speedier recoveries = fewer days in hospital (reduced HC cost)
  - Incremental costs to the health care system for opioid-induced GI events up to \$36,152 per patient\*

# MoxDuo<sup>®</sup>IR

Changing the opioid treatment paradigm



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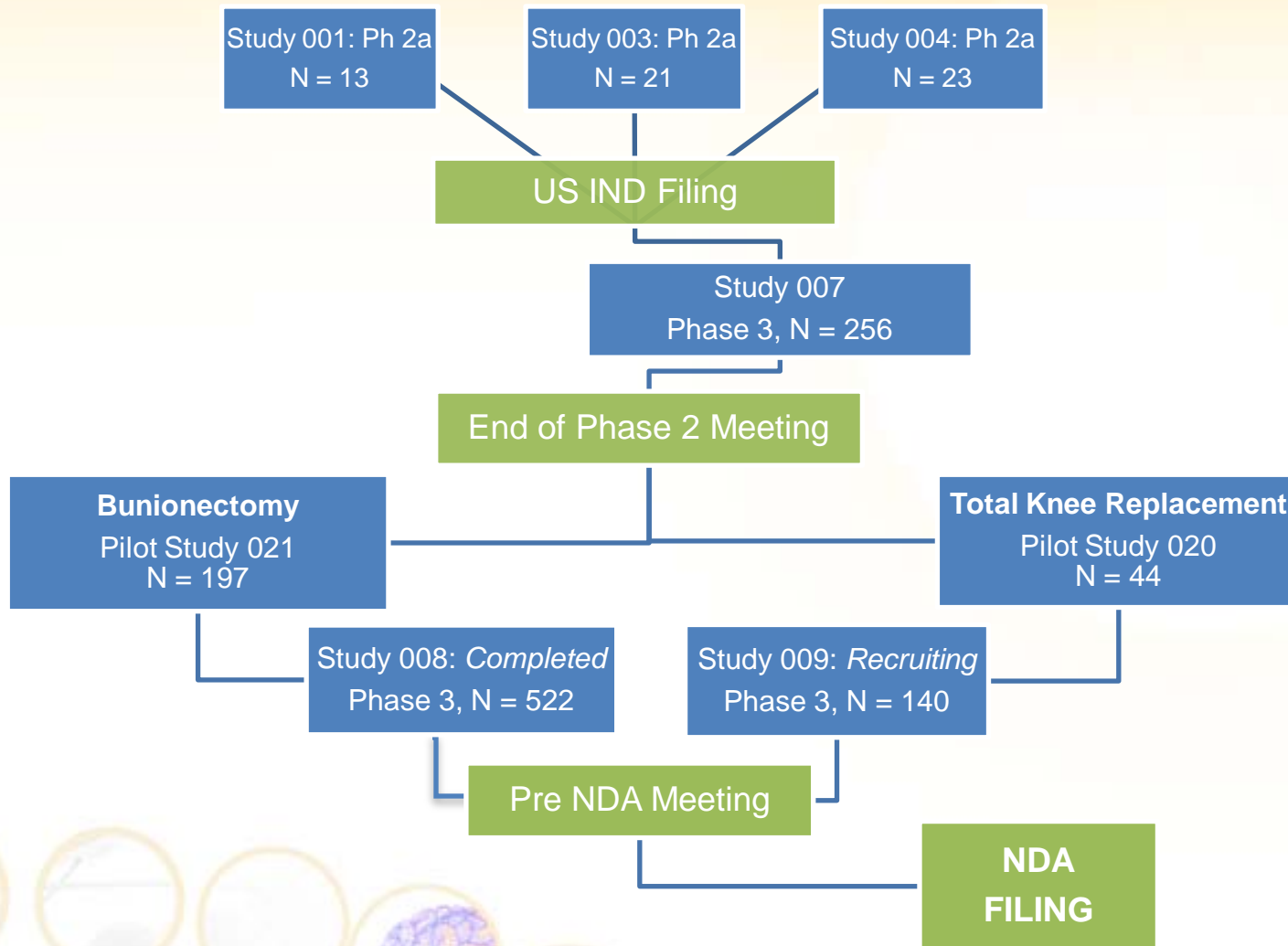
# MoxDuo IR: Product Profile

- Drug class: analgesic
- MOA: Mu, Kappa-Opioid Receptor Agonist
- Immediate release dual-opioid™
- Initial indications: moderate to severe post-surgical pain
- Phase 3 clinical trials
  - Bunionectomy
    - Study 021: Pilot study completed April 2009: double blind, placebo controlled
    - Study 008: Pivotal Phase 3 completed April 2010
  - Total Knee Replacement
    - Study 020: Pilot study completed August 2009
    - Study 009: Pivotal Phase 3 ongoing

# Streamlined Route to Approval

- FDA requirements:
  - Combination Rule requires that two drugs together show better pain relief than the components alone
  - Two Pivotal, Phase 3 studies
- 505(b)(2) regulatory path
- Anticipate NDA filing of MoxDuo IR with the FDA in Q1, 2011

# Clinical Development Path



# Bunionectomy: Trial Designs

Study Number	021	008
Phase	Pilot	Phase 3
N	197	522
U. S. Sites	6	6
Design	Double blind, Placebo controlled	Randomized, Double blind FDA Combination Rule
Doses	MoxDuo IR 12/8mg vs. Morphine 12mg vs. Oxycodone 8mg	MoxDuo IR 12/8mg vs. Morphine 12mg vs. Oxycodone 8mg
Schedule	Every 6 hours for 2 days	Every 6 hours for 2 days
Primary/Secondary Endpoints	Superiority of MoxDuo IR over its components	SPID <sub>48</sub> / SPID <sub>24</sub>
Status	Completed April 2009	Completed April 2010
Outcome	<ul style="list-style-type: none"> <li>• Demonstrated superiority in both efficacy and safety</li> <li>• Confirmed efficacy, optimal dose, and sample size</li> <li>• Enhanced tolerability</li> </ul>	Both Primary & Secondary Endpoints Achieved

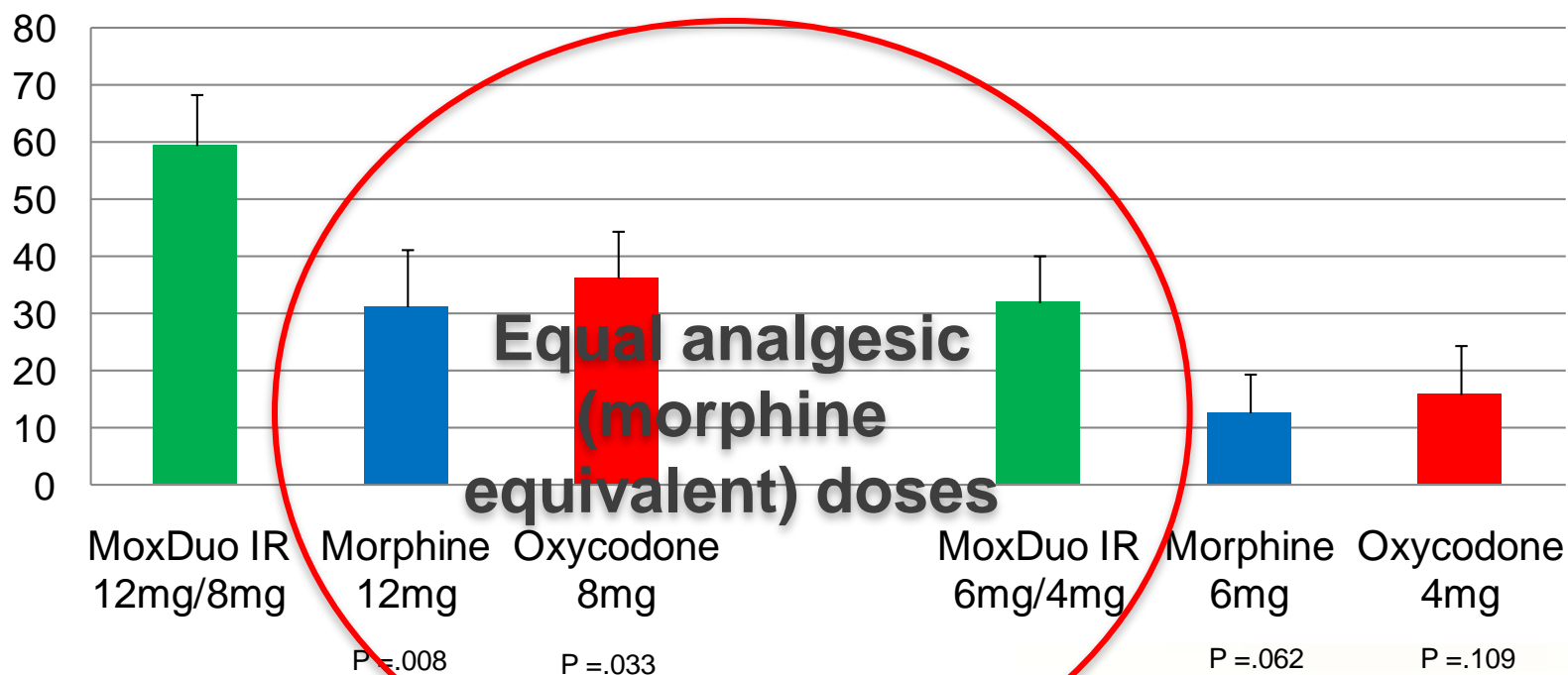
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SPID = Sum of Pain Intensity Data 010

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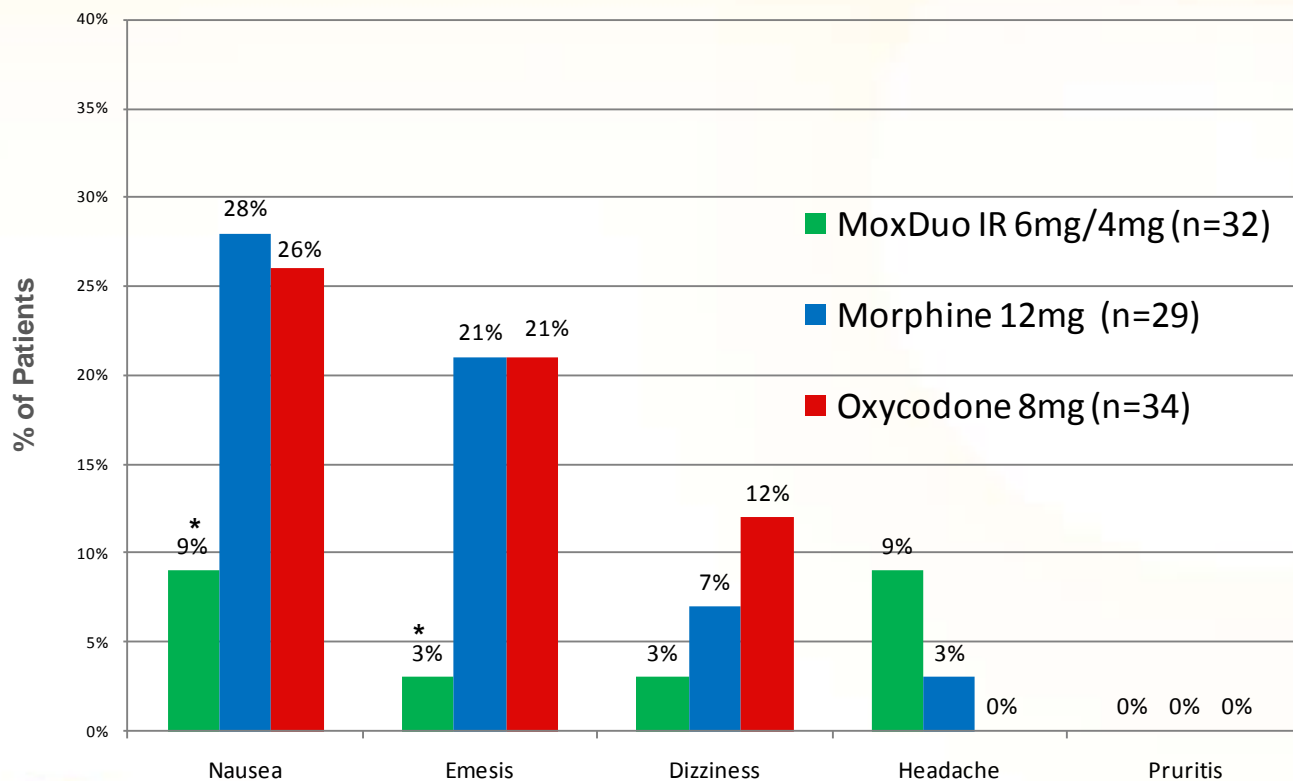
# Half the dose provides the same relief

Study 021: SPID<sub>24</sub> Scores by Treatment (mean ± se)



# Most Adverse Events Reduced

## Study 021: Morphine Equivalent Comparisons



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

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# Pivotal Phase III Endpoints Met

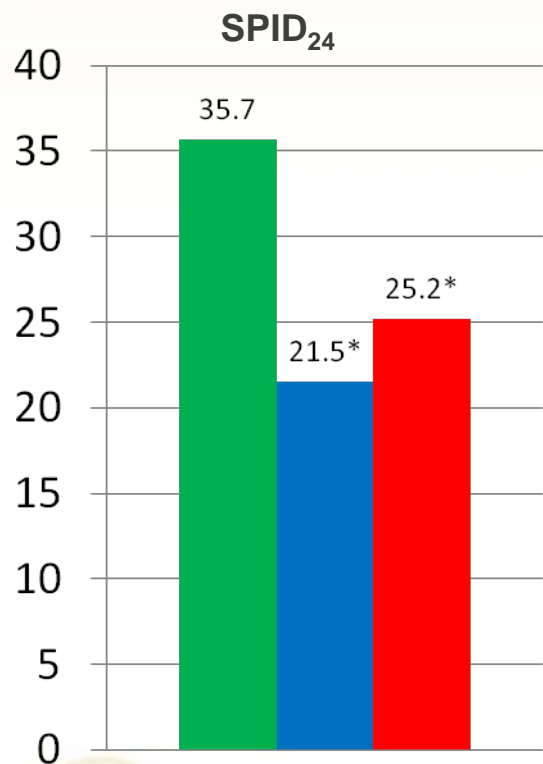
Study 008

		MoxDuo IR 12/8 mg	Morphine 12 mg	Oxycodone 8 mg
<b>Primary Endpoint</b>	SPID <sub>48</sub> : Mean	107	83	83
	P-value (vs MoxDuo IR)		0.014*	0.011*
<b>Secondary Endpoint</b>	SPID <sub>24</sub> : Mean	35.7	21.5	25.2
	P-value (vs MoxDuo IR)		0.003*	0.026*

\*Statistically significant

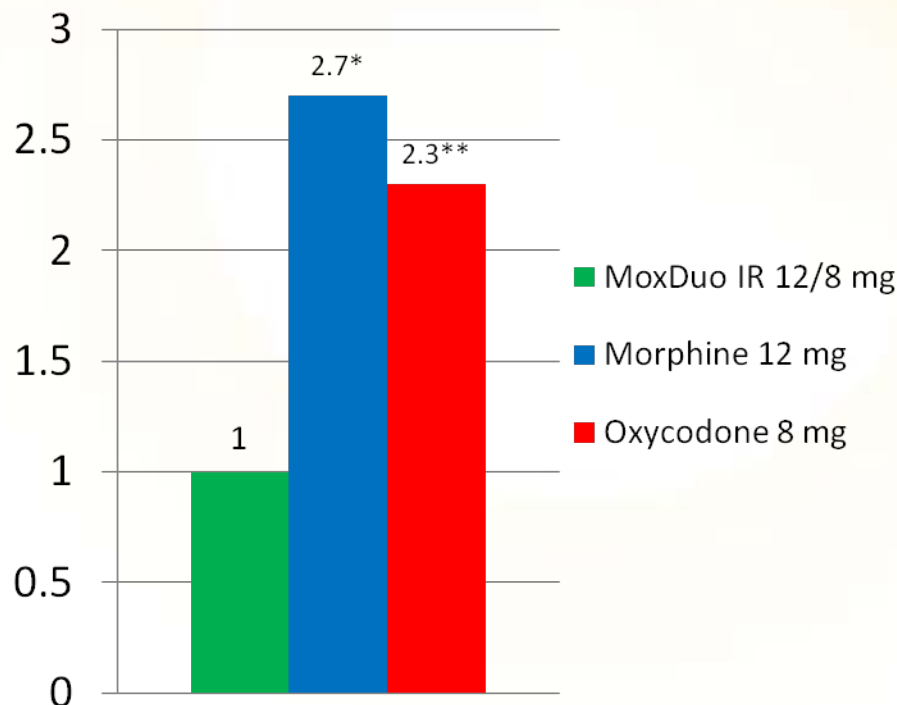
# MoxDuo IR Superior to its mg Components

## Study 008: Secondary Efficacy Endpoints



(\*p<0.01)

**Likelihood (Odds Ratio) of the Need to Use a Rescue Medication<sup>1</sup>**



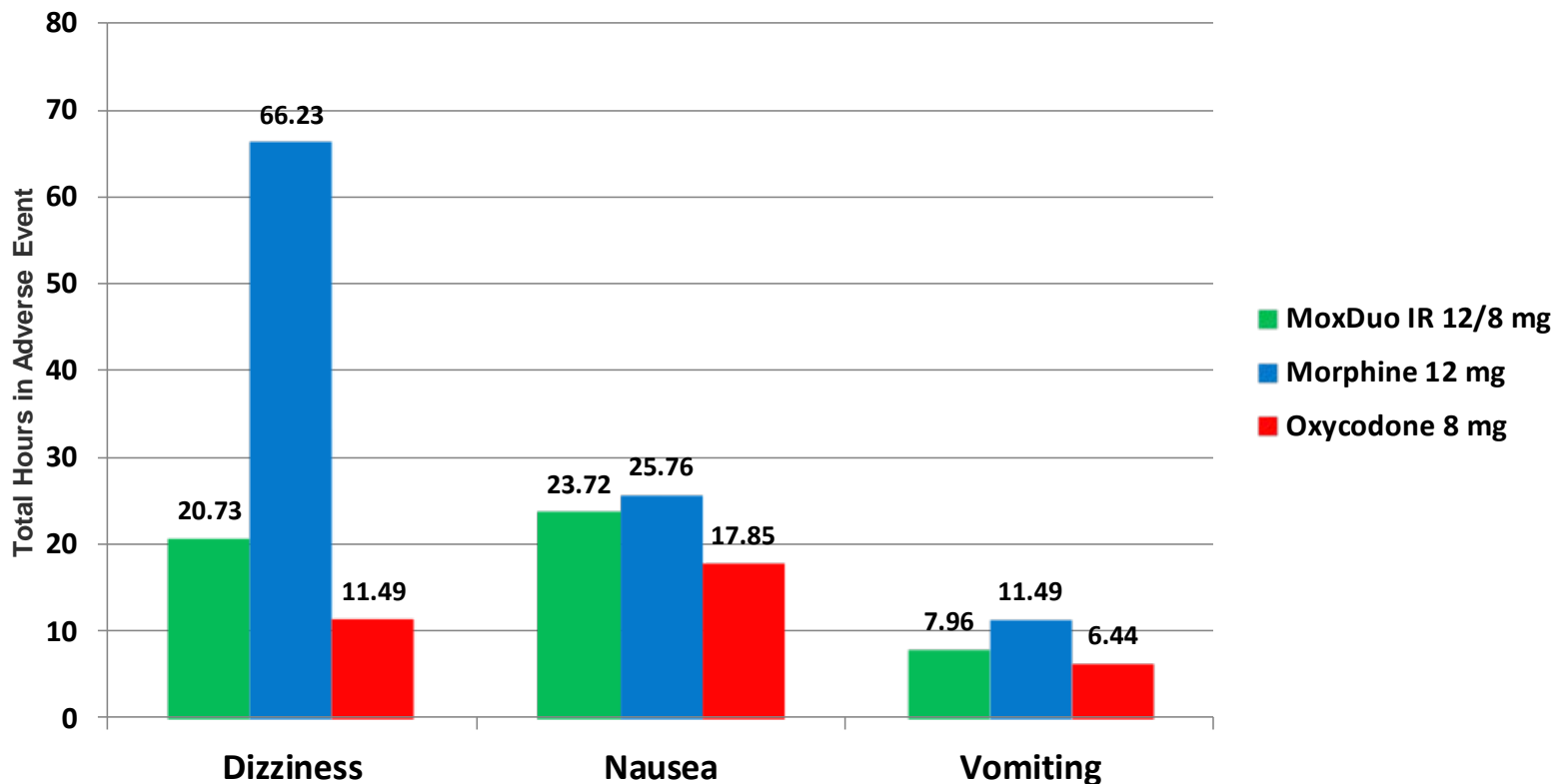
(\*p<0.01, \*\*p<0.05)

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<sup>1</sup>Rescue Medication: ibuprofen 400 mg

# Duration of Adverse Events Favorable

Study 008



Moderate to Severe Adverse Event

# Positive Safety Results from Both Trials

- Pilot Study 021
  - 50-75% lower frequency of moderate to severe nausea, vomiting and dizziness compared to equianalgesic components
- Pivotal Study 008
  - Compared a higher dose of MoxDuo IR to each individual component (required regulatory filing)
    - Expectation: more adverse events with MoxDuo IR than with lower dose morphine or oxycodone
  - Despite delivering twice the opioid dose/analgesic response, MoxDuo IR was well tolerated
    - Same dropout rate as less effective doses of morphine and oxycodone)
  - No SAEs reported

# Bunionectomy Trials: Conclusions

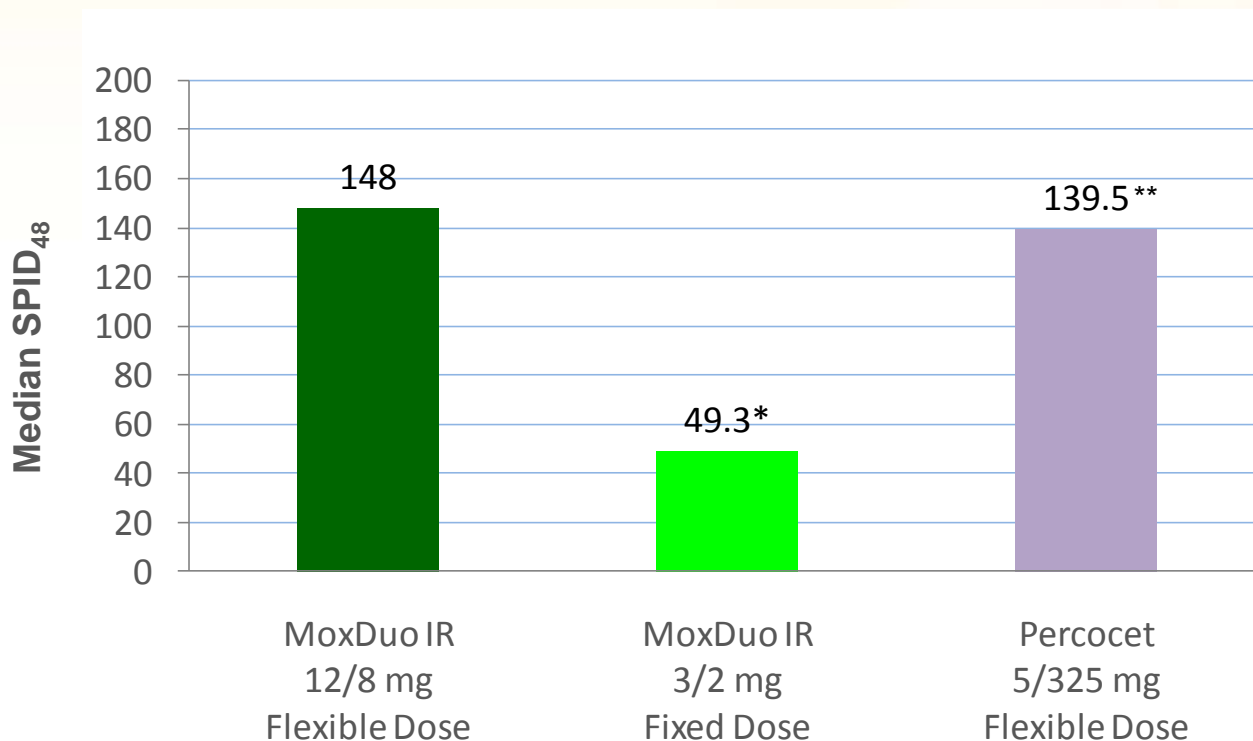
- Pilot study demonstrates superiority in both tolerability and efficacy
- Phase 3 Combination Rule met primary analgesic efficacy endpoint ( $p < 0.01$ ) vs morphine and oxycodone
- MoxDuo IR 12/8mg proven superior to its components on secondary efficacy measures
- Despite higher dose of MoxDuo IR than the controls, the AE rate and duration was not statistically different

# Total Knee Replacement: Trial Designs

Study Number	020	009
Phase	Pilot	Phase 3
N	44	140
U. S. Sites	5	10
Design	Randomized, Double Blind	Randomized, Double Blind
Dose/Schedule	MoxDuo IR (12/8 mg) every 6 hours vs Percocet	MoxDuo IR (12/8 mg) 4-6 hours vs MoxDuo IR (3/2 mg) every 6 hrs
Primary/Secondary Endpoints	Compare efficacy/safety profile vs control	SPID <sub>48</sub> / SPID <sub>24</sub>
Status	Completed August 2009	Commenced February 2010 Expected Completion Q3, 2010
Outcome	<ul style="list-style-type: none"> <li>• Confirmed control and sample size</li> <li>• Delivered better pain relief with less nausea, vomiting, hypotension and constipation</li> </ul>	
Safety	Demonstrated enhanced tolerability over equianalgesic dose of Percocet®	

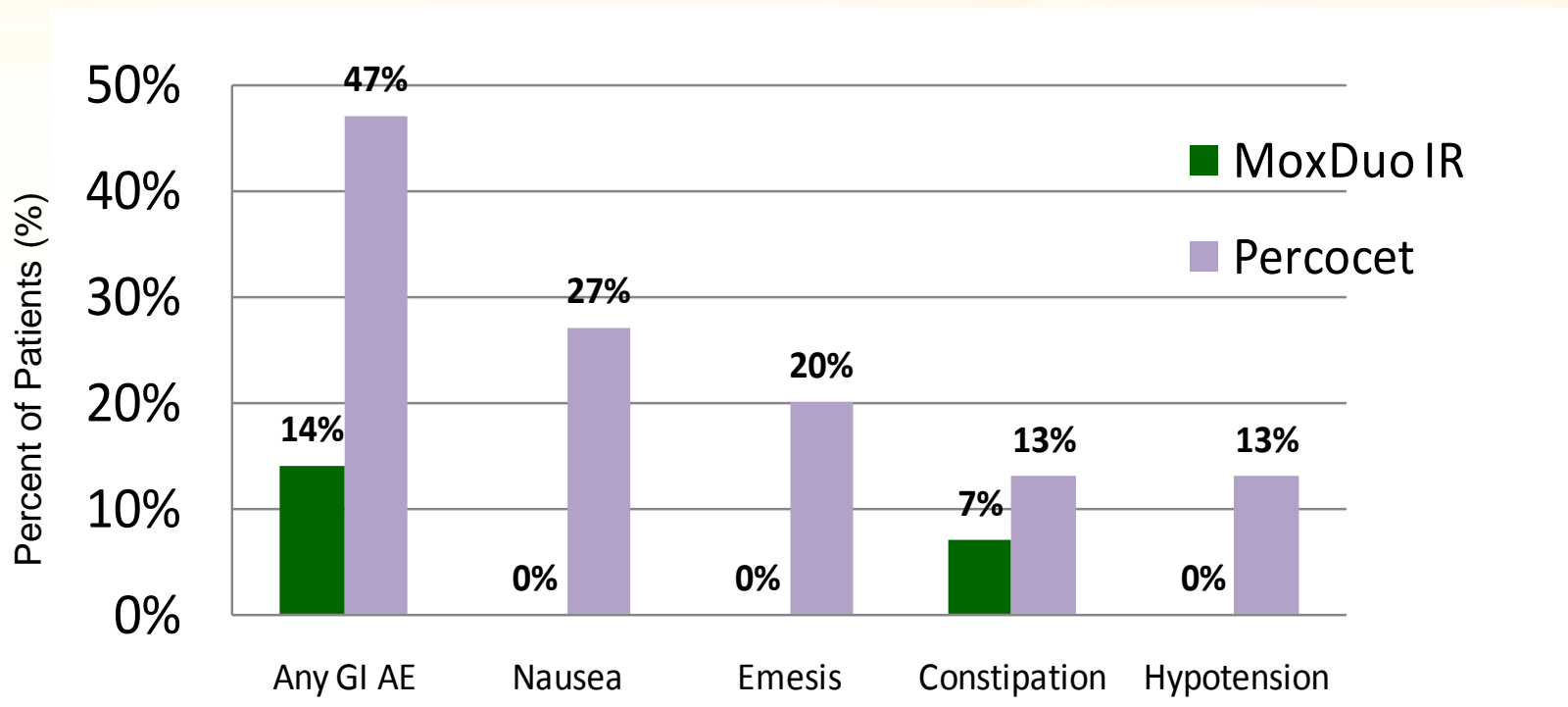
# Summary of Efficacy

Study 020: SPID<sub>48</sub>



# MoxDuo IR has Fewer AEs vs Percocet

Study 020



# ADDITIONAL PROGRAMS

MoxDuo<sup>®</sup>IV  
MoxDuo<sup>®</sup>CR  
CNS Program

# MoxDuo® IV Development Status

- Comparative proof-of-concept study completed July 2010
  - MoxDuo IV vs. IV morphine alone
    - Moderate to severe post-operative pain (hip replacement)
- February 2010: Aoxing strategic alliance
  - Collaborate in the development of MoxDuo IV
  - Aoxing funds clinical development of MoxDuo IV in exchange for exclusive marketing rights in China
    - Significant royalties to QRxPharma
  - QRxPharma retains ownership of MoxDuo IV and rights to clinical work for product registration outside China

# MoxDuo<sup>®</sup>CR

- Controlled-release (CR) dual-opioid<sup>™</sup> tablet designed to provide 12 hours of pain relief with abuse/tamper resistance
  - Patients suffering from moderate to severe chronic pain (i.e. cancer, lower back, osteoarthritis and neuropathic)
- Phase 1 PK profile consistent with expectations for a twice-daily formulation
  - Component doses of MoxDuo CR vs. Oxycontin<sup>®</sup> 20 mg (sustained release oxycodone)
  - N=14 normal, healthy volunteers, single dose crossover design
  - Compared the rate at which key components of the CR formulation were absorbed, distributed, metabolized and eliminated


# MoxDuo Market Opportunity

- Blockbuster potential in growing market
- KOL and payor acceptance of value/clinical benefit
- Broad spectrum platform technology to treat patients from hospital to home
  - Complementary Dual-Opioid™ formulations: immediate release (IR), intravenous (IV), and controlled release (CR)
- Patents cover composition of matter, mechanism of action and new formulations
  - Protect against similar opioid combinations
  - Patent applications lodged which if granted are expected to extend market exclusivity through 2029 (all formulations)

# CNS Program

- Reduce protein misfolding linked to neurodegenerative diseases
  - Dystonia, Huntington's, Parkinson's and Alzheimer's
- Primarily funded by the Michael J. Fox Foundation
- Treat at causative level, not temporary symptomatic relief
  - Exclusive rights to novel IP
  - Sponsored research agreement with University of Alabama
  - Drug targets to increase activity of normal Torsin A
- Development approach
  - NCE discovery
  - Partnering discussions ongoing

# CORPORATE OVERVIEW



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# Leadership Team

- **Board of Directors**

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

- **Management**

- John Holaday (CEO)
- Chris Campbell (CFO)
- Warren Stern (Exec. VP, Drug Development)
- Janette Dixon (VP Global Business Development)
- Phil Magistro (Chief Commercial Officer)
- Patricia Richards (Chief Medical Officer)

# Scientific Advisory Board

- Solomon Snyder, MD (Chair)
- Lester Crawford, DVM, PhD
- Robert Lenox, MD
- Guy A. Caldwell, PhD
- Michael J Cousins, MD, AM
- Horace H Loh, PhD
- Gavril Pasternak, MD, PhD
- David Janowsky, MD
- Ed Rudnic, PhD

# 2010 Milestones

## Achieved

- ✓ Completed “combination rule” pivotal Phase 3 trial for MoxDuo IR
- ✓ Initiated second pivotal Phase 3 trial for MoxDuo IR
- ✓ Formed strategic alliance for development of MoxDuo IV (hospital pain) and license of MoxDuo IR in China
- ✓ Completed Phase I trial for MoxDuo CR (chronic pain)
- ✓ Completed Phase 2 investigator trials for MoxDuo IV

## Outstanding

- Complete second Phase 3 trial for MoxDuo IR
- File additional patent applications for MoxDuo and neurodegenerative disease program
- Conduct additional comparator trial for labeling claims in U.S. and Europe
- Submit New Drug Application for MoxDuo IR to U.S. FDA (Q1, 2011)

# Financial Summary

(23 July 2010)

**Shares on issue:** 102 million (ordinary)

**Market cap:** AUD\$108 million

**Cash on hand:** AUD\$12.8 million (30 June 2010)

**Burn rate:** cash runway into CY2011

**Share registry:** +80% institutional

**Listing:** ASX: QRX / OTCQX: QRXPY

# Key Differentiators

- Billion dollar market; broad spectrum technology
- Opened therapeutic window; equal or greater analgesia with fewer side effects than monotherapy
- ‘De-Risked’ program; 505(b)(2) regulatory path
- Global IP strength (all products/formulations); expected exclusivity through 2029
- Revenues expected in 2012
- Highly credentialed management, BOD, SAB

# Contact Information

## Australia

QRxPharma Limited

1/194 Miller Street

North Sydney, NSW 2060

+61 2 9492 8021

+61 2 8920 0314 (fax)

## United States

1430 US Highway 206

Suite 230

Bedminster, NJ 07921

(908) 506-2900

(908) 506-2918 (fax)