

## ResolutionRx Ltd.

# Background

ResolutionRx Ltd, an unlisted public Australian company (ACN 664 925 651, ABN 17 664 925 651), was formed on 11<sup>th</sup> January 2023 by RespireRx Pharmaceuticals Inc., a U.S. public company (OTC: RSPI). RespireRx has contributed, via sublicense and license agreements with ResolutionRx, its cannabinoid drug development program subject to certain liabilities. ResolutionRx is engaging in the research and development (R&D) associated with that program, initially for the development of a new oral formulation of dronabinol for use in a Phase 3 clinical trial and the filing of regulatory approval for the treatment of obstructive sleep apnea ("OSA").

## **Dronabinol for the Treatment of Obstructive Sleep Apnea** (OSA)

OSA occurs due to airway blockage during sleep, which can interfere with breathing 5 – 50 times per hour. 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. OSA has been linked to increased risk for hypertension, heart failure, depression, and diabetes. The annual economic cost of OSA in the U.S. alone exceeds \$160 billion. The current standard of care for OSA, continuous positive airway pressure (CPAP), involves a mechanical device that has poor patient compliance, adherence, and satisfaction. Despite these shortcomings, the sleep apnea devices market size exceeds US\$6.2 billion. There are no approved drug treatments for OSA, and we believe that approximately 80% of patients are undiagnosed. We also believe that the market will dramatically increase as a result of the recent introduction of "at home" test kits and as more patient friendly treatment alternatives, such as ours, become available.

## Dronabinol - A Breakthrough Treatment for OSA

- Dronabinol, a synthetic form of Δ-THC, was the first pharmaceutical cannabinoid approved by U.S. FDA (Food and Drug Administration) in 1985 and is currently prescribed and sold in the U.S. for the treatment of anorexia in AIDS patients and nausea and vomiting in cancer patients undergoing chemotherapy. ResolutionRx intends to re-purpose dronabinol for the treatment of OSA.
- In two, successfully completed Phase 2 clinical trials, dronabinol produced statistically significant, dose-related improvements in the Apnea-Hypopnea Index (AHI), a primary endpoint measure of OSA. Next day sleepiness, as measured by the Epworth Sleepiness Scale, and patient satisfaction were also significantly improved. The results of the Phase 2a and Phase 2b studies have been published in three peer-reviewed journal articles

## **Novel Formulation Technology**

Because of dronabinol's insolubility, the commercial formulation of dronabinol suffers from poor and highly variable absorption, low blood levels resulting from rapid and extensive first pass liver metabolism, as well as a relatively brief half-life (approximately 2-3 hours) requiring high doses in order to achieve sustained, therapeutic blood levels for 4 hours or longer. Using state of the art, proprietary lipid nanoparticle technology, we have designed dronabinol formulations that display (i) appropriate water solubility and dissolution to improve absorption, (ii) nanoparticle size and resistance to stomach acid conditions in order to reduce first pass liver metabolism and achieve higher and longer blood levels, as well as (iii) stability and ease of manufacturing to support commercial scale. We believe that these formulations may broaden the dronabinol market to include not only OSA but other indications and other cannabinoids, as well.

### **Financing Status**

- 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, an amount equal to
  25% of the clinical trial research and development budget for the cannabinoid program.
- ResolutionRx is eligible to participate in the Australian R&D tax credit, a refund of 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.

## **ASSETS**

*Market Potential* - Underserved, potential multibillion dollar market.

*Intellectual Property* - Patents Pending to 2042 claiming composition of matter, use, dose, blood levels and extended release.

Chemical Supply - Supply agreement whereby Noramco/Purisys will provide all active pharmaceutical ingredient (API)

#### Partners

- iNGENu CRO Pty Ltd, an Australian contract research organization, focused on cannabinoid research, provides R&D services, including regulatory, compliance, clinical studies and other services, either directly or through sub-contractors.
- RespireRx provides management, R&D and general and administrative services in support of business operations and research and development activities
- Bentley's SA/NT provides accounting services and consulting services with regard to R&D Tax Incentives
- DLA Piper, a global law firm with offices in Brisbane, Melbourne, Perth, and Sydney, provides legal services in healthcare, finance, intellectual property, life sciences and several other areas of interest to ResolutionRx.
- In negotiation with an Australian company to provide manufacturing services.

# MANAGEMENT TEAM

Jeff Margolis - Director, Co-CEO and CFO Arnold Lippa, PhD - Director ,Co-CEO, CSO Michael Burfield - Director Ty Burton - Director

## OFFICE LOCATION

Registered office c/- Bentleys (SA) Pty Ltd Level 5 63 Pirie Street Adelaide SA 5000

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## Special Note Regarding Forward-Looking Statements

## Not a Securities Offering

This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sales of securities in any jurisdiction in which such offer, solicitation or sale of securities would be unlawful before registration or qualification under the laws of such jurisdiction.

### Cautionary Note Regarding Forward-Looking Statements

This document 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," "frojects," "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 press release.

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 recognize 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.