



#### Company Overview March 2012

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#### **Morphine + Oxycodone**



### **Investment Highlights**

Expected worldwide patent exclusivity through 2029

Blockbuster potential: global opioid market estimated at \$US14bn<sup>1</sup>

MoxDuo IR commercialisation partnership with Actavis, Inc.

Product nearing market; anticipated US launch 3Q CY 2012

US FDA PDUFA date of 25 June for MoxDuo IR (Immediate Release)

'De-Risked' clinical program; 505(b)(2) regulatory path

#### MoxDuo product portfolio offers key advantages

Equal or better pain relief with fewer side effects than morphine, oxycodone and Percocet®



### Acute Pain Market AT-A-GLANCE



#### **US Market Opportunity**

- \$2B+ US Market with 210M+ 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**

- Reduction in opioid-related AEs, specifically GI & CNS
- Inadequate postoperative pain management
- Improved pre-, peri- and postoperative acute pain management

Acute opioid market is very large.

In the US, 6+ prescriptions are written for an acute opioid every second.

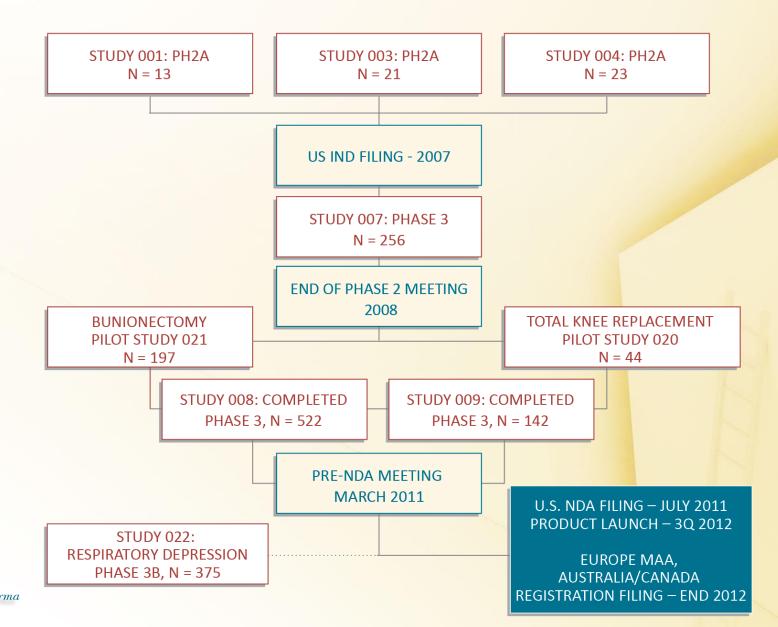


### MoxDuo Product Portfolio: From Hospital to Home

	MoxDuo®IR	MoxDuo <sup>®</sup> CR	MoxDuo <sup>®</sup> IV
Delivery	Immediate Release	Controlled Release	Intravenous
Status	U.S. FDA PDUFA Date 25 June 2012	Phase 1	Phase 2; concurrent formulation development
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. US commercialisation		Aoxing Pharmaceuticals Strategic Alliance



### **MoxDuo IR Clinical Development Path**



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## **MoxDuo Safety Advantage**

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

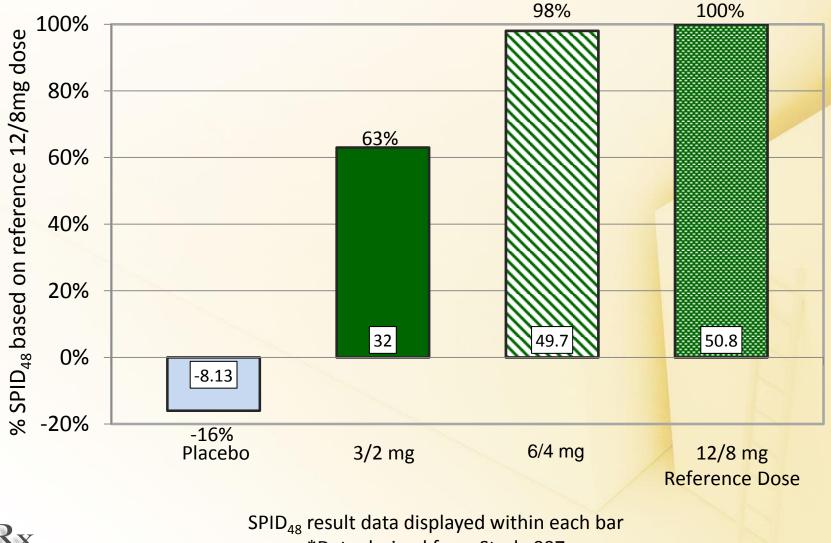
QRx STUDIES		
MoxDuo IR Study 022 (bunionectomy)	>	Oxygen desaturation less severe and of shorter duration compared to equianalgesic doses of Morphine or Oxycodone
MoxDuo IR Study 021 (bunionectomy)	>	50-75% reduction in moderate to severe nausea, vomiting and dizziness compared to equianalgesic doses of Morphine and Oxycodone
MoxDuo IR Study 020 (knee replacement)	>	100% reduction in moderate to severe nausea and emesis compared to the Percocet
MoxDuo IV Study (hip replacement)	>	35% reduction in nausea and 38% reduction in emesis 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<sup>1</sup>

Blumenthal et al 2007 (Spinal discectomy)	>	80-100% reduction in nausea and emesis 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 emesis compared to Morphine.



#### **MoxDuo IR Pain Relief Compared to Placebo\***

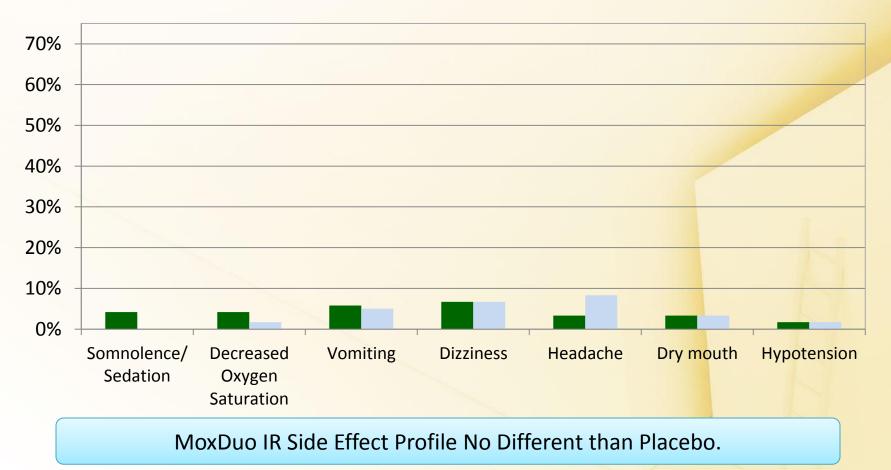


\*Data derived from Study 007

### Adverse Reactions Reported by at Least 2% of Patients Receiving Analgesic MoxDuo IR Doses

MoxDuo 3 mg/2 mg to 6mg/4mg N=120 n (%)

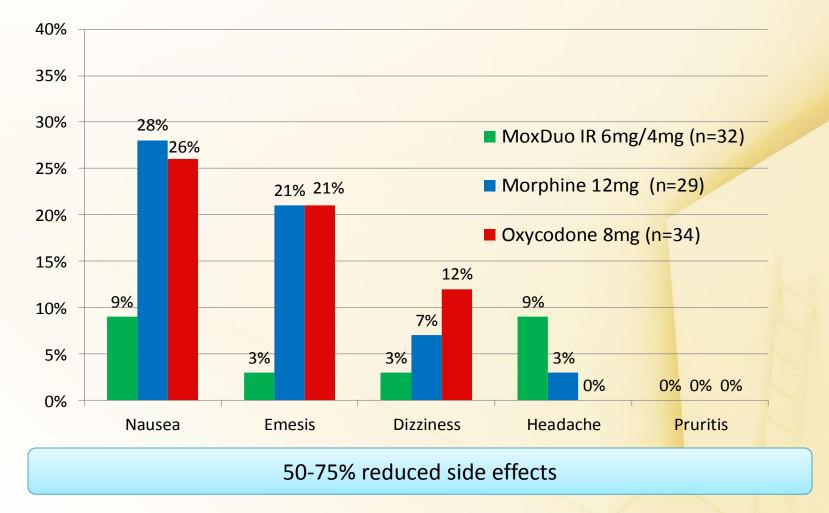
Placebo N=60 n (%)





Referenced from MoxDuo Draft Package Insert Section 6.1, Table 2

### Same Pain Relief; Fewer Side Effects than Morphine and Oxycodone





## **MoxDuo Pharmacoeconomic Benefits**

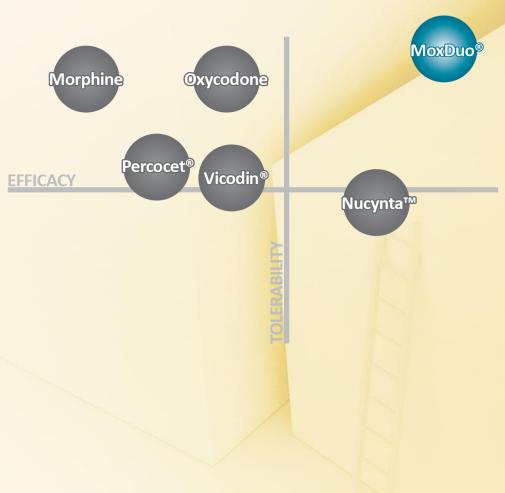
- TKR study demonstrated compared to Percocet<sup>®</sup> patients treated with MoxDuo IR were out of bed faster, walked and slept better
- Industry estimates up to \$30,000 per patient is spent on managing opioid-related side effects<sup>1</sup>
  - Extended hospitalization, increased nursing care and re-admissions
- QRxPharma met with reimbursers, managed care providers and KOLs
  - Decreasing hospitalization by as little as 4 hours, or recovery room time by 20 minutes, would be an enormous benefit and enhance MoxDuo IR prescriptions

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



#### **MoxDuo Value Proposition = Greater Tolerability**

- Increases therapeutic window; enables titration of effectiveness in severe pain
- Delivers equivalent analgesia and greater safety than standard regimens
- Less risk of opioid-induced respiratory failure
- Broad patient suitability; expanded utilization of a known, established and physician-trusted drug class
- Pharmacoeconomic benefit: faster hospital discharge and rehab; lower associated healthcare costs







#### **MoxDuo IR Commercialisation Plan**



### **MoxDuo IR: Actavis Strategic Partnership**

- Actavis has exclusive commercialisation and development rights in US; pays all product launch, marketing and sales costs
- QRxPharma Royalties: 10%-30% based on net sales thresholds from launch
  - Except for a period starting 3-6 months following launch, where QRxPharma will receive a 50% royalty on US\$150 million in cumulative sales
- QRxPharma retains a co-promotion/profit-share right
  - Create sales force and provide up to 25% of the effective selling effort to US prescribers at any time following first 12 months after launch
- QRxPharma retains full flexibility to market MoxDuo IR outside US
- Binding LOI secured by US\$6M non-refundable, upfront signing fee payment





- Wholly owned US subsidiary of Actavis Group hf, a privately held European company
  - Revenues of ~EUR 1.8 billion & 10,000 employees worldwide
- World's 4<sup>th</sup> largest generic pharmaceutical company; leading manufacturer of branded and generic opioids worldwide
  - US sales highlighted by Kadian<sup>®</sup> (extended release morphine)
- MoxDuo IR to be Actavis flagship as Kadian transitions to generic market
- US Launch of MoxDuo IR anticipated in 3Q CY 2012
  - Pre-launch preparations underway



### **Commercialisation Strategy**

#### Q1 2012

- > Launch strategy finalized
- Existing 60 person pain sales force stays in place, training programme underway
- Implement medical science liaison strategy and stake holder targeting

#### Q2 2012

- > Implement pre-launch messaging strategy
  - Identify and prioritize access channels
  - Appropriate pricing, contracting and patient pull-through
- > Identify key geographic areas for activity
- > Implement MoxDuo pre-launch promotional message
- > Begin recruitment of additional Actavis territory managers,
- > Expand sales force to 120 with ultimate goal of up to 200 reps

#### Q3 2012

- Continued sales force expansion, ship trade product, secure Federal Supply listing
- Launch product (intensify stakeholder outreach: physicians, MCOs, pharmacies, institutions)

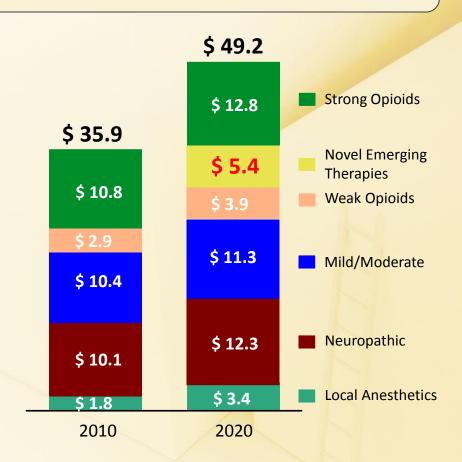




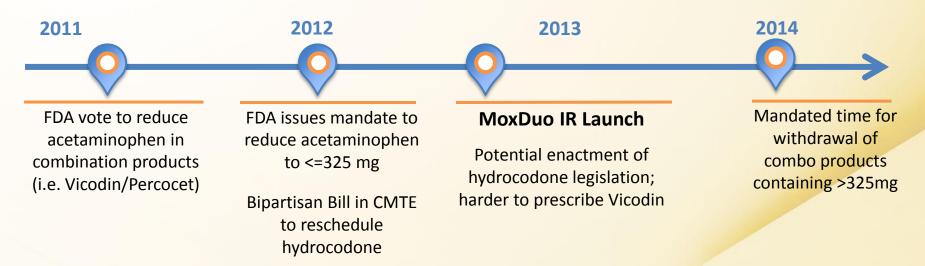
## **Current Global Pain Market**

- Large market opportunity: US\$14 billion<sup>1</sup>
- 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"

Drug Class Sales for Pain in Major Pharmaceutical Markets, 2010 – 2020 (US\$ billions) <sup>1</sup>



### **Acute Pain Market Future**



#### MoxDuo IR launches into advantaged market

- FDA mandated lower strength opioid/APAP combos will decrease efficacy and increase number of patients needing acute pain medicine
- Potential rescheduling of Vicodin to Schedule 2 will make it harder to prescribe and decrease number of prescriptions



## Disrupted Acute Pain Market Provides MoxDuo IR Opportunity

2010 US Prescription Market Share for Acute Pain Opioids





## **Mitigating Reimbursement Risk**

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



## **MoxDuo: US Peak Sales Potential**

	MoxDuo IR	MoxDuo CR	MoxDuo IV
Market Size	■ ~200 mm Rx (2012)	■ ~34 mm Rx (2015)	■ ~29 mm Rx (2014) <sup>1</sup>
	Annual market growth 1.0%	Annual market growth 3.0%	Annual market growth 1.0%
	• QRx targets ~ 50% of market	• QRx targets 100% of market	• QRx targets 100% of market
Market	Initial share: 1.0% (2012)	<ul> <li>Initial share: 1.4% (2015)</li> </ul>	Initial share: 1.5% (2014)
Penetration	Peak share: 5.0% (2015)	Peak share: 13.9% (2020)	Peak share: 13.0% (2018)
Pricing	<ul> <li>Initial price: \$112 based on 4 doses per day and 14 days of therapy</li> </ul>	<ul> <li>Initial Rx Price: \$180 based on 2 doses per day and 30 days of therapy</li> </ul>	<ul> <li>Initial price: \$32 based on 4 vials per day and 2 days of therapy</li> </ul>
	Annual price increase: 5.0%	Annual price increase: 5.0%	Annual price increase: 5.0%
	■ Peak sales: ~\$680 mm	Peak net sales: ~\$1,300 mm	Peak net sales: ~\$150 mm
Blockbuster	Paracetamol Limitation -Peak sales: ~\$1,250 mm	• OxyContin - \$3 billion/year - off	
Opportunity	sales: ~\$1,350 mm ■ plus Vicodin Rescheduling - Peak sales: ~\$2,000 mm	patent in 2013, opening market for MoxDuo CR in 2015	





#### **Company Overview**



## **Leadership Team**

#### **Senior Management**

- John Holaday, PhD (CEO)
- Chris Campbell (CFO)
- Ed Rudnic, PhD (COO)
- Richard Paul, MD (EVP Drug Development)
- Warren Stern, PhD (Clinical Consultant)
- Janette Dixon, PhD (VP Global BD)
- Patricia Richards, MD, PhD (CMO)
- Phil Magistro (Chief Commercial Officer)
- Steve Casey (VP Corporate Development)

#### **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 (1 March 2012)

Shares on issue:	144 million (ordinary)
Market cap:	A\$265 million
Cash on hand:	
31 December 2011	A\$32.9 million (last reported)
Cash burn:	FY2013*
Share registry:	+80% institutional / HNW
Listing:	ASX: QRX / OTCQX: QRXPY

\*Future burn to be offset from royalties post launch of MoxDuo IR in US



### Value Drivers: Key Milestones

JULY 2011	> MoxDuo IR NDA submission to US FDA
DECEMBER 2011	> Strategic partnership signed with Actavis, Inc.
25 JUNE 2012	> US FDA PDUFA Date
Q3, 2012	> Bring MoxDuo IR to market with Actavis
CY 2012	<ul> <li>MoxDuo CR for chronic pain: complete three Phase 1 trials and initiate Phase 2 trial</li> <li>Submit Marketing Authorisation Application (MAA) in Europe and Australia/Canada NDA for MoxDuo IR</li> </ul>



## **Investment Highlights**

- Product nearing market: Anticipated US launch 3Q CY 2012; US FDA PDUFA date of 25 June for MoxDuo IR
- Actavis commercialization partnership: MoxDuo IR to be flagship product
- Advantaged market: regulatory and potential prescription scheduling changes in US are favourable for MoxDuo IR commercialization
- Blockbuster potential: global opioid market estimated at \$US14bn<sup>1</sup>
- **Strong IP:** Expected worldwide patent exclusivity through 2029
- Cash Inflows: further progress MoxDuo CR and MoxDuo IV products



#### **QRxPharma Contact Information**

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# Appendix



## **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<sup>®</sup>



## **MoxDuo IR: Key Trial Conclusions**

- Bunionectomy Trials: Pilot 021 and Pivotal 008 (n=719 patients)
  - Satisfied FDA Combination Rule
  - Met primary analgesic efficacy endpoint vs. morphine and oxycodone
    - MoxDuo IR proven superior to components on efficacy measures
  - Consistent safety advantage
    - Pilot: 50% -75% lower frequency of moderate to severe nausea, vomiting and dizziness when 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
- Total Knee Replacement Trials: Pilot 020 and Pivotal 009 (n=186 patients)
  - Met all primary analgesic efficacy endpoint 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 (time to walk, sleep, etc. improved)



## **Respiratory Adverse Events Study 022**

- Respiratory depression is the leading cause of death from opioids
- MoxDuo IR Phase 3B showed significant respiratory advantage; primary comparative study objective
- Secondary endpoints also show advantage
  - Moderate to severe vomiting was significantly (p<0.05) reduced (32% vs. 42%) in MoxDuo IR treated subjects compared to oxycodone alone
  - MoxDuo IR produced significantly less vomiting than oxycodone (despite FDA requirement to administer anti-nausea medication to patients that vomited)
- Regulatory impact
  - Met safety threshold for BfArM (European regulatory authority) to support planned EU MAA filing in 2012
  - Can augment U.S. NDA although not required for product approval

To our knowledge, a safety benefit for adverse respiratory changes has never been reported for any opioid





- Pain drug developer with comprehensive portfolio around MoxDuo<sup>®</sup> product line
  - Multiple clinical trials for IR (Immediate Release) formulation have shown equal or better pain relief with fewer side effects than current standard of care: morphine, oxycodone and Percocet<sup>®</sup>
  - Pipeline contains Controlled Release (CR) and Intravenous (IV) formulations of MoxDuo for "hospital-to-home" pain management
- Imminent product launch (3Q 2012) of MoxDuo IR in US market with commercialisation partner
- \$US14 billion<sup>1</sup> global opioid market
- Strong international IP position with expected exclusivity through 2029

