InhaleRx

Developing revolutionary pain management & mental health therapies

Company Overview 2025

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About InhaleRx

InhaleRx Limited (ASX: IRX) is a clinical stage drug development company focused on therapeutics that **address unmet medical needs** in **pain management** and **mental health.**

Three drug candidates in development in areas with significant unmet clinical need

SRX-25 – new oral therapy added to portfolio, oral Esketamine + CYP-450 inhibitor to treat TRD.

Manufacturing complete to start dosing patients with IRX-211 (Phase 2), and healthy volunteers with IRX-616a (Phase 1).

IRX-211	Phase 2 – Breakthrough Cancer Pain (BTcP)
IRX-616a	Phase 1 – Panic Disorder (PD)
SRX-25	Phase 1 – Treatment Resistant Depression (TRD)

Innovation patent approved, indication-specific provisionals lodged, Method of use patents lodged, and FTO scope is underway for the new asset.

Fully funded clinical development plans - partner secured for clinical development expenditure across all three programs.

New Oral Asset – New Look

Subject to Shareholder Approval, the Company is planning to rebrand for reclassification purposes and to accommodate the new oral asset.

This is required given the Company will no longer specialise solely in the development of inhaled therapies.

Nexalis Therapeutics (ASX:NX1) has been reserved with the ASX.

Nexalis is a preparation for the next stage of growth for the Company and we are looking forward to sharing further details with shareholders in due course.

The Rise of Ketamine as a Pharmaceutical – The Blockbuster Opportunity

InhaleRx

J&J's Spravato momentum points to commercial viability of psychedelics for mental health, analysts say

Published: 20:25 15 Apr 2025 BST

FDA's New Commissioner's National Priority Voucher: Ketamine's Expedited Development and Global Implications

Marketinsider · 7 Minutes Ago · 0 · 4 Mins Mins

PHARMATHER

PharmaTher Announces Sale of Ketamine ANDA with Potential to Generate Over US$25 Million in Milestone and Profit-Sharing Payments

October 01, 2025 08:00 ET | Source: PharmaTher Holdings Ltd.

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January 22, 2025 07:30 AM EST | Pharma

J&J's Spravato hit $1B in revenue in 2024

Max Bayer
Pharma Reporter

Johnson & Johnson's burgeoning depression treatment Spravato eclipsed $1 billion in revenue in 2024 as the pharma's neuroscience pipeline comes into view.

SRX-25 –
New Oral Asset Explained

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Esketamine – NMDA receptor antagonist modulates neurotransmission & produces rapid antidepressant effects.

SRX-25 combines esketamine & a CYP-450 inhibitor in an oral fixed-dose treatment for TRD.

CYP-450 inhibitors block metabolism of esketamine thereby increasing the amount of the therapeutically active drug in circulation.

Oral esketamine is rapidly broken down by CYP-450 enzymes in the liver (first-pass metabolism) before it enters the circulation.

What Is Treatment Resistant Depression (TRD)

Treatment-resistant depression (TRD) occurs when a person with major depressive disorder does not adequately respond to at least two different antidepressant treatments given at appropriate doses and durations.

It is a chronic and recurrent condition that significantly impacts quality of life, and is associated with more severe symptoms, greater functional impairment.

TRD affects roughly 20–30% of individuals diagnosed with major depressive disorder. It is more common in women than men.

Higher rates are associated with earlier onset of depression, co-occurring anxiety, chronic medical conditions, and socioeconomic stressors.

SRX-25 - Commercial Opportunity – TRD

SRX-25 COMMERCIAL OPPORTUNITY

1. By 2030, the global TRD market is projected to exceed USD 4 billion[1]
2. U.S. currently makes up over 50% of the global TRD market[1]
3. Significant demand for a more accessible and tolerable form of esketamine therapy[3]
4. Regulatory pathway defined by approvals for Symbyax and more recently Spravato and Auvelity[4]

$50b USD
Total Addressable Market (TAM) for TRD in U.S.[2]

1. https://www.fortunebusinessinsights.com/treatment-resistant-depression-treatment-market-102820
2. 2.8M (number of TRD patients in the USA) times the av. annual cost per patient (USD18,000), suggesting large gap in market
3. Spravato administration requires 2 hours of monitoring and cannot be taken home thereby limiting access
4. https://www.accessdata.fda.gov/

SRX-25 – Oral Drug Therapeutic targeting Treatment-Resistant Depression (TRD)

SRX-25 has potential to provide an alternative to intranasal esketamine (Spravato), **which currently generates US$1b+ annual sales (J&J).**

SRX-25 is designed to **replicate Spravato's pharmacokinetics** while improving adherence, convenience & **therefore opening a larger treatment population.**

Development via 505(b)(2) regulatory pathway, **leveraging existing safety data & reducing cost and time**.

Fully funded clinical development plans under existing funding agreement

Potential to reach Phase 3 readiness within three years.

Value creation opportunities via **licensing, asset sale, and co-development** opportunities.

IRX-211 – Inhaled Drug / Device Therapeutic targeting BTcP

IRX-211 will be a registered prescription-only medication to treat **Breakthrough Cancer Pain (BTcP)**.

Ph1 clinical trial complete – very promising insights and no SAE's. **Ph2 approved by HREC and about to start dosing** to demonstrate safety and efficacy in the BTcP patient population.

Targeting FDA approval(s) that will allow a marketing claim. PIND complete with very supportive narrative from the FDA.

An FDA approval will **open up the door to approvals with the EMA and TGA.**

Access to government reimbursements + regulatory levers creates a **strong commercial and competitive position.**

FDA Food and Drug Administration

IRX-211 – Commercial Opportunity

IRX-211 COMMERCIAL OPPORTUNITY

1. By 2040, the global cancer burden is projected to reach approximately 29.5 million new cases annually.
2. 20%-40% U.S. cancer patients reporting cannabis use to help treat their condition
3. Growing demand / widening gap in the market for a non-opioid therapeutic options.
4. Regulatory pathway well defined via PIND and 6 medications having achieved NDA for BTcP.

$11b USD
Total Addressable Market (TAM) for the Cancer Pain Market by 2028.

https://www.mordorintelligence.com/industry-reports/pain-management-market
https://www.globenewswire.com/news-release/2023/9/28/2750975/28124/en/Global-Cancer-Pain-Market-2023-2028-Eli-Lilly-Company-and-Johnson-Johnson-at-the-Forefront-of-Personalized-Pain-Management-for-Cancer-Patients.html
https://epi.grants.cancer.gov/
https://www.who.int/news/item/01-02-2024-global-cancer-burden-growing--amidst-mounting-need-for-services

Planning to commence IRX-211

MILESTONE	COMPLETE	EXPECTED (QUARTER)
Funding Secured	✓	
CRO appointed	✓	
Spec Work Completed in UK	✓	
Component Sourcing + Tech Transfer	✓	
HREC Approval for Ph2 trial	✓	
Protocol Amendment with HREC Approved	✓	
Batch Manufacturing Complete	✓	
Recruitment Commenced and First Patient Pre-screened	✓	
First Patient Screened		**Q4 2025*** **(*Site Dependent)**
First Patient Dosed		**Q1**

IRX-616a – Inhaled Drug / Device Therapeutic targeting Panic Disorder

IRX-616a will be a registered prescription-only medication to treat **Panic Disorder**.

HREC approved, this trial will be followed by a Ph2 to demonstrate safety and efficacy in the Panic Disorder patient population.

Regulatory approval(s) with the FDA will allow a marketing claim. **PIND complete, IND already submitted with feedback received.**

An FDA approval will open up the door to approvals with the EMA and TGA.

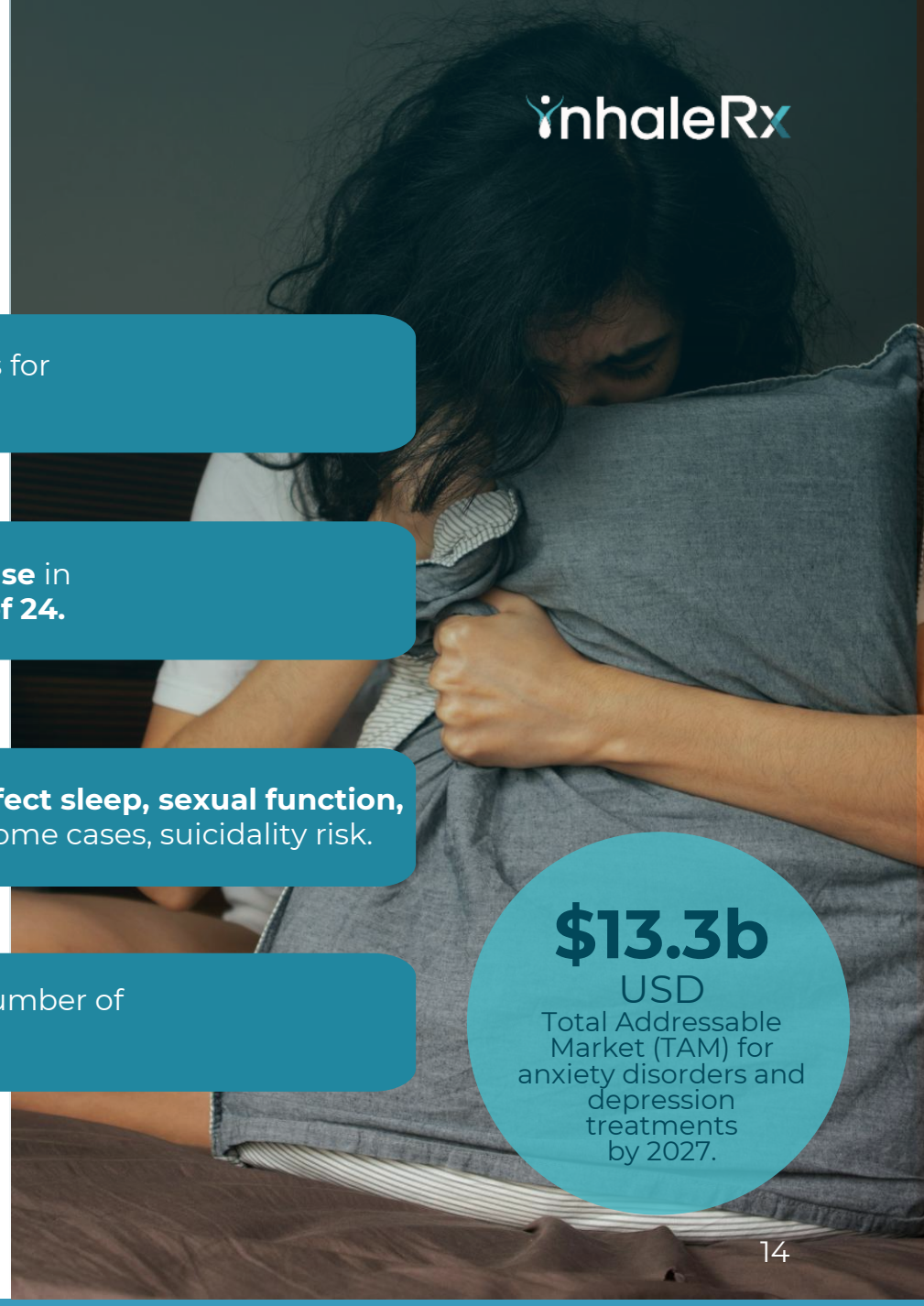
No competition in terms of inhaled FDA approved medications to treat PD.

Access to government reimbursements + regulatory levers creates a **strong commercial and competitive position**.

IRX-616a – Commercial Opportunity

IRX-616a COMMERCIAL OPPORTUNITY

1. There are currently **no FDA approved drugs** for treating Panic Disorder via inhalation.
2. **Covid-19 triggered a 25% increase** in prevalence, **median onset age of 24.**
3. Existing drugs **like SSRI's can affect sleep, sexual function, carry drug interactions** and in some cases, suicidality risk.
4. **Regulatory pathway well defined** with a number of on-label oral drugs FDA approved.



$13.3b
USD
Total Addressable Market (TAM) for anxiety disorders and depression treatments by 2027.

Anxiety Disorders and Depression Treatment Market - Share, Size, Growth & Analysis (mordorintelligence.com)
https://pubmed.ncbi.nlm.nih.gov/15297936/
https://www.fortunebusinessinsights.com/anxiety-and-depression-treatment-market-102787
https://www.who.int/news/item/02-03-2022-covid-19-pandemic-triggers-25-increase-in-prevalence-of-anxiety-and-depression-worldwide
https://pubmed.ncbi.nlm.nih.gov/22112673/
https://www.globenewswire.com/news-release/2022/06/13/2460905/0/en/Anxiety-Disorders-and-Depression-Treatment-Market-Size-worth-USD-13-03-Billion-by-2027-at-CAGR-of-2-6.html

Planning to commence IRX-616a

MILESTONE	COMPLETE	EXPECTED (QUARTER)
Funding Secured	✅	
Medical writing complete	✅	
Spec Work Completed in UK	✅	
Component Sourcing + Tech Transfer Completed	✅	
CRO appointed	✅	
HREC Application	✅	
HREC Approval	✅	
Batch Manufacturing	✅	
First Patient Screened	✅	**Q1 2026**
First Patient Dosed		**Q1 2026**

Pipeline – Three Assets Under Development

Drug	Indication	Planning	Phase 1	Phase 2	Funded Value
IRX-211	Breakthrough cancer pain		→		**$15.5m**
SRX-25	Treatment-resistant depression		→		**$12.6m**
IRX-616a	Panic disorder		→		**$16.1m**

All three programs are fully funded for clinical development costs under the Linlithgow Family Office agreement

Capital Structure

Financial Information (ASX: IRX)	
Share price – 9 Dec 2025	$0.025
Market cap	A$6.2m
Cash balance[1 2]	A$0.92m
Enterprise value	A$5.28m

[1] The Company's clinical trial costs are fully funded via $52.3m funding agreement with Linlithgow Family Office
[2] Pro-forma – 30 September 2025 cash balance + cash for shares issued as part of Placement announced 26/11/25. Additional up to $250,000 rights issue pending.

Board & Management	
Sean Williams	Non-Executive Chairman
Dr Ron Wise	Non-Executive Director
Tony Fitzgerald	Non-Executive Director
Darryl Davies	Chief Executive Officer
James Barrie	Company Secretary

Share Price & Volume - YTD

Investment Highlights

Three drug candidates in development in both pain and mental health, with **significant opportunity** and unmet clinical needs.

IRX-211 – Phase 2 – HREC Approved - Ready to Dose.

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IRX-616a – Phase 1 – HREC Approved – Ready to Dose.

SRX-25 – Phase 1 – Planning Stage

SRX-25 – an exciting new oral therapy added to Company portfolio.

Oral Esketamine + CYP-450 inhibitor designed to treat TRD.

Over $44m in fully committed funding to execute clinical development plans - partner secured for clinical development expenditure across all three programs.

Manufacturing already complete to start dosing patients for Ph2 in the patient population for IRX-211, and; healthy volunteers for IRX-616a (Ph1).

Innovation patent approved, lodged, **indication-specific provisionals, Method of use patents lodged**, and Freedom To Operate scope is underway for the new asset.

InhaleRx has a solid pipeline with three fully funded assets under development supporting a potential blockbuster opportunity.

Thank you

Darryl Davies
CEO

darryl.davies@inhalerx.com.au