QRx Pharma

Company Overview

March 2013

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Morphine + Oxycodone

QRxPharma Snapshot

- Australian based pain drug developer with offices in Sydney and Bedminster, NJ (ASX:QRX, OTCQX:QRXPY)
- Comprehensive 'hospital to home' MOXDUO portfolio and product line adjacencies
- Blockbuster potential: $14 billion annual market opportunity[1]
- Strategic commercialisation collaborations with Actavis Inc. (US) and Paladin Labs Inc. (Canada)
- Immediate release MOXDUO US Filing Status:
  - Complete Response Letter (CRL) issued by the US FDA in June 2012
  - NDA refiled February 2013; FDA Advisory Committee mid- 2013; FDA decision anticipated Q3 2013

Source: [1] Avos Life Sciences (Decision Resources)

Solid Foundation for Growth

- MOXDUO delivers equal or better pain relief with fewer side effects than current treatments
- Patent exclusivity expected through 2029
- Potential changes in US regulatory policy are favourable for commercialisation of MOXDUO IR
- Double digit royalties on sales of MOXDUO IR in the US and Canada
- Experienced management team and board of directors
- KOL confidence in MOXDUO IR as a potential therapeutic option; Company commitment to bringing product to market

MOXDUO Product Portfolio
From Hospital to Home

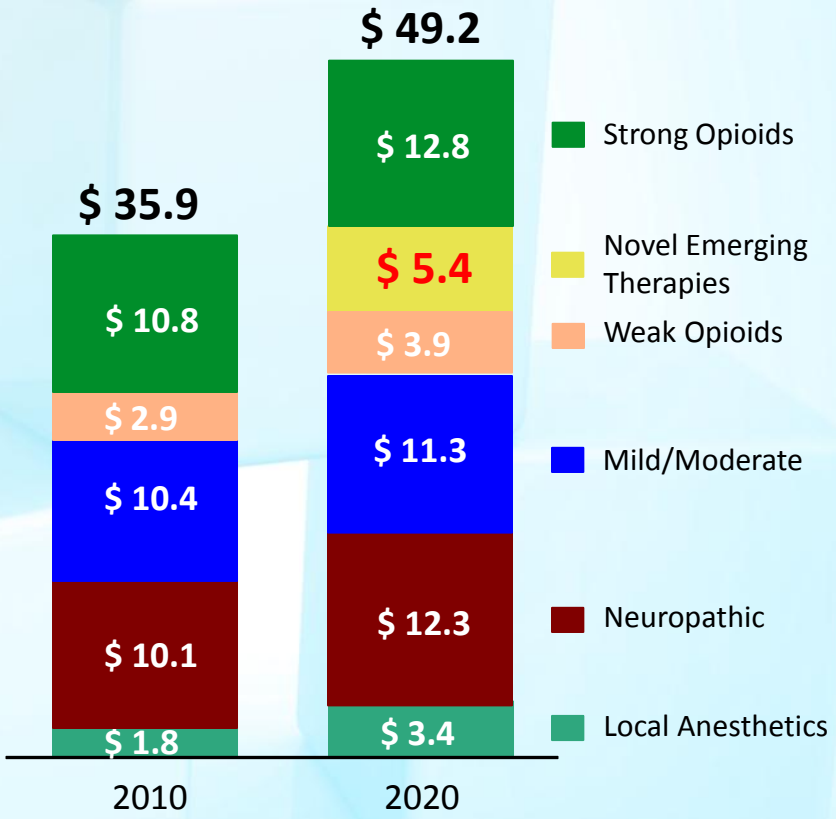
	MOXDUO® IR	MOXDUO® CR	MOXDUO® IV
Delivery	Immediate Release	Controlled Release	Intravenous
Target	Moderate to severe acute pain	Chronic pain (i.e. osteoarthritis, back, neuropathic)	Hospital based: moderate to severe acute pain
Formulation	Oral Capsule	Oral tablet w/abuse deterrent	Injectable
Partnerships	Actavis Inc. and Paladin Labs Inc. *US and Canada commercialisation*		
Status	NDA refiled February 2013 in response to CRL MAA filings – Canada, Europe and Australia in 1H 2013	Phase 1 Complete	Phase 2 Formulation development

THE PAIN MARKET

Current Global Pain Market

Drug Class Sales for Pain in Major Pharmaceutical Markets, 2010 – 2020 (US$ billions) [1]

- Large market opportunity: US$14 billion[1]
- **Opioids are the "gold standard"**
- Limited product innovation
- Strong opioids forecasted to maintain sales dominance through 2020 (aging population)
- **Payors and KOLs: "need for better pain relief with fewer side effects"**



Source: [1] Avos Life Sciences (Decision Resources)

Acute Pain Market
AT-A-GLANCE

US Market Opportunity

- $2.5B US Market with 230M+ annual Rxs (CAGR of 5-6%)
- Acute pain affects 75M Americans
- Limited product innovation; regulatory hurdles for new therapies
- Limited branded competition expected near-term

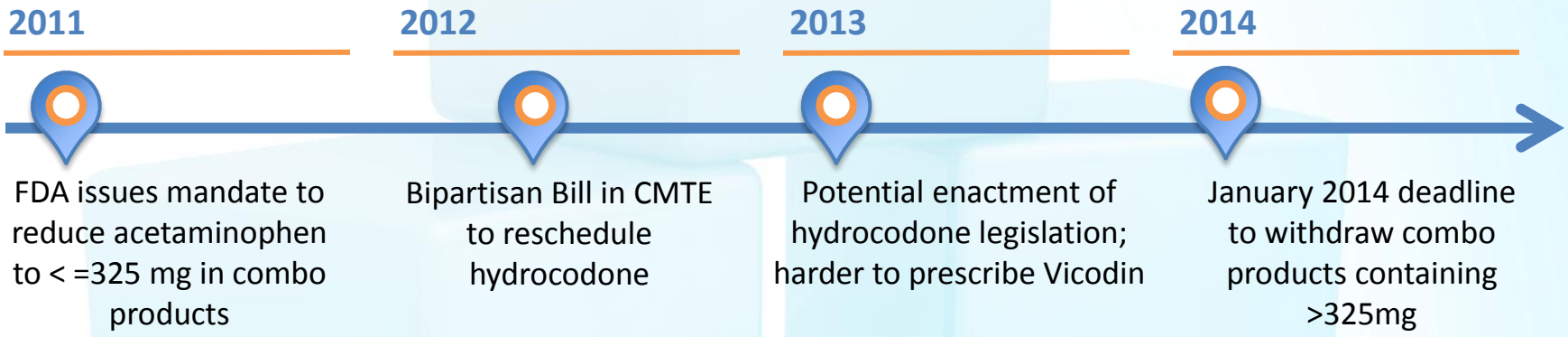
Clinical Unmet Needs

- Inadequate postoperative pain management
- Reduction in opioid-related AEs, specifically GI & CNS that limit their use
- Existing acute pain drugs associated with hepatic and GI toxicities

In the US, 7+ prescriptions are written for an acute opioid every second.

Source: Datamonitor 2010. Decision Resource IMS 2012.

Proposed U.S. Regulatory Changes



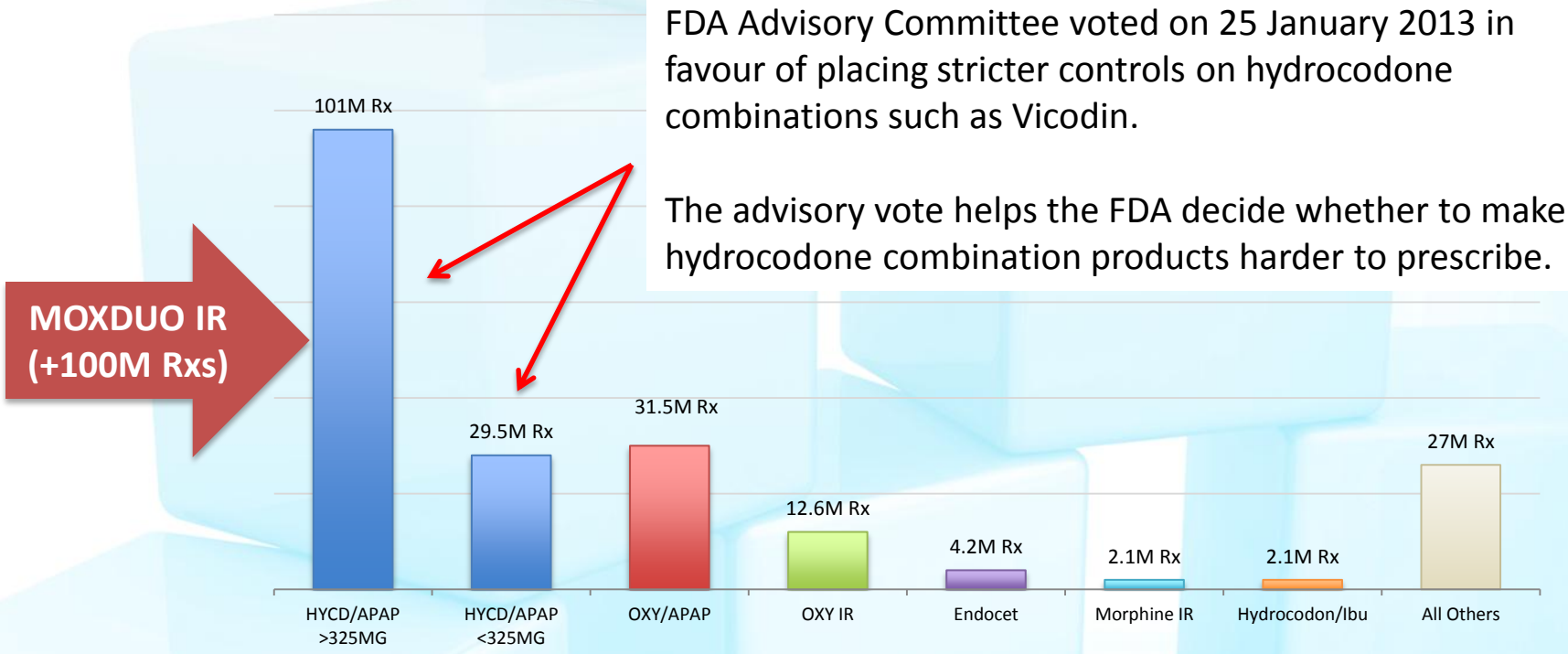
- FDA mandated lower strength opioid; APAP combos will decrease efficacy and increase number of patients needing acute pain medicine
- Creates void in approximately 50% of acute pain market (100 million Rx's)
- Potential rescheduling of Vicodin to Schedule 2 will even the playing field, placing 130 million Rx's in play
- Assuming approval, MOXDUO will have the majority of the sales/detail voice, launching in Q4 2013

Disrupted Acute Pain Market Provides MOXDUO IR Opportunity

2010 US Prescription Market Share for Acute Pain Opioids

FDA Advisory Committee voted on 25 January 2013 in favour of placing stricter controls on hydrocodone combinations such as Vicodin.

The advisory vote helps the FDA decide whether to make hydrocodone combination products harder to prescribe.



Source: IMS 2010

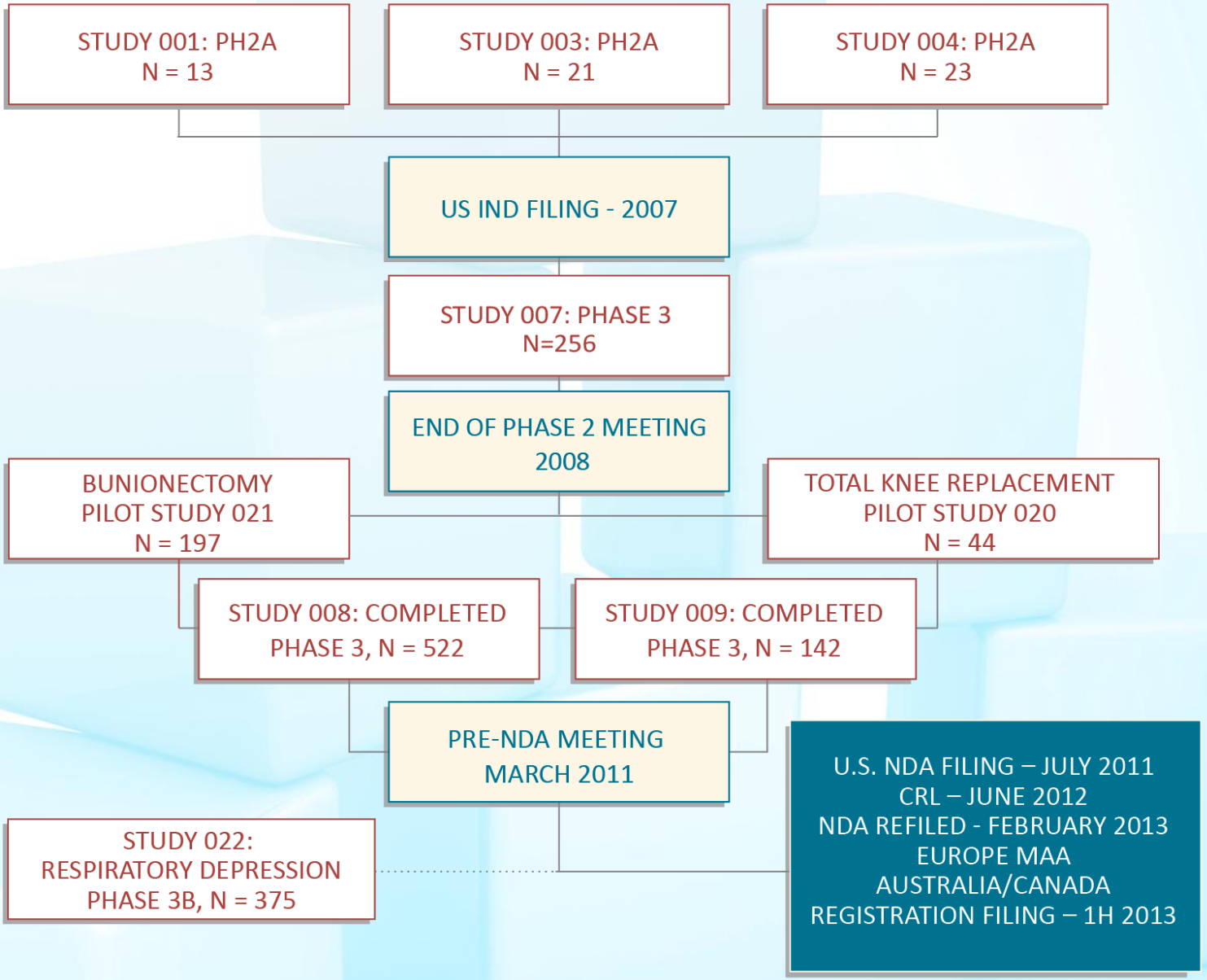
IMMEDIATE RELEASE (IR)

MOXDUO IR Product Profile

Key Features

- First line therapy for the treatment of moderate to severe acute pain
- Only opioid-opioid combination product available
- Immediate release formulation of morphine and oxycodone in a fixed 3:2 ratio in capsules of the strengths:
  - 3 mg/2 mg
  - 6 mg/4 mg
  - 9 mg/6 mg
  - 12 mg/8 mg
- Four to six hourly dosing
- Demonstrated reduction in the occurrence and intensity of clinically significant opioid-related side effects compared to morphine, oxycodone and Percocet®

MOXDUO Clinical Development Path



Key Trial Conclusions

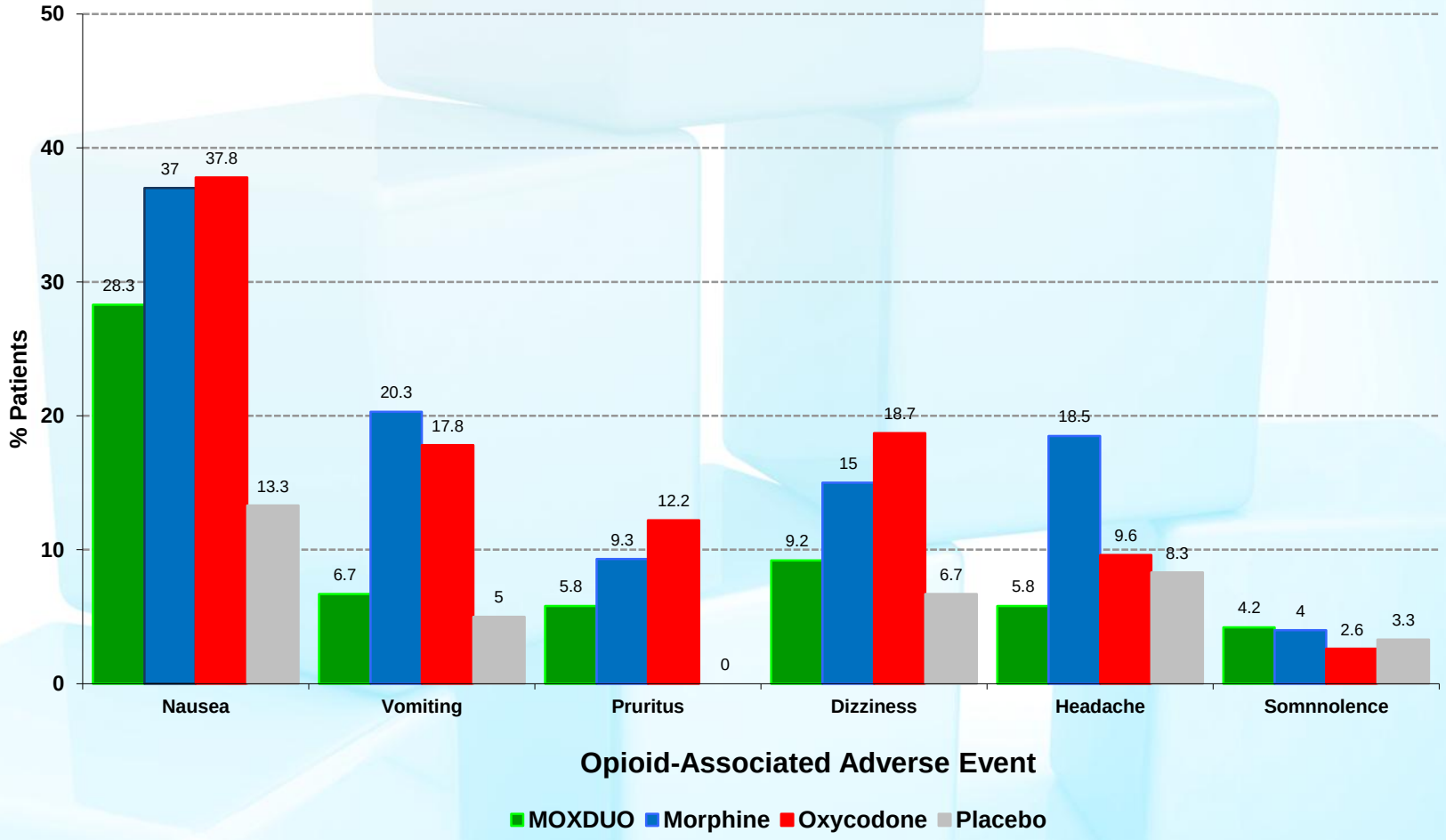
- **Bunionectomy Trials: Pilot 021 & Pivotal 008 (n=719)**
  - Met primary analgesic efficacy endpoint vs. morphine and oxycodone
    - MOXDUO IR proven superior to components on efficacy measures
  - Consistent safety advantage of MOXDUO IR
    - Pilot: 50-75% lower frequency of moderate to severe nausea, vomiting & dizziness compared to equi-analgesic doses of morphine or oxycodone
    - Phase 3: Despite higher dose and better pain relief of MOXDUO than morphine or oxycodone, AE rate and duration not statistically different

Key Trial Conclusions

- **Total Knee Replacement Trials: Pilot 020 & Pivotal 009 (n=186)**
  - Met all primary analgesic efficacy endpoints vs. Percocet
    - Pilot: MOXDUO superior to Percocet
    - Pivotal: MOXDUO high dose better pain relief than low dose
  - Frequency of AEs much lower than Percocet
  - Significant pharmacoeconomic benefit: improved time to walk, sleep, etc.

Tolerability Advantage of MOXDUO

Equi-analgesic doses of MOXDUO, Morphine, Oxycodone, vs. Placebo – All Studies



Oxygen Desaturation Outcomes Study 022

Exploratory Phase 3 Study 022

Respiratory Depression Study

Objectives

- **Europe**: Support MAA as per 2010 Scientific Advice Meeting with the BfArM; comparative AE labeling; respiratory safety advantage; overall risk / benefit
- **US**: Prepare for future definitive studies for comparative AE information in PI
- **US NDA**: Provide important safety information regarding MOXDUO respiratory function advantages relative to equi-analgesic doses of morphine and oxycodone

Study Design and Outcome	
Phase	Phase 3
N	375
US Sites	6
Design	Randomized 1: 1: 1, double-blind, multicenter, repeat dose, 3 arms stratified by gender and by age (≥ 60 yrs or < 60 yrs; 40% of patients were age 60+)
Doses / Schedule	**MoxDuo IR 12 mg/8 mg vs. Morphine 24 mg vs. Oxycodone 16 mg** **Every 6 hours for 48 hours**
Primary Endpoints	Effects of MoxDuo IR relative to morphine and oxycodone comparators on oxygen desaturation, a measure of respiratory impairment
Secondary Endpoints	Percent of subjects with moderate or severe, spontaneously reported, treatment emergent events of nausea, vomiting or dizziness

Effects of Opioids on Blood Oxygen Levels

- Respiratory depression is enhanced by opioids
- Death from opioid overdose is due to respiratory depression
- Pulse oximetry continuously monitors blood oxygen levels (SpO_2) using finger sensor
- SpO_2 normal values 96-100%; <90% = oxygen desaturation
- This study used electronic records of SpO_2 values
- SpO_2 desaturations (intensity and incidence) are key endpoints

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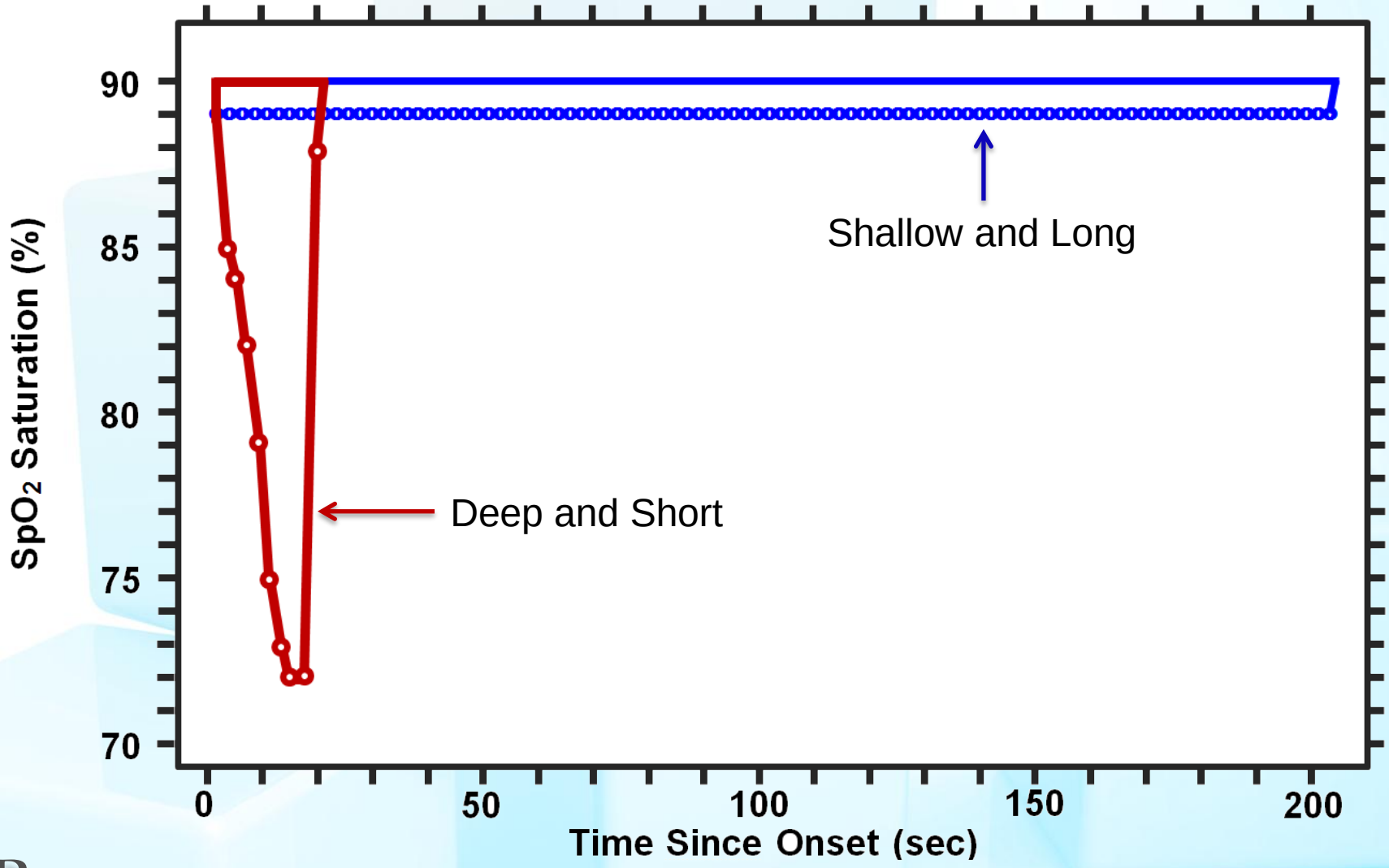
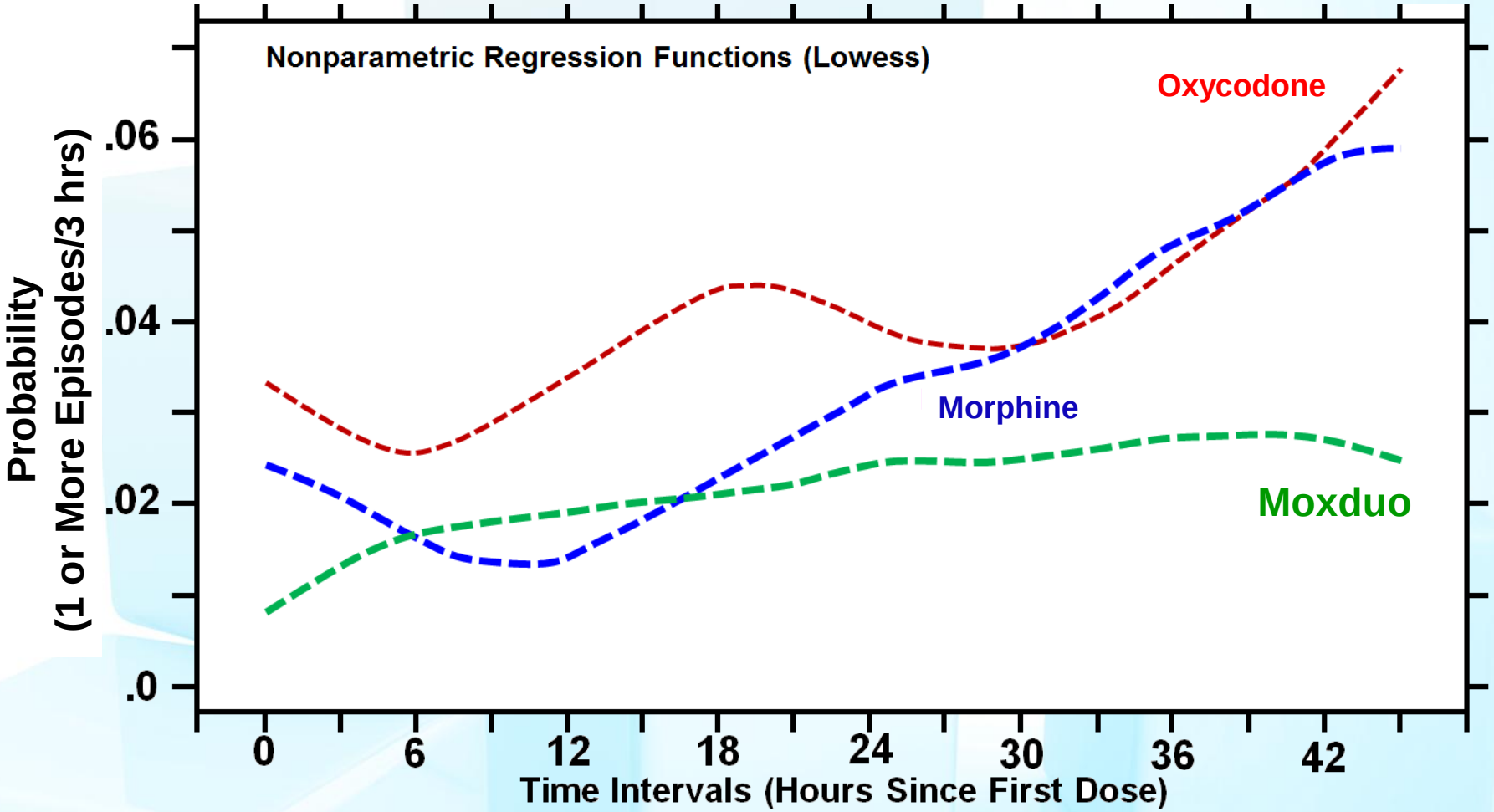
Actual Curves of Different SpO_2 Desaturations

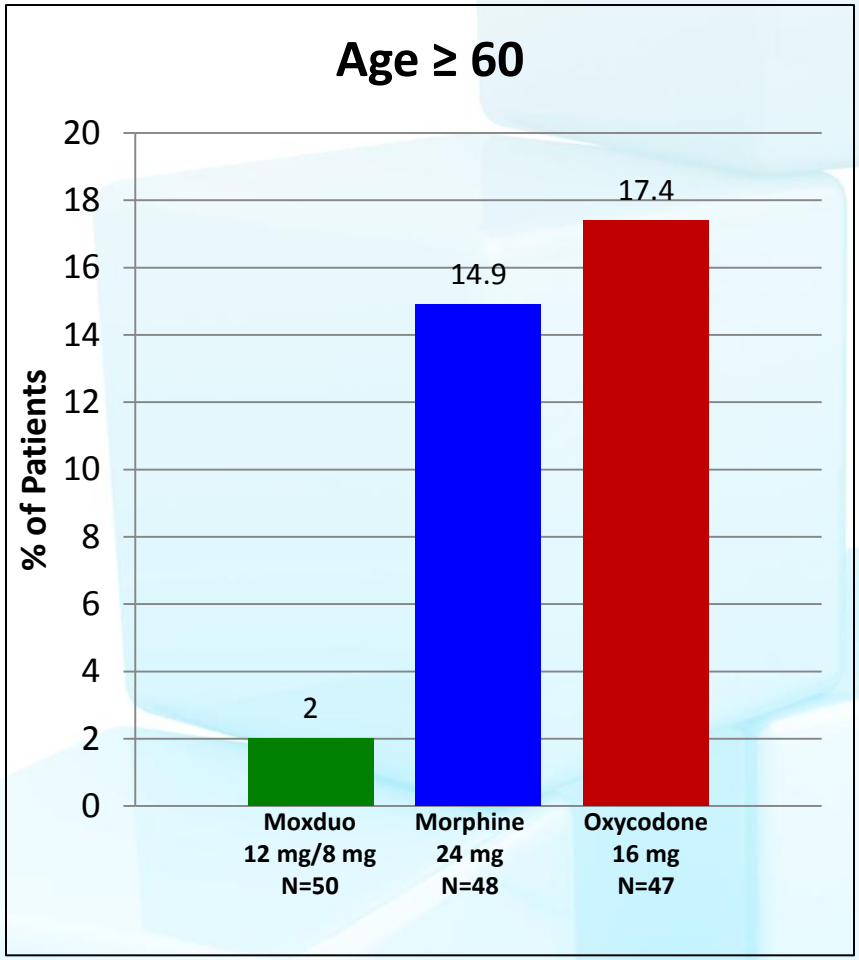


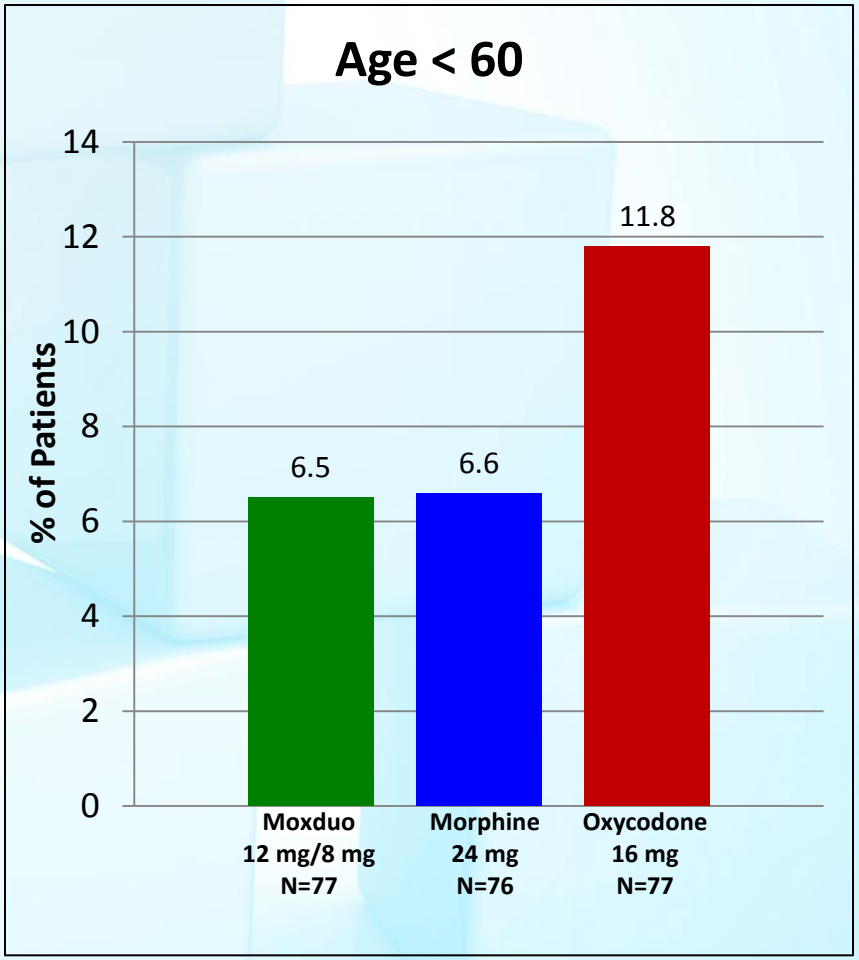
Probability of Having a Serious* O_2 Desaturation



*Below 80% SpO_2

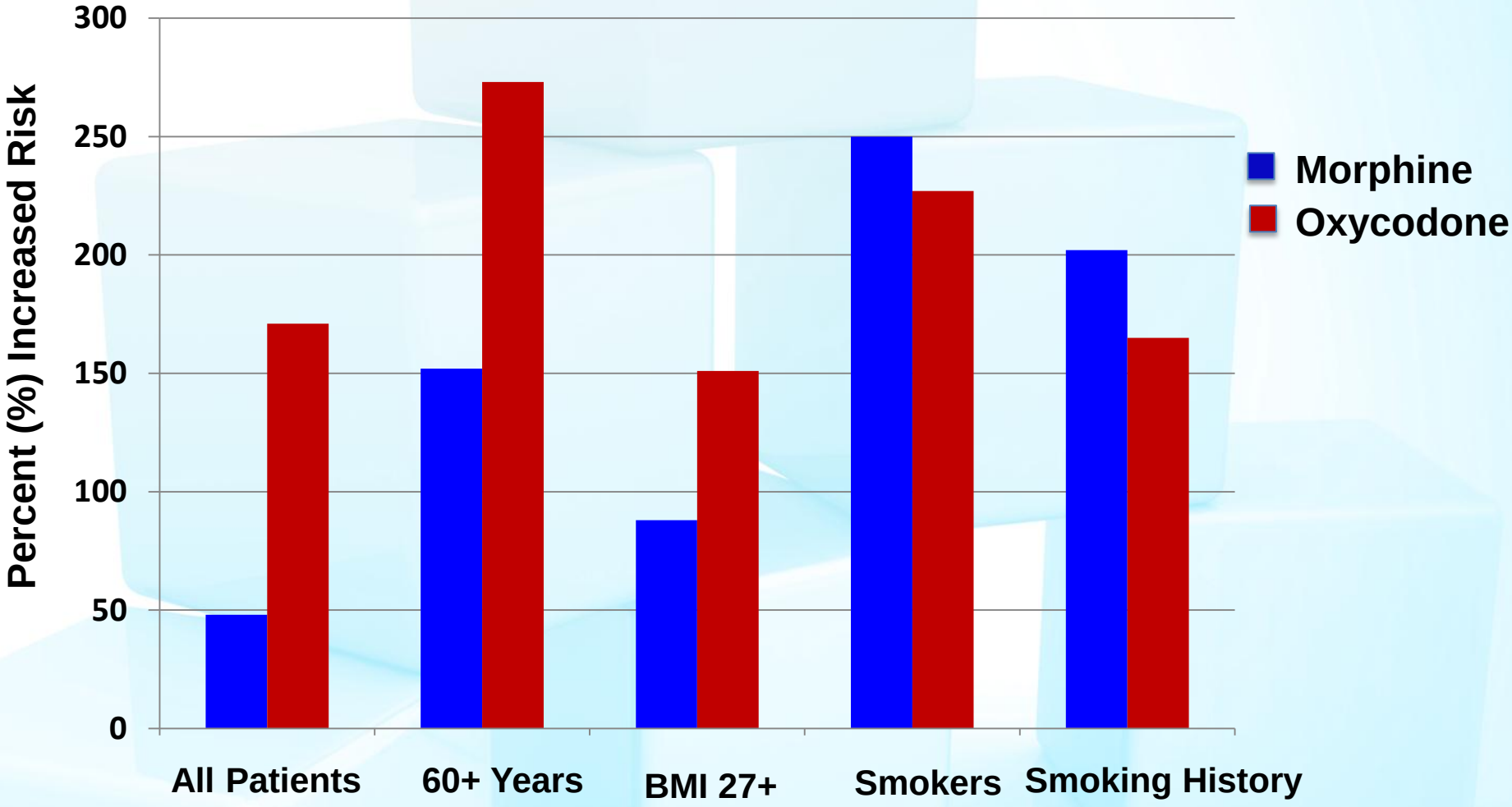
Effect of Age on Observed Very Serious* O_2 Desaturations





*Below 70% SpO_2

Increased Percent Chance of Having a Deep Oxygen Desaturation* by Risk Factor, Relative to MOXDUO



* SpO_2 at or below 75%

Respiratory Safety Conclusions

- Data demonstrate a beneficial safety signal relative to equi-analgesic doses of morphine and oxycodone
- Risk of patients experiencing medically significant desaturations is appreciably less for MOXDUO than morphine or oxycodone
- Lower likelihood of severe desaturations over time may reduce respiratory morbidity when patients are discharged from the hospital
- Data from older patients (≥ 60 y/o) provides evidence of a respiratory safety benefit for MOXDUO in an important patient subpopulation

Conclusions

- Patients receiving morphine or oxycodone were 9%-96% more likely to experience an opioid-like adverse event than MOXDUO treated patients
- When compared to equal-analgesic doses of either morphine or oxycodone, differences in favor of MOXDUO were seen for the following TEAES
  - Nausea, vomiting, dizziness, pruritus, headache, somnolence/sedation and oxygen desaturation

MOXDUO Safety Advantage

STUDIES OF COMBINED OPIOIDS CONSISTENTLY PROVIDE EQUIVALENT EFFICACY WITH A SIGNIFICANT REDUCTION IN OPIOID-RELATED MODERATE TO SEVERE ADVERSE EVENTS

QRx STUDIES

MOXDUO IR Study 022 (bunionectomy)	>	Oxygen desaturation less severe and of shorter duration compared to equianalgesic doses of Morphine or Oxycodone
MOXDUO IR Study 021 (bunionectomy)	>	50-75% reduction in moderate to severe nausea, vomiting and dizziness compared to equianalgesic doses of Morphine and Oxycodone
MOXDUO IR Study 020 (knee replacement)	>	100% reduction in moderate to severe nausea and vomiting compared to the Percocet
MOXDUO IV Study (hip replacement)	>	35% reduction in nausea and 38% reduction in vomiting compared to IV Morphine
MOXDUO Two Phase 2 trials in Australia (chronic pain)	>	34-40% decrease in the amount of drug to achieve equianalgesia compared to oral morphine. Decreased rate of drowsiness, dizziness, constipation and nausea.

INDEPENDENT STUDIES[1]

Blumenthal et al 2007 (Spinal discectomy)	>	80-100% reduction in nausea and vomiting compared to PCA Morphine
Jamison et al 1998 (Chronic low back pain)	>	17-49% reduction in intensity of a range of adverse events compared to Oxycodone
Lauretti et al 2004 (Cancer pain)	>	86% reduction in nausea and 100% reduction in vomiting compared to Morphine

[1]*Full references upon request.*

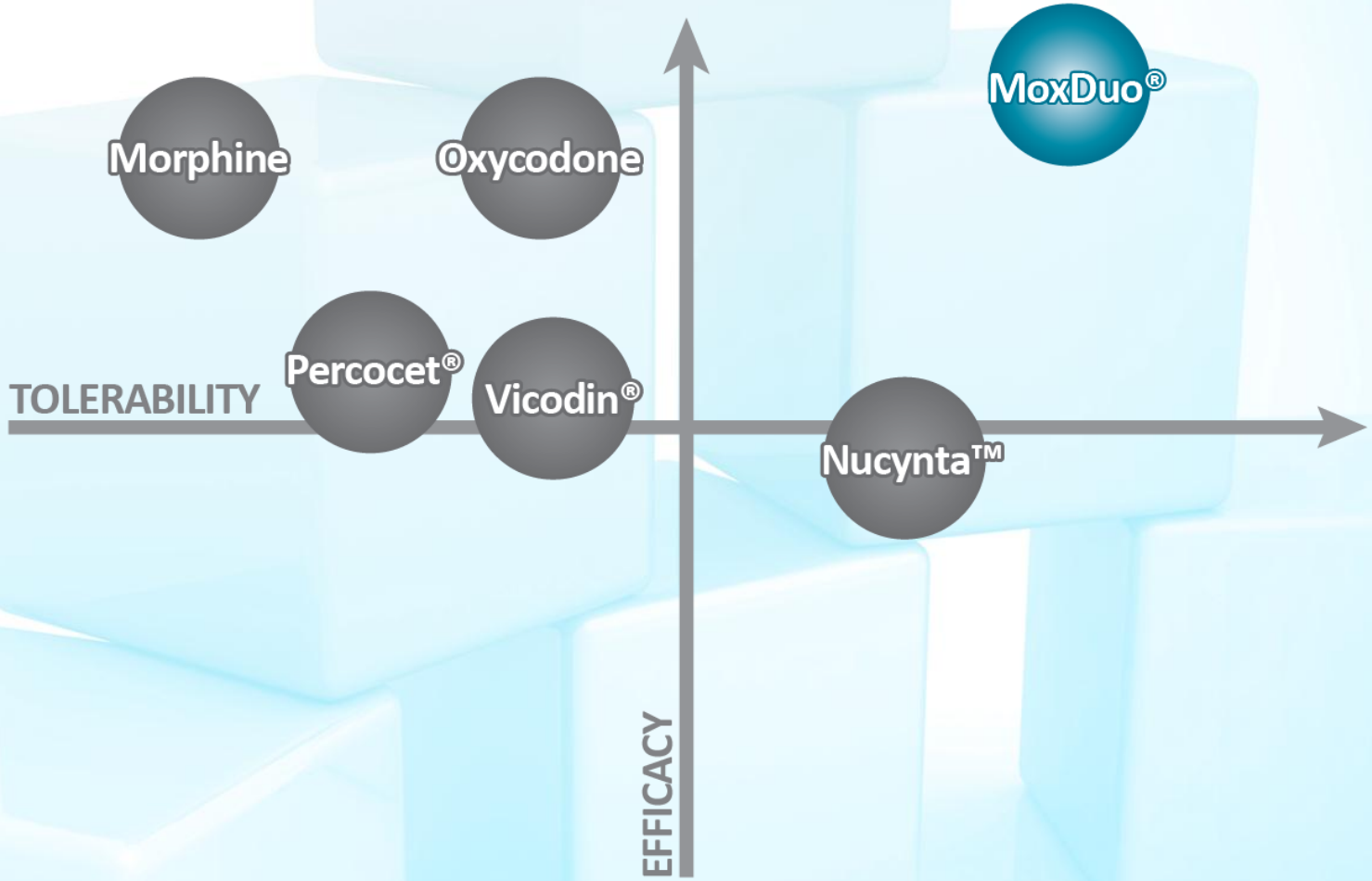
MOXDUO Pharmacoeconomic Benefits

- Versus Percocet® TKR study, MOXDUO IR patients were out of bed faster, walked and slept better
- US study finds $4,880 - $36,152[1] incremental costs in patients suffering GI side effects following treatment with IR opioids
  - Extended hospitalization, increased nursing care and re-admissions
- Reimbursers, managed care and KOL feedback
  - Significant benefit from decreasing hospitalization by as little as 4 hours or recovery room time by 20 minutes

MOXDUO's advantageous safety profile may improve patient recovery, decrease hospital time and lower total cost of care.

Source: [1] W Kwong, J Diels and S Kavanagh 2010

MOXDUO IR Value Proposition = Greater Tolerability + Equal/Better Analgesia



Immediate Release Commercialisation Plan

Actavis Strategic Partnership

- Exclusive US commercialisation and development rights for MOXDUO IR
  - Actavis pays all product launch, marketing and sales costs
- 10%-30% royalties based on net sales thresholds from launch
  - Except 50% royalty on $150m of cumulative sales (starting circa 3 months following product launch)
- QRxPharma retains a right to co-promotion/profit-share
  - Option to create sales force and provide up to 25% of the effective selling effort to US prescribers after first 12 months of launch
- QRxPharma retains ownership of MOXDUO IR outside the US (and Canada)

Actavis

- Actavis and Watson merger completed November 2012 with Actavis name retained (NYSE: ACT) January 2013
  - Global headquarters Parsippany, NJ and International Headquarters in Zug, Switzerland
  - Third-largest generics prescription drug manufacturer
  - ~$8.0 billion projected 2012 pro forma combined revenue
  - 750 products marketed globally through more than 60 countries
  - Maintaining commitment to branded marketplace
- MOXDUO IR commercialisation preparation ongoing

- Strategic collaboration with Paladin Labs for Canadian commercialisation rights of immediate release MOXDUO
- QRxPharma to receive double-digit royalties and up to US$25M in milestone payments on achievement of specific sales, regulatory and reimbursement targets; upfront payment of US$500,000
- Paladin Labs pays all regulatory, product launch, marketing and sales costs
- QRxPharma retains Canadian rights to MOXDUO IV and CR
- Paladin Labs is a leading specialty pharmaceutical company based in Montreal and listed on the Toronto Stock Exchange
  - Branded pain products include: Metadol®; Pennsaid®; Tridural®; and Abstral®

Mitigating Reimbursement Risk

- Appropriate pricing, contracting and patient pull-through
- Advantaged market – other acute pain products (Vicodin® and Percocet®) being reduced due to safety issues and potential rescheduling
- Potential for significant pharmacoeconomic benefits recognized by payers/KOLs
- Reimbursement strategy = Tier 3 Formulary
  - Insurance companies will not have to pay more
  - Customer co-pays are manageable

Pipeline Potential

MOXDUO CR (Controlled Release)

- Sustained release formulation to provide at least 12 hours of analgesia for moderate to severe chronic pain
- Abuse deterrent and tamper resistant features
- Phase 1 results showed:
  - High bioavailability and complete absorption
  - One fifth the variability of OxyContin; will provide very stable plasma levels when given twice daily
  - Lower peaks and higher troughs should lead to better safety & lower side effects; better tolerability at higher doses
  - Should be an effective once or twice daily treatment
- Current formulation will progress to Phase 2

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MOXDUO: Peak Sales Potential

	MOXDUO IR	MOXDUO CR	MOXDUO IV
Market Size	▪ ~200 mm Rx (2012) ▪ Annual market growth 1.0% ▪ QRx targets ~ 50% of market	▪ ~34 mm Rx (2015) ▪ Annual market growth 3.0% ▪ QRx targets 100% of market	▪ ~29 mm Rx (2014)[1] ▪ Annual market growth 1.0% ▪ QRx targets 100% of market
Market Penetration	▪ Initial share: 1.0% (2012) ▪ Peak share: 5.0% (2015)	▪ Initial share: 1.4% (2015) ▪ Peak share: 13.9% (2020)	▪ Initial share: 1.5% (2014) ▪ Peak share: 13.0% (2018)
Pricing	▪ Initial price: $112 based on 4 doses per day and 14 days of therapy ▪ Annual price increase: 5.0% ▪ **Peak sales: ~$680 mm**	▪ Initial Rx Price: $180 based on 2 doses per day and 30 days of therapy ▪ Annual price increase: 5.0% ▪ **Peak net sales: ~$1,300 mm**	▪ Initial price: $32 based on 4 vials per day and 2 days of therapy ▪ Annual price increase: 5.0% ▪ **Peak net sales: ~$150 mm**
Blockbuster Opportunity	▪ Paracetamol Limitation -**Peak sales: ~$1,350 mm** ▪ plus Vicodin Rescheduling - **Peak sales: ~$2,000 mm**	▪ **Oxycontin - $3 billion/year - off patent in 2013, opening market for MOXDUO CR in 2015**	

1 Rx represents "eaches".

Company Overview

Leadership Team

Senior Management

- John Holaday, PhD (CEO)
- Ed Rudnic, PhD (COO)
- Chris Campbell (CFO)
- Warren Stern, PhD (Clinical Consultant)
- Janette Dixon, PhD (VP Global BD)
- Patricia Richards, MD, PhD (CMO)

Board of Directors

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

Scientific Advisory Board

- Solomon Snyder, MD (Chair)
- Lester Crawford, DVM, PhD
- Robert Lenox, MD
- Michael J Cousins, MD, AM
- Horace H Loh, PhD
- Gavril Pasternak, MD, PhD
- Richard Payne, MD

Financial Summary (28 February 2013)

Shares on issue:	145 million (ordinary)
Market cap:	A$145 million
Cash on hand:	
31 December 2012	A$16.6 million (last reported)
Cash burn:	CY2013
Share registry:	+80% institutional / HNW
Listing:	ASX: QRX / OTCQX: QRXPY

MOXDUO IR Key Milestones

DATE	MILESTONE
✓ July 2011	NDA submission to FDA
✓ December 2011	Signed strategic collaboration with Actavis
✗ 25 June 2012	NDA PDUFA Date; CRL Received
✓ August 2012	FDA Review Meeting
✓ October 2012	Signed strategic collaboration with Paladin
✓ February 2013	MOXDUO NDA Refiled
• Q3, 2013	Anticipated decision from FDA on the refiled MOXDUO NDA
• 1H, 2013	Submit additional regulatory filings: Europe, Australia & Canada
• 2H, 2013	Product launch in the US

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Investment Highlights

- **Comprehensive Portfolio:** MOXDUO delivers equal or better pain relief with fewer side effects than current treatments
- **Commercialisation partnerships: Actavis: US; Paladin Labs: Canada;** MOXDUO IR to be key branded pain product for Actavis
- **Advantaged market:** Favourable US regulatory and potential prescription scheduling changes
- **Blockbuster potential:** Global opioid market estimated at $US14bn[1]
- **Strong IP:** Expected patent exclusivity through 2029
- **Expanded pipeline:** Further progress MOXDUO CR and MOXDUO IV products

Source: [1] Avos Life Sciences (Decision Resources)

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