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ASX:PAB

Bridging Gaps in Therapeutic Care

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A Faster, Lower-Risk Path to a >US\$2B Delirium Market



Proven Drug

- ✓ Quetiapine already widely used in clinical practice
- ✓ Safety and efficacy well understood
- ✓ Extensive human clinical data available



Reformulated for ICU

- ✓ **New proprietary Injectable formulation** with patent protection extending to ~2042¹
- ✓ Immediate onset vs oral dosing
- ✓ Suitable for ICU, palliative and aged care settings



Accelerated Development Pathway

- ✓ FDA **505(b)(2)** regulatory pathway
- ✓ **3-5 year** development timeline
- ✓ **~\$20-30M** development cost vs ~\$1.2B for new drugs

Reformulating a proven drug to deliver a faster, lower-risk path to market



Traditional Biotech

New molecule discovery

10-15 years

~\$1.2B



Patrys Reformulation

Known drug reformulated

3-5 years

~\$20-30M

Combining drug development, commercialisation and capital markets expertise

Therapeutic Development	ASX Governance	Biotech Commercialisation	Healthcare & Biotech Investment	Capital Markets, Finance & Investor Relations	Clinical Trial Operations
Dr Samantha South CEO • Extensive CNS medical research background • Founding Director and COO of Argenica • 10 yrs Director experience at multiple companies • Technology transfer and commercialisation in medtech / biotech over 15 yrs	Peter Christie CHAIRMAN • 25+ years ASX governance and board experience • Chairman of multiple ASX-listed companies • Current Chairman of ASX:MOH and Non-Executive Director of ASX:MRD.	Brian Leedman DIRECTOR • Biotech entrepreneur with strong ASX healthcare track record • Co-founder of ResApp Health (acquired by Pfizer) • Chairman or Director of multiple ASX-listed companies including Blinklab, Alcidion, Oncosil and NeuroScientific Biopharmaceuticals.	Dr Anton Uvarov DIRECTOR • Healthcare and biotech investment specialist • Former Citigroup healthcare equities analyst • Co-founder and director of multiple ASX-listed companies, including BlinkLab (ASX:BB1), Elsight (ASX:ELS), Dimerix (ASX:DXB), Actinogen (ASX:ACW) and Neuroscientific Biopharmaceuticals (ASX:NSB).	Leanne Kite DIRECTOR • Capital markets, finance and investor relations executive with 20+ years' experience • Investor relations for ASX 200 lithium producer Liontown Resources • Co-founder Reliis	Dino Cercarelli DIRECTOR • Clinical trial and healthcare operations leader • COO of Australian Clinical Trials Alliance • Co-founder of Reliis

Delirium: Severe and Acute Brain Dysfunction

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Confusion

Disorientation

Altered Thinking
& Behaviour

Cognitive
Decline



Increased
Risk Of
Dementia¹

Up to 80% of ICU
patients
experience
delirium

3 Forms

- **Withdrawn** (Hypoactive)
- **Mixed**
- **Aggressive** (Hyperactive)

Estimated Serviceable Addressable Market
>US\$2 Billion per year

The Problem: Current Treatment Challenges

- No approved drug treatments[#]
- Current treatments used “OFF-LABEL”
- Oral quetiapine difficult to administer to delirium patients



“OFF-LABEL” Antipsychotic & Benzodiazepine

- Haloperidol
- Risperidone
- Dexmedetomidine
- Benzodiazepines
- Sedatives



Quetiapine: Atypical Antipsychotic

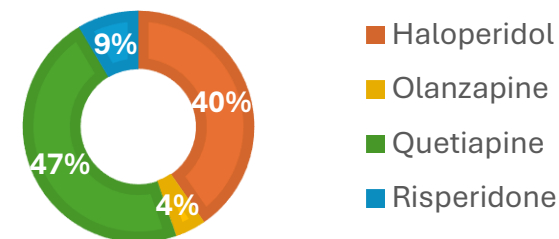
- Only available as oral formulation
- Slow onset of action (1-2h)
- Difficult to administer to delirium patients



Limitations of current “OFF-LABEL” treatments

- Variable Effectiveness
- Low quality data supporting use
- Significant adverse side-effect profiles

Oral Quetiapine commonly prescribed¹

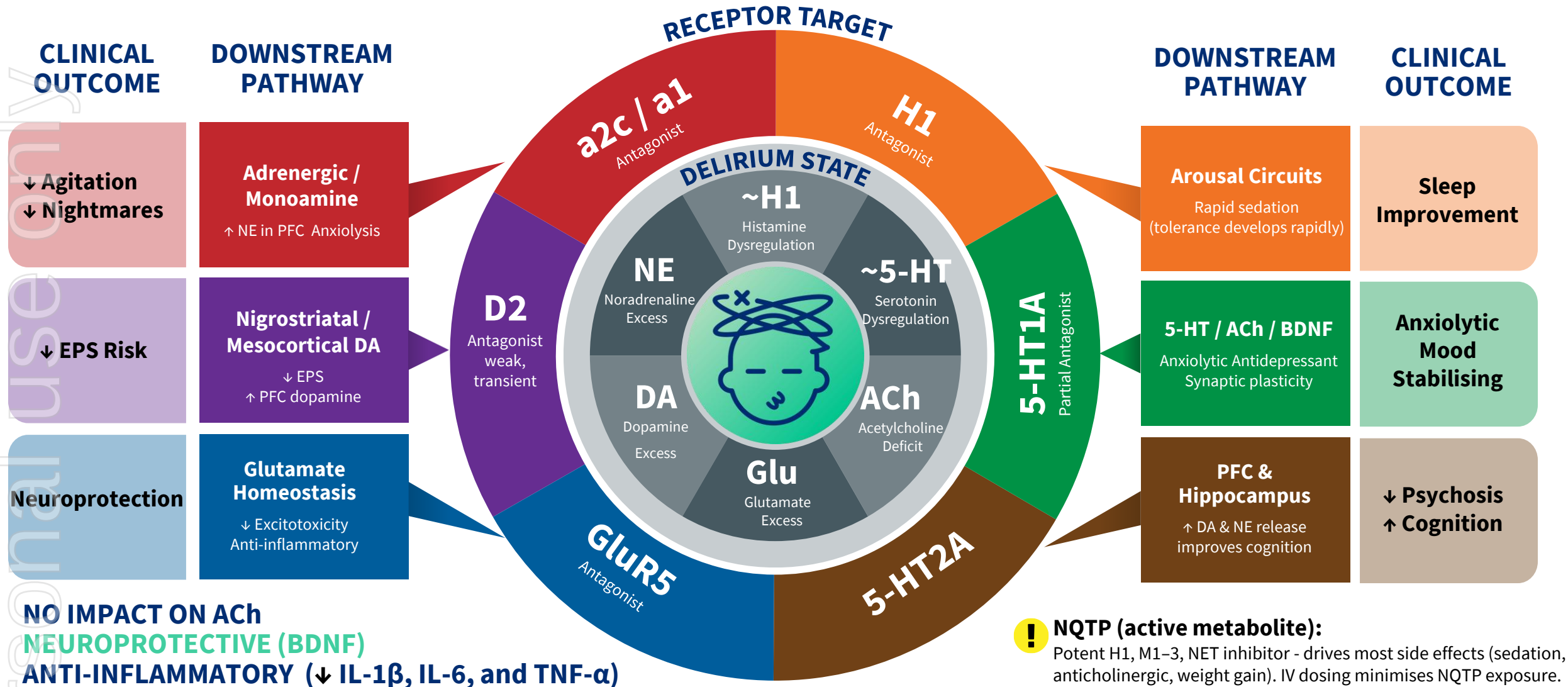


Oral Quetiapine demonstrated comparative **Evidence of Benefit in Delirium** patients and a lower side effect profile²

[#] 8 of the 27 member States of the EU have approved oral and IM Haloperidol for delirium- only if non-pharmacological approaches fail (not for prevention and not for post-operative delirium)

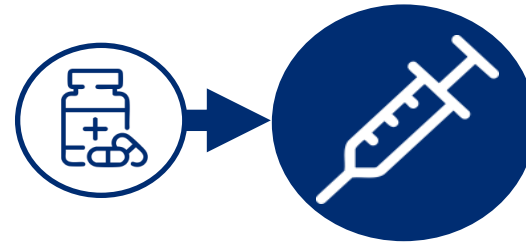
1. Alghadeer et al., 2024 | 2. Devlin et al., 2010; Oztuzzi et al., 2020

Quetiapine (QTP) Mechanism of Action in Delirium



Solution: Proprietary Injectable Quetiapine

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Rapid control of acute agitation episodes



Faster resolution of delirium



Improved safety for patients and staff



Shorter ICU and hospital stays



Cost of care reduced

- Provisional patent application No. 2022901032
- Wholly owned by Patrys with no trailing obligations
- New IP developed: Provisional Patent Application filed in 2026



Australia

Australian Provisional Patent No. 2022901032



Entered National Phase* Q4 2024

World Intellectual Property Office (WIPO) (PCT/AU2023/050316).

- US • EU/UK • Australia



Covers

- New formulation composition
- Method of Use Delirium
- Delivery formulation

Reformulation strategy enables faster, de-risked drug development



Traditional Drug Development

- ◆ Full Clinical Studies Required
- ◆ High Cost
Extensive New Studies
- ◆ Lengthy Process
Prolonged Trials & Research
- ◆ High Investment Risk



505(b)(2) Pathway

- ◆ Utilises Existing Safety & Efficacy Data
- ◆ Lower Cost
Leverage Existing Data
- ◆ Faster Approval
Accelerated Timelines
- ◆ Reduced Time & Expense

2–3X
Higher Success Rate
vs Novel Drugs

40–60%
Lower Cost
& Shorter Timeline

A Structurally De-Risked Opportunity

Compared to a typical biotech program, this asset is de-risked across all major value drivers

	Risk Factor	Risk Typical Biotech	This Asset	Investor Takeaway
	Market Demand & Unmet Need	HIGH - Competing with approved drugs - Must displace established therapies	LOW - No approved drug - Clear unmet need in large, growing market	Open market with clear demand - no incumbent to displace
	Intellectual Property Defence	HIGH - Workarounds feasible - Weak IP	LOW - Technical complexity creates a structural barrier for workarounds - Not relying on reg exclusivity (Hatch-Waxman)	Defensible IP supports premium valuation and limits competition
	Manufacturing & Scale-Up Risk	MEDIUM - Unproven scale-up - Process risk	LOW - Already manufactured at commercial scale - No scale-up required	Low execution risk – no scale-up required
	Regulatory & Reimbursement Risk	HIGH - Long approval timelines - Payer resistance without clear clinical need	LOW - Accelerated reformulation pathway - Established efficacy profile supports reimbursement	Clear and accelerated path to approval and reimbursement
	Clinical & Formulary Adoption	HIGH - Uncertain reimbursement coverage - Slow adoption timelines	LOW - Designed for clinical workflow - Positioned for formulary inclusion	Strong adoption potential driven by clinical need and workflow fit

Reformulation Examples

In 2024 the FDA approved many (~25) drugs under the 505(b)(2) reformulation pathway.

Oral to IV Examples

Successful products specifically reformulated from an oral to i.v. formulation to alleviate acute conditions include:

- **Zometa®**: hypercalcemia of malignancy
- **Caldolor®**: perioperative pain management
- **Ofirmev®**: postoperative pain management
- **Nexterone®**: acute cardiac care

Comparable Reformulations

	Original Indication		Reformulated Indication	Deal
 (paracetamol)	Chronic pain management (oral)	→	Acute post operative pain management (IV) Ofirmev®:	Mallinckrodt \$1.4B acquisition
 (diazepam nasal spray) ©	Anxiety (1963) Oral tablet	→	Epilepsy (2020) Nasal spray	Global Licensing Agreements
 risperidone Long-Acting Injection 12.5mg, 25mg, 37.5mg, 50mg	Schizophrenia (1993) Oral tablet	→	Schizophrenia (2003) Injectable	Teva upfront Clinical trial costs \$112M in milestones plus royalties
	Paediatric respiratory infection (Oral)	→	cUTIs (2022)	GSK US\$66M upfront \$525M milestones

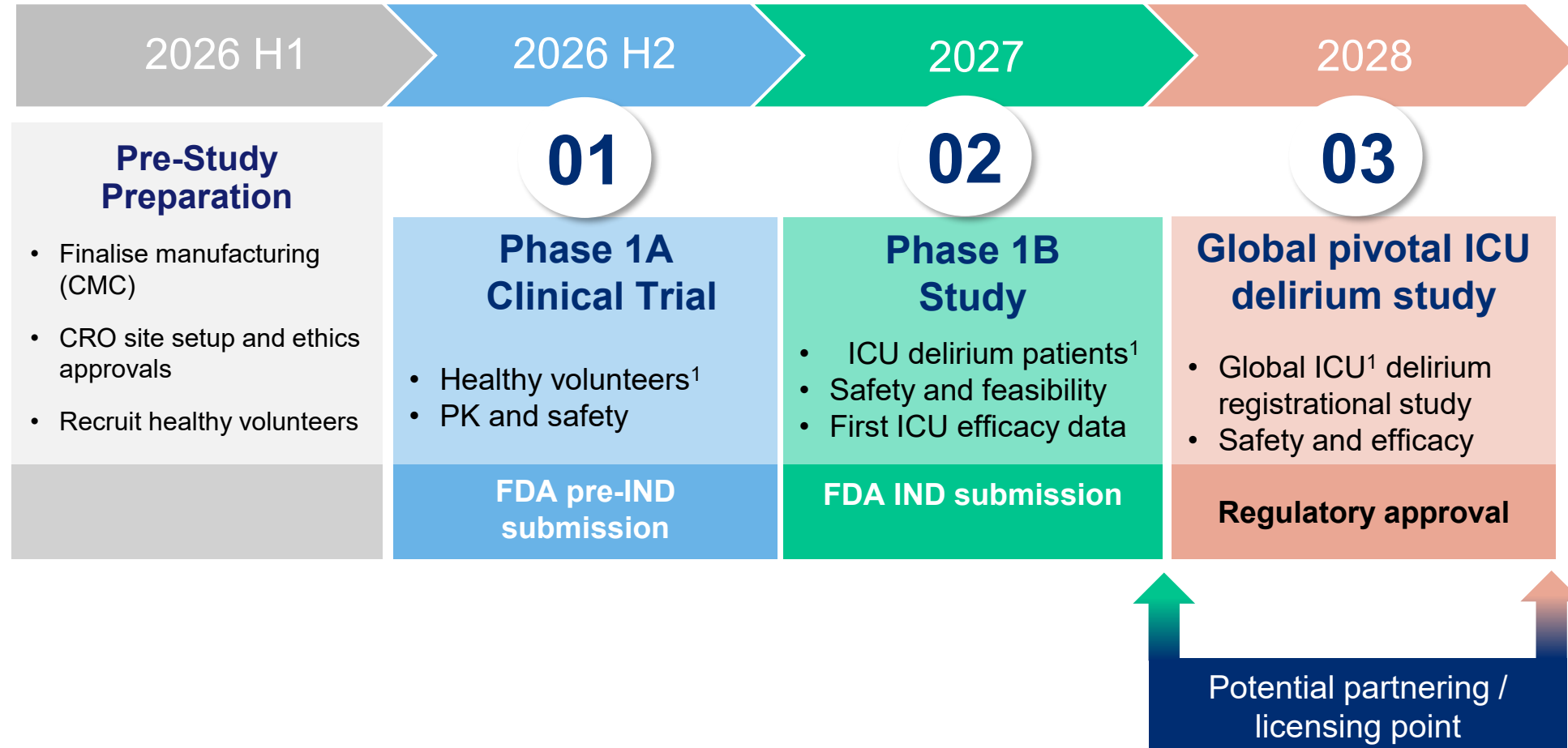
Accelerated Clinical Development Pathway

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Bridging Studies Required

- Human micro-dosing + PBPK modelling
- Predict human dose and administration
- Leverages existing quetiapine safety data

Extensive prior safety data reduces development risk



¹Subjects and Patient numbers are subject to Regulatory and Ethics approvals

Clinical Development Timeline and Key Value Catalysts



- Extensive existing clinical data**
Decades of clinical use of oral quetiapine significantly reduces technical and regulatory risk for the IV reformulation program
- Capital efficient development pathway**
Key development activities are conducted ahead of and alongside Phase 1A to enable rapid progression into Phase 1B
- Phase 1A: Dose Confirmation**
Phase 1A confirms dosing and safety for the IV formulation using the established clinical profile of quetiapine
- Phase 1B: Safety in ICU setting**
Phase 1B evaluates safety of the IV formulation in a small number of ICU patients

Because we are reformulating a drug with extensive clinical history, the bridging studies focus on confirming dosing and clinical safety rather than discovery

Multiple near-term clinical and regulatory milestones expected over the next 18–24 months.	
Event	Target Date
Ethics Approval for Phase 1A	Q3 2026
Phase 1A trial Initiation	Q3 2026
GMP clinical batch release	Q4 2026
Phase 1A Completion	Q4 2026
FDA pre-IND submission	Q1 2027
6 months DP stability for CMC	Q1 2027
Ethics approval Phase 1B	Q2 2027
Phase 1B first patient dosed	Q3 2027
Phase 1B completion	Q4 2027
IND submission	Q1 2028

Capital Structure	
Shares on issue ¹	674,845,324
Share price ²	3.7c
Market capitalisation	\$25.64M
Cash ³	\$3.36M
Debt	Nil
Enterprise Value	\$22.3M

Market Opportunity

~US\$2B

Serviceable addressable delirium treatment market

Share Price History



- Notes:
- 1. Shares on issue is shown undiluted.
 - 2. Share price as at 24 July 26
 - 3. Cash balance as per June Quarterly disclosed on 22nd July 2026.

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RLS-2202

Set to revolutionise delirium care in acute care settings

Watch online: <https://www.youtube.com/watch?v=BNjPXENiSa0>

Patrys Limited (ASX:PAB)

Proven drug, better delivery. De-risked investment.

Contact

Dr. Samantha South

Phone: +61 421 117 241 Email: info@patrys.com

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Injectable Quetiapine: Faster Onset. Superior Safety.

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Current pharmacologic treatments for delirium are used off-label

+++ strong / favourable
++ moderate
+ limited

AQS

Oral
Quetiapine

IV
Haloperidol

IV
Dexmedetomidine

SL
Olanzapine

Being
assessed

Clinical efficacy

+++

++

+

+

+++

Speed of onset

+++

+

+++

++

++

IL-6 INHIBITOR

MINOCYCLINE

+++ None / limited
++ Some negative
+ unfavorable

AQS

Oral
Quetiapine

IV
Haloperidol

IV
Dexmedetomidine

SL
Olanzapine

Adverse effects

+++

+++

+

++

++

Cardiac risk (QTc)

+++

+++

+

+++

++

Sedation risk

++

+++

++

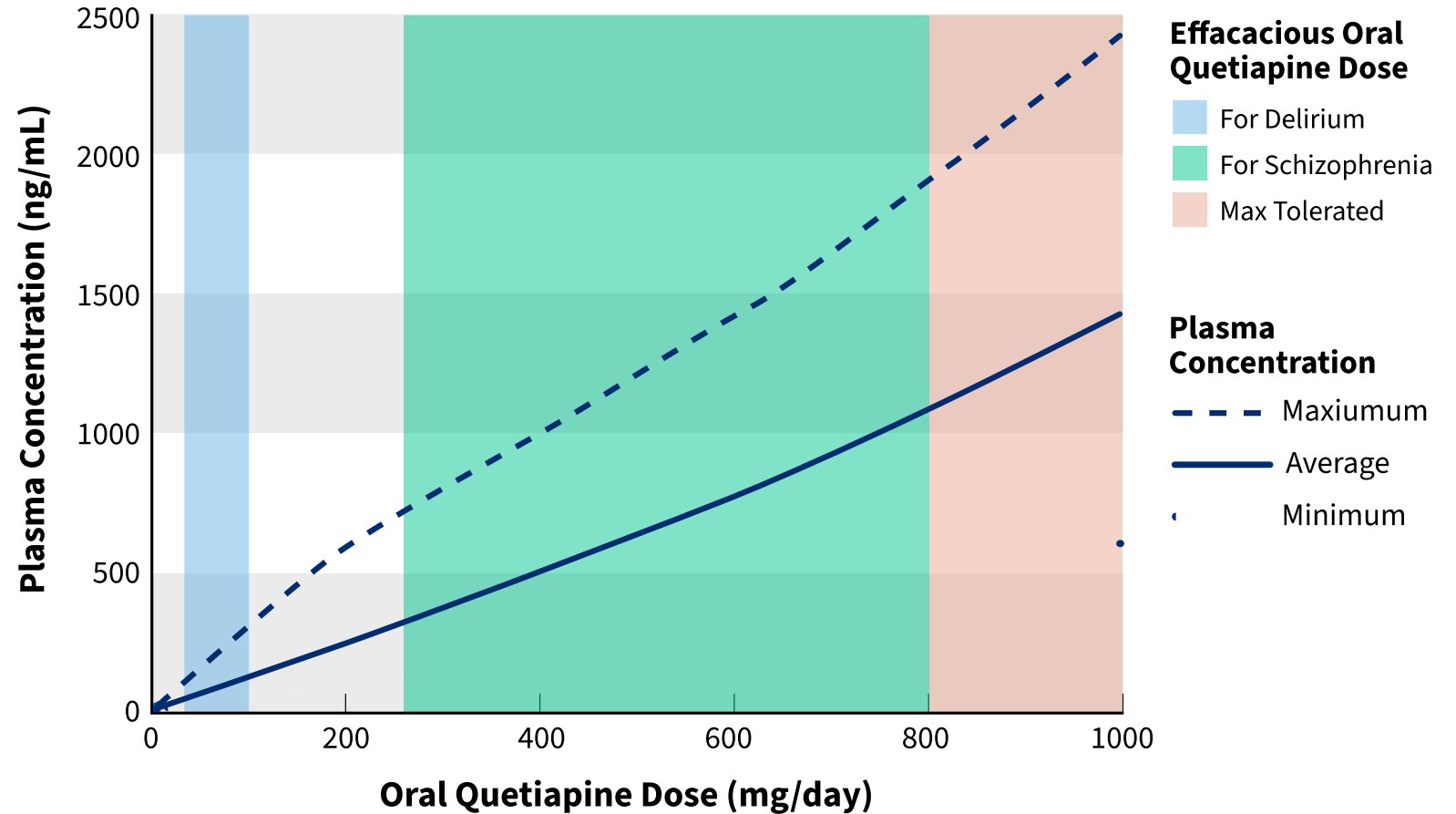
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AQS combines rapid onset with a favourable safety profile versus current off-label treatments

What we know:

- Oral pharmacokinetics
- Know oral dose works delirium (25–100 mg/day)
- Lower than oral dose schizophrenia >250–800 mg/day
- Maximum tolerated dose (MTD) of 800–1000 mg/day
- High oral variability due to first pass metabolism



Need to confirm IV starting dose for clinical trial