



inhalerRx

The Future of Inhaled Medicine

Investor update presentation

**Annual General Meeting
May 2023**

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InhaleRx Overview



- InhaleRx Ltd (IRX) is an Australian biotechnology company focused on the development of precision medicine delivered via inhalation.
- Leaders in the development of innovative inhaled therapeutics for the global health care market.
- Targeting acute episodes in two therapeutic areas, Mental Health, and Pain.



Executive Summary



CLINICAL FOCUS

- Targeting acute episodes in two therapeutic areas. Mental Health, and Pain.
- The company is pursuing New Drug Approvals (NDA's) with the Food & Drug Administration (FDA).



COMPETITIVE ADVANTAGES

- World first development plan for inhalation drugs to target unmet clinical needs.
- Real world data from 10,000+ Australian patients across a wide range of indications.
- Carefully designed and measured dose drug formulations.



LEADING PROGRAMS AND TRACTION

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



IP AND PROTECTION

- Provisional patents lodged for pain indications and ready to submit for Panic Disorder.
- Innovation composition patent No **2021101157**.

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



Dr. 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.



Management Team



Darryl Davies
Chief Executive Officer



Dr. Rob Jenny
Chief Scientific Officer



Dr. Sud Agarwal
Medical Science Consultant

- Clinical psychology background with over 17 years experience in healthcare and harm minimisation.
- Co-founder of multiple companies operating in the supply chain management and clinical research sectors.
- Commercialisation track record with creating and scaling healthcare pathways to bring new drugs to market.
- Darryl has global experience in cannabinoid and psychedelic drug development.

- 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.

- 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.



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	✓	✗	✓	✓

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

Targeting both mental health and pain



Pain (TBC) Indication

The company is currently investigating and comparing pain indications that will best position the company with the Food and Drug Administration (FDA).



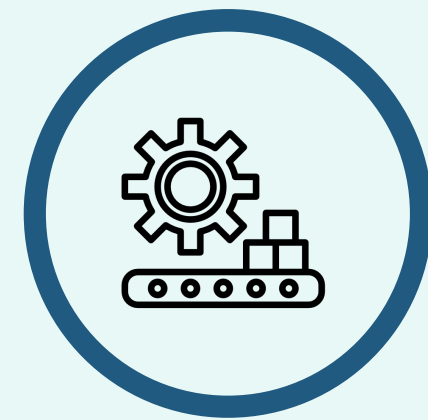
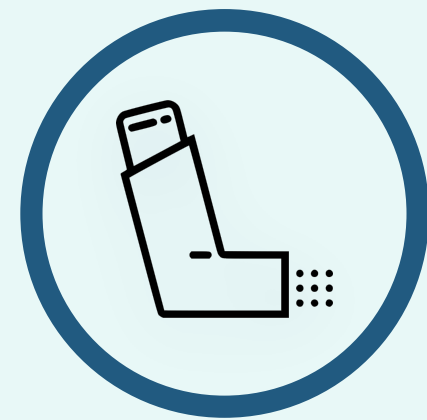
Panic Disorder

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

Current assets under development

Drug suspensions formulated using FDA-approved ingredients.

IRX has filed prov patents and owns an approved innovation patent for the inhalation of synthetic cannabinoids.



Formulations developed for both Anxiety, Panic Disorder (**IRX616a**) and Pain (**IRX211**).

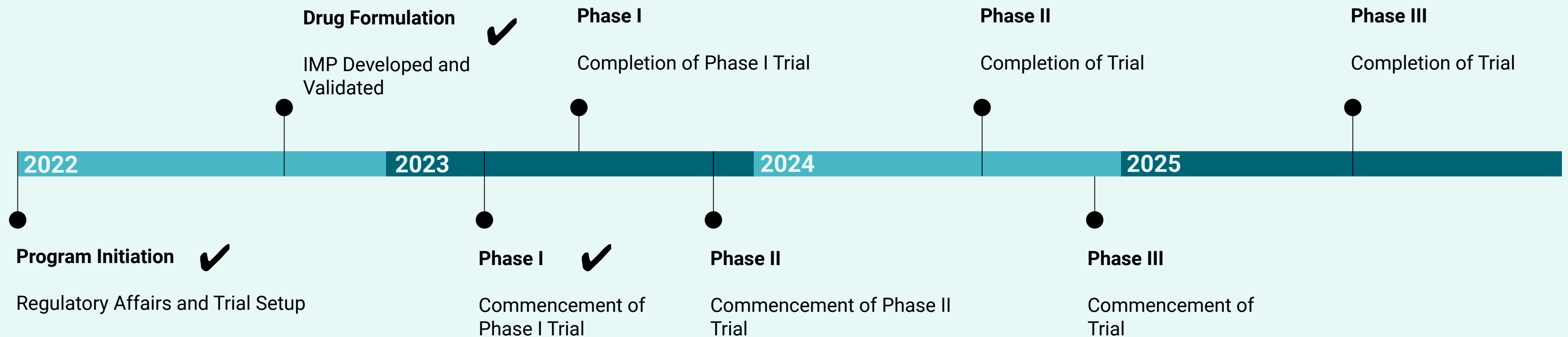
Finished dose form for clinical trials manufactured in Australia under Good Manufacturing Practice (GMP).

Cannabinoid drug-device combinations undergoing clinical trials plan to commence in 2023.



Pain Indication (IRX211)

- Pain indication is being strategically re-evaluated.
- While Complex Regional Pain Syndrome (CRPS), has been an initial focus other acute pain indications may provide a more cost effective and time efficient route to an New Drug Approval (NDA).
- Phase 1 commences regardless of this opportunity.



IRX211 Progress Summary & Regulatory Update

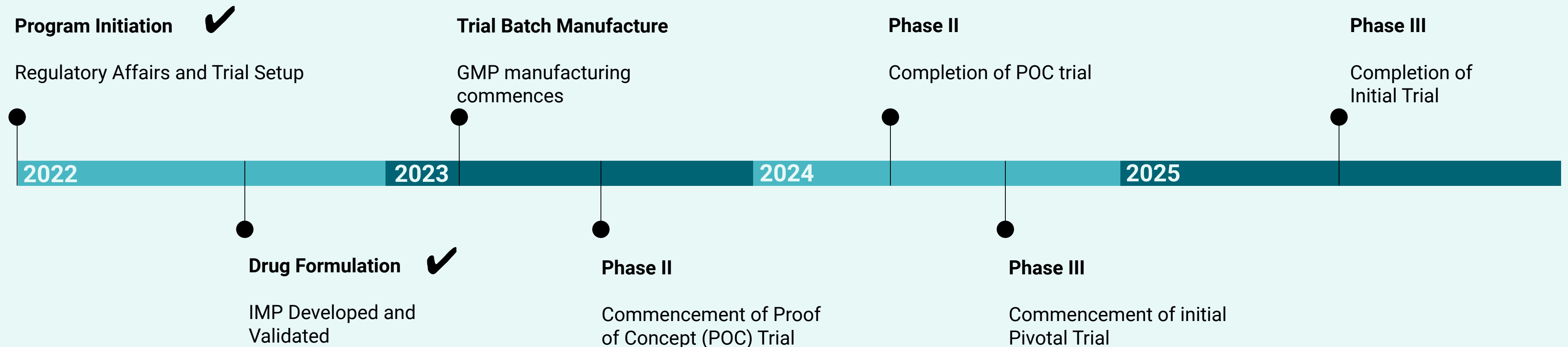


Pain Indication (IRX211)

- ❑ Pre-IND meeting occurred in Q4 2022.
- ❑ Manufacturing commissioned and complete for Phase 1.
- ❑ IMP delivered to the Phase 1 site.
- ❑ Ethics approval for the Ph1.
- ❑ First Patient Screened is expected to occur in Melbourne before the end of the month.
- ❑ The Phase 1 trial will inform dosing to be used in the Phase 2.
- ❑ Investigational New Drug (IND) application has been drafted, submission plans are on track and the company expects to have lodged in Q3 2023.
- ❑ 3 year data exclusivity available if New Drug Approval (NDA) is granted which creates a window for further defensible IP to be created.
- ❑ The vast majority of the ethics submission work for the Phase 2 has been completed with the Principle Investigator and Site assigned.

Panic Disorder (IRX616a)

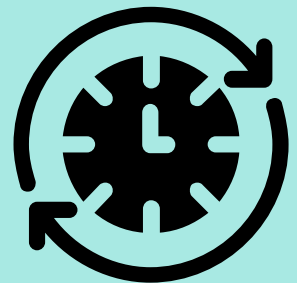
Prevalence:	6.97m American Adults suffering with Panic Disorder, which is an estimated 2.7% of U.S. adults ¹
TAM:	USA: approx. USD 45.15b² (based on prevalence x annualised cost of medical costs)
Existing Drugs:	Antidepressants (SSRI), benzodiazepines, gabapentin, and mirtazapine reduce frequency of future attacks and requires ongoing medication. The sudden onset of unexpected panic attacks cannot currently be managed satisfactorily.
Reg. Pathway	FDA 505(b)(2)



IRX616a Progress Summary & Regulatory Update

- ❑ Pre-IND meeting occurred in Q4 2022.
- ❑ Endpoints clearly defined.
- ❑ Manufacturing commissioned and scheduled to commence Q3 2023*
- ❑ Investigational New Drug (IND) application has been drafted, submission plans are on track and the company expects to have lodged prior to the IRX211 program and before the end of Q3 2023.
- ❑ 3 year data exclusivity available if New Drug Approval (NDA) is granted which creates a window for further defensible IP to be created.
- ❑ The vast majority of the ethics submission work for the Phase 2 has been completed with the Principle Investigator and Site assigned.
- ❑ The company is working on achieving an ethics approval with Belberry by the end of Q3 2023.

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



Faster approval process

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



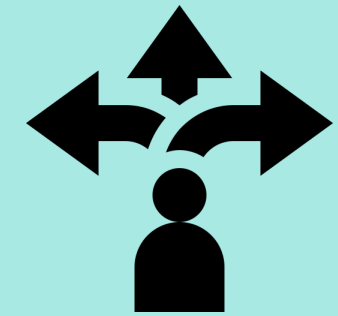
Cost Savings

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



Reduced regulatory burden

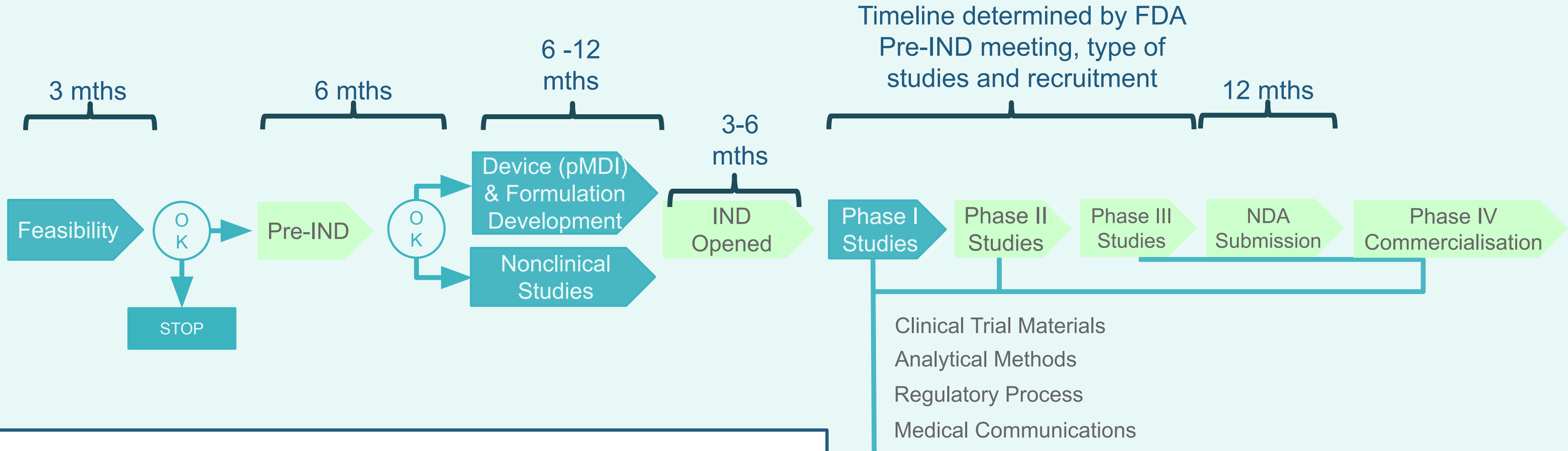
The 505(b)(2) pathway may have a reduced regulatory burden compared to alternative pathways, as the FDA does not require a full complement of preclinical and clinical studies.



Increased flexibility

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

FDA 505(b)(2) Pathway to Registration



FDA DRUG-APPROVAL PROCESS



- Faster and more cost effective pathway to NDA.
- Leveraging existing data reduces risk and cost.
- Time to approval with 505(b)(2) only 3 to 4.5 years compared to the 10+ years through alternative pathways to NDA.

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.
- ❑ International financial institutional investors in the Top 20.

Market Cap: \$8.54m

Stock Price: \$0.045c

Shares on Issue: 189,766,957

Accurate date of close 22nd May 2023

Thank you



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Authorised by the Board of Directors.

1. <https://adaa.org/understanding-anxiety/facts-statistics>
2. <https://pubmed.ncbi.nlm.nih.gov/16075454/>