InhaleRx

Developing the next generation of pain management & mental health therapies

Clinical Development Outlook 2026

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Rebrand to Nexalis Therapeutics (ASX:NX1)

The Company is currently rebranding for reclassification purposes and to accommodate the new oral asset, given the Company no longer only specialises in inhaled delivery.

Nexalis Therapeutics (ASX:NX1) website is complete, all digital assets are templated and the Company is awaiting the official change in ASX code before formally making the change expected within days.

Nexalis is a preparation for the next stage of growth – a launchpad for the advancement of the Company's clinical programs.

Company Snapshot

Nexalis Therapeutics (ASX:NX1) is developing the next generation of pain management & mental health therapies by addressing unmet and mismatched medical needs of patients globally.

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.

HREC Approved and manufacturing complete to start dosing in IRX-211 (Phase 2), and 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)

Robust Patent Strategy including regulatory exclusivity, and procedural mechanisms to maintain early-market positioning.

Over $50m secured – fully funded clinical development plans across all three programs.

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

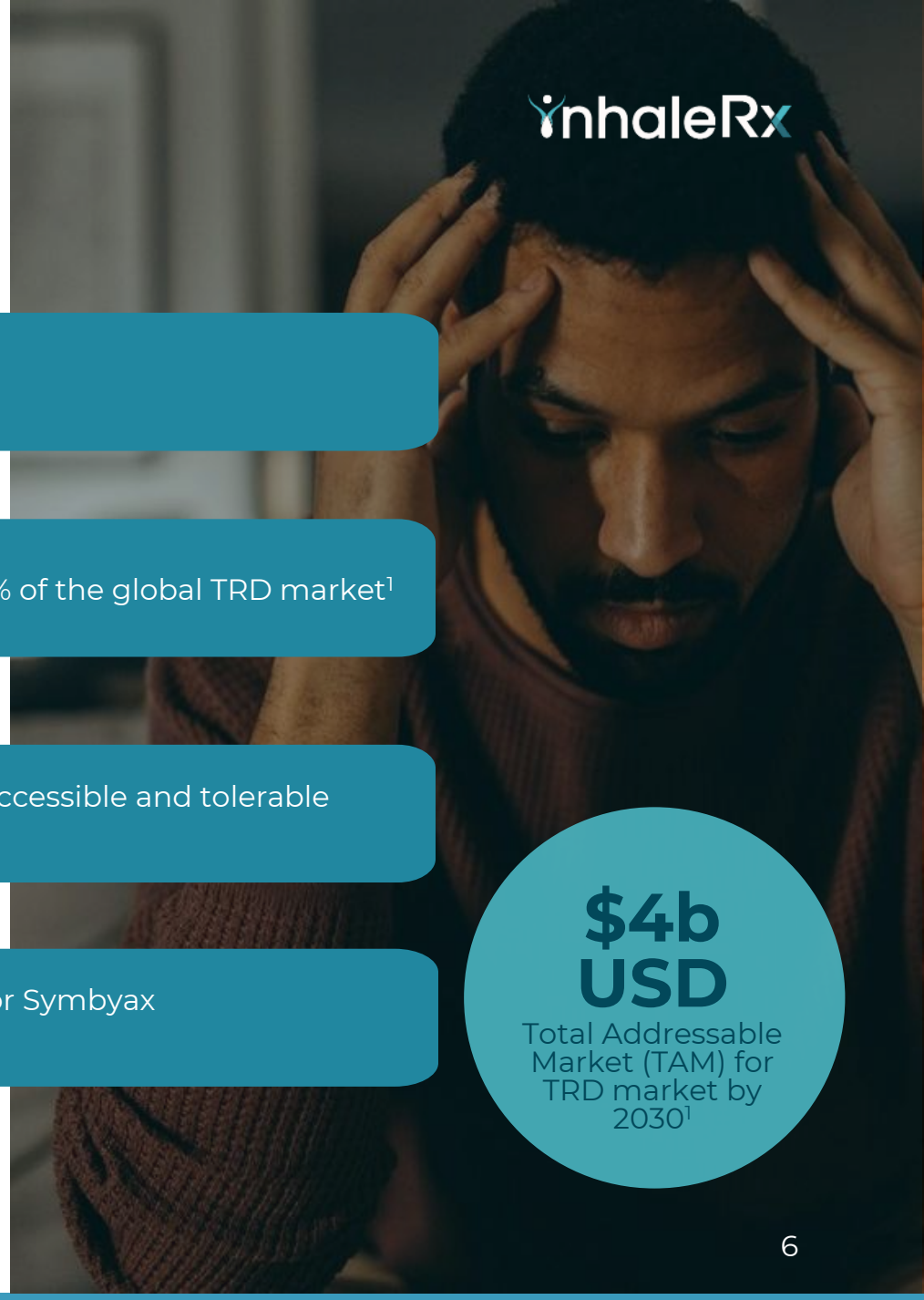
Potential to reach Phase 3 readiness within three years.

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

SRX-25
Commercial Opportunity – TRD

SRX-25 COMMERCIAL OPPORTUNITY

1. 2.8 million TRD patients in the US alone
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[2]
4. Regulatory pathway defined by approvals for Symbyax and more recently Spravato and Auvelity[3]



$4b USD
Total Addressable Market (TAM) for TRD market by 2030[1]

1. https://www.fortunebusinessinsights.com/treatment-resistant-depression-treatment-market-102820
2. Spravato administration requires 2 hours of monitoring and cannot be taken home thereby limiting access
3. https://www.accessdata.fda.gov/

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.

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, manufacturing complete and site activated to start screening and 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. Provisional patent lodged WO2025129263A1.

Lead site Vitalis activated, Genesis site initiation dates confirmed. First Patient In expected before the end of Q1 CY26.

Regulatory approval(s) with the FDA will allow a marketing claim and allow access to government rebates + regulatory levers that provide 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 option.
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	✓	
Site Activated and Site Staff Trained	✓	
First Patient Screened		**Q1 2026**
First Patient Dosed		**Q1 2026**
Expand to Multiple Sites, a further 4 sites lined up in Australia		**Q2 2026**
Make IRX-211 available under SAS in parallel to acquire real-world insights from a diverse pain management patient population		**Q2 2026**

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

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

HREC approved, this trial will be promptly 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.**

Patent attorneys engaged to pursue protection for the IRX616a program, and an application is currently being prepared for filing to align with clinical development plans.

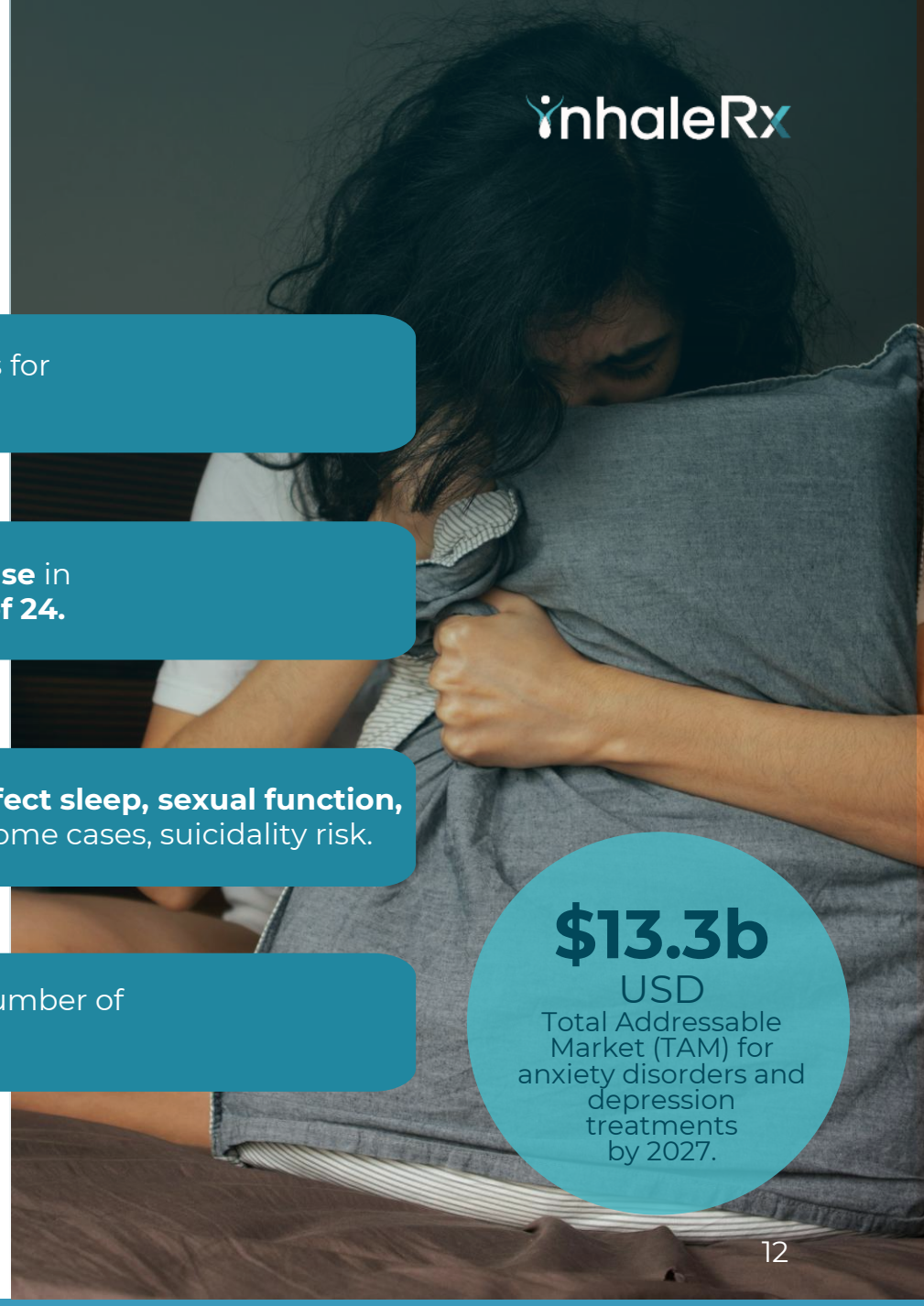
No competition in terms of inhaled FDA approved medications to treat PD.

Access to government rebates + 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	✓	
Site CTRA Executed and SIV Complete	✓	
First Patient Screened		**Q1 2026**
First Patient Dosed		**Q1 2026**
Planning to dose last participant by the end of Q2		**Q2 2026**

Pipeline – Three Assets Under Development

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

All three programs are fully funded for clinical development costs amount to over $50m under the Linlithgow Family Office agreement

Summary of Outlook for 2026

Unique funding position with over $50m secured for clinical development plans + company running costs covered following recent capital raise.

Two HREC Approvals secured with both trials ready to commence.

Recruitment activities imminent across IRX-211 and IRX-616a.

Excellent and unprecedented positioning with IRX-211.

A potential world first for IRX-616a with no FDA approved drug via inhalation to treat Panic Disorder.

Fantastic opportunity with SRX-25 in a proven market.

Phase 1 planning underway.

IRX-616a has a Ph1 all planned out with CMAX. the intent of LPLD in q2.

Thank you

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