16 January 2024

ResolutionRx

# DEVELOPING A REPURPOSED DRUG FOR OBSTRUCTIVE SLEEP APNOEA

- Company Profile
- About Pharmaceutical Cannabinoids
- Dronabinol
- Obstructive Sleep Apnoea - A Worldwide Epidemic
- Foundation of ResolutionRx
- ResolutionRx Business Plan

# FORW ARD LOOKING STATEMENT

**Cautionary Note Regarding Forward-Looking Statements**

This presentation contains certain forward-looking statements which should not be unduly relied upon. These might include statements regarding the Company's future plans, targets, estimates, assumptions, financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about research and development efforts, including, but not limited to, preclinical and clinical research design, execution, timing, costs and results, future product demand, supply, manufacturing, costs, marketing and pricing factors.

In some cases, forward-looking statements may be identified by words including "assumes," "could," "ongoing," "potential," "predicts," "projects," "should," "will," "would," "anticipates," "believes," "intends," "estimates," "expects," "plans," "contemplates," "targets," "continues," "budgets," "may," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words, and such statements may include, but are not limited to, statements regarding (i) future research plans, expenditures and results, (ii) potential collaborative arrangements, (iii) the potential utility of the Company's product candidates, (iv) reorganization plans, and (v) the need for, and availability of, additional financing. Forward-looking statements are based on information available at the time the statements are made and involve known and unknown risks, uncertainties and other factors that may cause our results, levels of activity, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements in this presentation..

These factors include but are not limited to, regulatory policies or changes thereto, available cash, research and development results, issuance of patents, competition from other similar businesses, interest of third parties in collaborations with us, and market and general economic factors, and other risk factors.

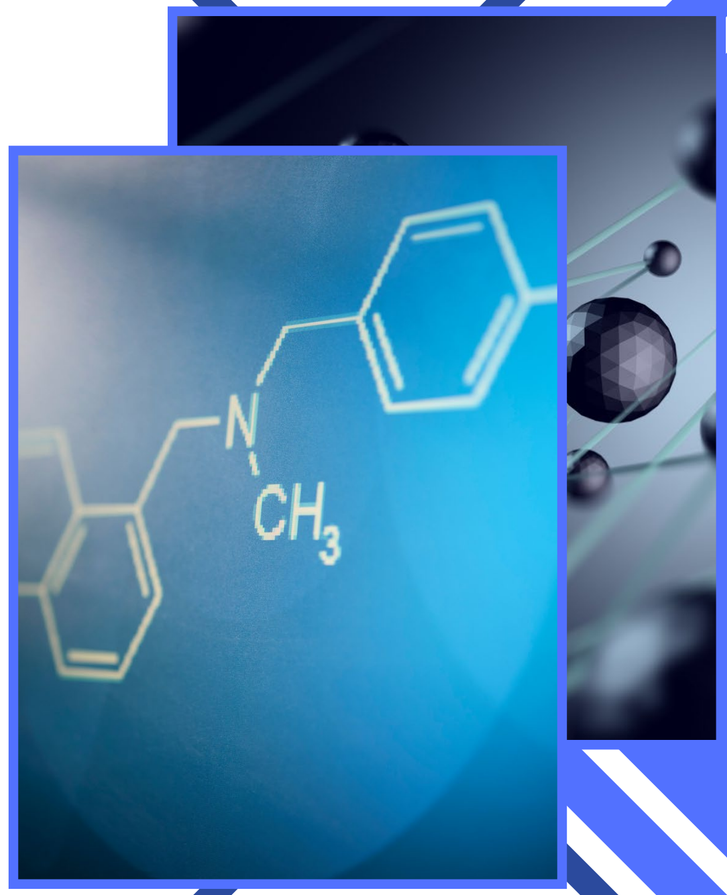
We caution investors, as well as potential collaborators and other potential stakeholders, not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognise that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties that we may consider immaterial or do not anticipate at this time. These forward-looking statements are based on assumptions regarding the Company's business and technology, which involve judgments with respect to, among other things, future scientific, economic, regulatory and competitive conditions, collaborations with third parties, and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the Company's control. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties. These risks and uncertainties are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time.

# Company Profile

ResolutionRx, an unlisted public Australian company, is focused on repurposing, developing and commercialising proprietary pharmaceutical product candidates, our first candidate being the repurposing of a pharmaceutical cannabinoid.

ResolutionRx was created by RespireRx Pharmaceuticals Inc. (US OTC: RSPI) (RespireRx), which has contributed its cannabinoid drug development program to ResolutionRx.

ResolutionRx is continuing the research and development (R&D) associated with that program, initially for the development of a new formulation of dronabinol for use as a treatment for obstructive sleep apnoea (“OSA”).



# OBSTRUCTIVE SLEEP APNOEA (OSA)

# A WORLDWIDE PROBLEM

*During OSA airflow is blocked*

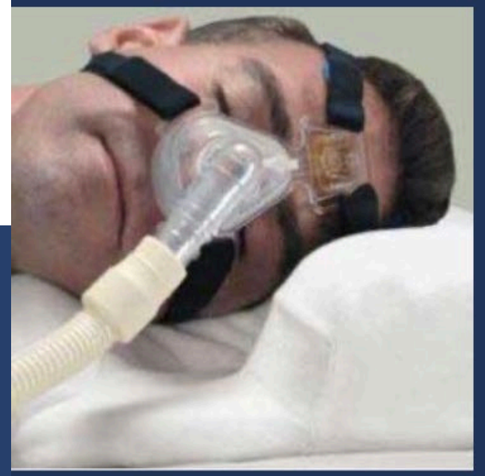
- A sleep-related breathing disorder that occurs when throat muscles intermittently relax and block airway during sleep
- With OSA a person typically stops breathing 5 – 50 times per hour during sleep
- OSA has reached near-pandemic levels with an estimated global incidence of approximately 1 billion people and more than 90 million people in the US, Australia, Germany and the UK alone*.
- The consequences of undiagnosed and untreated OSA are medically serious and economically costly.
- Co-morbidities include cardiovascular disorders, type II diabetes and even early mortality.
- In the U.S. alone, the annual estimated economic burden is approximately $162 (U.S.) billion

SLEEP APNEOA IS NOT MERELY SNORING

* Source: Lancet Respiratory Medicine - 2019 Aug 7(8): 687-698 Benjafield, A et al

# THERE ARE NO DRUG THERAPIES FOR OSA

## C-PAP IS THE STANDARD TREATMENT FOR OSA



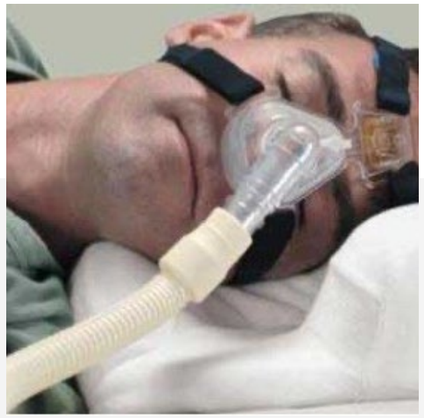
IS THIS YOU ?

**Low Compliance Rate Reduces C-PAP Effectiveness**

- 30% of patients prescribed CPAP never initiate treatment
- Over 50% of patients stop using CPAP in the first year
- Dronabinol for patients who cannot or will not tolerate CPAP

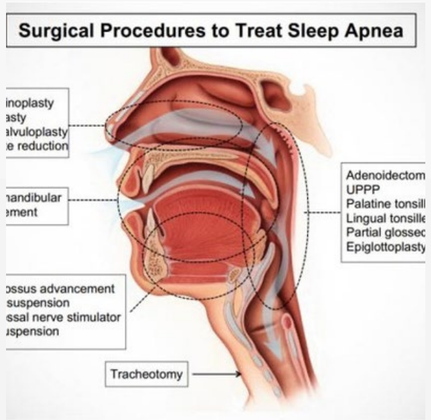
# CP AP AND ALTERNATIVES NO DRUGS

**Current Approved Treatments Include Devices and Surgery**

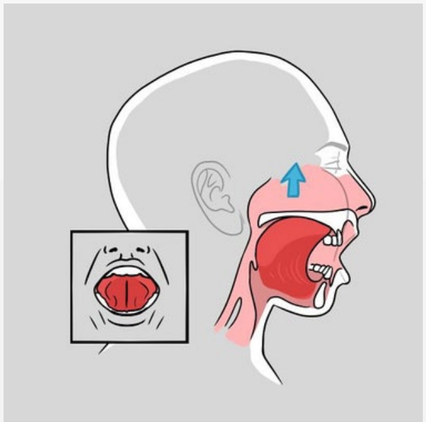


CPAP Device


Dental Devices




Surgery



Exercises and stimulant drugs for next day sleepiness

# WHAT ARE PHARMACEUTICAL CANNABINOIDS?

Cannabinoids are pharmacologically active substances found in the cannabis (marijuana) plant.

Whether extracted from plants or synthetically manufactured, medical claims and uses of cannabinoids must be approved by U.S. FDA and other international regulatory authorities.

Scientific study has focused on the two major cannabinoids, Δ9-tetrahydocannabinol (THC) and cannabidiol (CBD) and led to several commercial products approved by regulatory authorities.

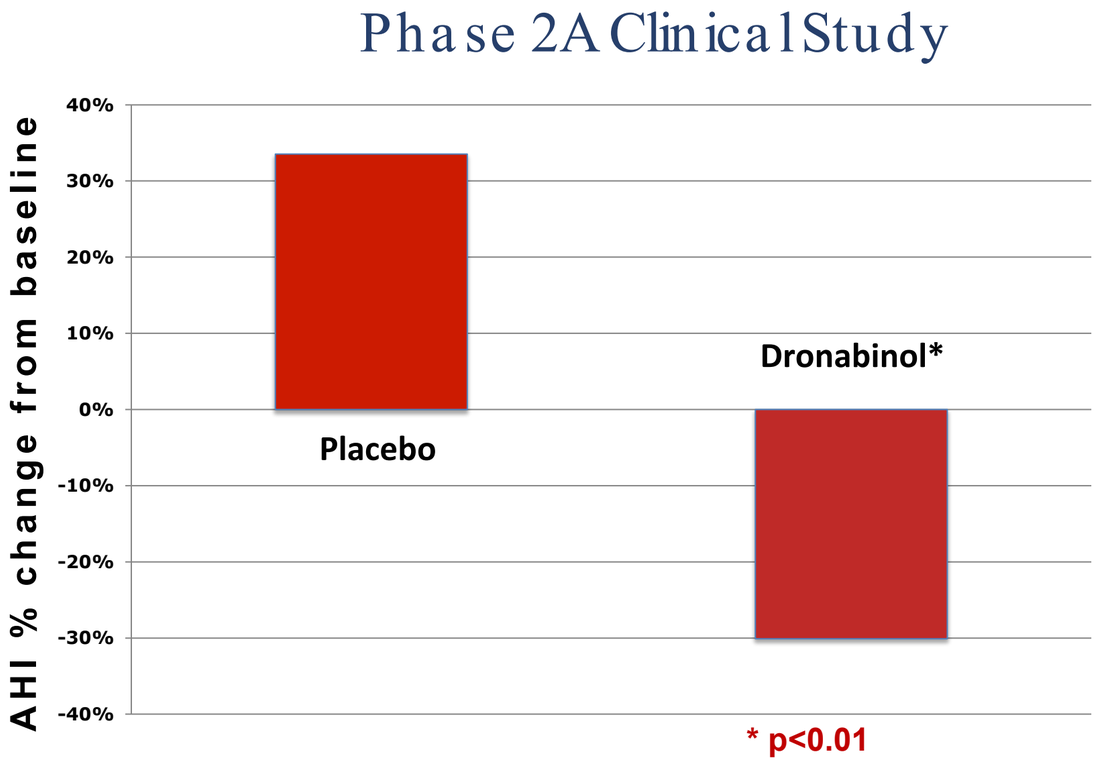
The commercialisation of these pharmaceutical cannabinoids has opened the door to a greatly expanding market sector

# DRONABINOL:
# A BREAKTHROUGH TREATMENT FOR OSA

## Dronabinol Overview

- Dronabinol is an example of our repurposing strategy to reduce risk, cost and create efficiencies in R&D
- Dronabinol is a synthetic form of THC, a psychoactive molecule in cannabis
- It was the first pharmaceutical cannabinoid approved by U.S. FDA in 1985
- Prescribed and sold in U.S. for the treatment of anorexia in AIDS patients and nausea and vomiting in cancer patients undergoing chemotherapy.

# DRONABINOL: A BREAKTHROUGH TREATMENT FOR OSA



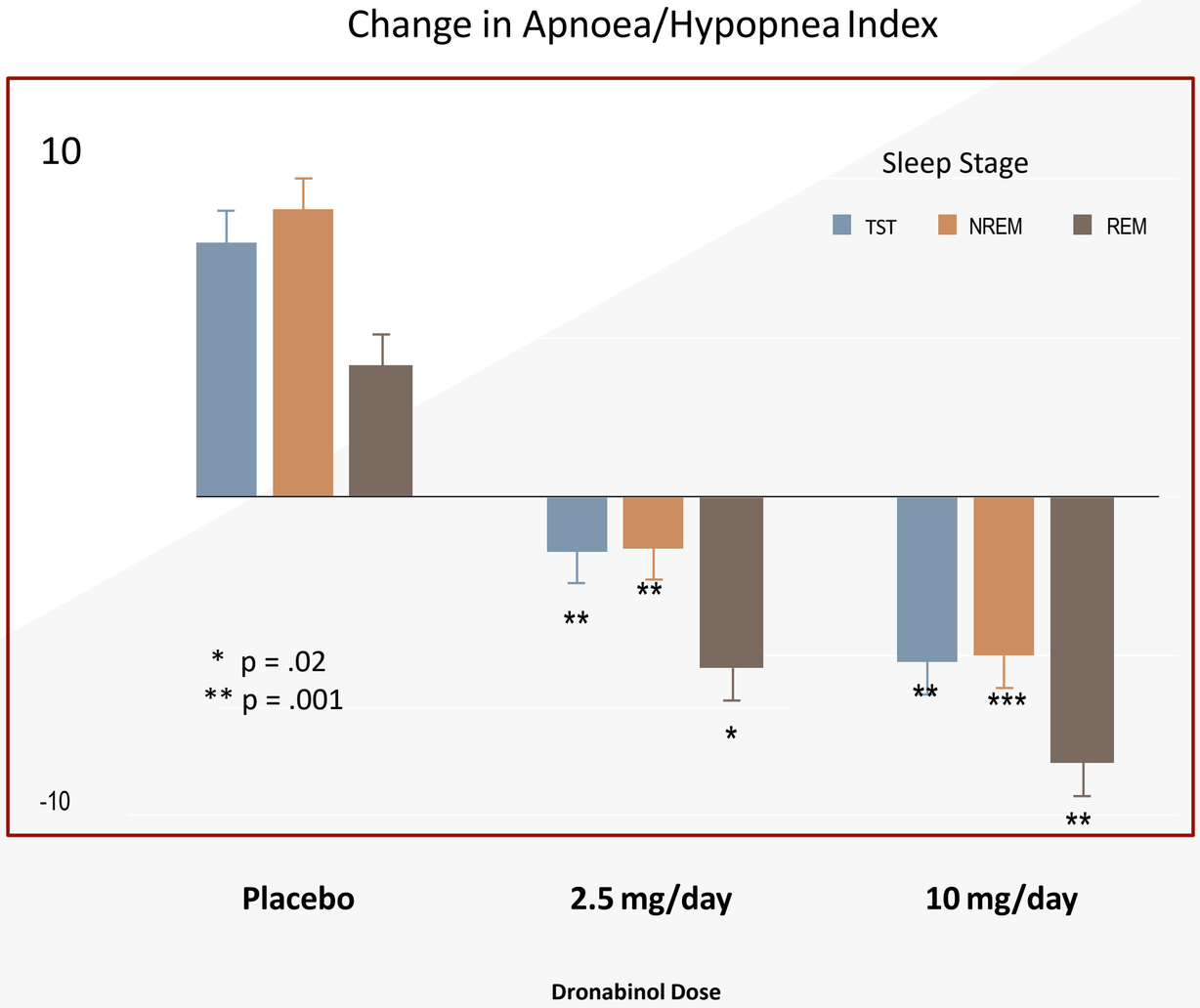

- Double Blind Placebo Controlled
- 2.5, 5 & 10 mg before bed
- 3-Week Dose-ascending Study
- n = 17

# THE PACE CLINICAL TRIAL

- Phase 2B Randomized, Placebo-controlled, Parallel Groups, Multi-site Trial in 73 Patients with Moderate to Severe OSA
- Subjects Administered Either Placebo, 2.5 mg or 10 mg Dronabinol 60 minutes before bedtime
- Primary Outcome Measure – Apnea-Hypopnea Index (AHI)
- Secondary Outcome Measures

# RESULTS OF 6-WEEK TREATMENT:

## Dronabinol Reduces AHI



# THE PHASE 2B PACE TRIAL IN OSA

## Final Overall Results

*Statistically significant improvement in Primary Outcome Measures*

**Apnea-Hypopnea Index (AHI)**

2.5 and 10 mg

**ESS Sleepiness Scale**

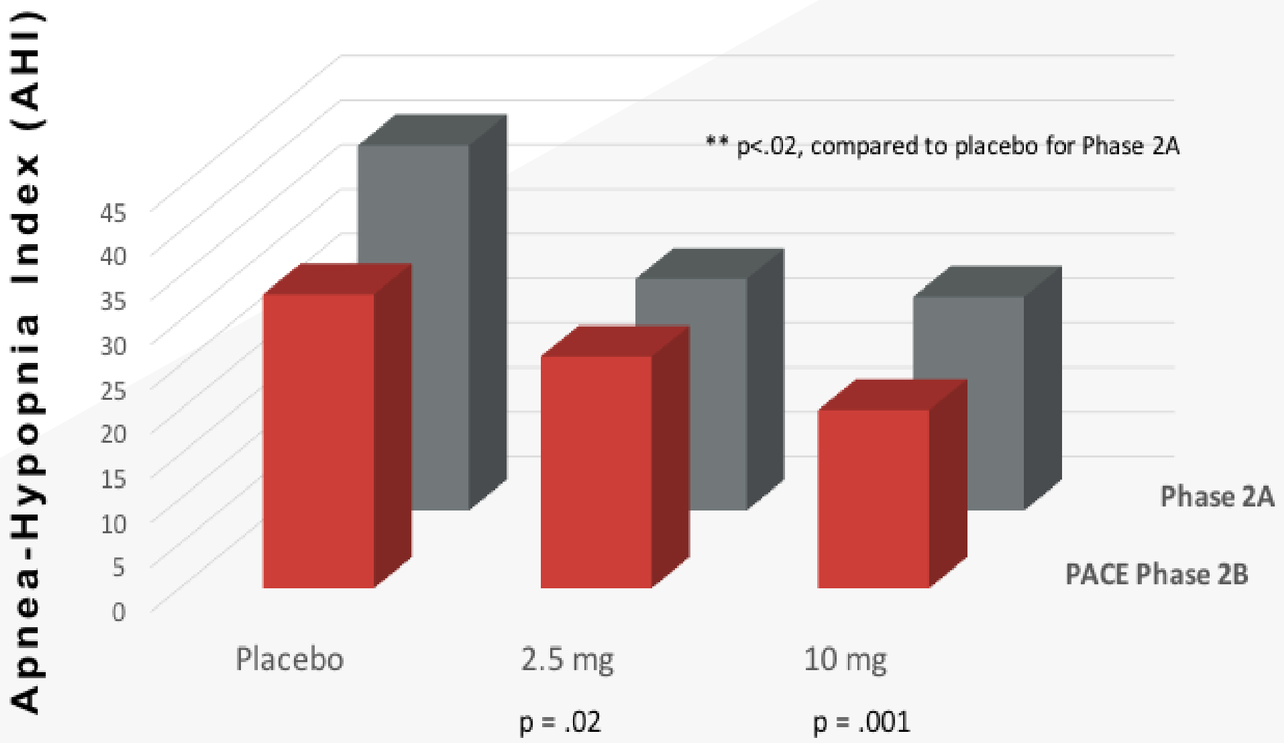
10 mg

**Overall Patient Satisfaction**

10 mg

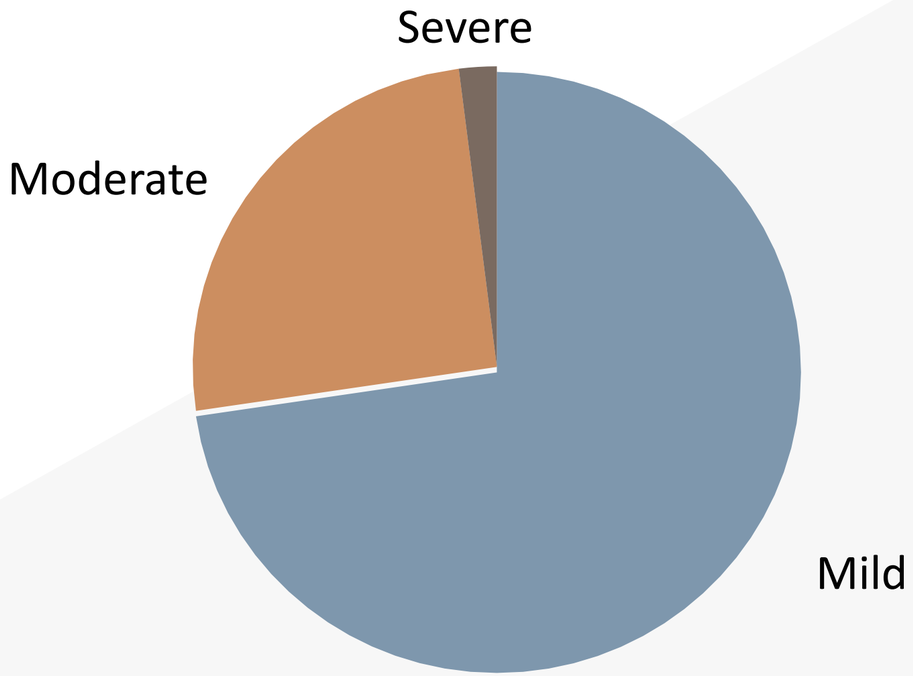
# THE PACE TRIAL REPLICATES THE PHASE 2A STUDY

**Two Phase 2 Trials Have Shown that Dronabinol Treatment Results in a Statistically Significant, Dose Related Improvement in AHI, a Primary Endpoint for U.S. FDA Approval**




* Double blind, placebo controlled dose-ascending study in patients with OSA, n=19

# DRONABINOL HAS AN EXCELLENT SAFETY PROFILE




- Adverse Events (AEs) in placebo and dronabinol groups did not differ
- Great Majority of AEs were mild to moderate
- Average Number of AEs = 4.1±4.0

# NEED FOR NEW DRONABINOL FORMULATIONS

**Present Commercial Dronabinol Gel-cap Formulations**

- Poor and erratic absorption due to insolubility, with some patients achieving very high levels and others achieving very low levels.
- Rapid and extensive first-pass liver metabolism, resulting in low blood levels and a relatively short half-life (approximately 2 - 3 hours) which is not optimally suited for therapeutic indications requiring blood levels to be sustained for 6 hours or longer.
- Undesirable side effects from high dosage strength required to achieve sustained, therapeutic blood levels

# NEW LIPID-BASED CANNABINOID FORMULATIONS

- Soluble with appropriate dissolution
- Room temperature stability
- Resistant to disturbance by stomach acids
- Particle size in the 50 - 150 nM range
- Lymphatic absorption to bypass liver metabolism
- Encapsulation efficiency
- Amenable to commercial scale production

# FOUNDATIONS OF RESOLUTIONRX

## Development Strategy for Pharmaceutical Cannabinoids

Repurposing known drugs and drug candidates to reduce risk, cost and achieve R&D efficiencies. In our case, this refers to the development of cannabinoids according to Australian TGA and U.S. FDA and other foreign accepted regulatory pathways to market and sell a new drug.

## Clinical Validation

Two Phase 2 clinical trials have been completed demonstrating the ability of dronabinol to significantly reduce the symptoms and quantitative measures of obstructive sleep apnoea (“OSA”), a sleep-related breathing disorder that afflicts an estimated 90 million people in the US, Australia, Germany and UK combined.

## Intellectual Property

Issued and pending patents claiming cannabinoid compositions and methods for treating cannabinoid-sensitive disorders, including sleep apnoea and other conditions, as well as novel dosage and controlled release compositions applicable to cannabinoids and other drug candidates.

## Defined Regulatory Route to Commercialization

505(b)(2) NDA in US and similar filings in other countries creates expedited path to market by allowing publicly available safety data.

## Business Plan

Business plan, financial projections and independent evaluation in place

# Corporate Structure

**Board of Directors**

- Ty Burton
  Director
- Arnold Lippa, Ph.D.*
  Director
  Acting Co-CEO and CSO
  - Jeffrey Witkin, Ph.D.*
    Senior Research
    Fellow
  - Richard Purcell*
    Senior VP
    Research & Development
  - Rok Cerne, Ph.D.*
    Senior Research
    Fellow
- Jeff Margolis*
  Director
  Acting Co-CEO and CFO
  - Will Clodfelter*
    Senior VP
    Business Development
  - Marc Radin*
    Controller
- Michael Burfield
  Director

* US employees or contractors of RespireRx working for ResolutionRx pursuant to Master Intercompany Services Agreement

# Partners and Service Providers

1. **iNGENu CRO Pty Ltd**

   ResolutionRx has entered into a services agreement with iNGENu CRO Pty Ltd, an Australian contract research organization, focused on cannabinoid research, to provide R&D services, including regulatory, compliance, manufacturing services either directly or through sub-contractors, as well as to conduct clinical studies. www.iNGENUCRO.com.au

2. **Ab Initio Pharma Pty Ltd**

   ResolutionRx has entered into a services agreement with Ab Initio, an Australian drug ingredient manufacturer and provider of other related services for the manufacture, formulation, testing and supply of therapeutic drugs based on our lipid nanoparticle technology licensed from RespireRx. https://ab-initio-pharma.com/

3. **RespireRx Pharmaceuticals Inc.**

   ResolutionRx has entered into a services agreement for RespireRx, ResolutionRx's, parent company, to provide management , R&D and general and administrative services in support of business operations and research and development activities. www.RespireRx.com

4. **Bentley's SA/NT**

   Bentley's will provide accounting services and consulting services with regard to R&D Tax Incentives
   https://www.bentleys.com.au/

5. **DLA Piper**

   DLA Piper is a global law firm operating through various separate and distinct legal entities. It has offices in Brisbane, Melbourne, Perth, and Sydney, providing comprehensive legal services in at least 27 practice areas. DLA Piper has substantial capabilities in healthcare, finance, intellectual property, life sciences and several other areas of interest to ResolutionRx. https://www.dlapiper.com/en/locations/australia

# RESOLUTIONRX

## FINANCING STATUS

- ResolutionRx is eligible to participate in the Australian R&D tax credit, a refund, in our case, expected to be 43.5% of qualified research and development expenditures.
- Radium Capital has agreed to provide a debt facility to finance 80% of ResolutionRx's Australian research and development tax incentives.
- Based on an independent pre-money net asset value of A$33.75M, ResolutionRx has mandated PrimaryMarkets Pty Limited as its non-exclusive advisor to raise A$18M through the sale of Series A Preference Shares at a per share price of A$1.35.
- ResolutionRx has entered into a binding Letter of Intent with Cantheon Capital for an intended investment of US$3,125,000 in the Series A Preference Shares which is 25% of the clinical trial research and development budget of the cannabinoid program.

# CONTACT

**JEFF MARGOLIS**

*Acting Co-CEO, CFO, Director*

jmargolis@resolutionrx.com.au

011 + 1 + 917-834-7206

**WILL CLODFELTER**

*Senior Vice President, Business Development*

wclodfelter@respirerx.com

011 + 1 + 858-361-3780