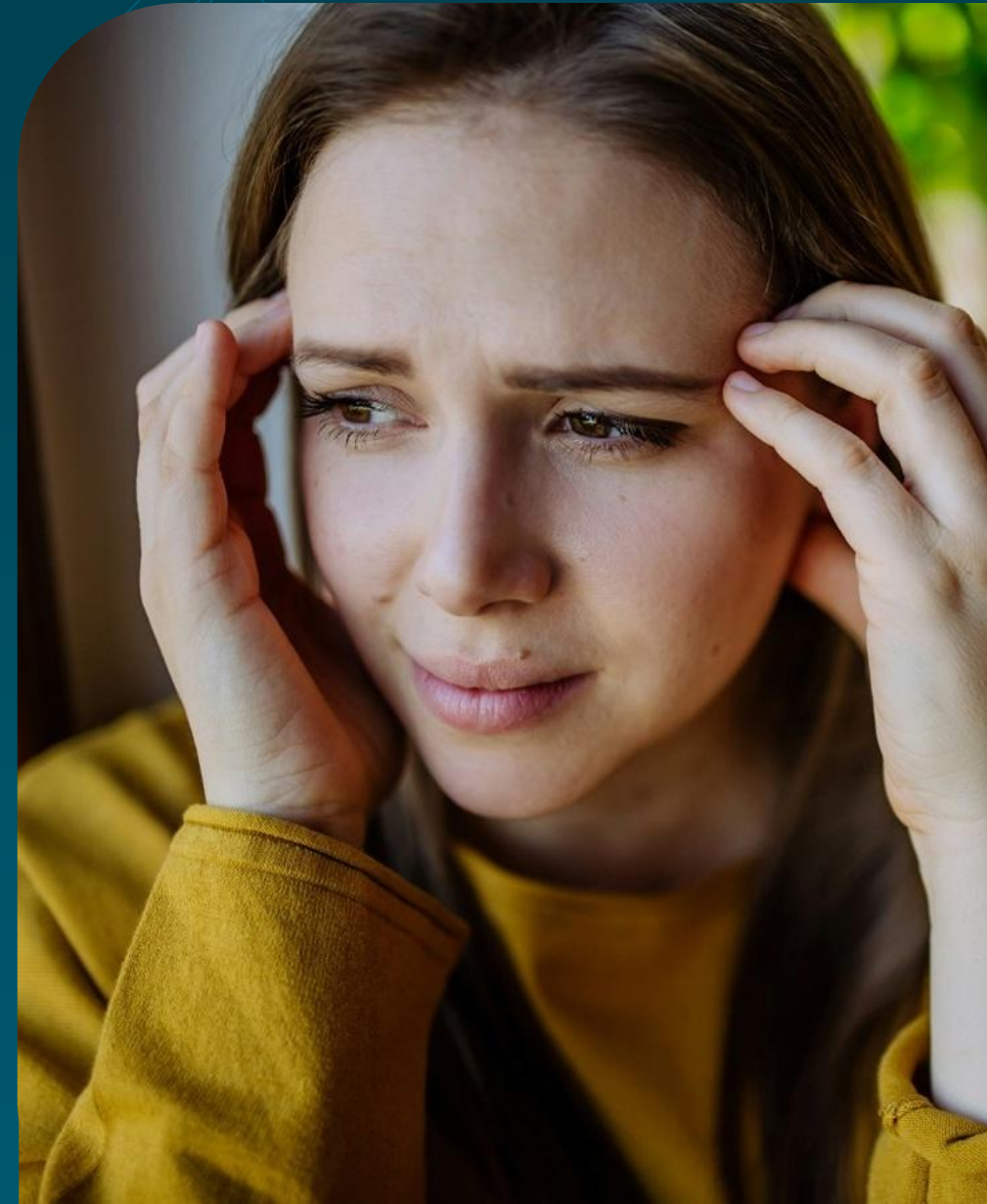




Developing the next generation of pain management & mental health therapies

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.



MacBook Pro

Company Snapshot

Nexalis Therapeutics (ASX:NXI) 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.**

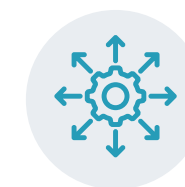


Development via 505(b)(2) regulatory pathway, **leveraging existing safety data & reducing cost and time.**



Fully funded clinical development plans under existing funding agreement

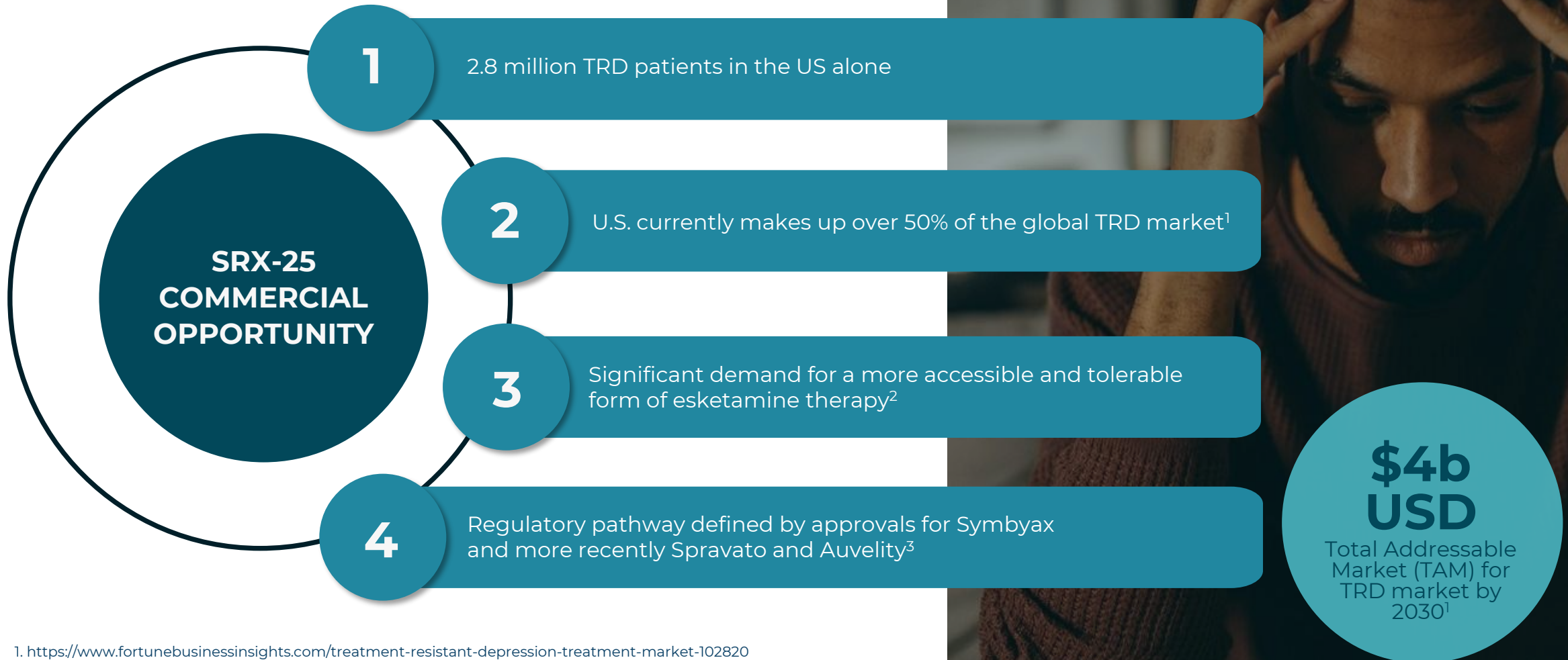
Potential to reach Phase 3 readiness within three years.



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

SRX-25

Commercial Opportunity – TRD



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

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

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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.

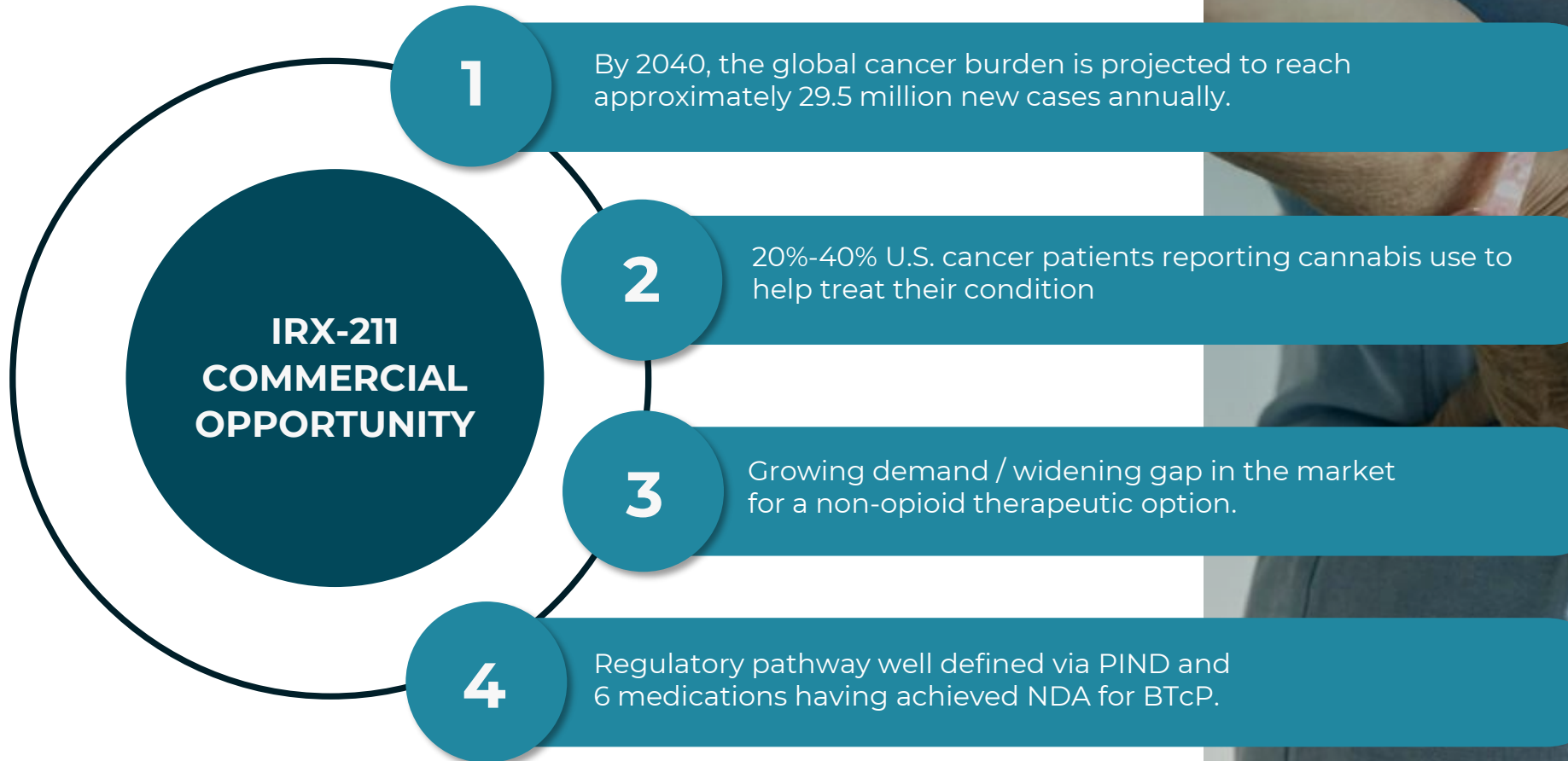
Lead site Vitalis activated, Genesis site initiation dates confirmed. First Patient In expected before the end of Q1 CY26.

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**.

inhaleRx



IRX-211 – Commercial Opportunity



**\$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.**

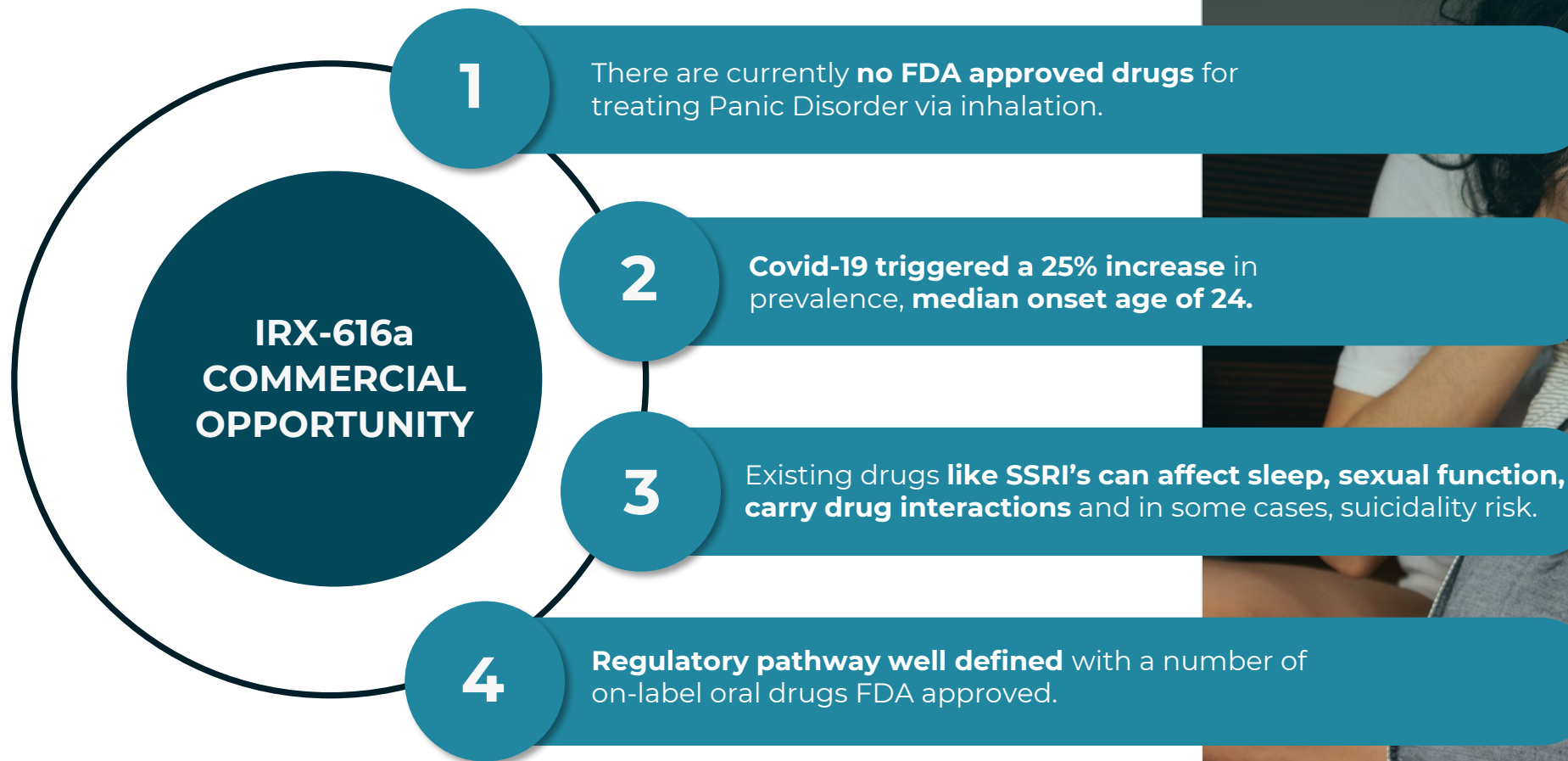
Patent attorneys engaged to pursue protection for the IRX616a program, and an application is currently being prepared for filing to align with clinical development plans.

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



\$13.3b

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

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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