The Future of Inhaled Medicine

May 2022

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The InhaleRx Ltd Team

Darryl Davies
Executive Director

- Chief Operating Officer & Co-founder of Cannvalate
- A Medicinal cannabis industry early adopter with over 15 years experience in clinical psychology, healthcare, harm minimisation.
- A hands-on executive with a global cannabis experience and a board director to a number a local and international cannabis companies .

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)
- Chief Medical Officer at Incannex Healthcare Ltd.

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

Key Strategic Business Focus

Short

Immediate Revenue

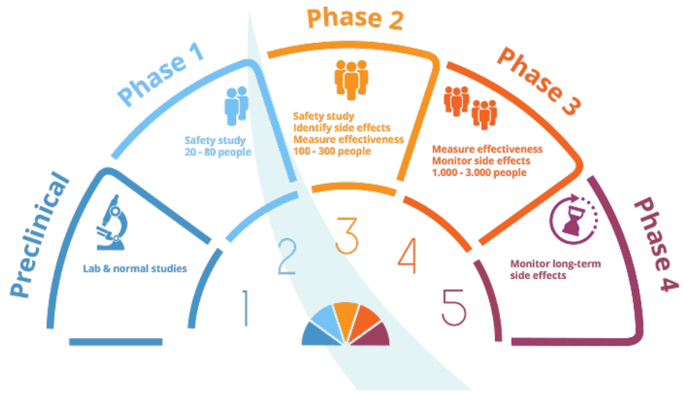
- Exclusive partnership with ITSUWA to sell ‘Medihale’ Voom vapes for use with Cannabis e-liquids.
- Supply deal with white label producers in the industry.
- Schedule 4 and 8 wholesale / supply scheduled medications.

Medium

New Product Development

- InhaleRX Ltd is partnering to develop medical grade devices to meet the clinical needs of doctors and patients.
- Accurately dosed devices are essential for the medical cannabis industry and a key focus for InhaleRx ltd.

Long



Clinical Trials and Registration

- We seek to develop the first ever FDA medically registered inhaled medical cannabis delivery systems.
- Comprehensive clinical trials program focused on registration of combination device drug combination products with the FDA.

Why inhaled therapies?

There are clear advantages to administering drugs via inhalation.

	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	✓	✗	✓	✓

✓ Fast speed of onset
peak effect of 4mins vs 2 hours for oral

✓ High bioavailability
>60% vs 5-9% for oral

✓ Patient preference

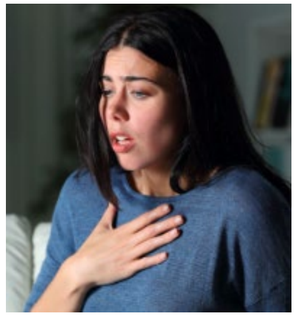
➢ Limited clinical data unearthing the potential of inhaled cannabinoids.

➢ Demand for flower increased significantly in the Australian industry, however, flower consumption comes with risks linked to combustion.

➢ There are no cannabinoid drug / device combination products currently registered with the TGA.

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

Embracing the therapeutic potential of innovative inhalation therapies



Panic Disorder (PD) - is a life-restricting, sudden, overwhelming anxiety syndrome which needs immediate onset anxiolysis to overcome anxious thoughts. Panic disorder is characterised by recurrent, unexpected panic attacks.

Complex Regional Pain Syndrome (CRPS) - is a debilitating chronic pain syndrome characterised by paroxysmal breakthrough pain which needs immediate onset pain relief to manage. Symptoms of CPRS can be crippling and have lifelong effects.

Current Landscape of Panic Disorder (PD)

Causes

- Panic disorder (PD) is characterised by recurrent, unexpected panic attacks.
- Thought to be caused by:
  - **chemical imbalance**, including abnormalities in gamma-amino butyric acid, cortisol, and serotonin.
  - **genetic and environmental factors**
  - **adverse childhood conditions.**
  - **hyper excitable neural circuitry** whereby certain areas of the brain are affected.

Effects

Signs and symptoms of PD include:

- palpitations or accelerated heart rate.
- sweating, trembling or shaking.
- sensations of shortness of breath or smothering, feelings of choking.
- chest pain or discomfort, numbness or tingling.
- nausea or abdominal distress.
- feeling dizzy, unsteady, light-headedness, or faint, chills or heat sensations.
- derealisation (feelings of unreality) or depersonalisation (being detached from oneself);
- fear of losing control and in some cases, fear of dying.

Treatments

- Psychological interventions:
  - cognitive-behavioral therapy.
  - motivational Interviewing.
  - breathing training.
- Pharmacological interventions:
  - antidepressants (SSRI).
  - benzodiazepines.
  - gabapentin.

The Panic Disorder (PD) opportunity

The sudden onset of panic attacks can currently not be managed satisfactorily.

Prevalence:

6.97m American Adults suffering with Panic Disorder, which is an estimated **2.7% of U.S. adults**[3]

Total Addressable Market (TAM):

USA: approx. **USD 45.15b**[4] *(based on prevalence x annualised cost of medical costs)*

Existing Drugs:

Antidepressants (SSRI), benzodiazepines, gabapentin, and mirtazapine help to reduce frequency of attacks.

Pathway:

FDA 505(b)(2)

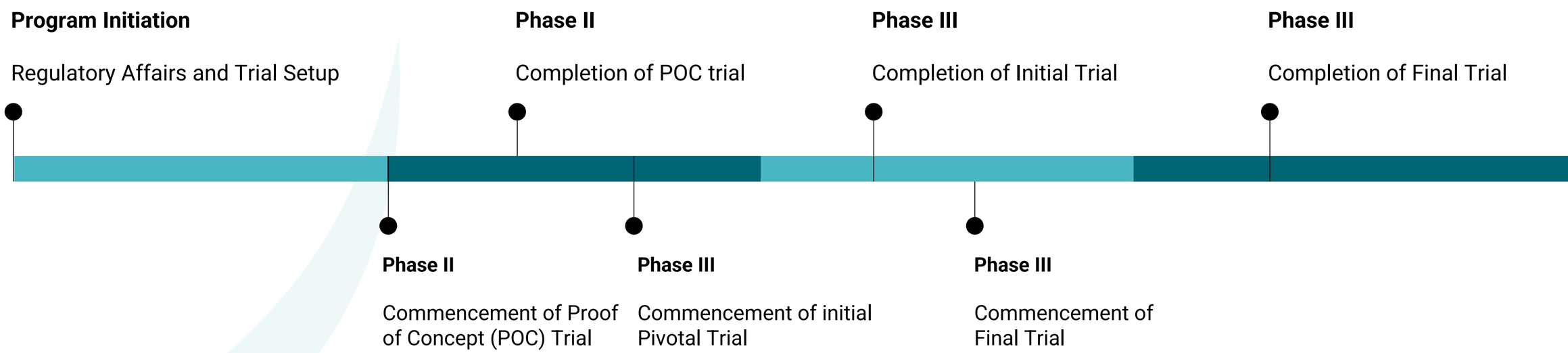
Total Addressable Market (TAM): also referred to as total available market, is the overall revenue opportunity that is available to a product or service if 100% market share was achieved.

References: PD TAM calculation: 209M*0.027*1000 = $5.6B
https://www.nimh.nih.gov/health/statistics/panic-disorder

Total Addressable Market - Learn How to Calculate the TAM (corporatefinanceinstitute.com)

Clinical trial programme timeline for PD

- ✓ **Protocol complete.**
- ✓ **Key Opinion Leader (KOL) engaged.**
- ✓ **Formulation finalised with stability commenced.**
- ✓ **Site feasibility commenced**



Key Opinion Leader (KOL): KOLs are well-known, respected, and trusted physicians with specialized knowledge in particular fields in the medical and pharmaceutical industries.

Reference: [The Role of KOL in Clinical Research | Within3]

Complex Regional Pain Syndrome (CRPS)

Causes

- The causes of CPRS are not completely understood. It is thought to be caused by an injury to or an abnormality of the peripheral and central nervous systems.

- There are two types of CRPS. Both exhibit similar signs and symptoms, but originate from different causes:

Type 1, also known as Reflex Sympathetic Dystrophy (RSD), occurs after an illness or injury that didn't directly damage the nerves in your affected limb. (approx 90%).

Type 2, once referred to as causalgia, has symptoms similar to those of type 1 but occurs after a distinct nerve injury.

Effects

Signs and symptoms of CRPS include:

- Continuous burning or throbbing pain, usually in your arm, leg, hand or foot.
- Sensitivity to touch or cold.
- Swelling of the painful area.
- Joint stiffness, swelling and damage
- Muscle spasms, tremors, weakness and loss (atrophy).
- Decreased ability to move the affected body part.
- Symptoms can be crippling and may lead to suicide.

Treatments

- Rehabilitation and physical therapy.
- Psycho- and sociotherapy in a multimodal treatment setting.
- Graded motor imagery.
- Medications (e.g. acetaminophen, NSAIDS, nortriptyline, gabapentin, pregabalin, duloxetine, amitriptyline, topical local anesthetic ointments, bisphosphonates, corticosteroids, opioids and NMDA-receptor antagonists).
- Spinal cord stimulation.
- Other types of neural stimulation.
- Spinal-fluid drug pumps.

Complex Regional Pain Syndrome (CRPS) opportunity

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

Prevalence:

219,317[1] cases in the United States, the total (2017) - *Confirmed Orphan Status*

Total Addressable Market (TAM):

USA: approx. **USD 7.08b**[2] *(calculated by the prevalence x the average rebate under ODD)*

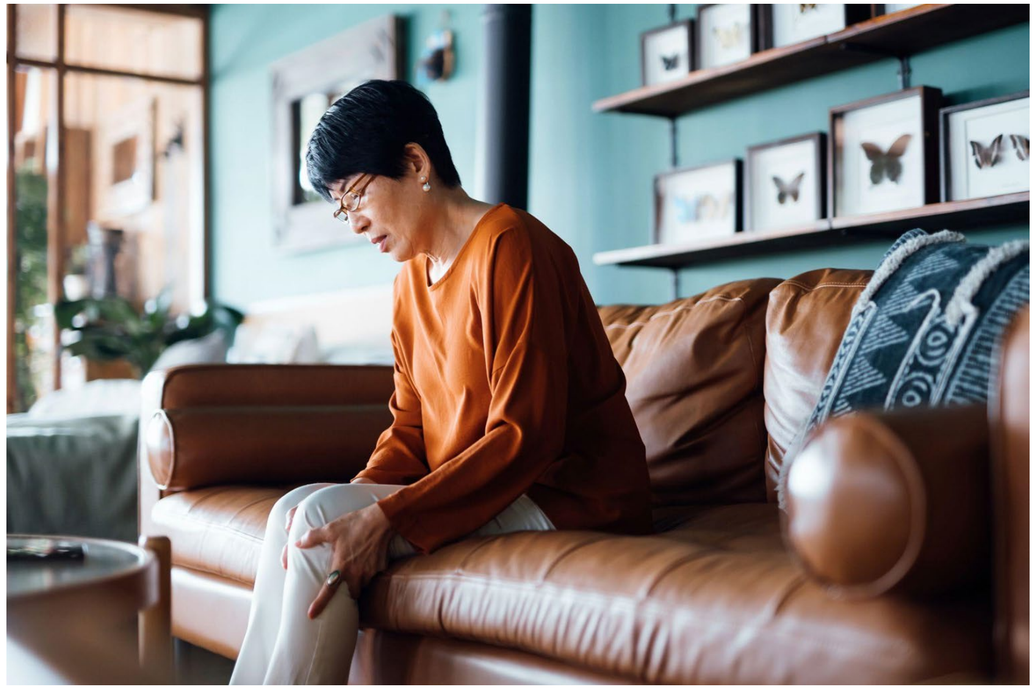
Existing Drugs:

No drugs have been specifically approved for CRPS.

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

Pathway:

FDA 505(b)(2) + Orphan Drug Designation (ODD)

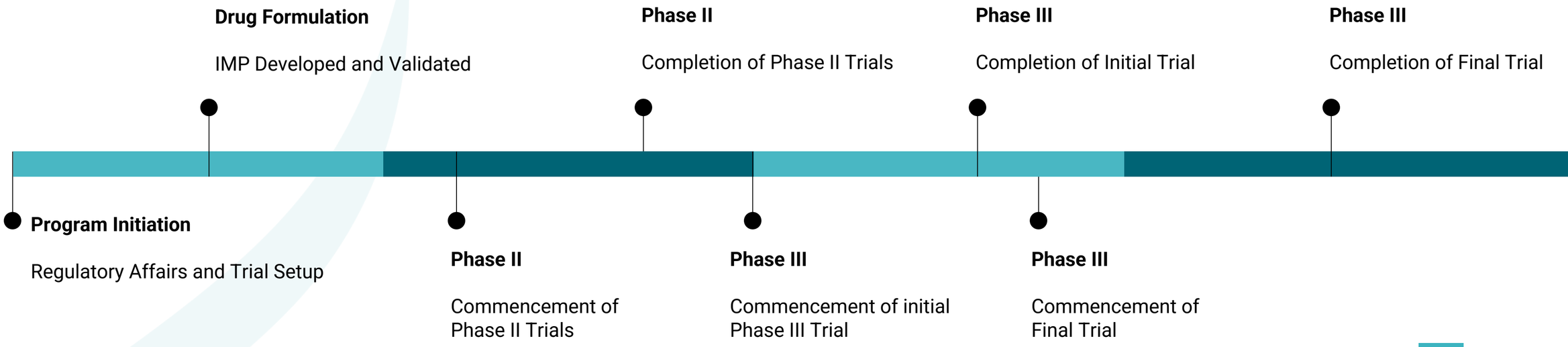


References: https://www.delveinsight.com/report-store/complex-regional-pain-syndrome

$30'000*219,317 cases = 660m

Clinical trial programme timeline for CRPS

- ✓ **Protocol complete**
- ✓ **Formulation near complete**
- ✓ **Site feasibility commenced**
- ✓ **CRO tender ready**



Innovative product development

Single API Cannabinoid Pressurised Metered Dose Inhalers (pMDI)

- Devices developed (510K ready).
- Drug suspensions formulated by UK consultants using FDA-approved ingredients.
- Finished dose form planned for clinical trials, Investigational Medicinal Product (IMP) preparation.
- Proof of concept trial protocols written by medical writing team highly experienced with inhaled drugs.
- Novel drug-device combinations undergo clinical trials (full GMP, solubilised and aerosolisable formulations using only excipients on FDA-database) with high likelihood of meeting necessary PK and safety parameters.

Understanding the market

Medihale™ Inhaler Device

Australia's first 'heat not burn' Cannabinoid Inhalation Device

We have developed relationships with both the medical community and industry with **Medihale Vape Devices** to administer cannabinoid formulations.

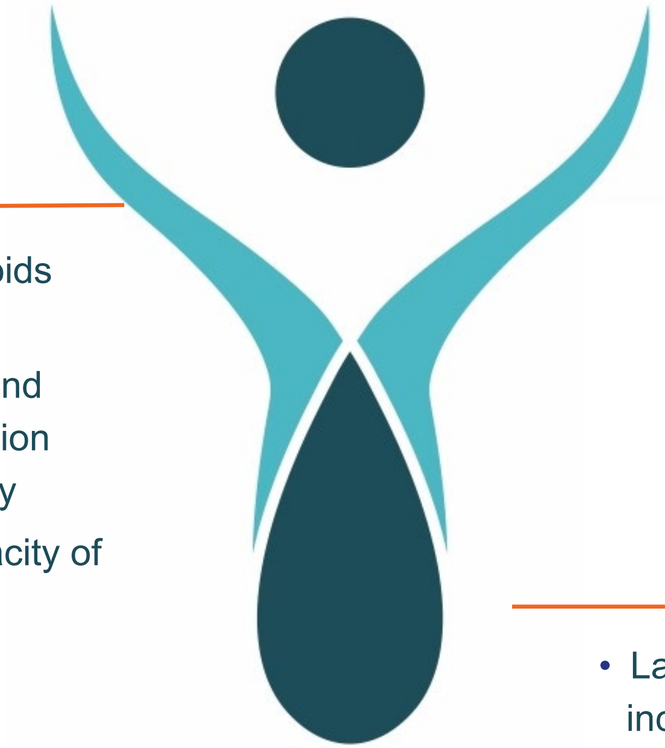
Currently the devices are used to administer compounded THC and CBD formulations prescribed using the Cannvalate physician network for primarily pain and anxiety indications.

The vision behind this is approach is not commercially focused, rather it is to;

- acquire knowledge and feedback from doctors regarding the position of inhalation devices.
- understand patient outcomes and the potential benefits.
- troubleshoot any issues so we can learn where the vulnerabilities are.
- monitor dosing regimes and calibration.

Carefully Selected Product Development Partners

- Supplier of cGMP Synthetic Cannabinoids and formulations
- Provide access to Syndros® USMDF and CMC data files critical for FDA submission process utilising FDA 505(b)(2) pathway
- Contract manufacturing and filling capacity of finished dose formulations



- Specialists in complex drug development programs where no playbook exists.
- Specialists in accelerated approval pathways, rare and specialty patient populations, and innovative science including orphan drugs, the 505(b)(2) FDA pathways.

- Large prescribing network in Australia, including telehealth options facilitating access to Medical Cannabis for patients across Australia
- Extensive patent portfolio around use of novel synthetic cannabinoids for the inhaled

Footnote: Premier research (formally known as Camargo Pharmaceutical Services) previously mentioned in the Quarterly Activities Report, released 31 Jan 2022.

Cannvalate and Benuvia have not been previously announced pursuant to Listing Rule 3.1, are not material to the Company.

Benefits of the chosen FDA 505(b)(2) pathway

What is FDA 505(b)(2)?

A pathway exists named 505(b)(2) to drug registration with the U.S. Food and Drug Administration (FDA). The 505(b)(2) pathway enables investigators and/or manufacturers to apply for approval without having to repeat all the drug development work done for an innovator drug.

Potential Benefits

- Far less expensive and much faster route to approval when compared to the alternative FDA pathways.
- Hybrid structure of 505(b)(2) when compared to the alternative FDA pathways.
- It can also eliminate the need for most nonclinical studies and extensive safety and efficacy tests.
- Potential of lower risk due to previous drug approval
- Faster development and lower cost due to fewer studies needed
- Potential to qualify for 3-7 years of market exclusivity

Benefits of Orphan Drug Designation (ODD) pathway (CRPS only)

What is Orphan Drug Designation (ODD)?

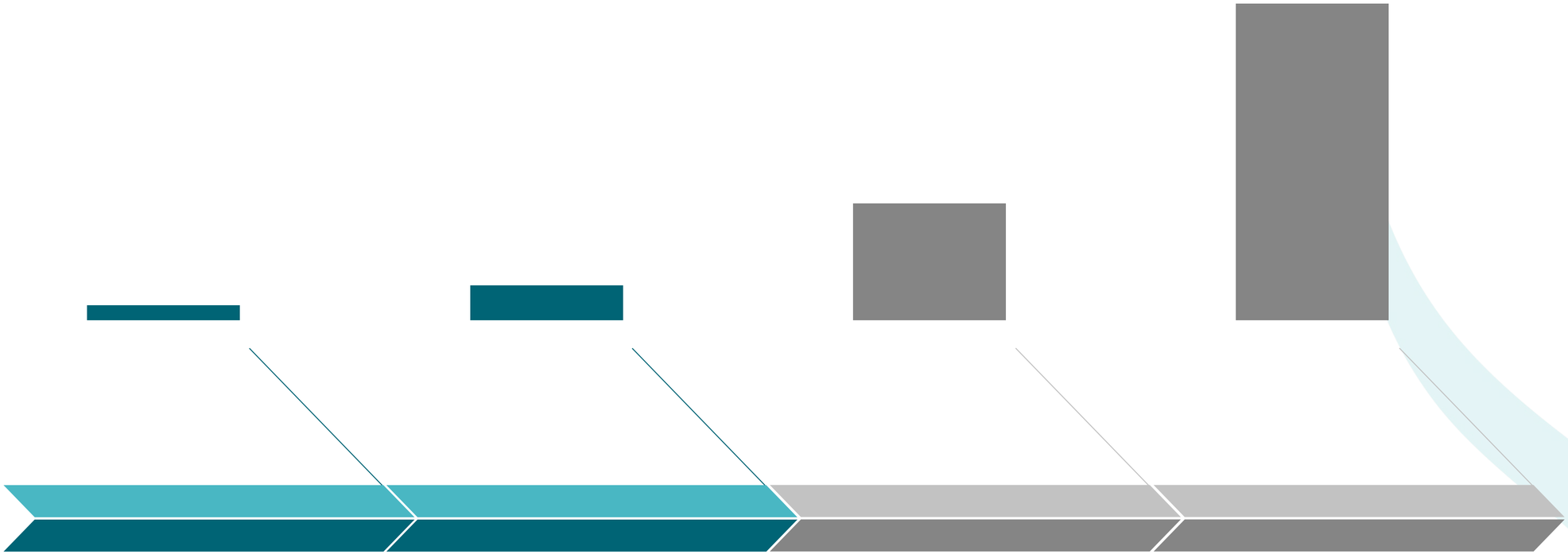
An orphan disease is a rare disease or condition that affects fewer than 200,000 people in the United States. In 1983, the U.S. government passed a law, called the Orphan Drug Act, to give drug companies certain financial benefits for developing orphan drugs. This law is designed to help bring more drugs to patients with rare diseases.

The Orphan Drug Designation (ODD) is a status given to certain drugs called orphan drugs, which show promise in the treatment, prevention, or diagnosis of orphan diseases that are also often serious or life threatening. CRPS is eligible for achieving this status and InhaleRx has already received feedback from the FDA regarding the next steps.

Potential Benefits

- waiving of PDUFA fees (approximately USD $2.2m).
- tax credits for clinical drug testing and;
- eligibility for market exclusivity for a period of 7 years after approval is granted.

Opening up an Investigational New Drug (IND)



Formulation and device development

Formulation and device testing completed
IP captured

pIND

Complete a formalised meeting with FDA to confirm aspects of registration

Phase II Study

Commence proof of concept in human studies to resolve magnitude of effect

IND Open

Investigational New Drug application opened

Registration of New Drug Approval (NDA)

Accelerated Timeline & Reduced Cost to New Drug Approval (NDA)

Leveraging existing data reduces risk and cost, but also time to approval - estimated 2 to 4 years (compared to the usual 7-10 years)

Summary

- **Focused strategic direction** targeting Inhaled drug delivery systems**.**
- Inhaled drug delivery provides patients with unique benefits favoring fast onset treatments for acute conditions.
- **Strong strategic partnerships validating the supply chain** and enabling InhaleRx devices to be sold in high growth markets.
- Long term clinical trial & regulatory strategy supported by short and medium term commercial strategies.
- **Accelerated regulatory pathway strategy** utilizing existing pre-clinical, USMDF and CMC data sets and the FDA 505(b)(2) pathway.
- **Significant Market Opportunity.** CRPS related treatment has a Total Addressable Market (TAM) of approx. **USD 7.08b**[2] in the US alone. PD treatment has a TAM of USD **$45.15b**[4] in the US alone.
- Tightly held, highly supportive share register with top **20 Shareholders currently holding 72% of shares**.

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/

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