



Town Hall Meeting  
23 July 2025

# DEVELOPING TOMORROW'S INHALED THERAPIES

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# ABOUT INHALERX

InhaleRx Limited (ASX: IRX) is a clinical stage biotechnology development company focused on **developing innovative inhaled therapeutics to address unmet medical needs in pain management and mental health treatment.**



Two drug/device candidates in development, IRX-211 and IRX616a



IP Portfolio including PCT, Innovation (approved) and provisionals



Targeting indications with a significant addressable markets



\$38.5m facility secured to accelerate our clinical development plans



Precision Dose pMDI's



Supportive Safety Data from the Ph1 trial (pain)



# DEVELOPING IRX-211 AS A THERAPEUTIC AGENT



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



Ph1 1 clinical trial complete, very promising insights and no SAE's.



**HREC resubmission approved**, and manufacturing has commenced as per the predicted timeline.



Cancer Pain Management Market grew from \$7.42 billion in 2023 to \$7.86 billion in 2024 and is expected to continue growing at a **CAGR of 6.09%, reaching \$11.23 billion by 2030**.



An FDA approval will allow access to government reimbursements + and open up the door to approvals with the EMA and TGA.



# PLANNING TO COMMENCE IRX-211

MILESTONE	COMPLETE	EXPECTED (QUARTER)
Funding Secured	✓	
Recut of trial design	✓	
Tender Commenced	✓	
Spec Work Commenced	✓	
Component Sourcing	✓	
HREC Approval for Ph2 trial	✓	
Additional Sites Secured	✓	
Protocol Amendment with HREC	✓	
MRL to the FDA with updated questions for BTcP	✓	
Batch Manufacturing	✓	
First Patient Screened		Q3
First Patient Dosed		Q3

# DEVELOPING IRX-616a AS A THERAPEUTIC AGENT



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



**Ph1 HREC submission**, once complete, this trial will be quickly followed by a Ph2 to demonstrate tolerability, safety and efficacy in the patient population.



**There is no competition in terms of inhaled FDA approved medications** specifically designed to treat PD.











The market of anxiety disorders and depression treatments is **estimated to be valued at 22.6b (USD)**.



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



# PLANNING TO COMMENCE IRX-616a

MILESTONE	COMPLETE	EXPECTED (QUARTER)
Funding Secured		
Medical writing complete		
Tender Commenced		
Spec Work Commenced		
Component Sourcing		
Tender complete		
Protocol Development		
HREC Application Sent To Site		
HREC Approval		Q3
Batch Manufacturing (Pilot followed by Active)		TBC
First Patient Screened		TBC
First Patient Dosed		TBC



# CORPORATE STRUCTURE

## Financial Information (ASX: IRX)

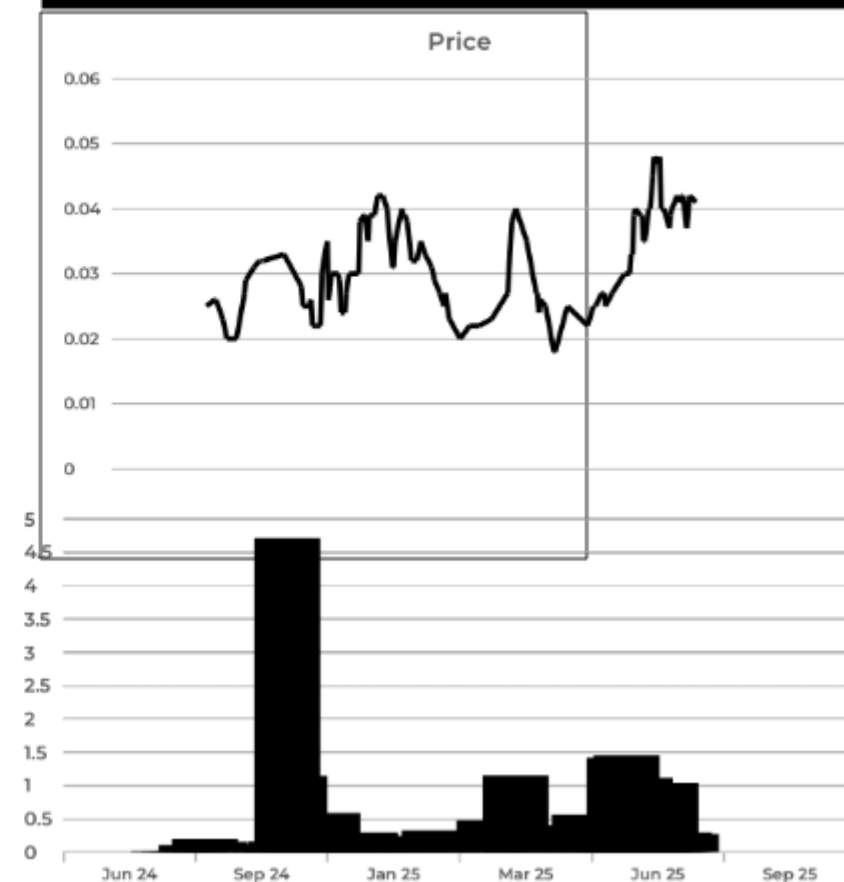
Share price – 21 July 2025	\$0.041
Market cap	A\$8.75m
Cash balance (30 June 2025)*	A\$0.40m
Enterprise value	A\$8.35m

\* InhaleRX's clinical trial costs are fully funded via \$38.5m funding agreement with Clendon Biotech Capital

## 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





## HIGHLIGHTS & SUMMARY

**Funding Partnership** the company has fully funded clinical development program with access to \$38.5m in funding to accelerate the execution of the trials.

**Forward Funding in Progress** the company is currently working with R&D advisors and forward funding to access a drawdown on activities for the fiscal year.

**Significantly reduced cash burn across the company** We run very lean with the management team being limited to myself, Dr Rob Jenny (CSO), and Dr Sud Agarwal (Medical Advisor).

**Experienced Board Members** that are very hands on and extremely motivated to navigate this company through the execution phase.

**Batch manufacturing commenced** for IRX-211 (Ph2) as we prepare to dose our first patient with BTcP symptoms. A Work Order for 616a has been executed as we prepare for the Ph1 at CMAX.

**Defined pathway with the FDA** the PIND meetings validated our planned primary endpoints.

**Media, PR, IR expertise engaged** with NWR Communications across the next 6 months.

**Scoping new opportunities** the company is actively scoping the potential to add complimentary assets to the pipeline.



# THANK YOU



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# **IRX-211 Clinical Trial Update**

**Inhaled Cannabinoid Therapy for  
Breakthrough Cancer Pain (BTcP)**

# A Novel, Inhaled Approach to BTcP Relief

**IRX-211: Inhaled cannabinoid  
delivered via handheld device**

**Developed for opioid-tolerant  
cancer patients**

**Designed for rapid relief  
during BTcP episodes**

**Incorporates dose personalisation and intra-  
patient control**

**Now entering multi-site clinical evaluation**



# Multi-Stage, Intra-Subject Controlled Study



## Trial Framework

- Observational baseline period
- Part A: Dose refinement via titration
- Part B: Randomised, double-blind treatment phase (active/placebo)
- Each patient acts as their own comparator
- Designed in collaboration with experienced BTcP clinicians

# Understanding Each Patient's BTcP Profile



**Extended baseline monitoring  
prior to investigational dosing**

No study drug administered



**Captures real-world episode  
patterns, response to SOC**



**Used to:**

- Characterise BTcP dynamics per patient
- Confirm eligibility and BTcP episode reproducibility
- Stabilise background opioid use

Baseline Observation Period

# Individualised Dose Identification

## Part A – Dose Refinement

- Sequential titration across multiple BTcP episodes
- Investigator-guided escalation of IRX-211
- Goal: Identify lowest effective and tolerable dose

## Criteria:

- Meaningful pain relief within a short time window
- Absence of dose-limiting side effects





# Blinded, Crossover Assessment

## Part B – Randomised Treatment Phase

**Patients receive a sequence of 10 blinded doses**

- 7 IRX-211 active doses
- 3 placebo doses

**Delivered during actual BTcP episodes**

**Randomised within subject; treatment unknown to both patient and clinician**

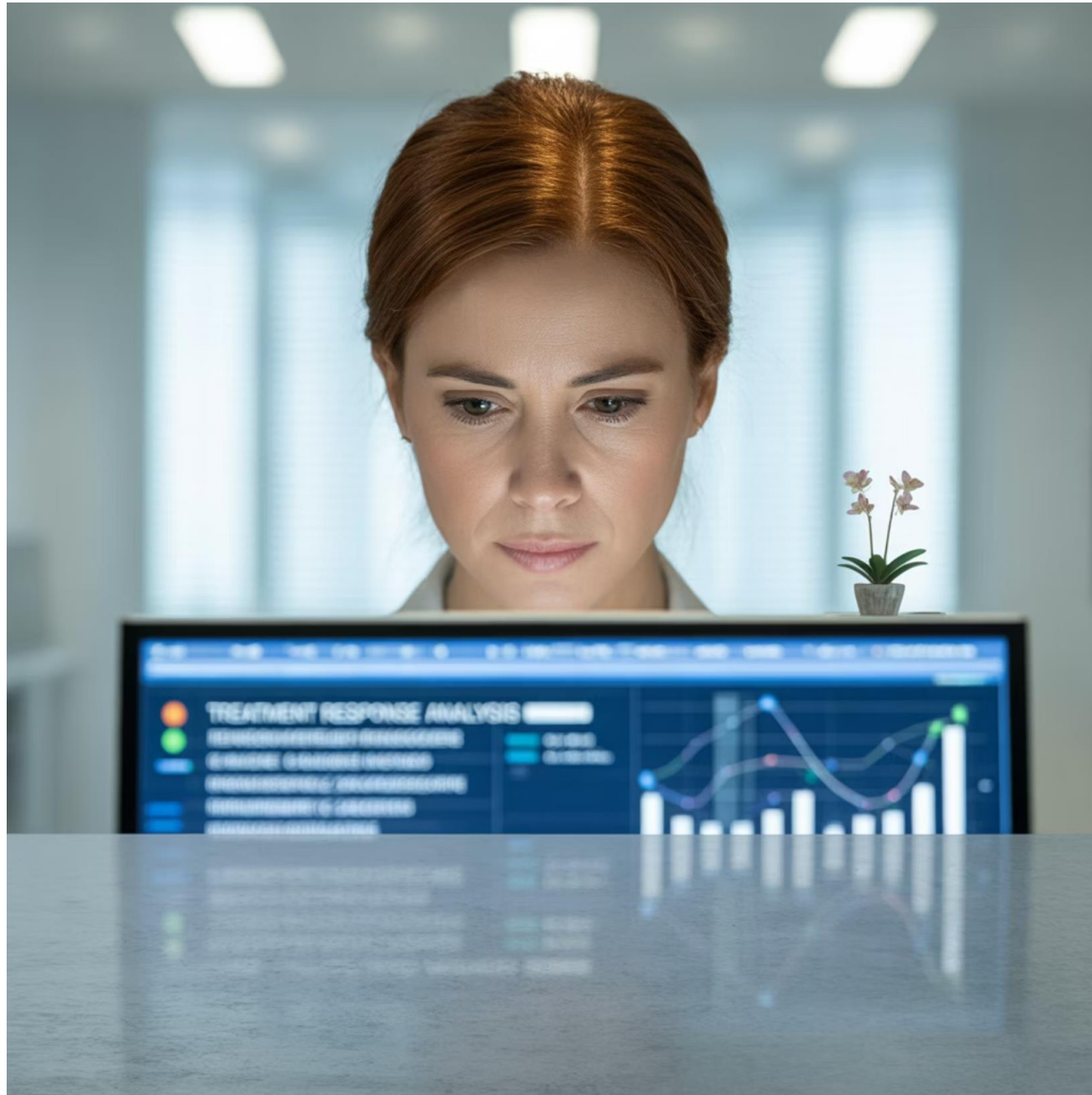
**Allows for intra-person comparison of efficacy and tolerability**



# Controlling for Inter-Patient Variability

## Intra-Patient Comparator Design

- Each patient serves as their own control
- Minimises confounding from pain tolerance, metabolism, disease stage
- Enhances signal detection with fewer subjects
- Supports high-precision exposure–response modeling





# Global Investigator Engagement

1

**Active interest from oncology and palliative care units in:**

- Australia: VIC, NSW, QLD
- Southeast Asia: Singapore, Malaysia, Thailand

2

**Study shaped by input from senior pain medicine and oncology advisors**

3


**Sites selected for experience in managing complex cancer pain cohorts**

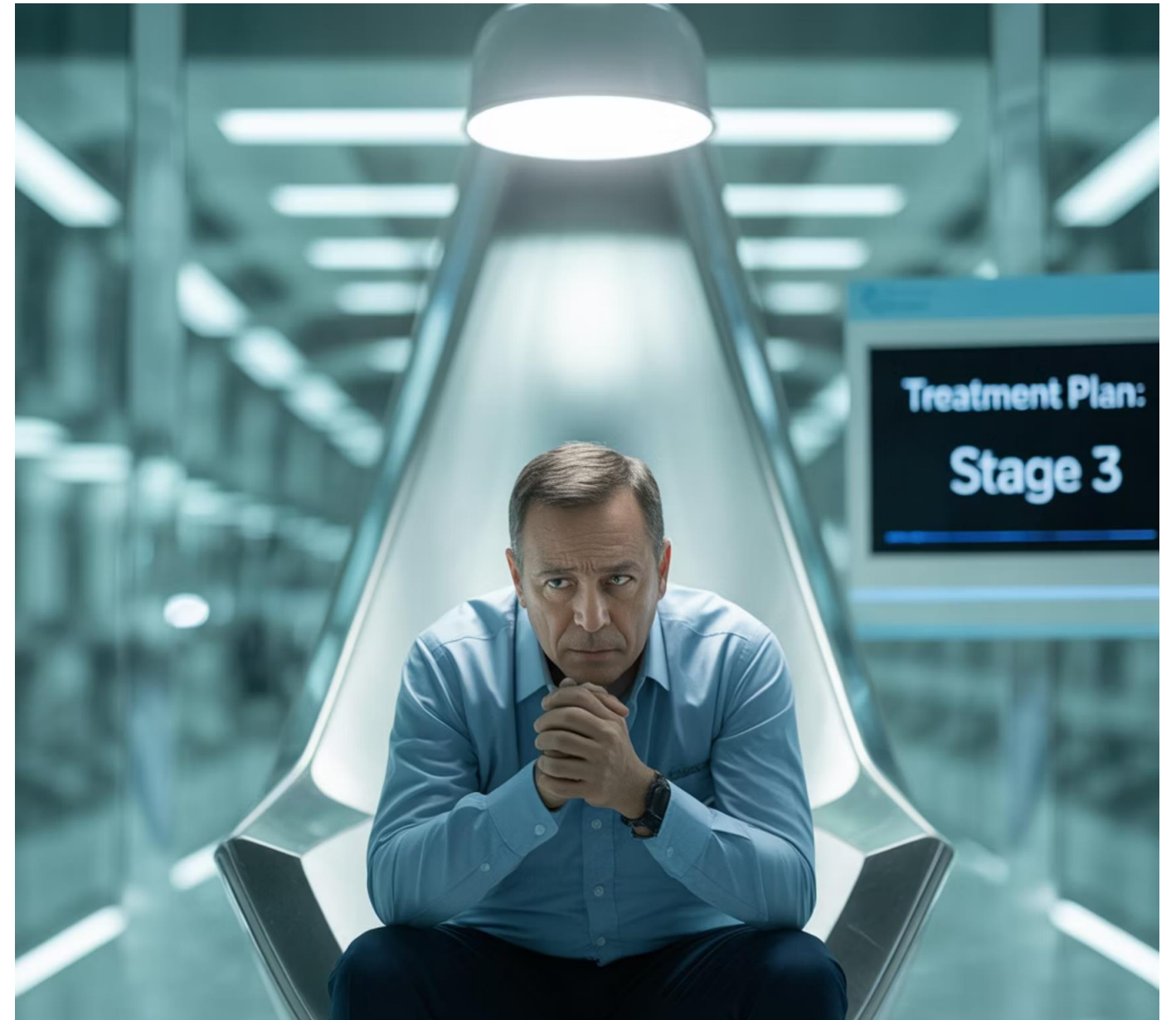
**Clinical Site & Advisor Network**

# A Field with Fewer and Fewer Options

## Addressing the Global BTcP Gap

- Transmucosal fentanyl (TIRFs) increasingly delisted worldwide
- IV opioids impractical for outpatient management
- Oral opioids too slow for true BTcP events
- Widespread clinical dissatisfaction with current standards

 IRX-211 offers a fast, non-invasive, non-opioid alternative with titratable delivery





# IRX-211: Targeted, Rapid, Individualised Relief

## Closing Remarks

- 1** Fills a growing void in BTcP treatment
- 2** Aligned with modern cancer pain management priorities
- 3** Designed with flexibility, control, and patient usability in mind
- 4** Supported by experienced investigators across key regions