InhaleRx

ASX Webinar Presentation
22nd November 2023

DEVELOPING TOMORROW'S INHALED THERAPIES

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INTRODUCTION

WELCOME

InhaleRx Limited (ASX: IRX) ("InhaleRx" or "the Company") is an Australian healthcare company that is at the forefront of developing innovative inhaled therapeutics for the global healthcare market.

The Company is developing unique inhalation medicinal drug-device products to address unmet medical needs in pain management and mental health sectors.

The Company's overarching goal is to develop U.S. FDA registered therapies, targeting anxiety and pain-related indications via more cost-effective New Drug Approval pathways, such as FDA's 505(b)(2).

Unmet needs:

1. **Inadequate (mismatched) treatment options**

2. **Existing fast-acting therapies carry significant side effect profiles and are prone to substance misuse.**

120+ years

in healthcare commercialisation and drug development

EXECUTIVE SUMMARY

TARGETING UNMET CLINICAL NEEDS

Clinical Focus

- Targeting acute episodes in two therapeutic areas: **mental health, and pain.**
- Pursuing New Drug Approvals (NDA) with the U.S. Food & Drug Administration (FDA).
- Leveraging the more **cost-effective and streamlined regulatory pathway –** 505(b)(2).

Competitive Advantages

- World-first development plan for inhalation drug development to address targeted indications.
- Real world data from **10,000+ Australian patients** for cannabinoid delivery across multiple indications.
- Carefully developed drug formulations using synthetic cannabinoids (dronabinol and cannabidiol) **for precise dosing delivery.**

Leading Programs and Traction

- Two drug development programs running in parallel.
- **IRX211** – Phase I passed the halfway mark with three of four cohorts dosed.
- **IRX616a** – Entering phase 2 clinical testing in panic disorder patients. Ethics application submitted, awaiting approval*.

IP and Protection

- Provisional patent lodged for pain indications and drafted, ready to submit for Panic Disorder.
- Innovation composition patent granted **(No 2021101157)**.

*commencement of dosing is subject to further capital raising.

AGILE AND EXPERIENCED TEAM

Darryl Davies
Chief Executive Officer

Over 17 years experience in clinical psychology, harm minimisation and healthcare commercialisation.

Drug development specialist with marketing that specialises in sponsor onboarding and clinical operational excellence.

Cross over experience from both the CRO and Sponsor side of drug development.

Cross border Board Director experience (ASX, NZX)

Dr. Rob Jenny
Chief Scientific Officer

A PhD-level scientist by training with significant experience in the commercialisation of research, project management, manufacturing, and business development.

Significant product development and GMP manufacturing experience.

Scientific, regulatory affairs, medical writing, and early-phase clinical drug development experience.

Sean Williams
Non-Executive Chairman

Senior executive who has had a successful career across the supply chain, health, pharmaceutical and investment management 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 Services.

Andrew Saich
Non-Executive Director

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 as a 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

Registered surgeon , a member of the Australian Hand surgery society and a Senior Lecturer in the department of surgery Monash University, Melbourne Australia.

He founded, and is the director of, the NGO "Aussie Health Abroad" which focusses on training surgeons in developing nations.

John has both worked with and cooperated with a number of other international NGO's in the health care sector.

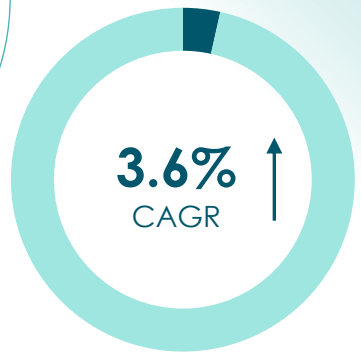
MARKET OPPORTUNITY

PAIN MANAGEMENT MARKET

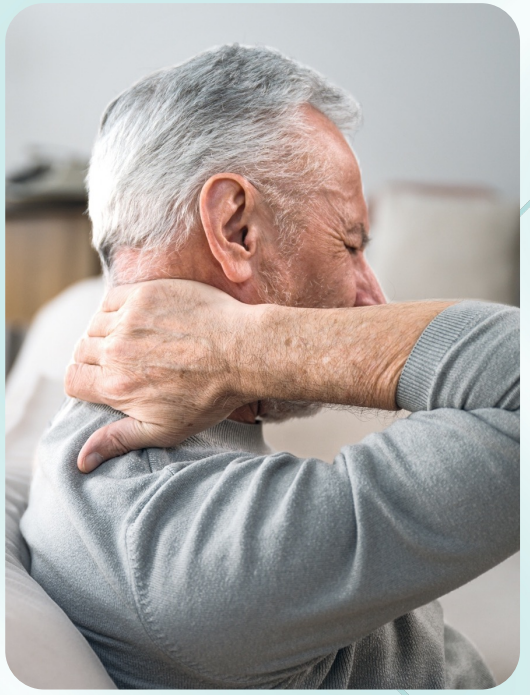
The pain management market is estimated to be worth **$75 billion (USD) in 2023, with a CAGR 3.6% between 2023 and 2028*.**

$75 billion (USD)

IN 2023



- Inhaled analgesic therapies outside of a clinical setting are uncommon.
- Nasal formulations of fentanyl (e.g. Lazanda) have shown to be efficacious, however these were **withdrawn due to safety concerns.**
- Sublingual fentanyl products (e.g. Actiq, and Fentora) remain as the main treatment options for intense breakthrough pain. **Abstral has also been withdrawn in the US.**

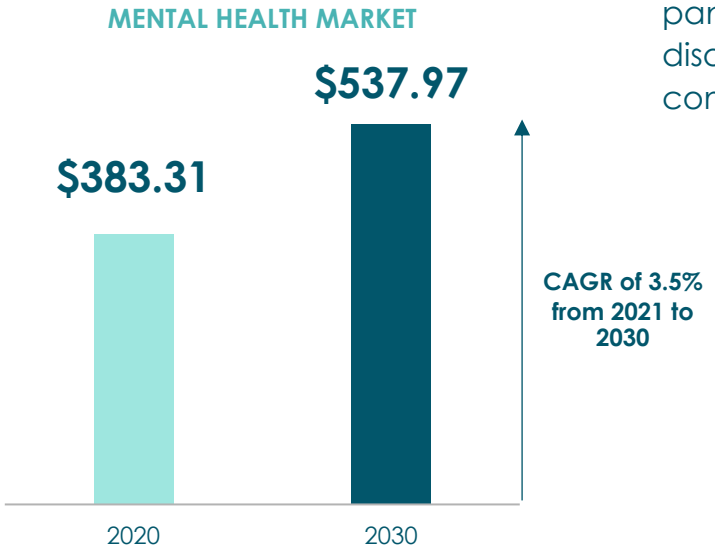


* https://www.mordorintelligence.com/industry-reports/pain-management-market

MARKET OPPORTUNITY

MENTAL HEALTH MARKET

The **global anxiety disorder treatment** market is projected to reach **USD 9 billion by 2030 at 2.9% CAGR** during the forecast period 2022-2030. It includes panic disorders, post-traumatic stress disorder (PTSD), phobias, and obsessive-compulsive disorder.



- Panic Disorder is estimated to affect approximately **3-5% of the general population**.
- More prevalent in women and typically begins in young adulthood. The exact prevalence of panic disorder is difficult to determine, as it is often **under-diagnosed and under-treated.**

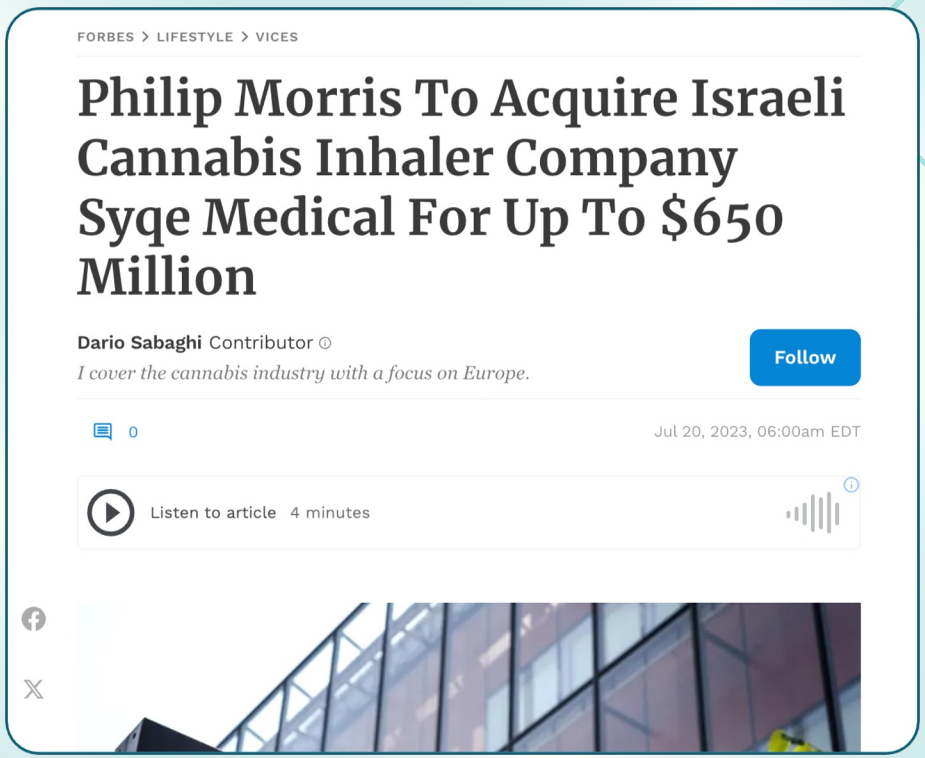
GLOBAL ANXIETY DISORDER TREATMENT MARKET

$9 billion (USD)

BY 2030

https://www.alliedmarketresearch.com/mental-health-market-A11770
https://www.marketresearchfuture.com/reports/anxiety-disorder-treatment-market-8455

UNMATCHED MARKET OPPORTUNITY



FORBES > LIFESTYLE > VICES

Philip Morris To Acquire Israeli Cannabis Inhaler Company Syqe Medical For Up To $650 Million

Dario Sabaghi Contributor

I cover the cannabis industry with a focus on Europe.

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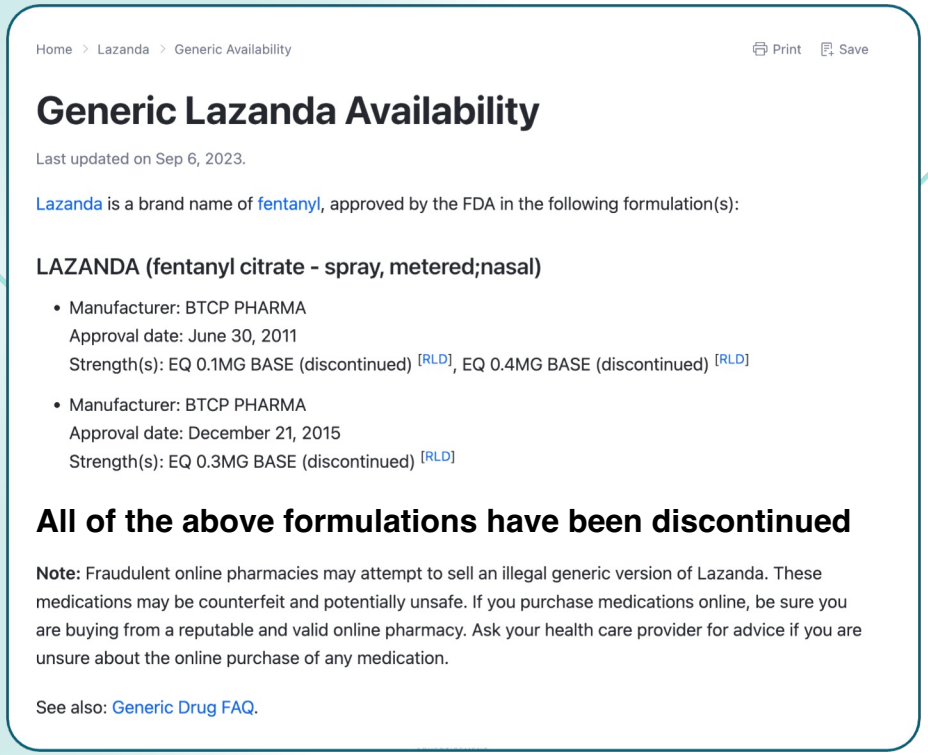


Home > Lazanda > Generic Availability

Print Save

Generic Lazanda Availability

Last updated on Sep 6, 2023.

Lazanda is a brand name of fentanyl, approved by the FDA in the following formulation(s):

LAZANDA (fentanyl citrate - spray, metered;nasal)

- Manufacturer: BTCP PHARMA
  Approval date: June 30, 2011
  Strength(s): EQ 0.1MG BASE (discontinued) [RLD], EQ 0.4MG BASE (discontinued) [RLD]
- Manufacturer: BTCP PHARMA
  Approval date: December 21, 2015
  Strength(s): EQ 0.3MG BASE (discontinued) [RLD]

All of the above formulations have been discontinued

Note: Fraudulent online pharmacies may attempt to sell an illegal generic version of Lazanda. These medications may be counterfeit and potentially unsafe. If you purchase medications online, be sure you are buying from a reputable and valid online pharmacy. Ask your health care provider for advice if you are unsure about the online purchase of any medication.

See also: Generic Drug FAQ.

https://www.forbes.com/sites/dariosabaghi/2023/07/20/philip-morris-to-acquire-israeli-cannabis-inhaler-company-syqe-medical-for-up-to-650-million/?sh=5dec242c1f27

WHY INHALED THERAPIES

Fast speed of onset

peak effect in ~4 mins vs ~2 hours for oral

Higher bioavailability

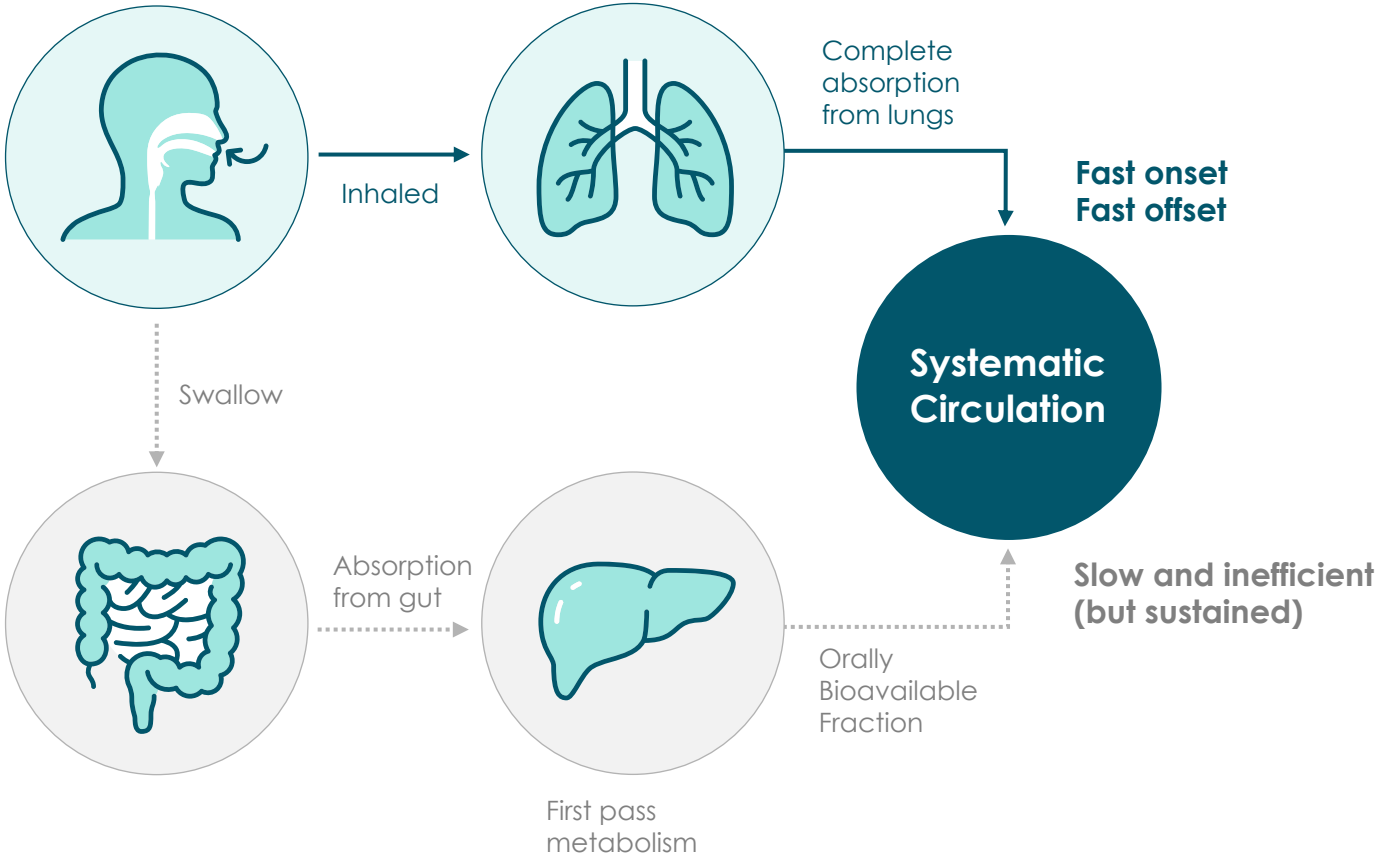
>60% vs 5-9% for oral

Ease of use

Targeting acute symptoms and potentially avoiding unnecessary long-term medicating

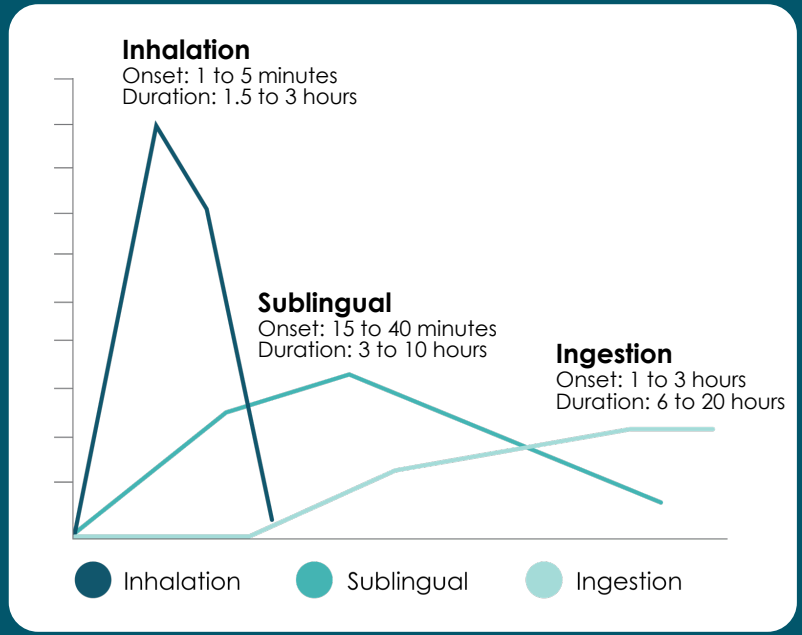
	Inhaled	Oral	Transdermal	Injectable
Onset of Action^	Fast	Slow	Slow	Fast
Offset of Action^	Fast	Slow	Slow	Fast
Bioavailability	High	Low	Low	High
Not impacted by 1st pass metabolism	✓	✗	✓	✓
Ease of patient use	✓	✓	✓	✗
Suitable for Acute Indications	✓	✗	✓	✓

EFFICIENT DRUG DELIVERY



INHALATION

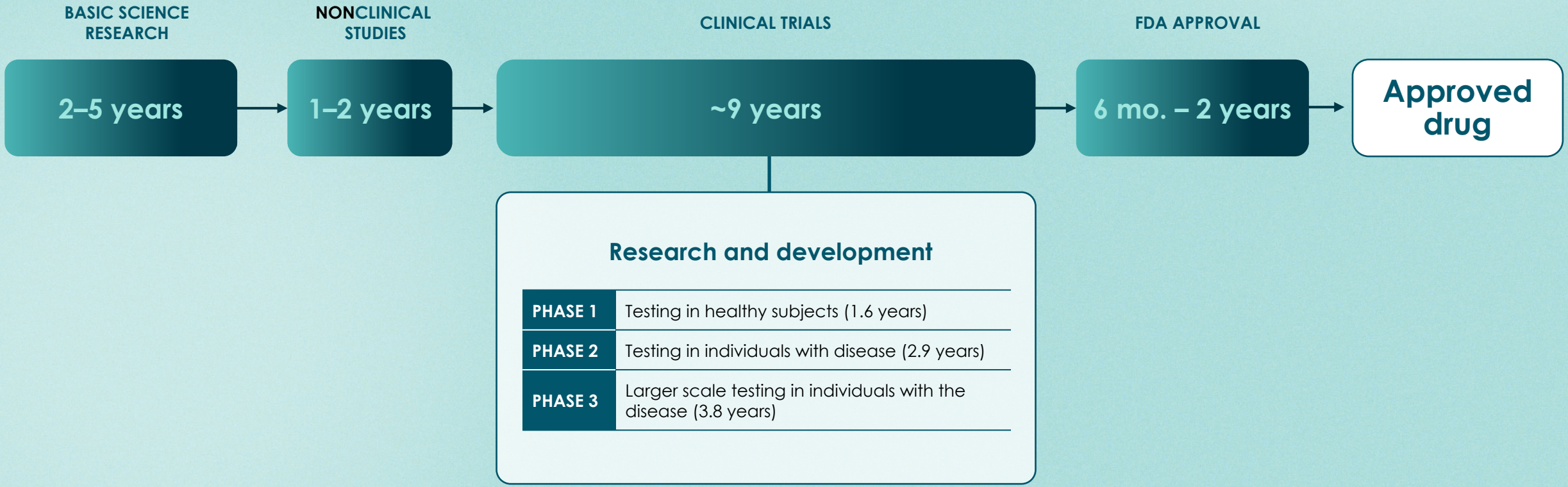
- Rapid absorption → 3-5 mins to peak blood level
- Transient effect
- **More efficient**



SUBLINGUAL

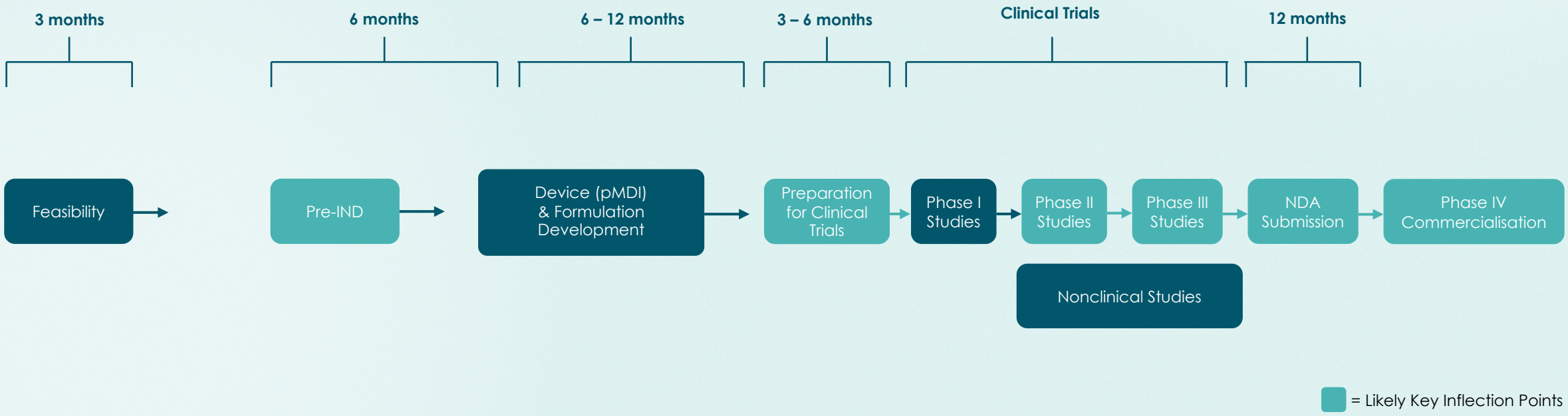
- Slow absorption + metabolism by liver → 60-150mins to peak blood level
- Sustained effect (incl. side effects)
- **Less efficient**

STANDARD DRUG DEVELOPMENT PATHWAY (FDA)



FDA 505(B)(2)PATHWAY TO REGISTRATION

Leveraging existing data reduces risk and cost



Time to approval – only 3 to 5 years (compared to the usual 10+ years)

DRUG CANDIDATE IRX211 – 3 YEAR PLAN

UNDISCLOSED PAIN INDICATION
Dronabinol based pMDI

Program Initiation
Regulatory Affairs and Trial Setup

Drug Formulation
IMP Developed and Validated

Phase I
Commencement of Phase I Trial

Phase I
Completion of Phase 1 trial

IND Submitted
Investigational New Drug submitted

Phase II*
Commencement of Phase II Trial

Phase II*
Completion of Phase 2 Trial

2022 2023 2024 2025

* Timing subject to further capital raising.

DRUG CANDIDATE IRX616 - 3 YEAR PLAN

PANIC DISORDER
Cannabidiol based pMDI

Program Initiation
Regulatory Affairs and Trial Setup

Drug Formulation
IMP Developed and Validated

GMP Manufacture
technology transfer completed

Phase II*
HREC application submitted
Commencement of Proof of Concept (POC) Trial*

IND submitted
Investigational New Drug application submitted with the FDA

Phase II*
Commencement of Ph2 trial

Phase II*
Completion of Ph2 trial

2022 2023 2024 2025

*timing subject to further capital raising

COMPETITIVE EDGE

Speed to market

Low cost

Experienced team

Barriers to entry for potential competitors

- FDA grants minimum data exclusivity of 3 years post new drug approval date (7 years for orphan drug designation).
- This means competitors will be prevented from leveraging the IRX generated efficacy data for the purpose of creating generic versions.
- If necessary, IRX may consider introducing a following-on product (line extension) prior to the culmination of IRX211's data exclusivity. This extends the line extension's exclusivity beyond that of the original drug product.

INVESTMENT OPPORTUNITY

- Significant M&A potential.
- IRX is currently **down 70% on all time highs** experienced in Feb 2021.
- We have **a loyal investor base** with **the top 20 own more than 70% of the share capital.**
- There is an **attractive entry point** to the stock now given the correction that the biotech industry has experienced in the last 12 months.
- Potential to **dramatically improve the health and wellbeing of millions of patients globally** as there's no approved fast acting (non-opioid) drug available on the market for patient self-administration.

**Data accurate as of Tuesday 21 2023*

$5.55m*
Market Cap

$0.030*
Share Price

189m
Shares on issue

91.52%
CHESS Holdings

Thank You

We welcome any further questions you may have