

**QRx**  
*Pharma*

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

April 2009

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# Defining Potential

- **Pain:** Better analgesia and greater tolerability
- **CNS:** Alleviate neurodegenerative disorders at causative level
- **Specialty Pharma:** Small sales force targets large market through specialty physician prescribers

# Company Profile

- **Specialty pharma: pain management and CNS**
  - US OTCQX: QRXPY and AU ASX: QRX
  - Development strategy: re-engineer drugs
    - Enhanced clinical and commercial value
    - Streamlined regulatory and commercialization paths
- **Late and early stage clinical pipeline**
  - Dual-Opioid™ portfolio; mid-Phase 3
  - T9001 (CNS); Phase 2 in 2010
- **Strong IP; broad international protection**
- **Low burn rate with 2 years COH**
- **Experienced board and executive team**

# Product Pipeline 2009

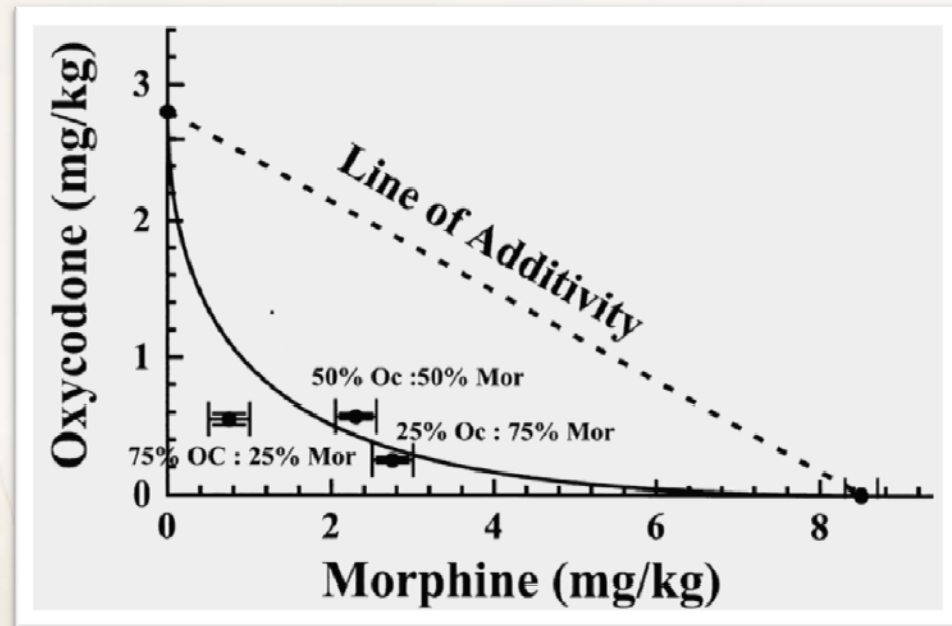
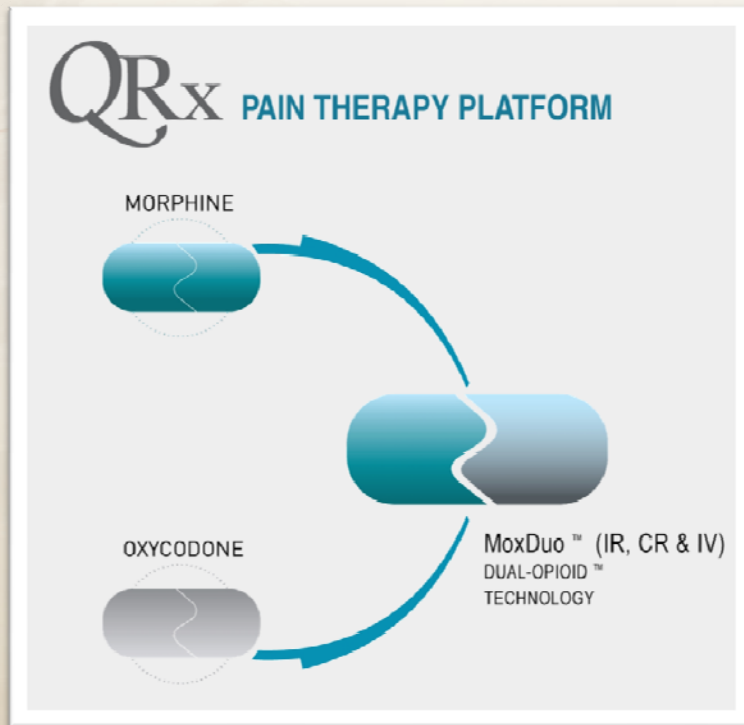
PRODUCT/PROGRAM	RESEARCH I	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
<b>PAIN MANAGEMENT</b>					
MoxDuo™ IR	██████████	██████████	██████████	██████████	██████████
MoxDuo™ IV	██████████	██████████	██████████	██████████	
MoxDuo™ CR	██████████	██████████			
<b>CNS</b>					
T9001 (DYSTONIA)	██████████	██████████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

# Pain Therapy Market

- **Large specialty pharma opportunity**
  - Excess of \$7 billion in US alone
- **Limited innovation; reliance on old therapies**
  - Opioids are the “gold standard” in treating pain
- **Need for product with greater tolerability and better pain relief**
  - Respiratory depression, sedation, constipation, nausea, vomiting, somnolence

# MoxDuo™

1<sup>st</sup> combination opioid product for the improved control of moderate to severe pain



Morphine – Oxycodone Synergy

# MoxDuo™ Key Differentiators

- **Broad spectrum platform technology**
  - Immediate release, intravenous, and controlled release product formulations
- **Combination greater than sum of its parts**
  - Superior pain relief and greater tolerability than morphine and oxycodone alone
- **Streamlined route to approval**
  - 505(b)(2) regulatory path and SPA filing



# 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
  - 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™ 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

# Comparative Benefits

- **Broader receptor occupancy with MoxDuo™; synergistic mechanism of action**
  - Morphine and oxycodone act on different opioid receptors
- **Analgesia at lower doses than monotherapy; fewer and less intense adverse events (AEs)**
  - Nausea, vomiting, dizziness, constipation, etc.
- **Preferential reduction of CNS and respiratory AEs irrespective of dose level**
  - Reduced somnolence, euphoria, cognitive impairment
  - Less respiratory depression, improved SpO<sub>2</sub>

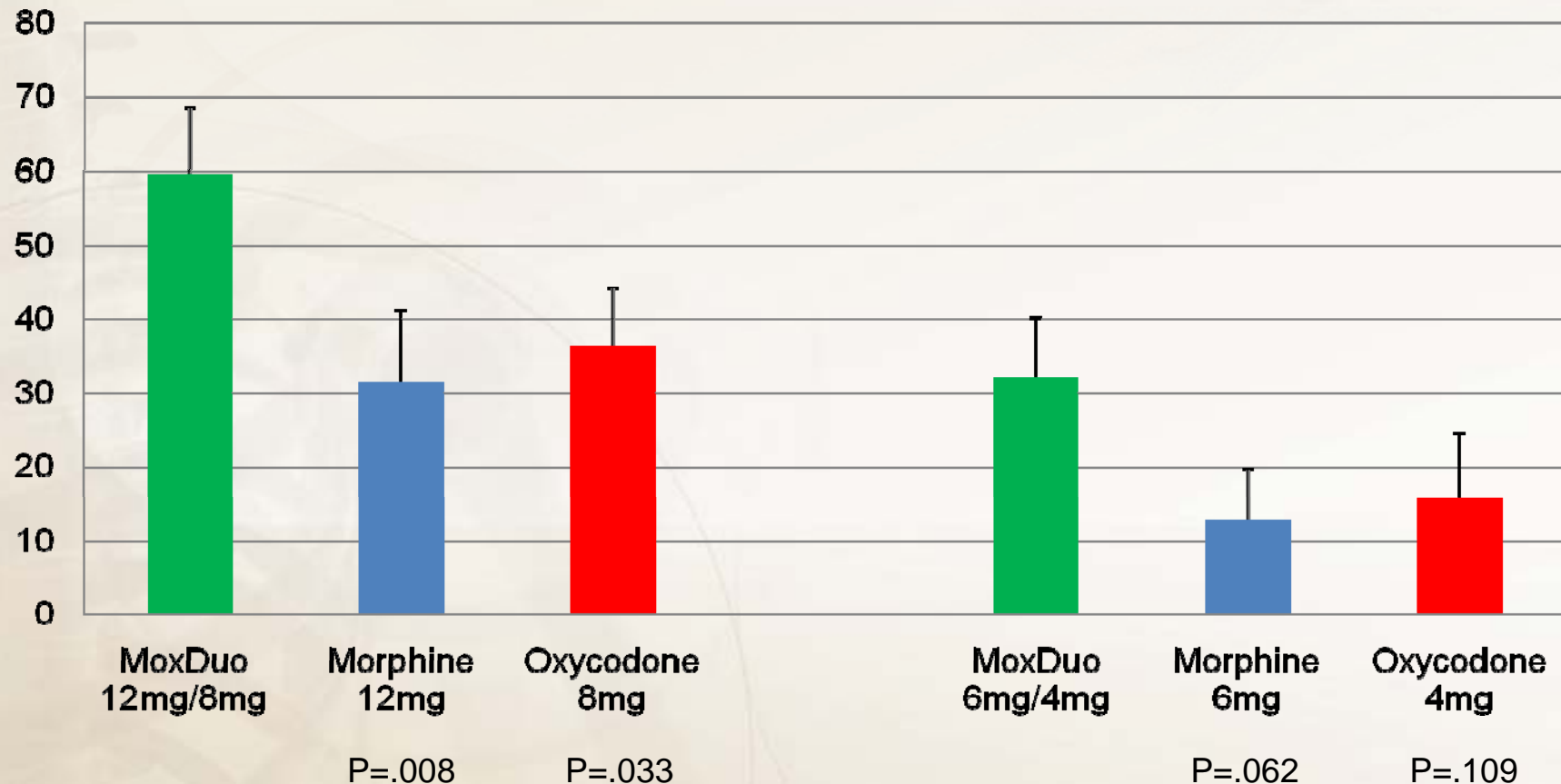
# Clinical Goals Achieved

## Comparative Pilot Study 021 (Acute Pain)

- **Demonstrate superiority of MoxDuo™**
  - Efficacy and safety comparison against morphine and oxycodone alone
- **Enhanced Tolerability**
  - Analgesic effect of MoxDuo™ IR 80% to 100% greater than components (SPID24)
  - Frequency of moderate to severe adverse events 25% to 75% lower than components
- **Data indicate Phase 3 Combination Rule trial will prove successful**
  - Confirmed dose for optimal efficacy and tolerability; set sample size parameters

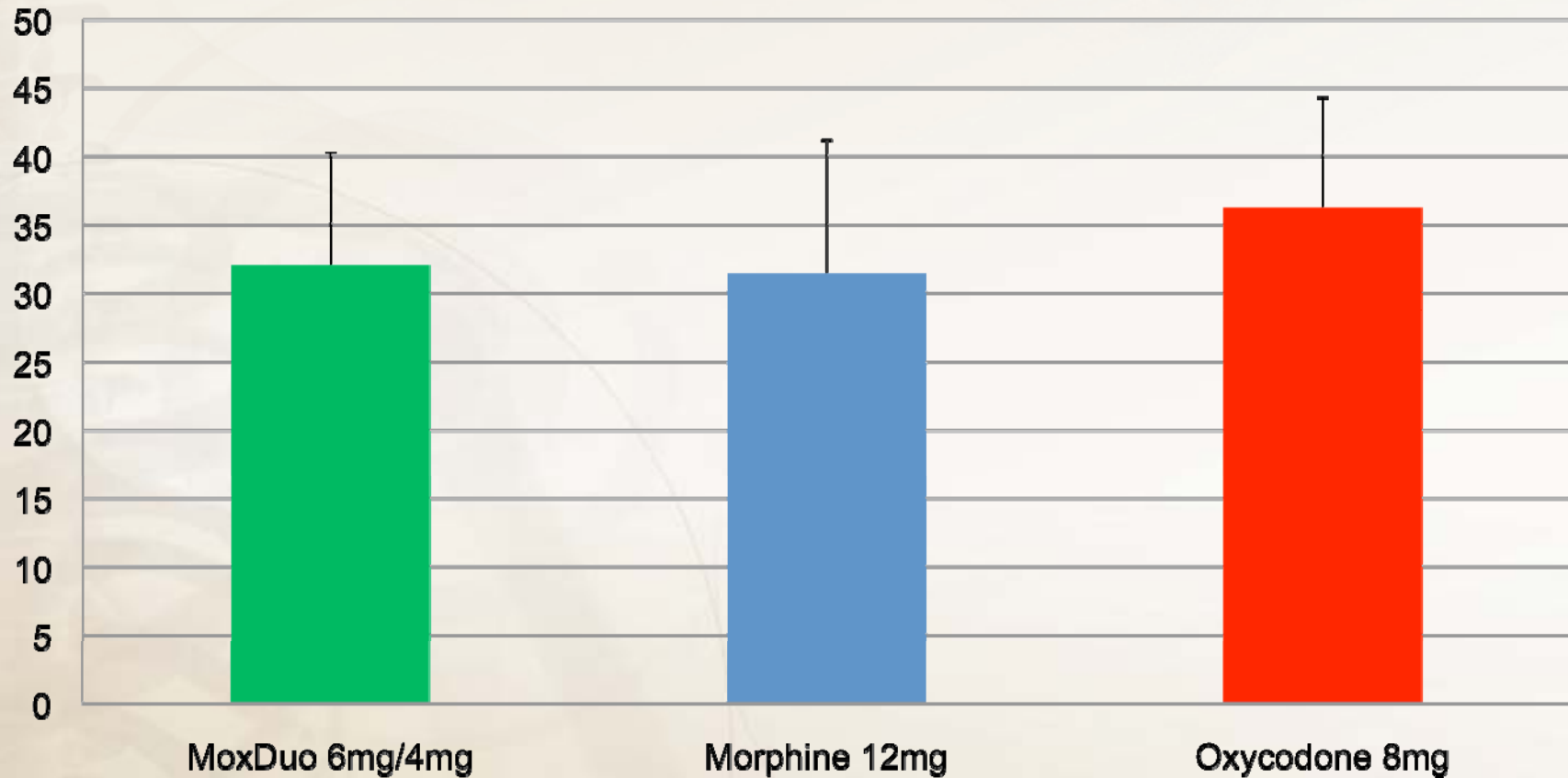
# Comparative Pilot Study 021

Primary Endpoint Summary of SPID24 Score by Treatment (mean  $\pm$  se)



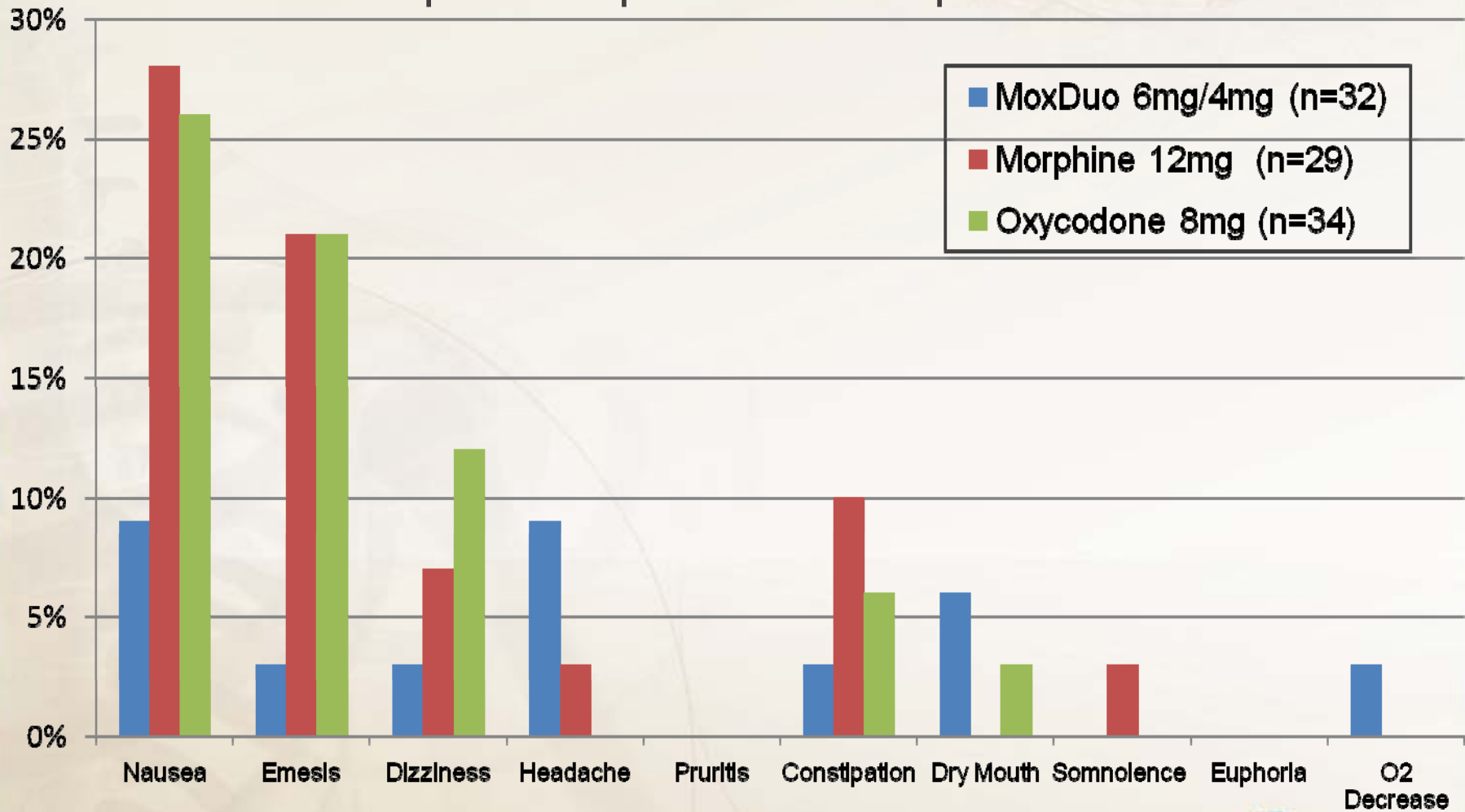
# Comparative Pilot Study 021

Morphine Equivalent Comparison of SPID<sub>24</sub>



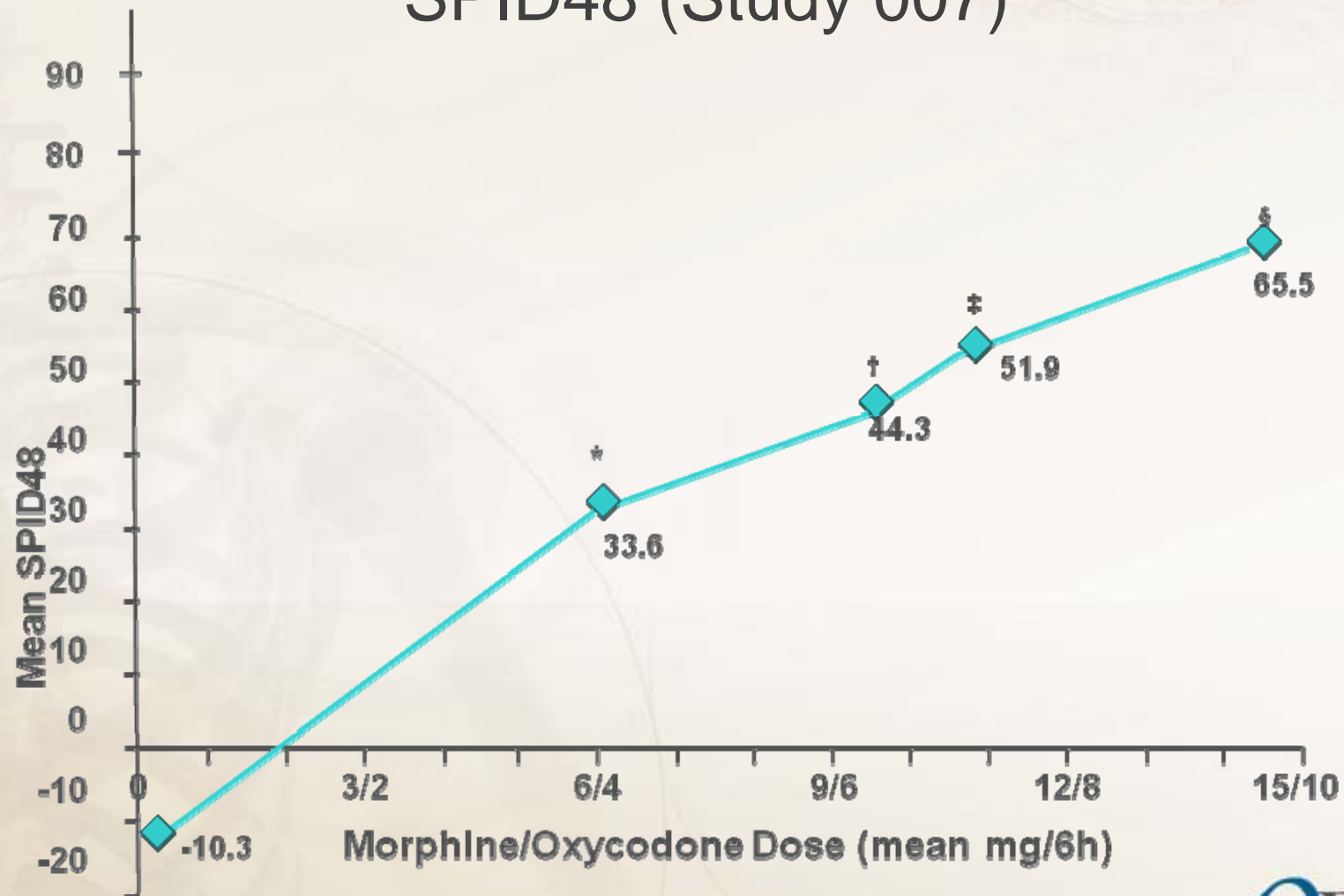
# Moderate-Severe Adverse Events

## Morphine Equivalent Comparisons



# Dose Response

## SPID48 (Study 007)





# Regulatory Path

- **FDA confirmed 505(b)(2) strategy**
  - Based on extensive knowledge of morphine and oxycodone
- **Well-defined immediate release (IR) NDA program**
  - Only 2 more Phase 3 studies before submission; expected NDA filing 2010
- **Special Protocol Assessment (SPA)**
  - FDA to pre-approve clinical protocols and accelerate review

# MoxDuo™ Program Highlights

- **Greater tolerability at equianalgesic doses; leads to enhanced effect**
  - Achieved equianalgesia with 40% reduction of morphine equivalent dosing
- **Enables titration to better pain relief**
  - Unlike morphine and oxycodone where side effects limit efficacy
- **Superior product for acute pain**

# MoxDuo™ Commercialization

- **Expected US launch of MoxDuo™ 2011**
  - Promote unique safety and efficacy profile
  - Leverage broad acceptance of key opinion leaders
  - Engage strategic partners
  - Recruit specialty pharma US sales force
  - Targets US\$10 Billion market for moderate to severe pain
  - Competition goes off patent or disallowed by FDA

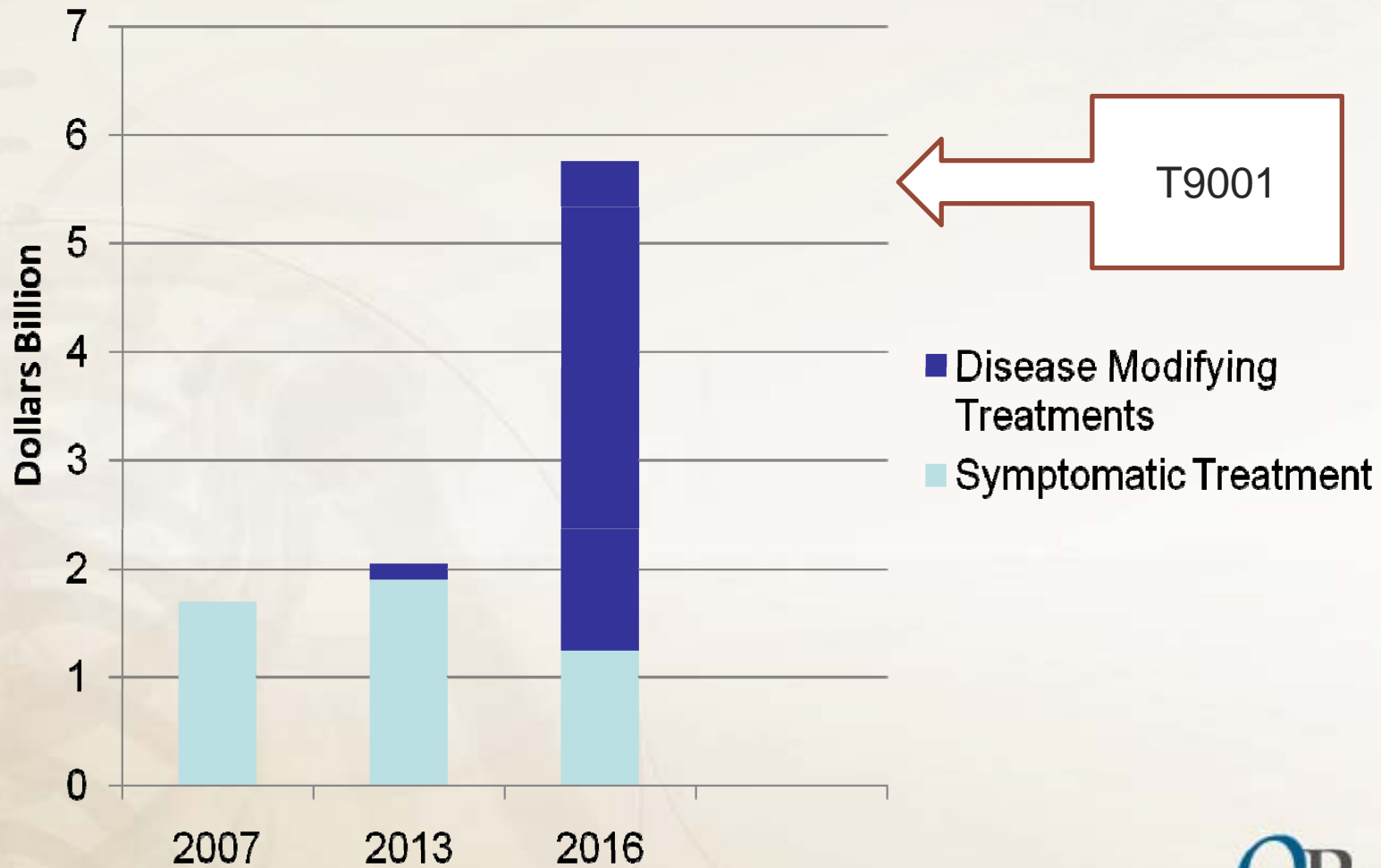
# CNS Program

- **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 via 505(b)(2)

# Lead Candidate: T9001

- **Repositioned small molecule**
  - Activates the Torsin system
    - Maintains proper folding of proteins
    - Combats intracellular stress
    - Integral maintaining normal brain function
  - Early data indicate T9001
    - Prevents mutations linked to neurodegenerative disease
    - Ameliorates pathophysiology of movement disorders
- **Structural analogs provide next generation new chemical entities (NCEs)**
- **Strategic partnerships for co-development**

# Disease Modifying Agents Drive Market Value



# Newsflow (Calendar Year)

- **Q2 2009**

- Comparative study data: MoxDuo™ IR vs. morphine & oxycodone (completed)
- Commence Dual Opioid™ IV Phase 2 Investigator study

- **Q3 2009**

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

# Newsflow (Calendar Year)

- **Q4 2009**

- FDA review MoxDuo™ IR Pain (Orthopedic) study SPA
- Initial strategic partnership
- Commence MoxDuo™ CR Phase 1 study

- **Q1 2010**

- Dual Opioid™ IV Phase 2 Investigator study data
- Model validation & candidate selection of neurodegenerative NCE candidate



# Experienced Management Team

- John Holaday, PhD (CEO)
- Chris Campbell (CFO)
- Warren Stern, PhD (Exec. VP, Drug Development)
- Jesus Soriano, MD, PhD, MBA (Exec. VP)
- Patricia Richards, MD, PhD (Chief Medical Officer)
- Phil Magistro (VP Commercial Operations)
- Joe Berry (VP Technical Operations)

# Leading Scientific Advisory Board

- Solomon H Snyder, MD, Chairman
- Lester Crawford, DVM, PhD
- Robert H Lenox, MD
- Felix A de la Iglesia, MD
- Guy A Caldwell, PhD
- Michael J Cousins, MD, AM
- Horace H Loh, PhD
- Anthony J Sinskey, ScD
- Gavril Pasternak, MD, PhD

# QRxPharma Value Proposition

- Strategic relationships; opportunities to accelerate product commercialization
- Public Company listed in Australia and U.S.
- Low burn rate, two years cash - A\$25.4 million (31 March 2009)
- Pipeline of Dual-Opioid™ & CNS products
- Executive team of pharmaceutical industry veterans
- Highly credentialed management team & SAB