



MoxDuo®
A Novel Dual-Opioid™ for
Moderate to Severe Pain Management

May 2010



Opening the therapeutic window for doctors and patients.

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Why QRxPharma?

- **Late and early stage clinical pipeline**
 - Dual-Opioid™ pain portfolio (3 distinct formulations): lead product late-Phase 3
- **Target global opioid pain market of est US\$12 billion***
- **Strong IP; broad international protection**
- **Specialty pharma: pain management and CNS**
 - AU ASX: QRX / Mkt Cap: AUD\$120 million
 - Re-engineer drugs to enhance clinical/commercial value
- **Experienced board and executive team**
 - New Jersey and Sydney offices
- **Strategic relationships**

Product Pipeline 2010

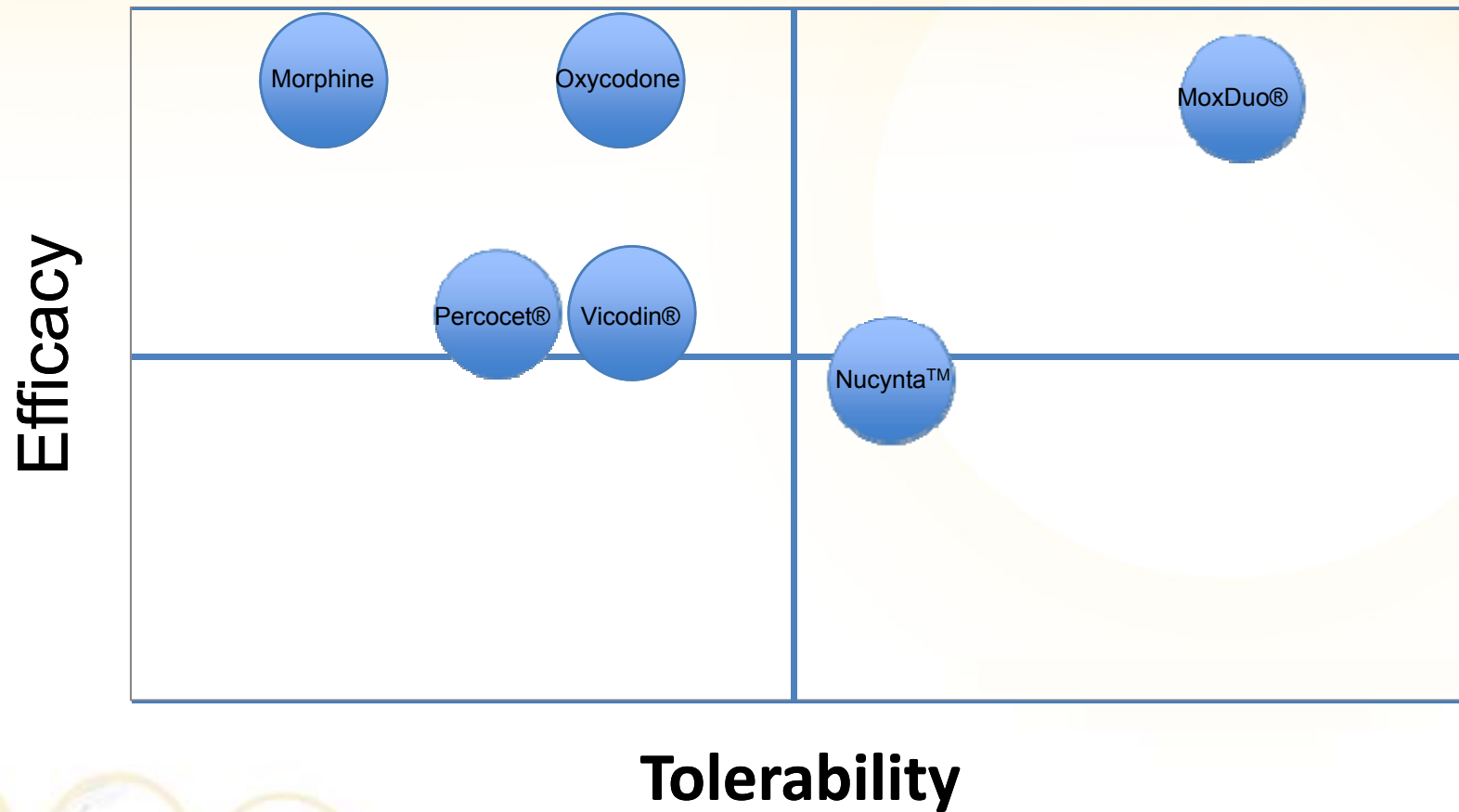
PRODUCT/PROGRAM	RESEARCH	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
PAIN MANAGEMENT					
MoxDuo® IR	██████████	██████████	██████████	██████████	██████████
MoxDuo® IV	██████████	██████████	██████████	██████████	
MoxDuo® CR	██████████	██████████	██████████		
NEUROLOGIC DISEASES					
T9001 (DYSTONIA)	██████████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



Pain Therapy Market

- **Large specialty pharma opportunity**
 - US\$12 billion globally; US\$7+ billion in US alone*
- **Limited innovation; reliance on old therapies**
 - Opioids are the “gold standard” in treating pain
- **Over 150 million people in the major pharmaceutical markets suffer from pain**
 - Acute pain is the most common reason people seek medical attention; more than 75 million Americans experience acute pain each year as a result of injuries or surgery
- **Need for products with better pain relief and fewer side effects/risk factors**
 - Respiratory depression, sedation, constipation, nausea, vomiting, somnolence

MoxDuo[®]IR Target Product Profile



MoxDuo[®]IR Key Differentiators

- **Broad spectrum platform technology**
 - 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)

Moderate to Severe Pain Market

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

In the US*:

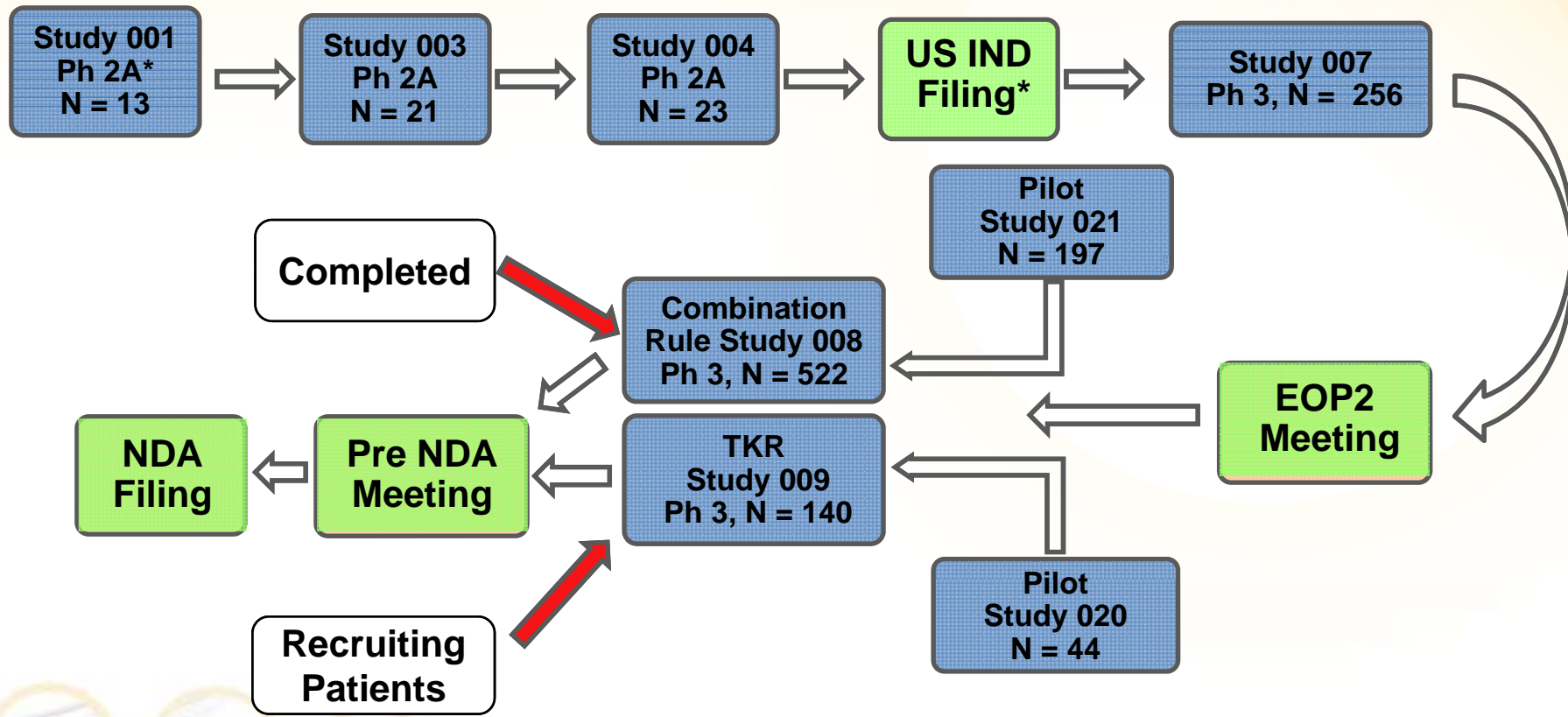
- **Immediate Release (IR) US\$1.8 billion:** Generic and branded led by generic Vicodin® US\$546 million together generic Percocet US\$420 million and branded Percocet® US\$143 million (Endo)
- **Intravenous (IV) US\$260 million:** 226 million vials dominated by generic Morphine, Fentanyl and Hydromorphone
- **Controlled Release (CR) US\$5.2 billion:** Branded and generic led by US\$2.9 billion OxyContin® (Purdue Pharma) followed by generic US\$0.9 billion Fentanyl

Lead Product: MoxDuo[®]IR

- **MoxDuo[®]IR opens therapeutic window for acute pain relief**
 - As good or better pain relief with fewer side effects than morphine, oxycodone, and Percocet[®]
- **Streamlined route to approval**
 - 505(b)(2) regulatory path
 - Anticipate NDA filing of MoxDuo[®]IR with the FDA in 2010

Lead Product: Clinical Information

MoxDuo®IR



Study 008: Combo Rule Pivotal Phase 3 MoxDuo[®]IR

- **Goal:** Demonstrate superior analgesic effect of MoxDuo[®] 12/8 mg vs morphine 12 mg and oxycodone 8 mg as required by FDA “combination rule”
- **Design:** Bunionectomy patients (522), double blind, randomised, dose every 6hrs for 2 days, SPID48 primary endpoint
- **Conduct:** Performed at 6 US sites
- **Status/Outcome:** Primary and secondary endpoints met!

Study 008: Combo Rule Pivotal Phase 3

MoxDuo[®] IR

SPID₄₈ - Primary Endpoint
 SPID₂₄ - Secondary Endpoint

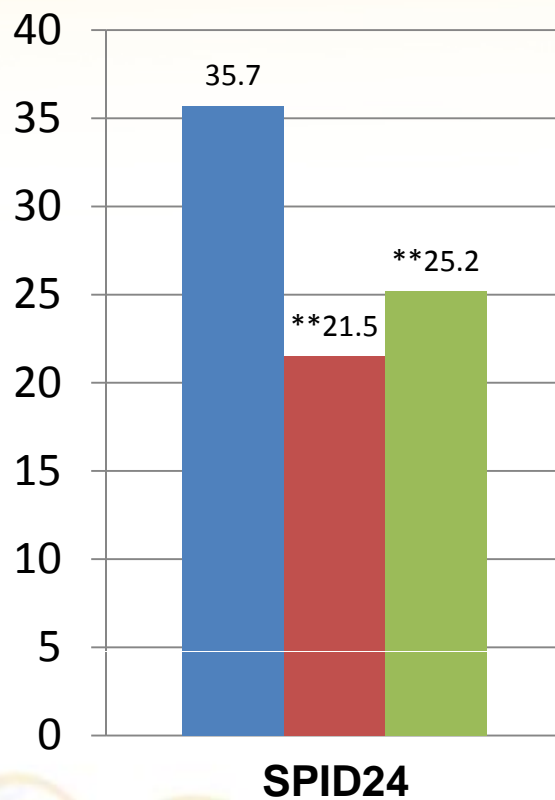
	MoxDuo [®] IR 12/8 mg	Morphine 12 mg	Oxycodone 8 mg
SPID ₄₈ : Mean	107	83	83
P-value (vs MoxDuo [®] IR)		0.014*	0.011*
SPID ₂₄ : Mean	35.7	21.5	25.2
P-value (vs MoxDuo [®] IR)		0.003*	0.026*

*statistically significant

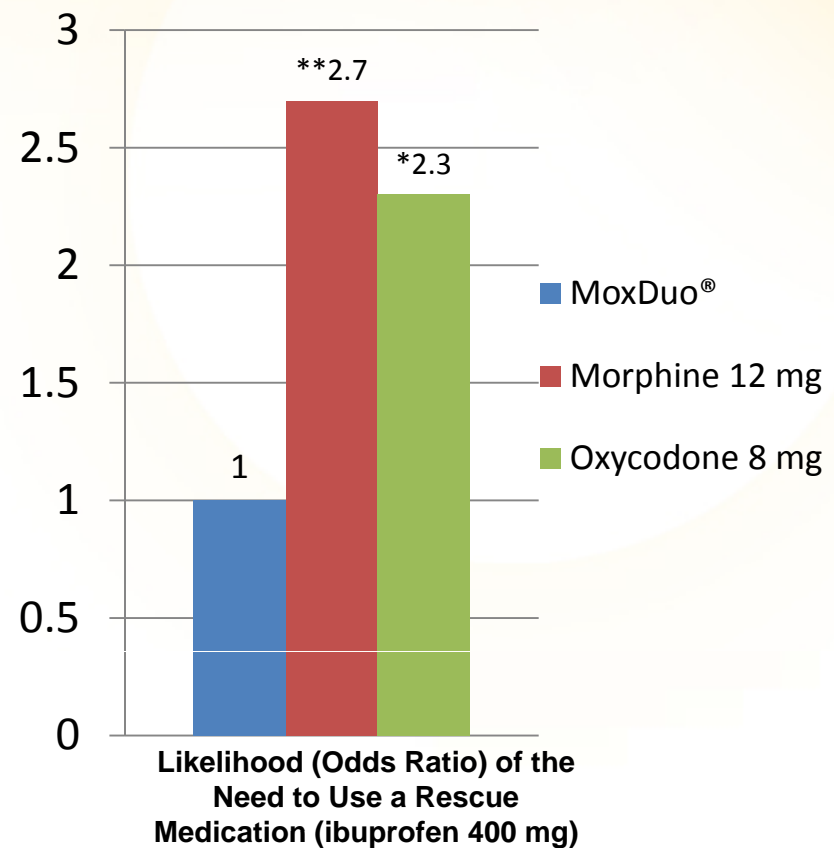
Study 008: Combo Rule Pivotal Phase 3

Secondary Efficacy Endpoints

MoxDuo[®]IR is superior to its mg components



(**p<0.01)



(*p<0.05; **p<0.01)

Study 008: Combo Rule Pivotal Phase 3

Adverse Events

- For regulatory purposes, the study compared a higher dose of MoxDuo[®]IR than each individual component. Therefore, one might expect more adverse events with MoxDuo[®]IR than with lower dose morphine or oxycodone.
- Despite twice the analgesic response, MoxDuo[®]IR was well tolerated (no SAEs) and had the same dropout rate as less effective doses of morphine and oxycodone.

Study 008: Combo Rule Pivotal Phase 3

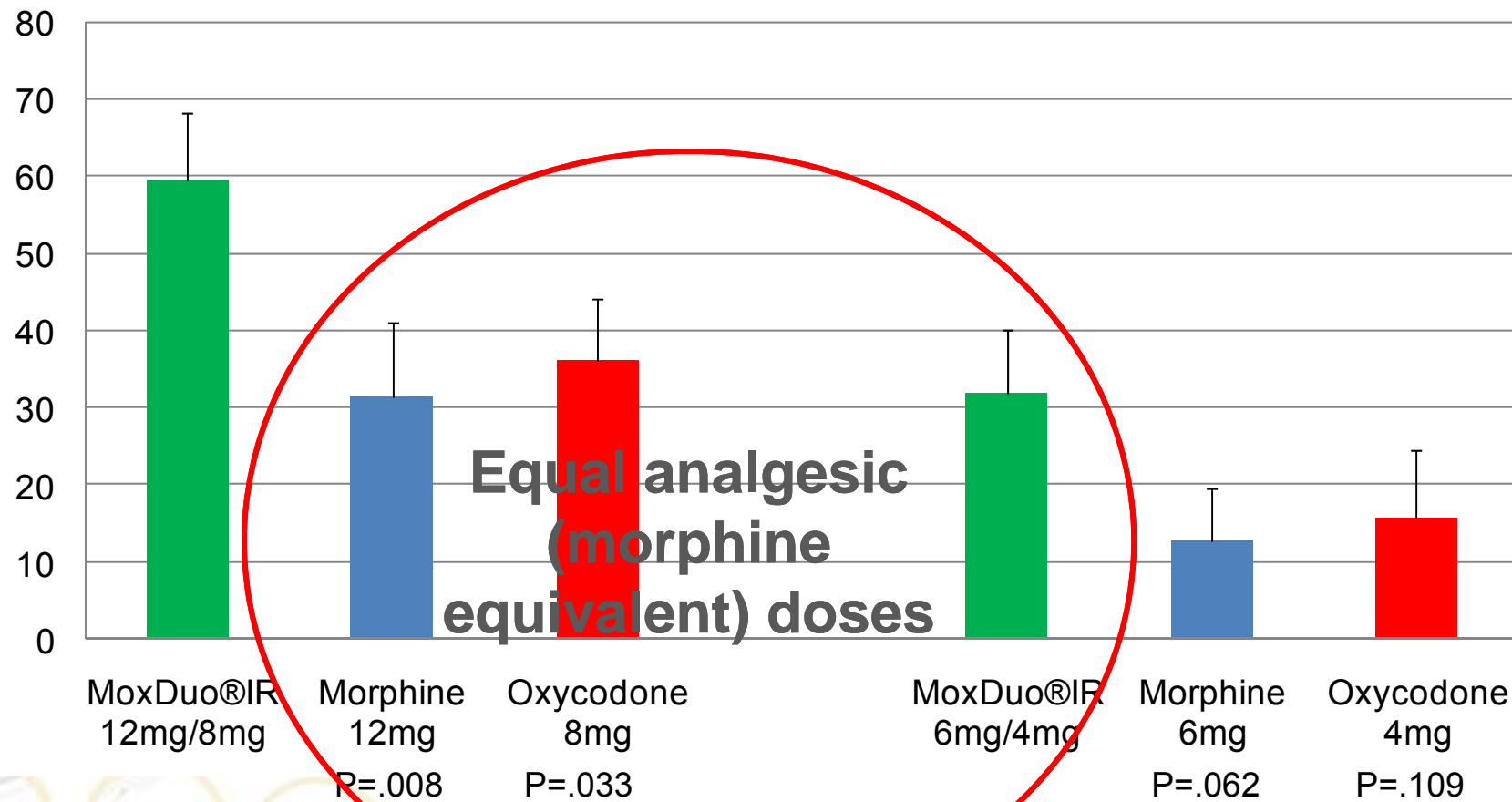
Conclusions - Combination Rule Study

- The primary analgesic efficacy endpoint was met ($p=0.01$) vs morphine and vs oxycodone
- MoxDuo[®]IR 12/8 mg was superior to its components on secondary efficacy measures
- Despite the higher dose of MoxDuo[®]IR than the controls, except for emesis the moderate-severe adverse event rate was not statistically worse

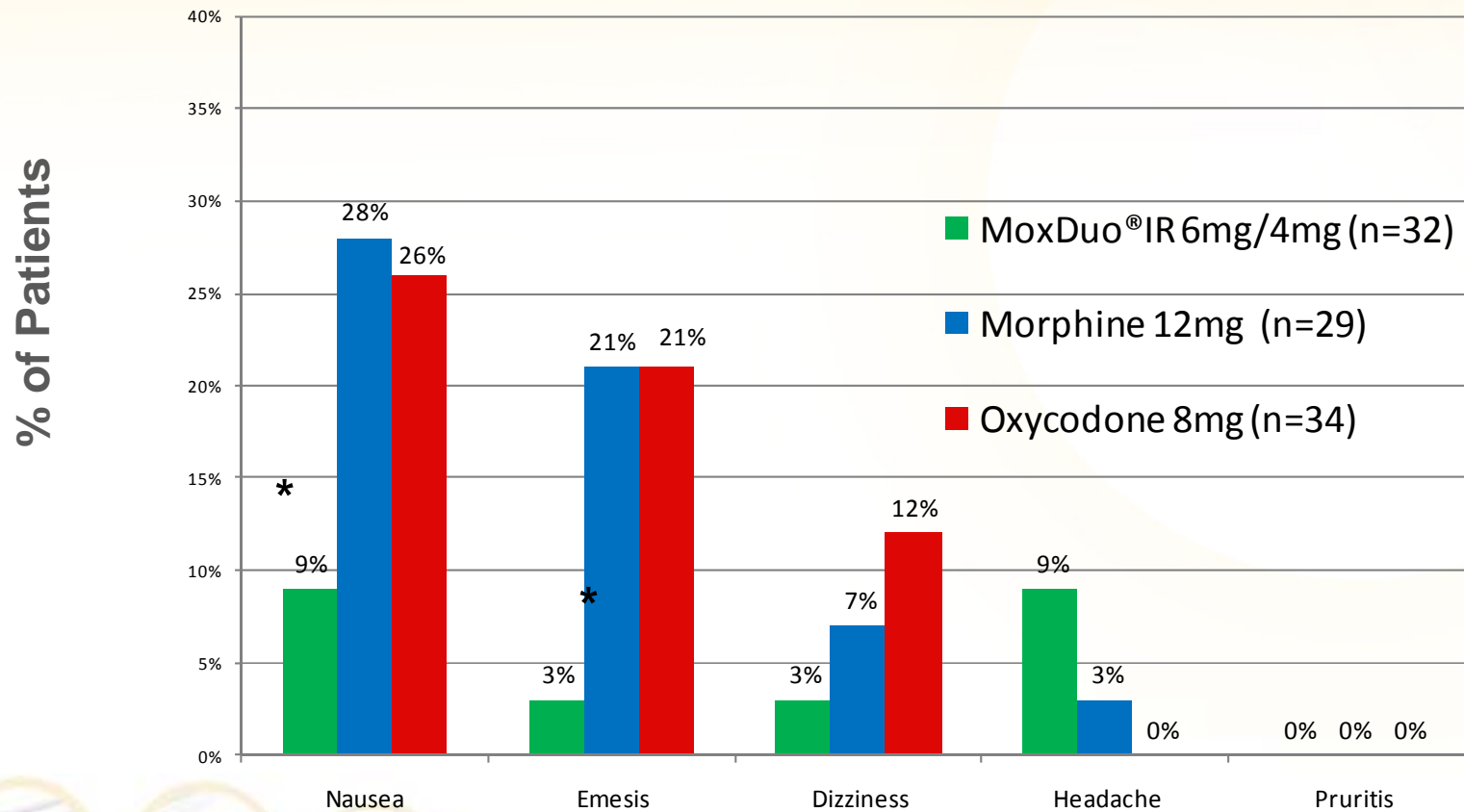
Study 021: Acute Pain (Bunionectomy)

- **Demonstrated superiority of MoxDuo[®]IR**
 - Efficacy/safety compared to morphine and oxycodone
- **Enhanced tolerability at component and equianalgesic doses**
 - Frequency of moderate to severe nausea, vomiting and dizziness 50% to 75% lower than components
- **Data indicate pivotal Phase 3 Combination Rule trial will prove successful**
 - Confirmed efficacy, optimal dose, and sample size

Summary of SPID₂₄ Score by Treatment (mean ± se)



Moderate-Severe Adverse Events: Morphine Equivalent Comparisons

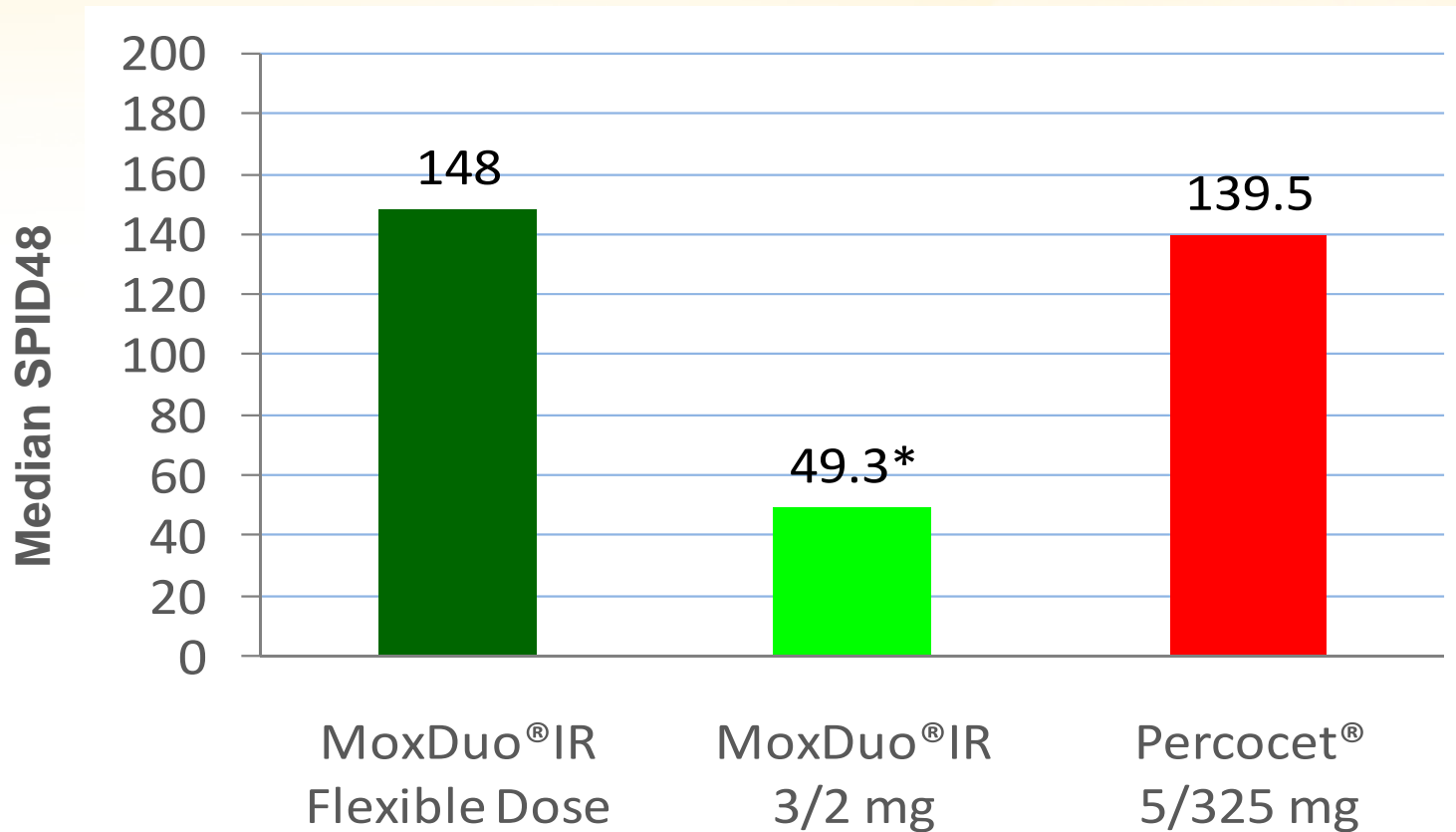


*: P<0.05 versus the combination of the oxycodone group with the morphine group

Study 20: Pilot Knee Replacement

- **Compared efficacy/safety profile of MoxDuo[®] IR to Percocet[®]**
 - Demonstrated enhanced tolerability over equianalgesic dose of Percocet[®]
 - Delivered better pain relief with less nausea, vomiting, hypotension and constipation
- **Selected control for pivotal Phase 3 TKR study**
- **Determined number of patients to power successful pivotal trial for NDA filing**

Summary of Efficacy (SPID₄₈)

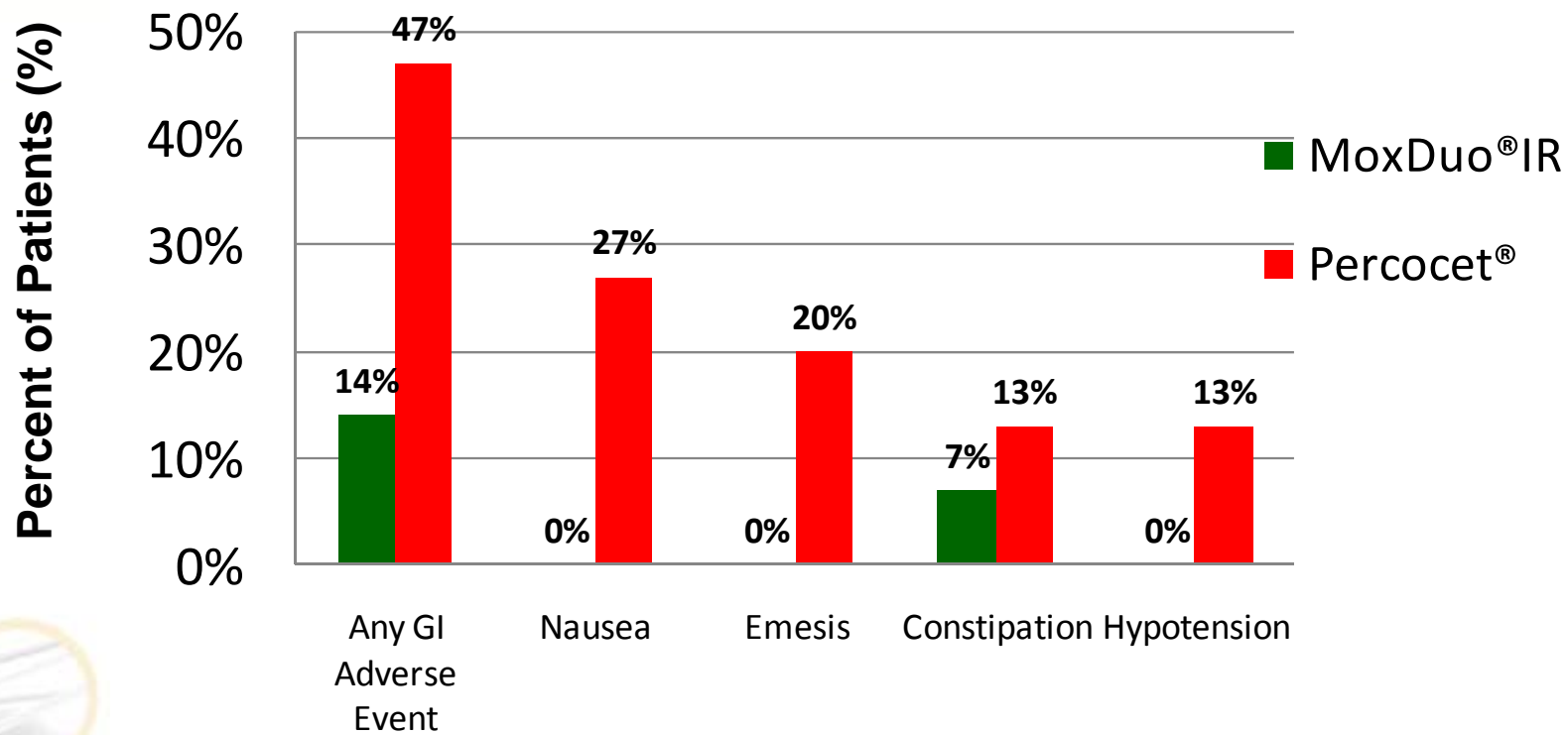


* P<0.048 Compared to MoxDuo[®] IR flexible dose

Comparing: MoxDuo[®]IR versus Percocet

Study 020: Pilot Study in Total Knee Replacement

Moderate to Severe Adverse Events Commonly Associated with Opioids (% patients)



MoxDuo[®]IR

Remaining Pivotal Study and NDA Filing

- **009 Total Knee Replacement Study (n=140)**
 - Submitted SPA: incorporated feedback
 - 70 subjects/arm. MoxDuo[®]IR (12/8 mg) 4-6 hours vs MoxDuo[®]IR (3/2 mg) every 6 hrs
 - **First patient enrolled February, 2010**
 - Expecting completion Q3 2010

MoxDuo[®]IR

Changing the Opioid Paradigm

*“The clinical advantages of MoxDuo[®]IR have the potential to change the traditional methods of treating moderate to severe pain by providing **better pain relief without many of the debilitating side effects** seen with traditional opioid drugs”*

– Dr. Bruce Nicholson, leading US pain physician

Dr. Nicholson is a Clinical Associate Professor of Anesthesia at the Penn State School of Medicine and Director of the Division of Pain Medicine at the Lehigh Valley Hospital and Health Network in Allentown, Pennsylvania

From Hospital to Home...

- **Broader selection of analgesic options to treat pain from the hospital to the home:**
 - **MoxDuo[®]IR** (Immediate Release) oral capsules
 - Target: Moderate to severe acute pain
 - Phase 3 studies near completion
 - Anticipate NDA filing of MoxDuo[®]IR with the FDA in 2010
 - **MoxDuo[®]IV** liquid formulation
 - Target: Hospital-based pain
 - Phase 2 and concurrent formulation development
 - **MoxDuo[®]CR** (Controlled Release) oral capsules
 - Target: Chronic pain (i.e. osteo-arthritis, back, neuropathic)
 - Phase 1

MoxDuo[®]IV

Strategic Alliance

- **February 2010: strategic alliance with Aoxing (NYSE AMEX:AXN) to 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 may use the clinical work completed by Aoxing for product registration outside China
 - Aoxing also licensed MoxDuo[®]IR for the Chinese marketplace, significant royalties to QRxPharma who provides the product for distribution.
 - **China is the world's fastest growing opioid marketplace!**

CNS Program

- **Focus on reducing protein misfolding linked to neurodegenerative diseases**
 - Dystonia, Huntington's, Parkinson's and Alzheimer's
- **Treat at causative level; not 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
 - Commercial partnering in discussion

Experienced BOD and Management

- **Board of Directors**

- Peter Farrell (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)

2010 Objectives

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
- ✓ Initiated Phase 1 trials for MoxDuo[®]CR (chronic pain)

Outstanding

- Complete Phase 2 investigator trials for MoxDuo[®]IV
- Complete second pivotal Phase 3 trial for MoxDuo[®]IR
- Submit New Drug Application for MoxDuo[®]IR to US FDA
- File additional patent applications for MoxDuo[®] and neurodegenerative disease program
- Develop global sales plan including strategic alliances for commercialisation

Financial Summary

(At 4 May 2010)

- ❖ **Shares on issue:** 102 million (ordinary)
- ❖ **Market cap:** AUD\$120 million
- ❖ **Cash on hand:** AUD\$17 million (31 March 2010)
- ❖ **Burn rate:** cash runway into FY2011
- ❖ **Share registry:** +80% institutional
- ❖ **Listing:** QRX (ASX), QRXPY (OTCQX)

The Opportunity

- ❑ Compelling data as part of its Phase 3 programme in US\$12 billion global opioid pain market*
- ❑ Late and early stage clinical pipeline with commercialisation of first product MoxDuo[®]IR in 2011
- ❑ Strategic relationships in negotiations
- ❑ Portfolio of early and late products
- ❑ Experienced management and board

*Source: Datamonitor 03/2009