



inhale Rx

The Future of Inhaled Medicine

EGM Presentation

17th February 2023

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‘Leaders in the development of innovative inhaled therapeutics for the global health care market’.

InhaleRx Ltd (IRX) is an Australian biotechnology company focused on the development of precision medicine delivered via inhalation.

We currently have two clinical programs across three clinical trials that will all commence this year.

IRX plan to open up new drug development programs in the inhalation sector to continue to address unmet clinical needs as new opportunities are identified.



Executive Summary

Clinical Focus

Mental Health and Pain.



Competitive Advantages

- World first development plans for inhalation drugs to target unmet clinical needs.
- Real word data from 10,000+ Australian patients across a wide range of indications.
- Carefully designed measured dose drug formulations.
- Leadership team with drug registration track record success.

Leading Programs & Traction

- Two programs running in parallel.
- Formulation work complete and manufacturing commissioned.
- Phase 1 & Phase 2 (Complex Regional Pain Syndrome), Phase 2 (Panic Disorder) all scheduled to commence this calendar year.

IP and Protection

Innovation composition patent **Patent No. 2021101157** approved for synthetic cannabinoids delivery via inhalation.

The InhaleRx Board of Directors



Sean Williams

Non-executive Chairman

- Senior executive who has had a successful career across the supply chain, health, pharmaceutical and investment sectors.
- Experience as CEO of investment company with Assets Under Management of \$475m+
- Ex- General Manager Finance and General Manager; Hospital Pharmacy & Dental Distribution Services for Symbion Pharmacy



Dr. Andrew Saich

Non-executive Director

- Andrew is a UK trained physician with a degree in physiology and a degree in medicine from the University of London.
- Andrew has vast experience within the pharmaceutical and medical cannabis industries
- Senior Executive leading the medical team at GW Pharmaceuticals,
- Chief Medical Officer at Senzer Pharmaceuticals & European Medical Director for Intercept Pharmaceuticals



John Crock

Non-executive Director

- Mr John Crock is a Board certified Plastic and Reconstructive surgeon.
- Senior Lecturer in the department of surgery Monash University, Melbourne Australia. He continues to supervise PhD students in various aspect of the surgical discipline.
- He founded, and is the director of, the NGO “Aussie Health Abroad” which focuses on training surgeons in developing nations.



The InhaleRx Management Team



Darryl Davies

Chief Operating Officer

- Clinical psychology background,, Chief Operating Officer & Co-founder of Cannvalate
- A medicinal cannabis industry early adopter with over 17 years experience in healthcare and harm minimisation.
- A hands-on executive with a broad-ranging cannabis experience including operations, education & sales.
- Darryl has global experience in cannabinoid and psychedelic drug development.



CANNVALATE



GREENFERN
INDUSTRIES



SHANTI
PHARMACEUTICALS



Dr. Rob Jenny

Chief Scientific Officer

- PhD trained scientist with significant experience in the commercialisation of research, project management, manufacturing and business development.
- Worked with a number of universities, biotech start-ups and pharmaceutical contract manufacturers.
- As Chief Scientific Officer he manages the regulatory affairs activities, and oversees the preparation and execution of the nonclinical and clinical studies.



CANNVALATE



Dr. Sud Agarwal

Medical Science Consultant

- Dr Agarwal is an anaesthetist and a Co-Founder of Cannvalate
- Global expert and global cannabis key opinion leader advocating for clinically-validated cannabinoid treatment
- Significant experience in drug development and clinical validation (Multiple open IND)
- Previously the Chief Medical Officer at Incannex Healthcare Ltd.



CANNVALATE



Inhalation innovation focused on solving unmet clinical needs

- InhaleRx has assembled an expert team to develop inhaled therapeutics to provide better health outcomes for patients.
- The company has a refined drug development plan across two cannabinoid drug assets with the overarching goal to achieve New Drug Approvals (NDA's) with U.S. Food & Drug Administration (FDA).

Why develop novel targeted dose inhaled medications?

- Unlike oral, transdermal, or injectable delivery of pharmaceutical medicines, inhalation offers a unique combination of fast onset (and offset) of action, minimal invasiveness, high bioavailability, relatively low exposure, and ease of use for the patient.
- Most current pharmaceutical medicine delivery systems offer some, but not all of these benefits.
- The administration via the inhaled route especially favours patient populations that are trying to manage acute episodes, such as breakthrough pain and anxiety.

Why inhaled therapies?

	Inhaled	Oral	Transdermal	Injectable
Onset of Action^	Fast	Slow	Slow	Fast
Offset of Action^	Fast	Slow	Slow	Fast
Bioavailability	High	Low	Low	High
Not impacted by 1 st pass metabolism	✓	✗	✓	✓
Ease of patient use	✓	✓	✓	✗
Suitable for Acute Indications	✓	✗	✓	✓

- ✓ Fast speed of onset
peak effect of 4mins vs 2 hours for oral
- ✓ High bioavailability.
>60% vs 5-9% for oral
- ✓ Patients can use with ease
- ✓ Doctors can prescribe for managing Acute episodes.

[^] comparison of delivery methods only, different medications have different half-lives and not all medications are suitable for all delivery methods

Developing fast-acting inhaled therapies for underserved markets



Complex Regional Pain Syndrome (CRPS)

A debilitating chronic pain syndrome characterised by paroxysmal breakthrough pain which needs immediate onset pain relief to manage.

Panic Disorder (PD)

A life-restricting, sudden, overwhelming anxiety syndrome which requires immediate onset anxiolysis to resolve unexpected episodes of panic.



Current assets under the development

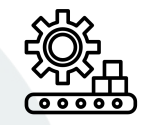
Single API Cannabinoid Pressurised Metered Dose Inhalers (pMDI)



Formulations developed for Panic Disorder (**IRX616a**) and Complex Regional Pain Syndrome (**IRX211**).



Drug suspensions formulated by using **FDA-approved ingredients**.



Finished dose form for clinical trials (IMP) manufactured in Australia under **GMP**.



IRX owns an innovation patent for the inhalation of synthetic cannabinoids.



Cannabinoid drug-device combinations undergoing **clinical trials commencing 2023**



Complex Regional Pain Syndrome (IRX211)

Prevalence: 219,317¹ cases in the United States, the total (2017) - *Confirmed Orphan Status*

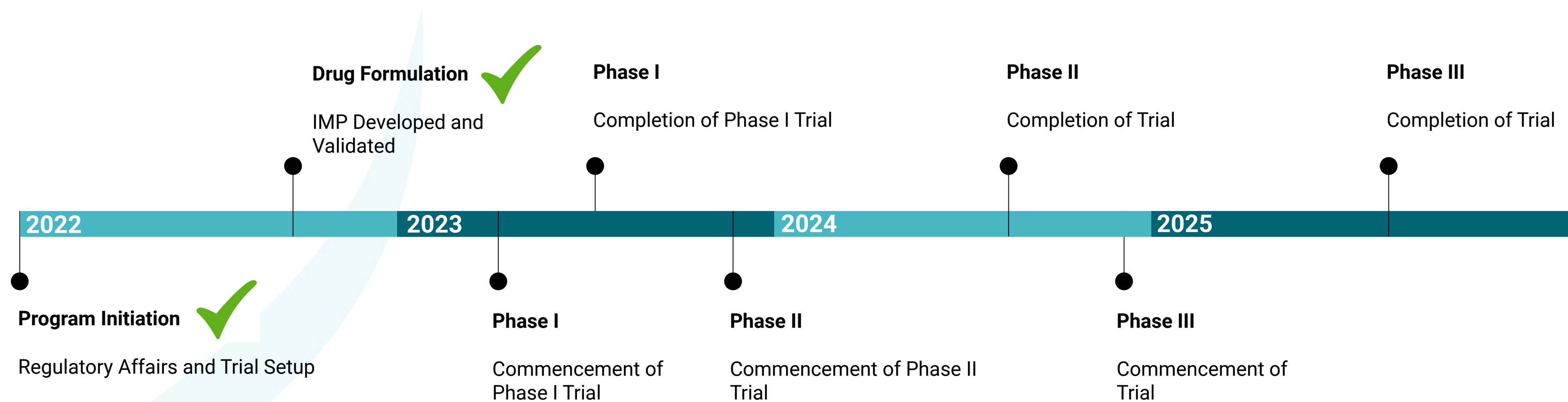
TAM: USA: approx. **USD 7.08b²** (*calculated by the prevalence x the average rebate under ODD*)

Existing Drugs: No drugs have been specifically approved for CRPS.

Patients resort to combination of opioids/lyrica and atypical antidepressants.

The sudden onset of pain and time to analgesic effect from current treatments is mismatched.

Reg Pathway: FDA 505(b)(2) + Orphan Drug Designation (ODD)



Panic Disorder (IRX616a)

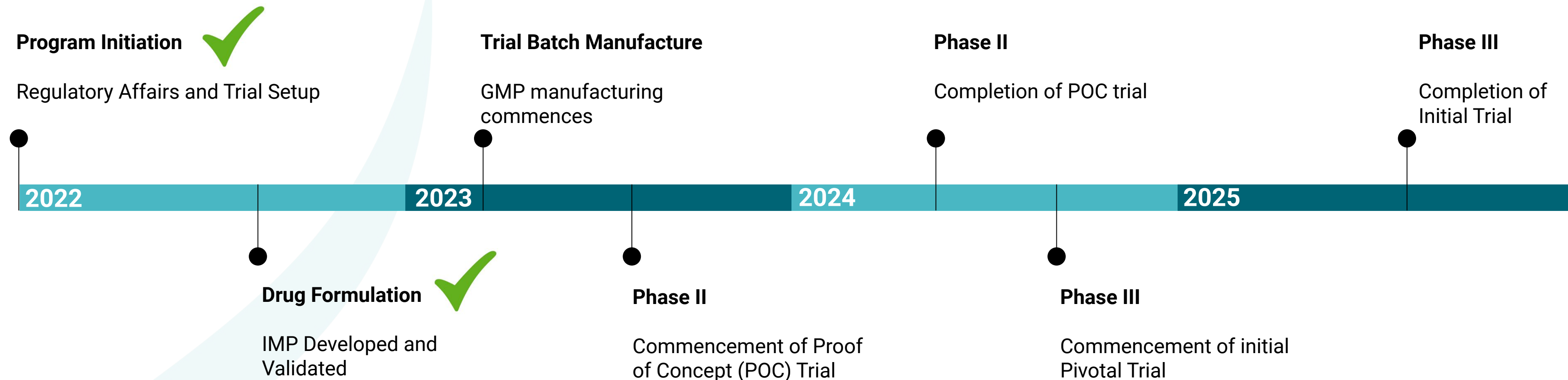
Prevalence: 6.97m American Adults suffering with Panic Disorder, which is an estimated 2.7% of U.S. adults³

TAM: USA: approx. **USD 45.15b⁴** *(based on prevalence x annualised cost of medical costs)*

Existing Drugs: Antidepressants (SSRI), benzodiazepines, gabapentin, and mirtazapine reduce frequency of future attacks and requires ongoing medication.

The sudden onset of unexpected panic attacks cannot currently be managed satisfactorily.

Reg Pathway: FDA 505(b)(2)



Notable progress across all three trials

Milestone	Phase 1 CRPS	Phase 2 PD	Phase 2 CRPS
Formulation complete	✓	✓	✓
GMP Manufacturing commissioned	✓	✓	✓
API in country	✓	✓	✓
Site selected	✓	✓	✓
Principle Investigator identified	✓	✓	✓
Pre-IND meeting with the FDA		✓	
Ethics submission	✓		
IND open			
First Patient In			

2023 milestones still to come

Panic Disorder (IRX616a)

- Ethics planned for Q1 2023.
- Manufacturing commissioned and scheduled to commence Q2 2023.
- Investigational New Drug (IND) submission expected before the end of the calendar year.
- First Patient In (FPI) planned for Q3 2023.

Complex Regional Pain Syndrome (IRX211)

- Ethics approval expected in Q1 for Phase 1. Phase 2 submission also planned for Q1 2023.
- Date for the Pre-IND meeting confirmed for end of Q1 2023.
- Manufacturing commissioned and scheduled to commence Q2 2023.
- Investigational New Drug (IND) submission expected before the end of the calendar year.
- First Patient In (FPI) for the Phase 1 planned for Q2 2023.
- First Patient In (FPI) for the Phase 2 planned for Q4 2023.

Why the 505(b)(2) over standard New Drug Approval (NDA) pathway?



Faster approval process

Relying on previously conducted studies can also result in a faster approval process as the FDA does not require the submission of extensive data typically required for a standard NDA.



Cost savings

The 505(b)(2) pathway allows companies to rely on previously conducted studies, which can reduce the costs associated with conducting their own clinical trials.



Reduced regulatory burden

The 505(b)(2) pathway may have a reduced regulatory burden compared to the standard NDA pathway, as the FDA does not require a full complement of preclinical and clinical studies.



Increased flexibility

The 505(b)(2) pathway provides more flexibility for companies to make changes or improvements to already approved drugs. This is because the FDA only requires that the new drug demonstrate improved safety, efficacy or other desired characteristics compared to the already approved drug.

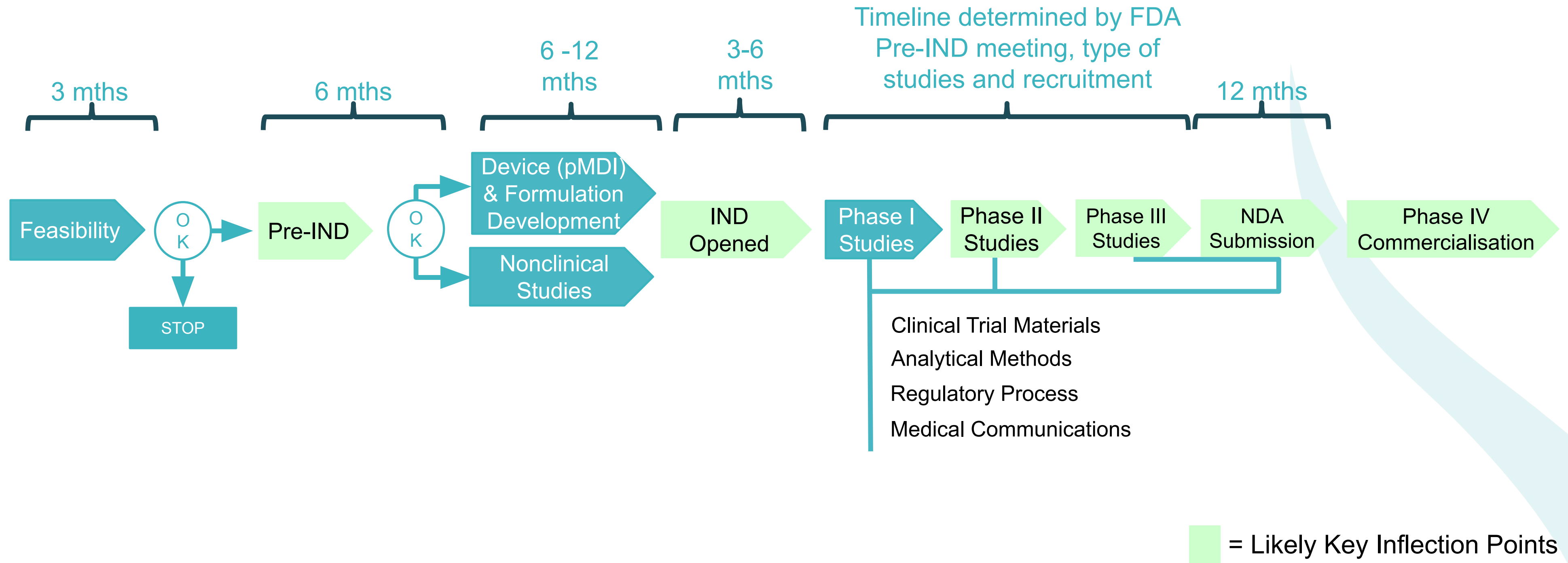
Traditional FDA Drug Approval Process

FDA DRUG-APPROVAL PROCESS



FDA 505(b)(2) Pathway to Registration

Leveraging existing data reduces risk and cost

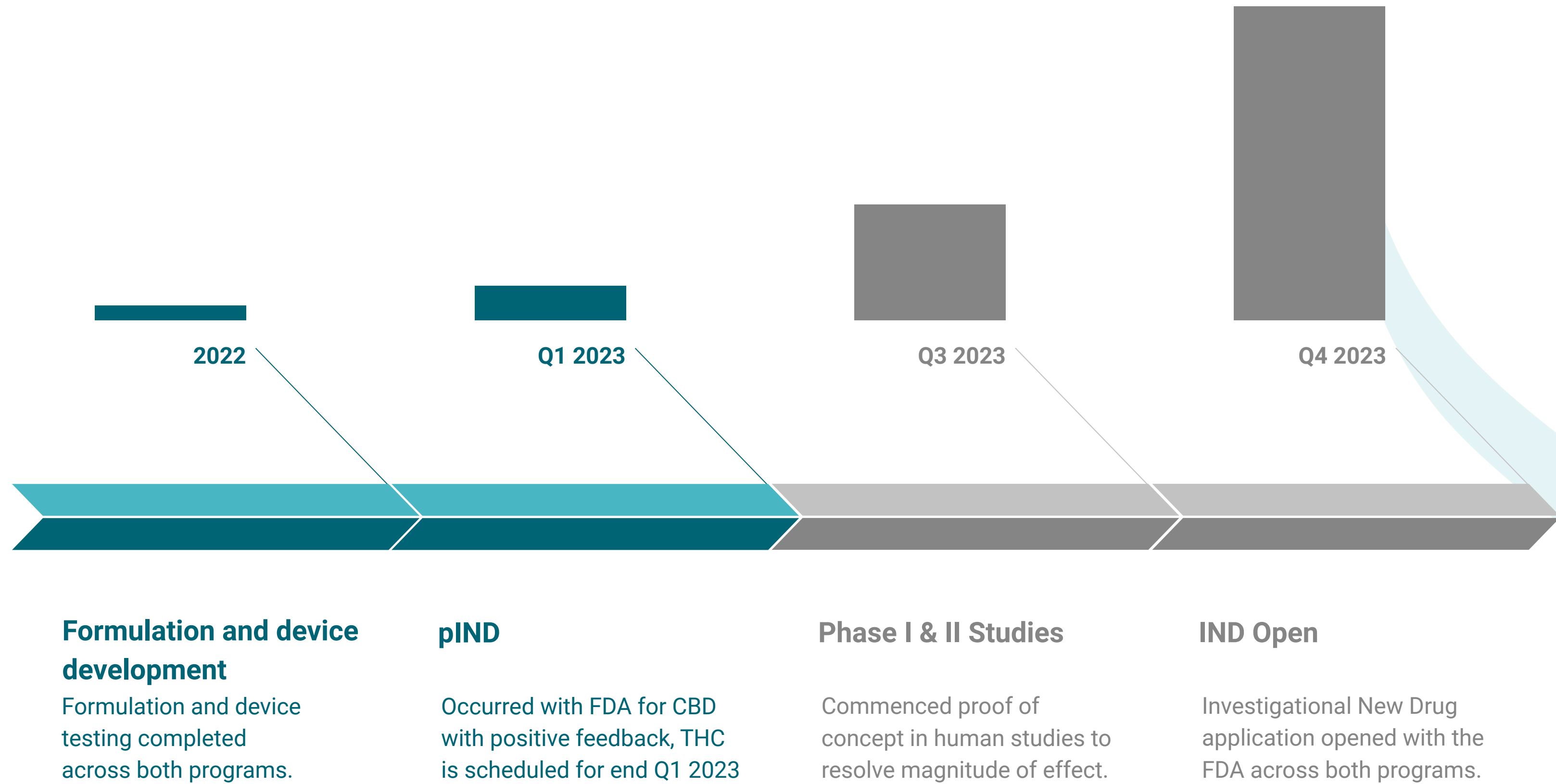


Time to approval - only 3 to 4.5 years (compared to the usual 10+ years)

Benefits of creating value by submitting an IND

- Submitting an IND application to the FDA is a significant step in developing a new drug.
- The value in opening an IND with the Food and Drug Administration (FDA) is that it provides a **mechanism for a company to conduct clinical trials and gather data to support eventual approval for marketing the drug.**
- If a drug is shown to be safe and effective through clinical trials, **approval by the FDA can lead to increased access for patients in need and commercial success.**
- Cleared IND results from **efficient pre-clinical development operations and fluency in regulatory affairs.**
- An IND application is a critical valuation determinant of publicly traded companies.
- 3 year data exclusivity once a New Drug Approval (NDA) is granted, 7 years with an Orphan Drug Designation (ODD).

Roadmap to open up IND's



Summary

- World-first rapid onset treatments for carefully chosen acute conditions where there's currently a significant TAM and unmet medical need.
- 2023 is the execution phase across both clinical programs.
- Focused strategic direction to develop targeted dose inhaled drug delivery systems.
- Robust regulatory plan that involves opening IND's across both programs.
- Australian, U.K and Canadian institutions as part of the Top 20.


Market Cap: \$10.3M
Stock Price: 0.6c
Shares on Issue: 187.2m

Thank you

1. <https://www.delveinsight.com/report-store/complex-regional-pain-syndrome>
2. <https://rarediseases.org/wp-content/uploads/2021/03/orphan-drugs-in-the-united-states-NRD-2020.pdf>
3. <https://adaa.org/understanding-anxiety/facts-statistics>
4. <https://pubmed.ncbi.nlm.nih.gov/16075454/>
5. https://www.optum.com/business/insights/pharmacy-care-services/page_hub_drug-approval-process.html

InhaleRx Ltd (ASX:IRX)
www.InhaleRx.com.au

 **Level 5, 126 Phillip Street,
Sydney, NSW 2000**

 **(03) 8678 4091**

 **info@InhaleRx.com.au**