



QRx Pharma

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

20 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**
 - Re-engineer drugs to enhance clinical/commercial value
- **Experienced board and executive team**
 - New Jersey and Sydney offices
- **Strategic relationships**

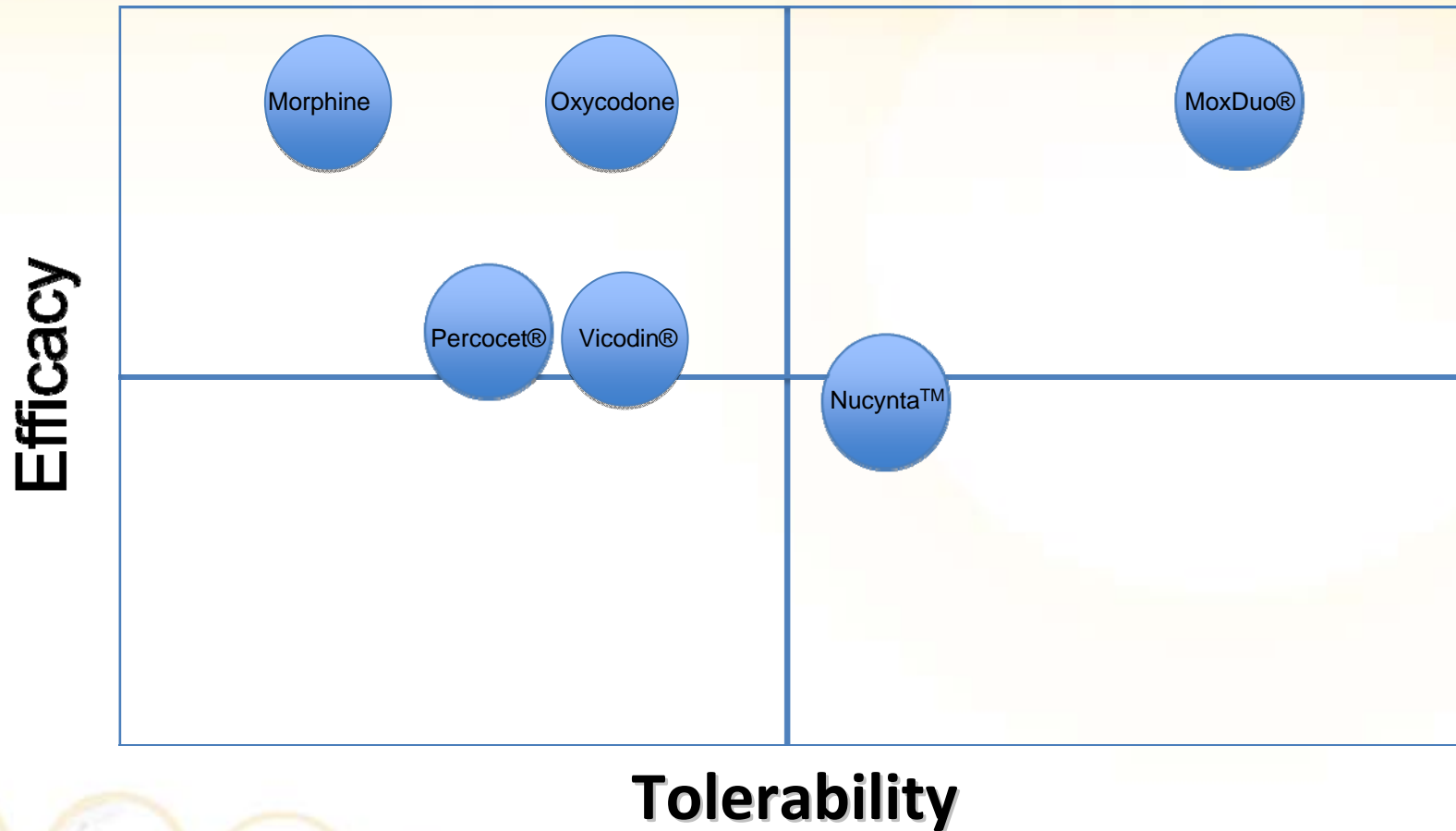
*Source: Datamonitor 03/2009

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	██████████				



MoxDuo[®]IR Target Product Profile



Moderate to Severe Pain Market

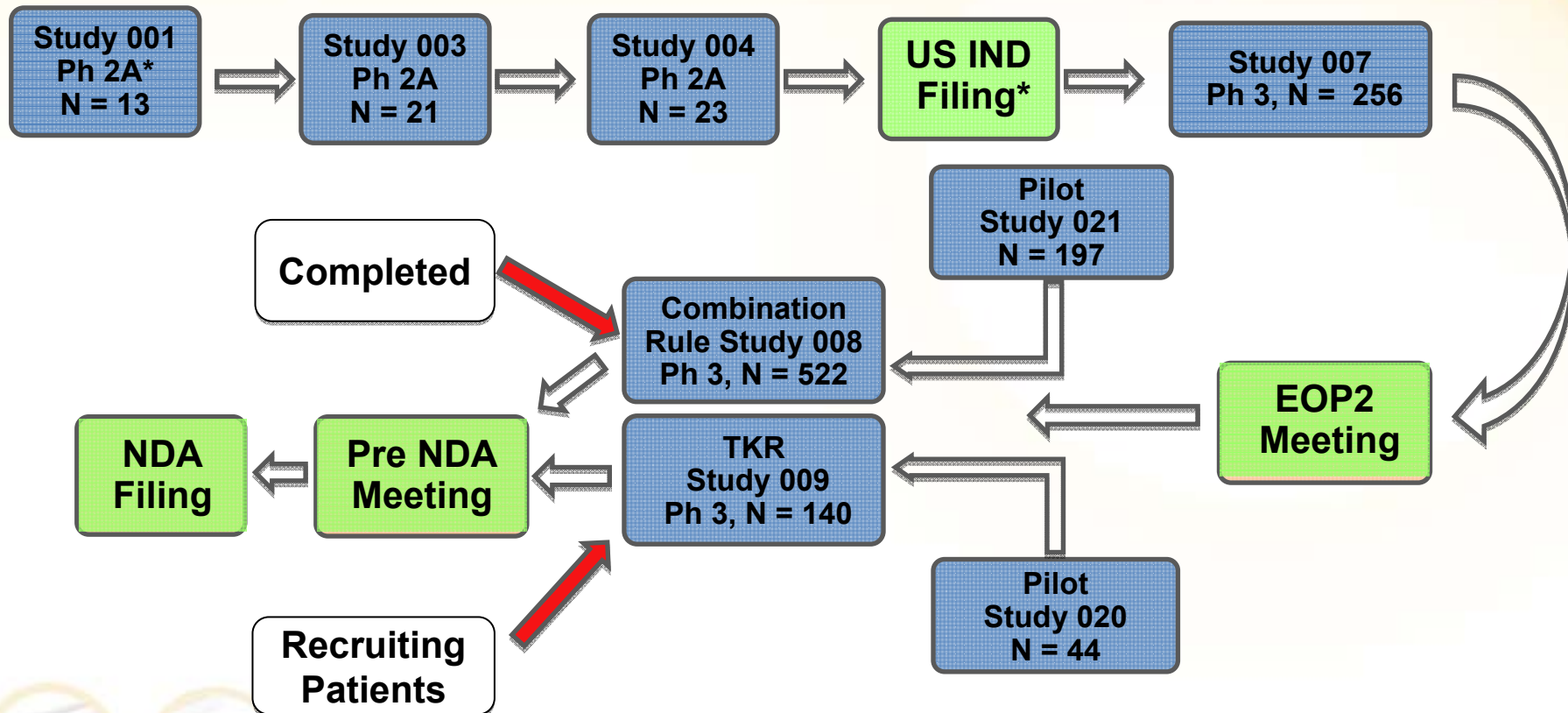
No one player “owns” the global moderate to severe pain market.

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: Clinical Information

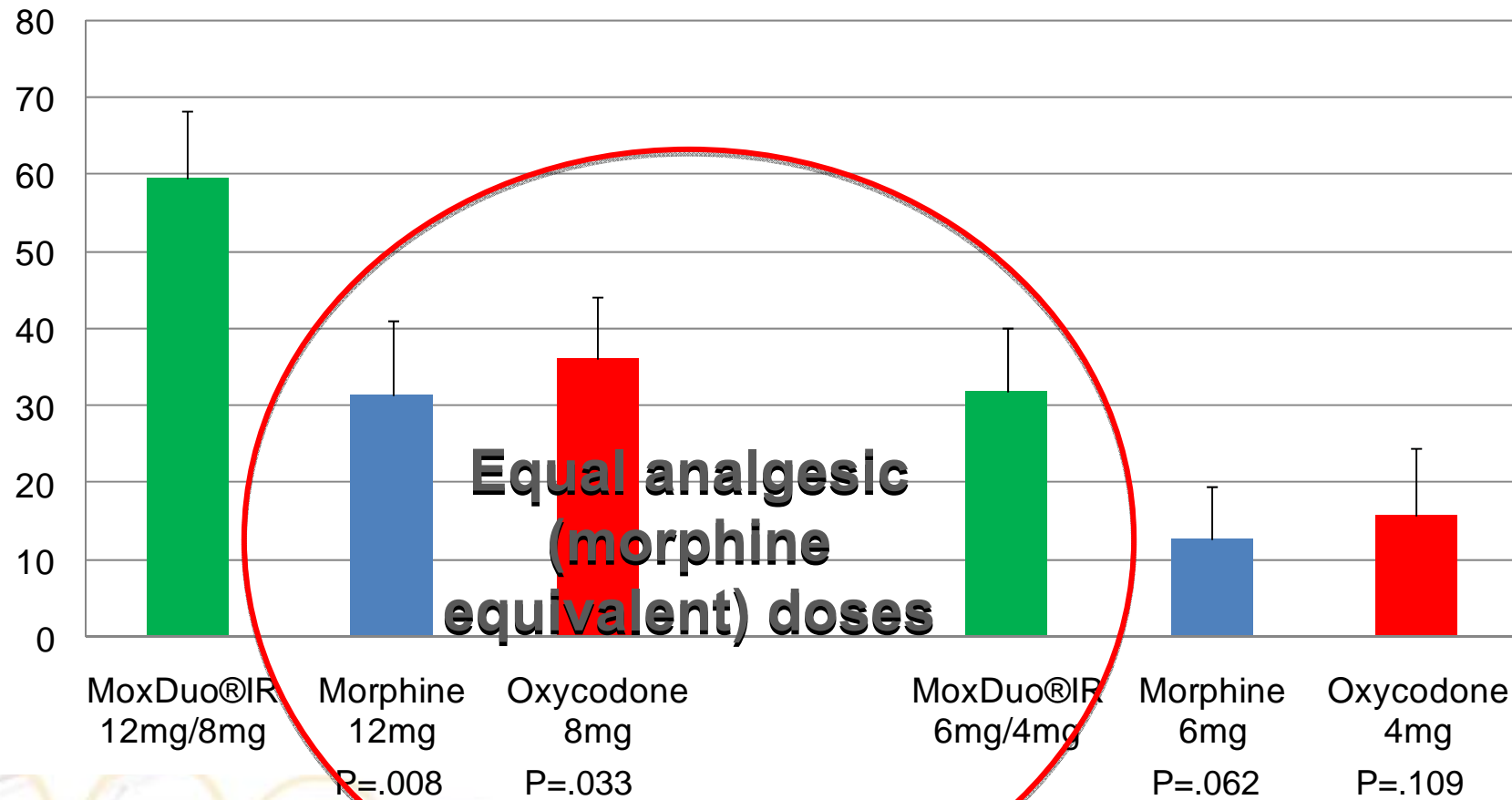
MoxDuo®IR



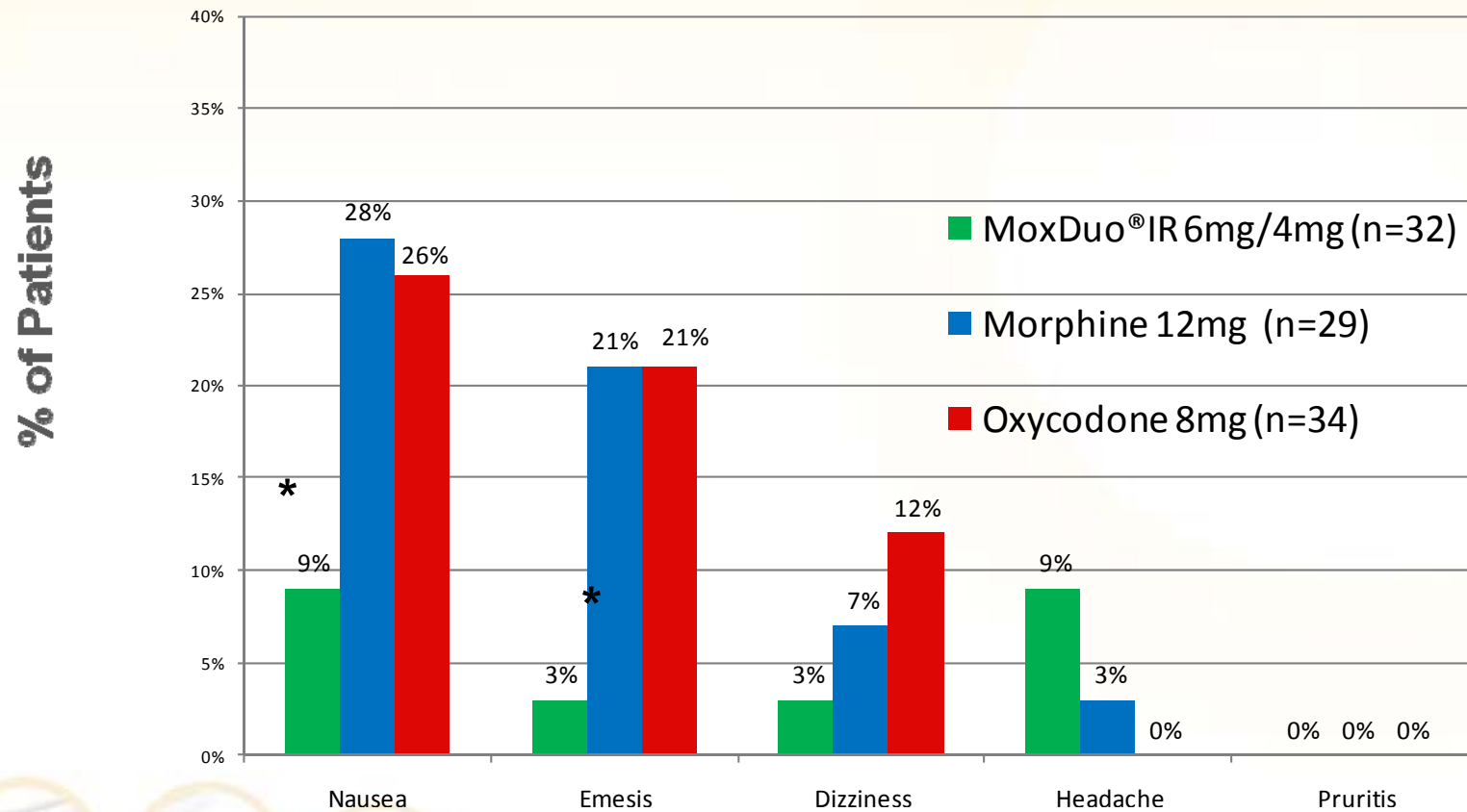
Study 021: Acute Pain (Bunionectomy)

- **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 SPID Score by Treatment (mean \pm se)



Moderate-Severe Adverse Events: Morphine Equivalent Comparisons

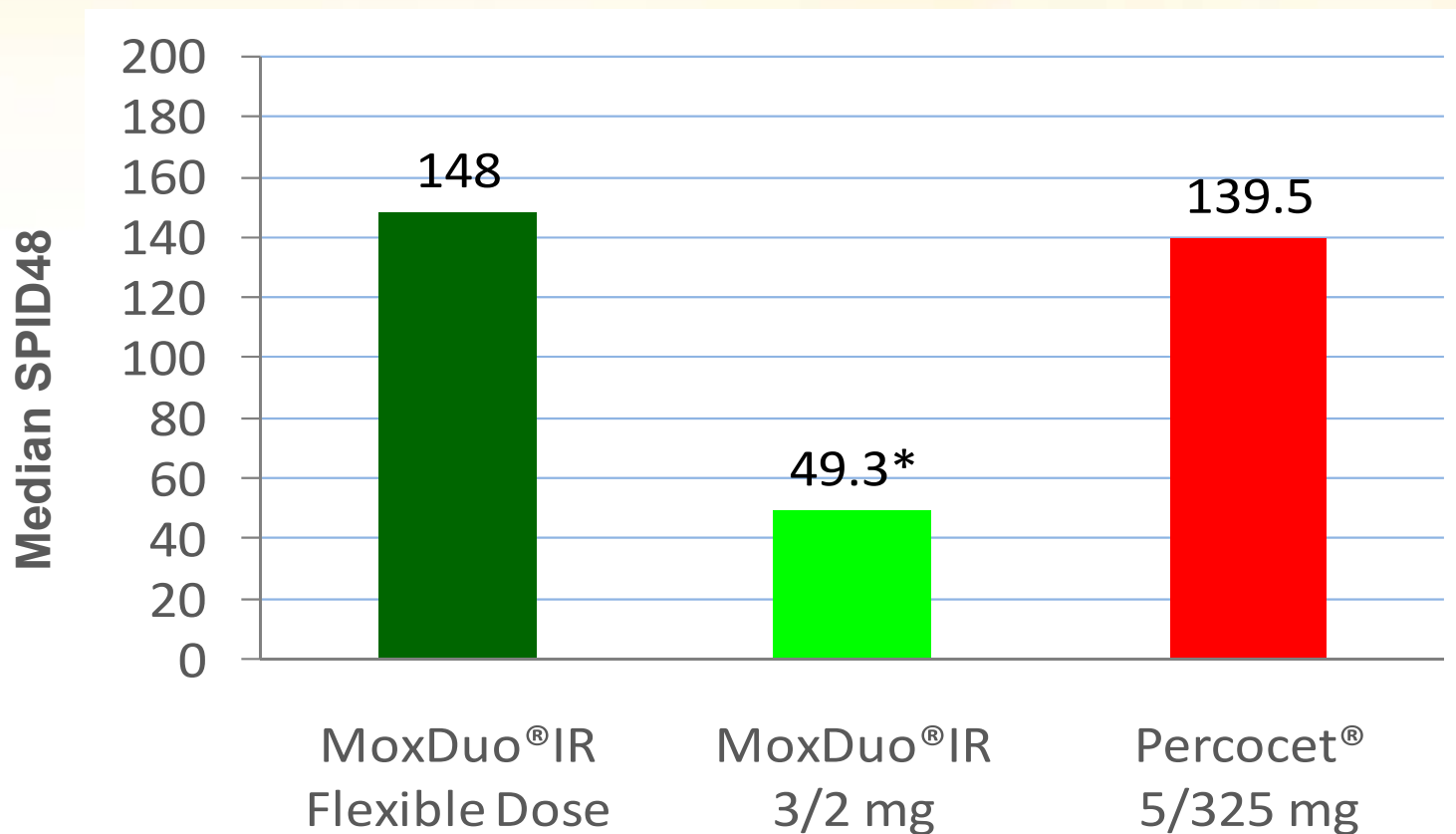


*: P<0.05 versus the combination of the oxycodone group with the morphine group

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)



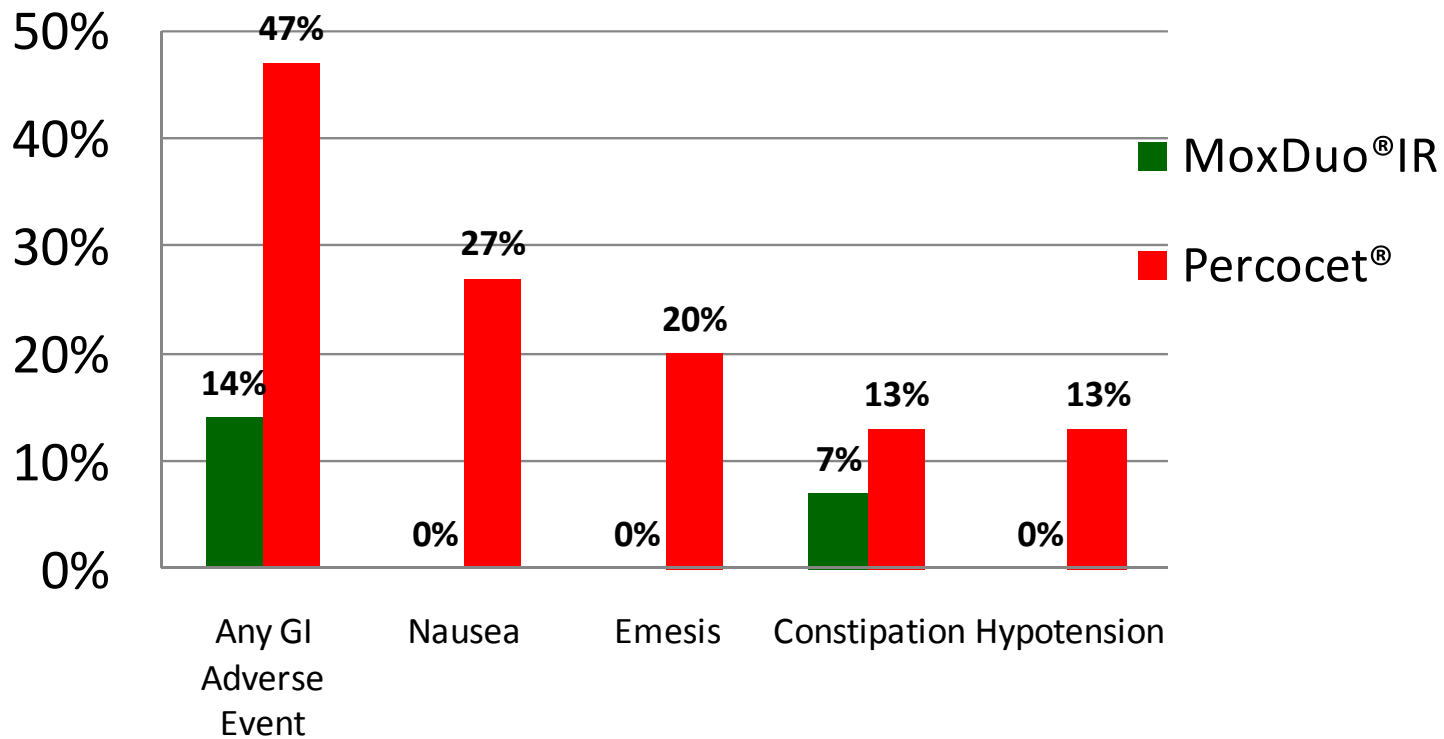
* P<0.048 Compared to MoxDuo[®] IR flexible dose

Comparing: MoxDuo[®]IR versus Percocet

Study 020: Pilot Study in Total Knee Replacement

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

Percent of Patients (%)



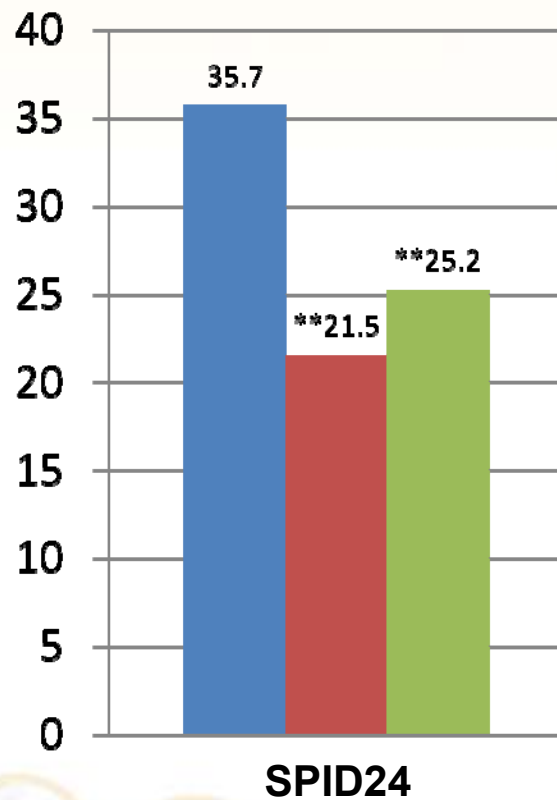
Study 008: Combo Rule Pivotal Phase 3 MoxDuo[®]IR

- **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!

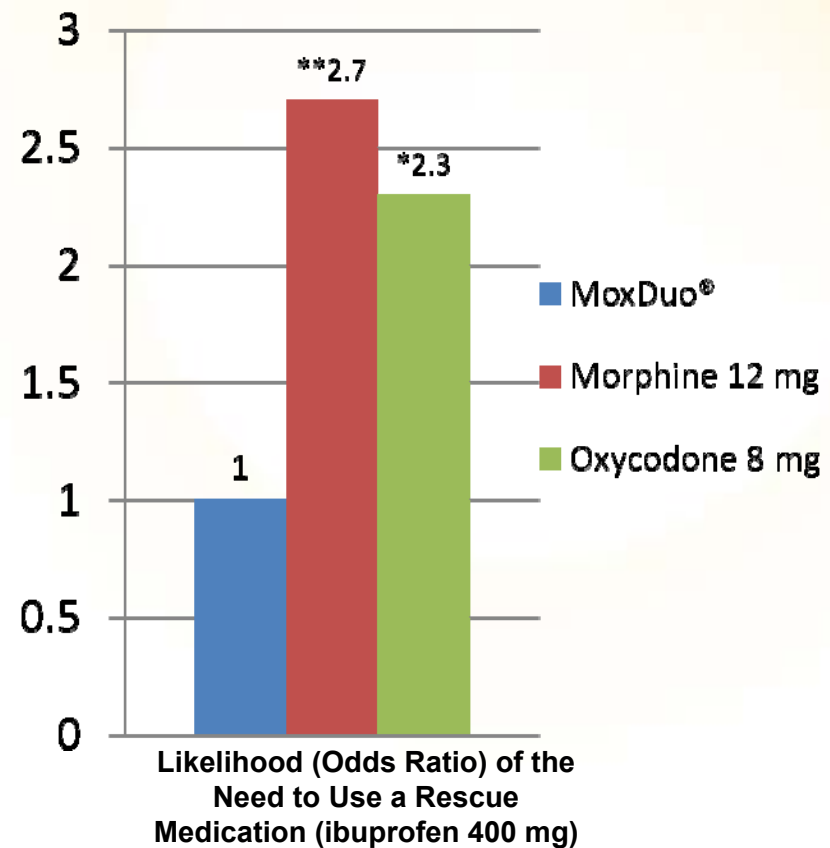
Study 008: Combo Rule Pivotal Phase 3

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

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

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

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

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 17 May 2010)

- ❖ **Shares on issue:** 102 million (ordinary)
- ❖ **Market cap:** AUD\$115 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)