ANNUAL GENERAL MEETING

#### **WELCOME AND AGENDA**

#### **Online attendees**

- If you have an IT-related issue, please click on the "Raise Hand" button
- If there is a question relating to a resolution, shareholders can ask questions by clicking on the Q&A button and typing in your question
- General questions (or not relating to the resolutions being put) will be answered during general Q&A's

#### <u>Agenda</u>

- 2023 Financial Statements
- Resolutions 1 to 6
- Poll on those resolutions
- Formal Meeting Close
- Business update
- General Q&A's

#### **2023 FINANCIAL STATEMENTS**

To receive and to consider the Annual Financial Report of the Company for the financial year ended 31 December 2023 together with the declaration of the Directors, the Directors' Report, the Remuneration Report and the Auditor's Report for that financial year.

As required by Section 317 of the Corporations Act, the financial statements of the Company for the year ended 31 December 2023 and the accompanying director's report and auditor's report are tabled before the Meeting.

Neither the Corporations Act nor the Company's Constitution requires a vote on the financial statements.

Shareholders may ask questions about the financial statements, including conduct of the audit.

To consider and, if thought fit, to pass the following Resolution as a non-binding, advisory ordinary resolution:

"That, for the purpose of Section 250R(2) of the Corporations Act and for all other purposes, approval is given for the adoption of the Remuneration Report as contained in the Company's Annual Financial Report for the financial year ended 31 December 2023."

VALID PROXIES RECEIVED	Votes	% Votes
For	34,519,237	98.48%
Open	500,000	1.43%
Against	34,350	0.10%
Abstain	0	
Excluded	200.000	

#### To consider and, if thought fit, to pass the following Resolution as an ordinary resolution:

"That James Barrie, a Director appointed as an additional Director and holding office until the next general meeting of the Company after his appointment in accordance with clause 108 of the Company's Constitution and ASX Listing Rule 14.4, be elected as a Director of the Company, effective immediately."

VALID PROXIES RECEIVED	Votes	% Votes
For	34,753,587	98.58%
Open	500,000	1.42%
Against	0	0.00%
Abstain	0	
Excluded	0	

To consider and, if thought fit, to pass the following Resolution as an ordinary resolution:

"That Sean Williams, a Director who retires by rotation in accordance with clause 104.2(d) of the Constitution and ASX Listing Rule 14.2, and being eligible, is elected as a Director."

VALID PROXIES RECEIVED	Votes	% Votes
For	34,553,587	98.57%
Open	500,000	1.43%
Against	0	0.00%
Abstain	200,000	
Excluded	0	

#### To consider and, if thought fit, to pass the following Resolution as a special resolution:

"That, for the purposes of ASX Listing Rule 7.1A and for all other purposes, the Shareholders approve the issue of Equity Securities up to 10% of the issued capital of the Company (at the time of issue) calculated in accordance with the formula prescribed in ASX Listing Rule 7.1A.2 and otherwise on the terms and conditions set out in the Explanatory Statement which accompanies and forms part of this Notice of Meeting."

VALID PROXIES RECEIVED	Votes	% Votes
For	34,738,587	98.54%
Open	500,000	1.42%
Against	15,000	0.04%
Abstain	0	
Excluded	0	

#### To consider and, if thought fit, to pass the following Resolution as an ordinary resolution:

"That, for the purposes of ASX Listing Rule 10.14 and for all other purposes, the Shareholders of the Company approve the issue and allotment of 2,000,000 unlisted Options, exercisable at \$0.15 (15 cents), and expiring 3 years from the issue date, under the Incentive Entitlements Plan to Mr Sean Williams, Director of the Company, and otherwise on the terms and conditions set out in the Explanatory Statement which accompanies and forms part of the Notice of Meeting."

VALID PROXIES RECEIVED	Votes	% Votes
For	34,534,237	98.52%
Open	500,000	1.43%
Against	19,350	0.06%
Abstain	200,000	
Excluded	0	

#### To consider and, if thought fit, to pass the following Resolution as an ordinary resolution:

"That, for the purposes of Listing Rule 10.1, and for all other purposes, Shareholders approve the appointment of Ingenu CRO Pty Ltd, a related party of the Company as the Contract Research Organisation, on the terms and conditions set out in the Explanatory Statement."

VALID PROXIES RECEIVED	Votes	% Votes
For	34,753,587	98.58%
Open	500,000	1.42%
Against	0	0.00%
Abstain	0	
Excluded	0	

#### <u>POLL</u>

#### Poll opened by the Chair

- Click on "For", "Against" or "Abstain", then click "Next" to move to the next resolution
- Shareholders and visitors who are not voting, click "Skip Poll"

**Poll closed by the Chair** 

Results will be released on ASX shortly after conclusion of the AGM

# MEETING FORMALLY CLOSED

# **BUSINESS UPDATE** AGM May 2024



Annual General Meeting Presentation 30th May 2024

# DEVELOPING TOMORROW'S INHALED THERAPIES TODAY



#### 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

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.

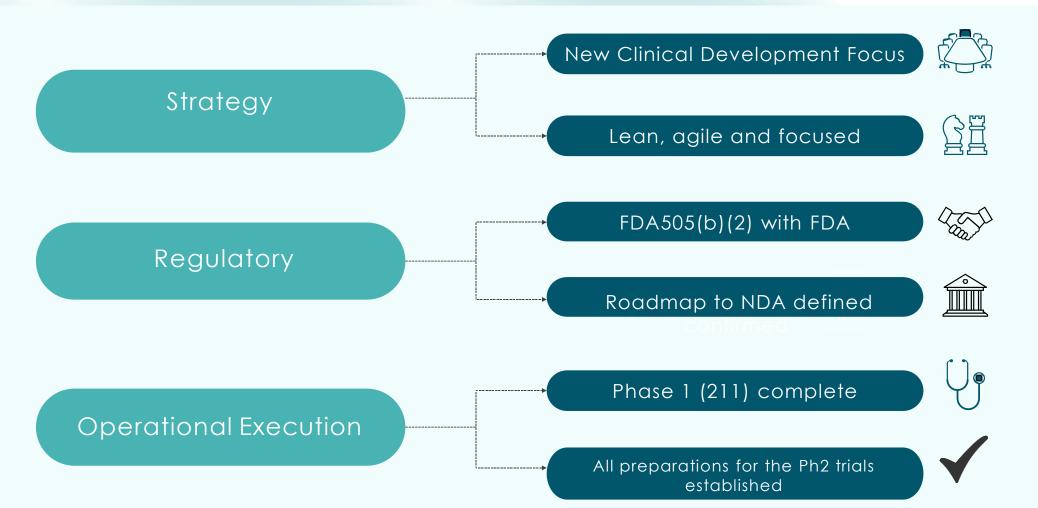
No representation or warranty, expressed or implied, is made as to the fairness, accuracy, completeness or correctness of the information, opinions and conclusions contained in this presentation. To the maximum extent permitted by law, none of InhaleRx and its related bodies corporate, or their respective directors, employees or agents, nor any other person accepts liability for any loss arising from the use of this presentation or its contents or otherwise arising in connection with it, including, without limitation, any liability from fault or negligence.

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.



#### A YEAR OF SIGNIFICANT PROGRESS







#### ABOUT INHALERX

InhaleRx Limited (ASX: IRX) ("InhaleRx" or "the Company") 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 candidates in development.



Provisional patents lodged



Rapid Onset Drug Devices



Innovation patent for synthetic cannabinoids approved



Multiple Phase I/II and Phase II/III Clinical Trials



Supportive Safety Data

# STRATEGY



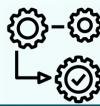
Focus on Pain Management



Focus on Mental Health



Focus on Inhalation Drug
Device Development



Focus on operational execution



# **OUR APPROACH**



Pursuing the path of least resistance



#### PAIN CANDIDATE - IRX-211

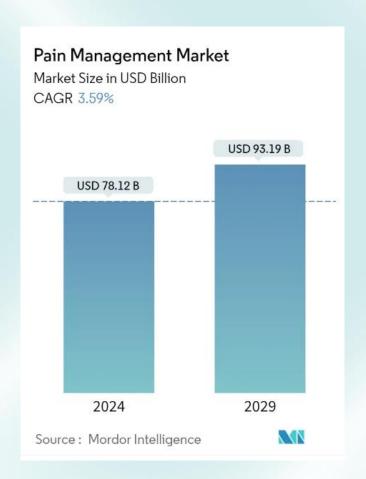
- Breakthrough Pain is the first pain indication that IRX is targeting.
- Phase 1 complete with Clinical Study Report expected in Q2.
- No SAE's and promising drug absorption data.
- **Pre-IND complete**, IND submission will require further non-clinical work.
- CRO & Site engaged, Investigator recruited for phase 2 trial.
- Phase 2 ethics submission imminent, SEV already completed.
- Provisional patents lodged for Breakthrough Cancer Pain and one prepared for Complex Regional Pain Syndrome.







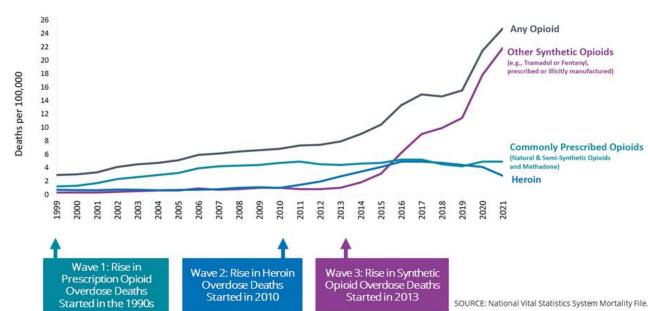
#### THE PAIN OPPORTUNITY





3.59% CAGR\*

#### Three Waves of Opioid Overdose Deaths

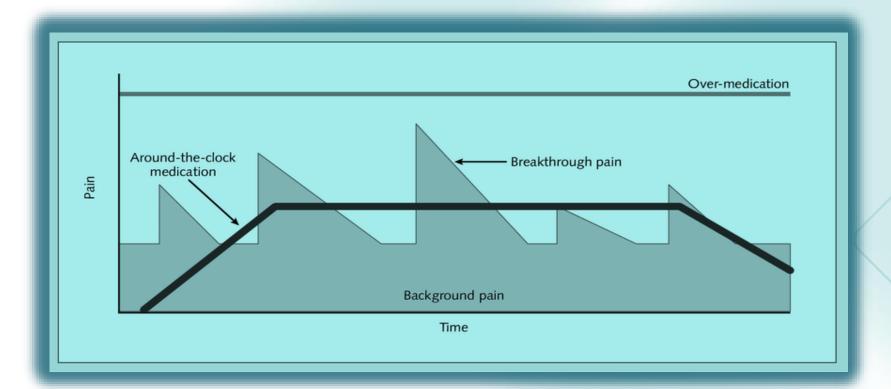


<sup>\*</sup> https://www.mordorintelligence.com/industry-reports/pain-management-market https://www.economist.com/graphic-detail/2021/03/30/opioid-deaths-in-america-reached-new-highs-in-the-pandemic

# BREAKTHROUGH CANCER PAIN (BTcP)

Cancer pain - caused by primary cancer, metastases or as a result of the cancer treatment itself.

**Breakthrough pain** - transient flare of pain occurring in opioid-tolerant patients experiencing persistent pain otherwise controlled with <u>around-the-clock</u> maintenance <u>opioid therapy</u>.



1 in 2
Cancer Patients
experience pain

1 in 2
patients with cancer pain also experience
BTCP

**2**BTcP episodes per day on average

**7.5** mean intensity of BTcP on a scale of 0–10.

#### YnhaleRx

### **DEVELOPING IRX-211 AS A THERAPEUTIC AGENT**



IRX-211 will be a registered prescription-only medication.



InhaleRx investment into clinical trials to show safety and efficacy.



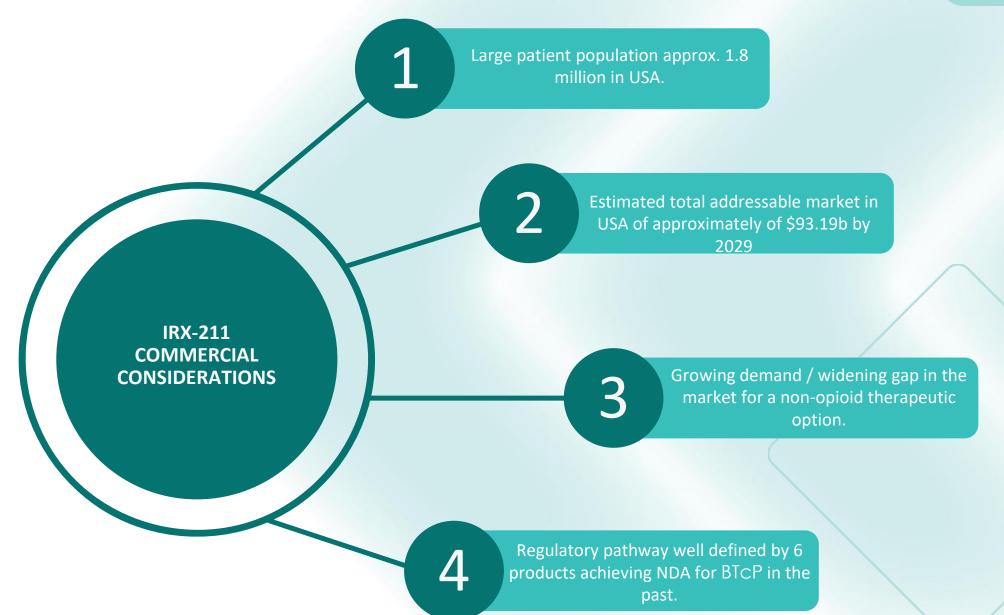
Regulatory approval(s) will allow InhaleRx to make a marketing claim.



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







https://www.mordorintelligence.com/industry-reports/pain-management-market



# REGULATORY COMPARISONS

Medication Name	Trade Name	Pivotal Endpoint	Year of Approval	Number of Pivotal Efficacy Clinical Trials	Status
Fentanyl citrate oral		Change in pain intensity from			
transmucosal	Actiq	baseline at 30 minutes post-dose	1998	2	Active
Fentanyl buccal tablet	Fentora	Change in pain intensity from baseline at 30 minutes post-dose	2006	1	Active
Fentanyl sublingual tablet	Abstral	Change in pain intensity from baseline at 30 minutes post-dose	2011	1	Discontinued (2020)
Fentanyl nasal spray	Lazanda	Change in pain intensity from baseline at 30 minutes post-dose	2011	1	Discontinued (2022)
Fentanyl iontophoretic transdermal system	lonsys	Change in pain intensity from baseline at 30 minutes post-dose	2006	3	Discontinued (2017)
Buprenorphine buccal film	Belbuca	Change in pain intensity from baseline at 30 minutes post-dose	2016	2	Active



MARKET OPPORTUNITY AND STATUS UPDATE

#### MENTAL HEALTH CANDIDATE – IRX616a

- Panic Disorder is the first mental health indication that IRX is targeting.
- Pre-IND meeting with FDA complete and provided confidence regarding our endpoints.
- Phase 2 ethics submission, feedback triggered the need to run a PK study (Phase 1).
- Phase 1 is ethics submission ready, all Medical Writing complete.
- CRO assignment is subject to shareholder approval.
- IND submission complete, submitted 30<sup>th</sup> May 2024.

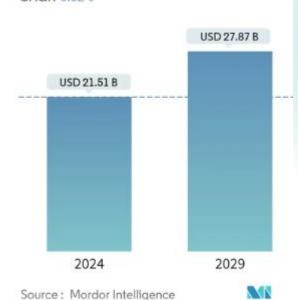


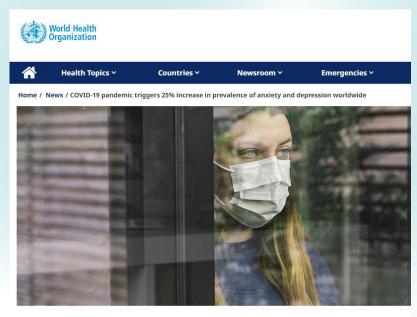


#### THE MENTAL HEALTH OPPORTUNITY

Global Anxiety Disorders and **Depression Treatment Market** 

Market Size in USD Billion CAGR 5.32%





**COVID-19 pandemic triggers 25%** increase in prevalence of anxiety

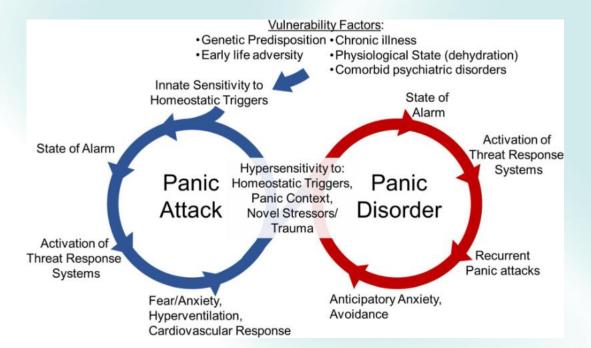


# PANIC DISORDER (PD)

**Anxiety Disorders** - are the World's most common mental disorders, affecting 301m people in 2019\*.

**Panic Disorder-** Panic disorder is a type of anxiety disorder characterised by recurrent panic attacks, which are sudden periods of intense fear or discomfort that may include palpitations, chest pain, and difficulty breathing. It is a common mental health condition that affects people of all ages, but it is more common in women and typically begins in young adulthood.

1 in 4
Diagnosed receive treatment



**4.7%**Of US Adults experience PD



#### **DEVELOPING IRX-616a AS A THERAPEUTIC AGENT**



IRX-616a will be a registered prescription-only medication.



InhaleRx investment into clinical trials to show safety and efficacy.



Regulatory approval(s) with the FDA will allow Inhalerx to make a marketing claim.



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

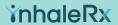


No competition in terms of inhaled FDA approved medications to treat PD.



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







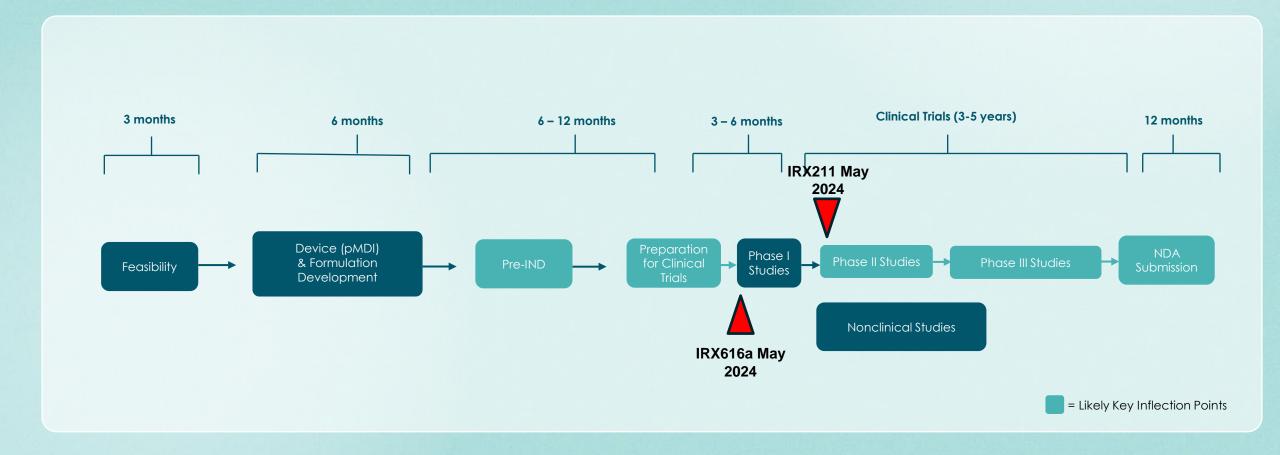


# REGULATORY COMPARISONS

Trade Name	Discolation of the land	Year of	
	Pivotal Endpoint	Approval	Status
	Poduction in panic attack		
Prozac	frequency and severity	1987	Active
Descil	Reduction in panic attack	1000	Aaliva
Paxii	frequency and severify	1772	Active
	Reduction in panic attack		
Zoloft	frequency and severity	1999	Active
Effector YP		1002	Active
LIIEXOI AK	nequency and severny	1773	Active
	Reduction in panic attack		
Xanax	frequency and severity	1981	Active
Klonopin		1997	Active
	Paxil Zoloft Effexor XR	Paxil Reduction in panic attack frequency and severity  Reduction in panic attack frequency and severity	Prozac frequency and severity 1987  Reduction in panic attack frequency and severity 1992  Reduction in panic attack frequency and severity 1999  Reduction in panic attack frequency and severity 1993  Reduction in panic attack frequency and severity 1993  Reduction in panic attack frequency and severity 1981  Reduction in panic attack



# CLINICAL PIPELINE - MAY 2024





#### OUTLOOK

- Focus on carefully selected clinical indications that represent a significant commercial opportunity.
- Trials have been all costed and capital management initiatives to fund these plans are progressing.
- Accelerated clinical development via rapid, and cost-effective proof off concept Phase 1 and Phase 2 trials in Australia.
- Strong regulatory expertise to navigate FDA 505(b)(2) pathway.
- Fully scoped and costed out Clinical Development plans up to Ph3 for both IRX-211 and IRX-616a.
- Focus on IRX 211 Ph2, followed by IRX-616a Ph1.





# THANK YOU

We welcome any further questions you may have

Darryl Davies CEO

Dr Sud Agarwal Medical Advisor

