

August 2007



# FY07 RESULTS

# Key Messages

- Developing and commercialising products for pain management and chronic central nervous system disorders
- Key “dual opioid” assets reposition existing opioid pain therapies with new clinical uses – low development risk
- Strong IP with international patent protection
- Large well-defined markets with unmet medical needs
- Abbreviated development path and accelerated “go-to-market” strategy
- Experienced management team with appropriate skills
- Funds in place to cover Phase III trials and submission of New Drug Application (NDA)
- Drug trial timelines running to plan

# The Opportunity in Pain Therapy

- Global market for pain management drugs estimated at US\$50 billion, forecast to reach US\$75 billion by 2010
- Opioids are the “gold standard” in treating moderate to severe pain
- Worldwide opioid market US\$9 billion in 2005
  - US market US\$6.6 billion
  - 13% annual growth 2001-2005
- Unmet need for improved drugs with fewer side effects (respiratory depression, nausea, vomiting, somnolence)
- Market has seen limited innovation
- Closely monitored and regulated market
- Enables establishment of sustainable branded competitive advantage

# Dual Opioid Overview

- QRxPharma's international patent-protected dual opioid technology
  - Combines existing opioid treatments
  - Creates a lower dosage formulation
  - Achieves pain relief with fewer side effects and lower associated risks
- Two lead oxycodone-morphine products
  - Immediate release Q8003IR
  - Controlled release Q8011CR
- Complementary products targeting the acute pain (Q8003IR) and chronic pain (Q8011CR) markets
- Products positioned to minimise generic substitution

# Further Clinical Study Support

- Recent 40 patient clinical study post spinal surgery by Blumenthal *et al*
- Investigated co-administration of oxycodone and morphine, compared to morphine with placebo
- Oxycodone / morphine combination demonstrated:
  - 12% reduction in opiate use
  - Significantly lower pain scores
  - Lower incidence of adverse effects, notably nausea and vomiting
- Study reinforces evidence that dual opioids deliver:
  - A lower dosage requirement
  - Superior pain control
  - Reduced side effects

# Q8003IR – Immediate Release Dual Opioid

- Refocus on acute pain market provides opportunity to:
  - Broaden the market reach
  - Reduce development costs
  - Abbreviate regulatory process
- Clinical trial and commercialisation timeline unaffected
- Critical steps and timeline to market launch
  - Late 2007: Phase III to commence
  - 2008: Completion of first Phase III, NDA manufacturing batches (stability assessment)
  - 2009: Completion of additional Phase III studies, safety study, filing of NDA
  - 2010: NDA approval, US launch, other markets

# New Survey Supports Q8003IR Refocus

- Further extensive market analysis conducted, including July 2007 survey of 65 high-prescribing physicians, which found:
  - There is a positive response to dual opioids and the broader therapeutic window they potentially offer
  - Physicians associate immediate release (IR) products with acute pain
  - Controlled release (CR) products are identified with chronic pain
  - An IR product has a defined role in Chronic Pain independent of labeling.
    - Eg: for intermittent pain, breakthrough pain etc.
  - Significant Opportunity exists in the Acute Pain segment, but we need:
    - The indication and acute pain data to maximize our penetration in this segment
- The refocus of Q8003IR towards acute pain will allow greater market acceptance, reduced cannibalisation between IR and CR formulations and a larger market opportunity overall

# Q8011CR – Controlled Release Dual Opioid

- Targeting chronic pain market
  - Strong market need for controlled release opioid
  - Complementary to Q8003IR acute pain focus
  - Inherent abuse-deterrent technology
- Critical steps and timeline to further development
  - Mid-2008: Phase I clinical trials complete
  - Late 2008: Targeted initiation of Phase II trials



# Dual Opioid “Go-to-Market” Strategy

- Initially targeting the US market – over 70% of current global opioid market
- Recruitment of specialty pharma sales force in US
  - One third of market can be covered by approximately 120-150 sales reps
  - Targeting specialised (pain) physicians, pain clinics, high prescribing MDs
  - Explore strategic partnerships to expand market penetration
- Relationship with Sigma Pharmaceuticals in Australia
- Licensing opportunities in Europe and Rest of World

# Movement Disorder Pipeline Drugs

- No drugs to address cause of Parkinson's disease or dystonia
- World-leading, patented research from University of Alabama, supported by Michael J. Fox Foundation
  - Role of torsin gene and protein in protein misfolding associated with the cause of movement disorders
  - Certain small molecules (antibiotics) activate torsin in preclinical models, and reverse progressive effects
- Specific antibiotic (T9001) modulates key torsin-related pathways
- Next development steps, dystonia
  - Lead drug candidates being selected from known drugs
  - Currently sourcing manufacturing
  - Negotiating to initiate pilot investigator Phase II clinical trial before end of 2007
- Targeted submission of grant application to advance studies in Parkinson's disease

# Business Development

- Ongoing licensing and partnering activities
- Actively pursuing grant opportunities to partially fund product development
- Next late-stage CNS drug candidate being analysed
- Other pipeline compounds include:
  - Early-stage Q8020TD (transdermal fentanyl/oxycodone patch), as a follow-on to Q8003IR/Q8011CR
  - Q8008 (recombinant peptide)
  - Q8010 (pro-coagulant)
  - Q70050 (venomics research program)

# Strong and Appropriate Resources

- QRxPharma draws on a depth of relevant experience in:
  - Product development for both public and privately held life sciences companies
  - Product commercialisation
  - Regulatory approval process
  - Managing and financing publicly traded companies
- That experience extends across the Board of Directors, senior management and a highly-credentialled Science Advisory Board
- Augmented by access to extensive network of industry consultants

# FY07 Results

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- Reported FY07 net loss of \$0.4 million - in line with expectations
- Exposure to US\$ managed through FX hedge program
- Net cash position of \$46.2 million - sufficient to fully fund Q8003IR clinical trial process

# Summary - Positioned to Execute

- A specialty pharmaceutical company with a clear focus on pain management and central nervous system disorders
- Dual opioid technology delivers pain relief with lower dosage and fewer side effects - answers specific need
- Large acute and chronic pain markets targeted through complementary products
- Early and late stage clinical trial timelines proceeding to plan
- Funds in place to take initial product (Q8003IR) through clinical trials and NDA filing
- QRxPharma has in place a management team with the necessary skills and experience to deliver on its potential

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