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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 refiling in Q1 2013; FDA Advisory Committee Q2 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

<table>
<thead>
<tr>
<th></th>
<th>MOXDUO® IR</th>
<th>MOXDUO® CR</th>
<th>MOXDUO® IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Delivery</strong></td>
<td>Immediate Release</td>
<td>Controlled Release</td>
<td>Intravenous</td>
</tr>
<tr>
<td><strong>Target</strong></td>
<td>Moderate to severe acute pain</td>
<td>Chronic pain (i.e. osteoarthritis, back, neuropathic)</td>
<td>Hospital based: moderate to severe acute pain</td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>Oral Capsule</td>
<td>Oral tablet w/abuse deterrent</td>
<td>Injectable</td>
</tr>
<tr>
<td><strong>Partnerships</strong></td>
<td>Actavis Inc. and Paladin Labs Inc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>US and Canada commercialisation</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>NDA to be refiled Q1 2013 in response to CRL MAA filings – Canada, Europe and Australia in 1H 2013</td>
<td>Phase 1 Complete</td>
<td>Phase 2 Formulation development</td>
</tr>
</tbody>
</table>
THE PAIN MARKET
Current Global Pain Market

- Large market opportunity: US$14 billion¹
- 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) ¹

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.

Proposed U.S. Regulatory Changes

2011
- FDA issues mandate to reduce acetaminophen to ≤325 mg in combo products

2012
- Bipartisan Bill in CMTE to reschedule hydrocodone

2013
- Potential enactment of hydrocodone legislation; harder to prescribe Vicodin

2014
- January 2014 deadline to withdraw combo products containing >325mg

- 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 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

MOXDUO IR (+100M Rxs)

FDAt 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

- **STUDY 001: PH2A**
  - N = 13

- **STUDY 003: PH2A**
  - N = 21

- **STUDY 004: PH2A**
  - N = 23

- **US IND FILING - 2007**

- **STUDY 007: PHASE 3**
  - N = 256

  - **END OF PHASE 2 MEETING 2008**

- **BUNIONECTOMY PILOT STUDY 021**
  - N = 197

  - **STUDY 008: COMPLETED PHASE 3, N = 522**

  - **STUDY 009: COMPLETED PHASE 3, N = 142**

- **TOTAL KNEE REPLACEMENT PILOT STUDY 020**
  - N = 44

- **PRE-ND A MEETING MARCH 2011**

- **STUDY 022: RESPIRATORY DEPRESSION PHASE 3B, N = 375**

- **U.S. NDA FILING – JULY 2011**
  - CRL – JUNE 2012
  - NDA RESUBMISSION Q1 2013
  - EUROPE MAA
  - AUSTRALIA / CANADA REGISTRATION FILING – 1H 2013
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.
Equi-analgesic doses of MOXDUO, Morphine, Oxycodone, vs. Placebo – All Studies

Opioid-Associated Adverse Event

- Nausea
- Vomiting
- Pruritus
- Dizziness
- Headache
- Somnolence

%Patients

- MOXDUO
- Morphine
- Oxycodone
- Placebo
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

<table>
<thead>
<tr>
<th>Study Design and Outcome</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase</strong></td>
<td>Phase 3</td>
</tr>
<tr>
<td><strong>N</strong></td>
<td>375</td>
</tr>
<tr>
<td><strong>US Sites</strong></td>
<td>6</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Randomized 1: 1: 1, double-blind, multicenter, repeat dose, 3 arms stratified by gender and by age (≥ 60 yrs or &lt; 60 yrs; 40% of patients were age 60+)</td>
</tr>
<tr>
<td><strong>Doses / Schedule</strong></td>
<td>MoxDuo IR 12 mg/8 mg vs. Morphine 24 mg vs. Oxycodone 16 mg Every 6 hours for 48 hours</td>
</tr>
<tr>
<td><strong>Primary Endpoints</strong></td>
<td>Effects of MoxDuo IR relative to morphine and oxycodone comparators on oxygen desaturation, a measure of respiratory impairment</td>
</tr>
<tr>
<td><strong>Secondary Endpoints</strong></td>
<td>Percent of subjects with moderate or severe, spontaneously reported, treatment emergent events of nausea, vomiting or dizziness</td>
</tr>
</tbody>
</table>
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 ($\text{SpO}_2$) using finger sensor
- $\text{SpO}_2$ normal values 96-100%; <90% = oxygen desaturation
- This study used electronic records of $\text{SpO}_2$ values
- $\text{SpO}_2$ desaturations (intensity and incidence) are key endpoints
Actual Curves of Different SpO₂ Desaturations

- Shallow and Long
- Deep and Short
Probability of Having a Serious $O_2$ Desaturation

*Below 80% $SpO_2$
Effect of Age on Observed Very Serious O$_2$ Desaturations (70% Cut Point)

Age ≥ 60

- Moxduo 12 mg/8 mg, N=50: 2%
- Morphine 24 mg, N=48: 14.9%
- Oxycodone 16 mg, N=47: 17.4%

Age < 60

- Moxduo 12 mg/8 mg, N=77: 6.5%
- Morphine 24 mg, N=76: 6.6%
- Oxycodone 16 mg, N=77: 11.8%
Odds of Having a Very Serious O₂ Desat by Risk Factor, Relative to MOXDUO

![Graph showing odds ratios for different risk factors.](image)

- **All Patients**
  - Morphine: 1.48
  - Oxycodone: 2.71
- **BMI 27+**
  - Morphine: 2.52
  - Oxycodone: 1.88
- **60+ Years**
  - Morphine: 2.51
  - Oxycodone: 3.73
- **Smokers**
  - Morphine: 3.50
  - Oxycodone: 3.27
- **Smoking History**
  - Morphine: 3.02
  - Oxycodone: 2.65

Even Odds: 1.00
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

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

## INDEPENDENT STUDIES

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

\(^1\)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 - $36,152¹ 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 from 3-6 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 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
### MOXDUO: Peak Sales Potential

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

<sup>1</sup> 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 (15 February 2013)

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares on issue:</td>
<td>145 million (ordinary)</td>
</tr>
<tr>
<td>Market cap:</td>
<td>A$137 million</td>
</tr>
<tr>
<td>Cash on hand:</td>
<td>31 December 2012 A$16.6 million (last reported)</td>
</tr>
<tr>
<td>Cash burn:</td>
<td>CY2013</td>
</tr>
<tr>
<td>Share registry:</td>
<td>+80% institutional / HNW</td>
</tr>
<tr>
<td>Listing:</td>
<td>ASX: QRX / OTCQX: QRXPY</td>
</tr>
</tbody>
</table>
## MOXDUO IR Key Milestones

<table>
<thead>
<tr>
<th>DATE</th>
<th>MILESTONE</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔ July 2011</td>
<td>NDA submission to FDA</td>
</tr>
<tr>
<td>✔ December 2011</td>
<td>Signed strategic collaboration with Actavis</td>
</tr>
<tr>
<td>✗ 25 June 2012</td>
<td>NDA PDUFA Date; CRL Received</td>
</tr>
<tr>
<td>✔ August 2012</td>
<td>FDA Review Meeting</td>
</tr>
<tr>
<td>✔ October 2012</td>
<td>Signed strategic collaboration with Paladin</td>
</tr>
<tr>
<td>● Q1, 2013</td>
<td>Refile MOXDUO NDA</td>
</tr>
<tr>
<td>● Q3, 2013</td>
<td>Anticipated decision from FDA on a refiled MOXDUO NDA</td>
</tr>
<tr>
<td>● 1H, 2013</td>
<td>Submit additional regulatory filings: Europe, Australia &amp; Canada</td>
</tr>
<tr>
<td>● 2H, 2013</td>
<td>Product launch in the US</td>
</tr>
</tbody>
</table>
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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