



14 March 2025

ASX Announcement

## **SHAREHOLDER TOWN HALL WEBINAR SLIDES**

InhaleRx Ltd (ASX: IRX), (“**InhaleRx**”, “**IRX**” or “**the Company**”) an Australian drug development company developing unique inhaled drug-device products to address unmet medical needs in the pain management and mental health sectors, attaches copies of the slides presented at its webinar on Thursday, 13 March 2025, that commenced at 4.00pm AEDT.

The webinar was led by the Company’s CEO, Darryl Davies, and Medical Advisor, Dr Sud Agarwal, who provided an update on recent developments and the Company’s progress in its clinical development programs for IRX-211 and IRX-616a.

The webinar has been recorded and will be made available in due course for viewing via the Company’s website: [www.inhalerx.com.au](http://www.inhalerx.com.au).

The Board were delighted with the number of attendees and the interest shown in the exciting next phase of the clinical development programs and thank attendees for their questions received both prior to and during the webinar.

The Company encourages shareholders and interested potential investors to continue sending questions they have on IRX to:

[info@inhalerx.com.au](mailto:info@inhalerx.com.au)

Authorised by the Board of Directors.

### **For further information:**

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## **About InhaleRx Limited (ASX: IRX) – [www.inhalerx.com.au](http://www.inhalerx.com.au)**

InhaleRx Limited is an Australian drug development company which is developing unique medicinal drug-device products to address unmet medical needs in pain management and mental health sectors.

The overarching goal is to pursue U.S. FDA approval and registration using rapid and cost-effective regulatory pathways, such as 505(b)(2).

There is a significant economic opportunity for IRX and the Company's shareholders, with the first medical indications under investigation being Breakthrough Cancer Pain ('**BTcP**') and Panic Disorder ('**PD**'), both of which currently have limited safe and effective treatment options.

IRX holds an innovation patent and provisional patents for the nominated indications and the Company plans to continue to strengthen this position.



Town Hall Meeting  
13<sup>th</sup> March 2025

# DEVELOPING TOMORROW'S INHALED THERAPIES



# DISCLAIMER

This presentation contains summary information about InhaleRx Limited ("InhaleRx" or "IRX" or "Company") and its activities current as at the date of this presentation. It should be read in conjunction with InhaleRx' other periodic and continuous disclosure announcements filed with the Australian Securities Exchange, available at [www.asx.com.au](http://www.asx.com.au)

This presentation is for information purposes only and is not a prospectus or product disclosure statement, financial product or investment advice or a recommendation to acquire InhaleRx shares or other securities. It has been prepared without taking into account the objectives, financial situation or needs of individuals.

Before making an investment decision, prospective investors should consider the appropriateness of the information having regard to their own objectives, financial situation and needs and seek legal and taxation advice appropriate to their jurisdiction. Past performance is no guarantee of future performance.

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This presentation may contain forward-looking statements including statements regarding our intent, belief or current expectations with respect to InhaleRx' business and operations, market conditions, results of operations and financial condition, specific provisions and risk management practices. When used in this presentation, the words 'plan', 'will', 'anticipate', 'expect', 'may', 'should' and similar expressions, as they relate to InhaleRx and its management, are intended to identify forward-looking statements.

Forward looking statements involve known and unknown risks, uncertainties and assumptions and other important factors that could cause the actual results, performances or achievements of InhaleRx to be materially different from future results, performances or achievements expressed or implied by such statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date thereof.

# 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)**.



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**.



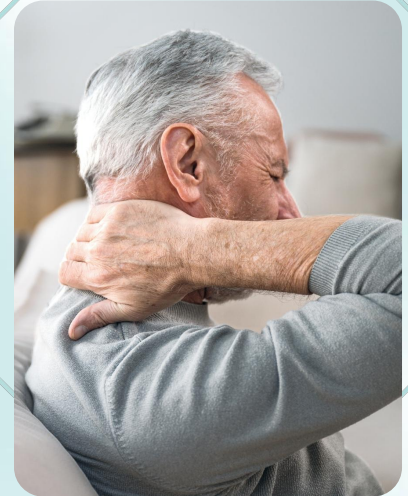
Ph1 1 clinical trial complete, very promising insights and no SAE's.



**HREC amendment** is the next stage to include the trial design changes, .



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	✓	
Protocol Amendment with HREC		Q2
Batch Manufacturing		Q2
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**.



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



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



**Preparing for a Ph1 HREC submission**, this trial will be followed by a Ph2 to demonstrate tolerability, safety and efficacy in the Panic Disorder patient population.



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	✓	
HREC Application		Q2/Q3
HREC Approval		Q3
Batch Manufacturing Complete		Q3
First Patient Screened		Q3
First Patient Dosed		Q3

## HIGHLIGHTS & SUMMARY

**Funding Partner Secured** the company has access of up to unique and exciting \$38m in funding to accelerate our clinical development plans.

**Slashed cash burn in the company** by over 70% since January 2024. Management Team is limited to myself, Dr Rob Jenny (CSO), and Dr Sud Agarwal (Medical Advisor).

**Experienced New Board Members appointed** and ready to take this company into the execution phase.

**Spec adjustment complete and trial batch manufacturing scheduled** for IRX-211 (Ph2) and 616a (Ph1).

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

**Timelines and all associated costs mapped out** extending right up to the Phase 3 multinational studies.

**Scoping new opportunities** the company continues to scope opportunities to add addition asset(s) to the pipeline.



# THANK YOU



**Any Questions?**  
**Please contact me at:**

Darryl Davies  
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Town Hall Meeting  
13<sup>th</sup> March 2025

# DEVELOPING TOMORROW'S INHALED THERAPIES



# IRX211 – Revolutionizing Breakthrough Cancer Pain Management

Breakthrough cancer pain (BTcP) lacks sufficient treatment options. Current therapies rely heavily on opioids, raising addiction concerns.

Our flagship product, IRX211, introduces a novel approach to address this medical need.

# Non-Opioid Analgesics: The Competitive Edge

## Market Context

Vertex's suzetrigine has emerged as a notable non-opioid analgesic. The landscape remains underserved.

## IRX211 Advantage

Our solution delivers rapid pain relief a unique mechanism. This creates market differentiation.

## Key Benefits

IRX211 shows superior PK profiles with enhanced safety margins. Also, its titration capabilities exceed current options.





# Perfect Titration: Precision Management

1

## Rapid Onset

IRX211 aspires to deliver immediate-onset relief when BTcP. This timing is crucial for effective management.

2

## FPE Avoidance

The formulation bypasses first-pass metabolism. This ensures higher bioavailability and more predictable effects.

3

## Precise Dosing

Patients receive exactly what they need. This improves adherence and satisfaction rates.



# IRX211: Compelling Phase 1 Results

## **Predictable Pharmacokinetics** **Pharmacokinetics**

The clinical study demonstrated a reliable safety profile response.

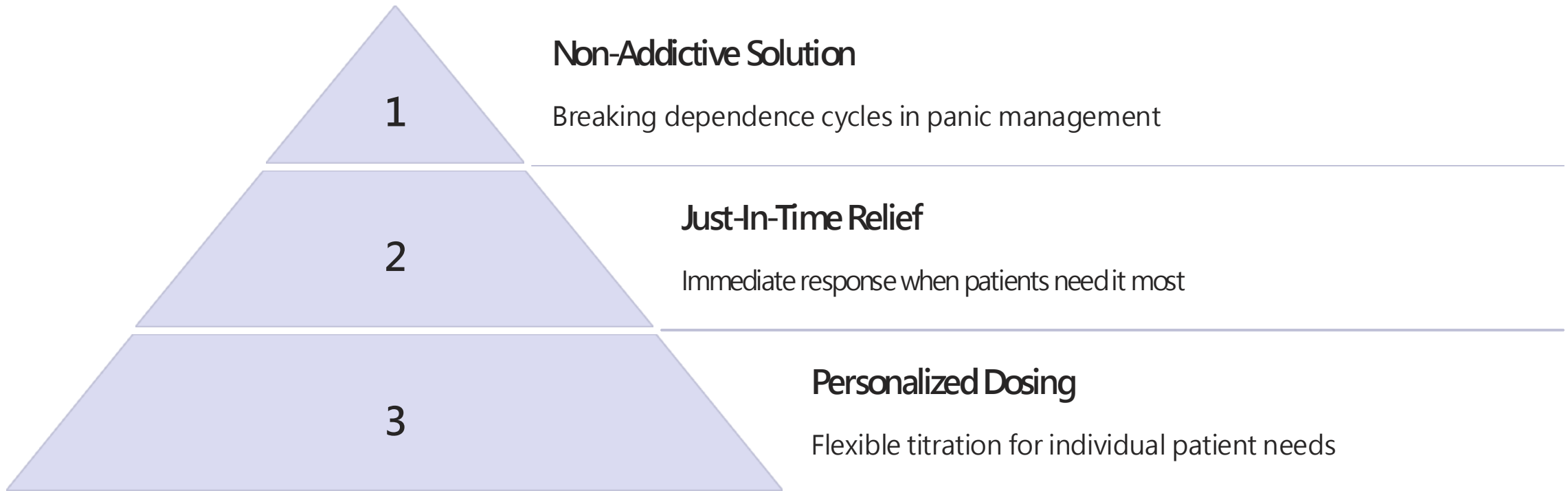
## **Safety Profile**

IRX211 showed excellent tolerability. Adverse events were minimal and mild.

## **Pathway Forward**

These promising results establish a solid foundation. We are confidently advancing to Phase 2 trials.

# IRX616: Transforming Panic Disorder Treatment



IRX616 represents our expanded portfolio addressing critical CNS conditions. Its innovative formulation provides targeted PD relief (anxiolysis) without (anxiolysis) without the normal addiction concerns of many other anxiolytics.





# Accelerated Clinical Development Strategy

## Phase 1 and Phase 2 in rapid succession

Intention is to move from Phase 1 to Phase 2 rapidly to minimize

1

2

## Data-Driven Decisions

Obtaining key PK data and guidance on maximum safe dose dropped into an already written phase 2 protocol.

## FDA Dialogue on trial design

Maintaining open dialogue with regulators to ensure a trial design that design that is suited to the FDA approval pathway

3

# THANK YOU

any questions?