

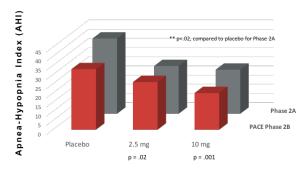
## **Dronabinol for the Treatment of Obstructive Sleep Apnea** (OSA)

OSA, the most common form of sleep-related breathing disorders, is a serious respiratory disorder that involves repetitive cessation of breathing during sleep. It is estimated that up to 30 million people in the United States suffer from OSA, which has been linked to increased risk for hypertension, heart failure, depression, and diabetes. According to the American Academy of Sleep Medicine, the annual economic cost of OSA in the U.S. was \$162 Billion in 2015. 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 is projected to exceed \$8.7 billion by 2023 (Global Market Insights, 2017). There are no approved drug treatments for OSA, and 80% of patients (23.5 million) are undiagnosed.

#### **Dronabinol**

Dronabinol is an FDA approved, generic, orally active cannabinoid that that has been shown to act at CB1 & CB2 receptors on neurons to stabilize respiratory patterns and augment upper airway muscles. In two, successfully completed Phase 2 clinical trials, dronabinol produced statistically significant, dose-related improvements in the Apnea-Hypopnea Index (AHI), a primary end-point measure of OSA. Next day sleepiness, as measured by the Epworth 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

# Clinical Trial Summary: Efficacy in the Treatment of OSA - AHI Scores



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

## **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 (approximately 80%) 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 novel, 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, as well.

## **Regulatory Strategy**

Because dronabinol already is an approved drug, we intend to use publicly available information, particularly safety data, in support of a 505(b)(2) New Drug Application ("NDA"), a more rapid route to FDA approval than a standard 505(b)(1) NDA.

### BACKGROUND

**RespireRx** is developing innovative and revolutionary treatments caused by disruption of neuronal signaling, such as OSA, ADHD, epilepsy, pain, spinal cord injury and certain orphan disorders. We are organized into two separate business units:

**ResolutionRx**, focused on pharmaceutical cannabinoids, is re-purposing dronabinol using proprietary formulations for new therapeutic indications, specifically OSA.

EndeavourRx, based on our neuromodulators platform, is made up of two programs: (a) our AMPAkines program, which is developing proprietary compounds that are positive allosteric modulators ("PAMs") of AMPA-type glutamate receptors to promote neuronal function and (b) our GABAkines program, which is developing proprietary compounds that are PAMs of GABAA receptors

# OBSTRUCTIVE SLEEP APNEA MARKET SIZE:

Prevalence:  $\sim 30 \text{ MM}$ Diagnosed:  $\sim 6 \text{ MM}$ Undiagnosed:  $\sim 24 \text{ MM}$ Device Market:  $\sim \$8.7 \text{ B}$ Economic Impact:  $\sim \$162 \text{ B}$ 

### INTELLECTUAL PROPERTY

Extensive IP Portfolio Patents Pending to 2042 Market Exclusivity

# MANAGEMENT TEAM

Arnold Lippa, PhD, Interim CEO, Interim President, CSO Exec Chairman Jeff Margolis, CFO, Senior VP Finance

## **OFFICE LOCATION**

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# 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 within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Company intends that such forward-looking statements be subject to the safe harbor created thereby. 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 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 disclosed in "Item 1A. Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC on April 15, 2022 (the "2021 Form 10-K").

You should read these risk factors and the other cautionary statements made in the Company's filings as being applicable to all related forward-looking statements wherever they appear in this document. We cannot assure you that the forward-looking statements in this document will prove to be accurate and therefore prospective investors, as well as potential collaborators and other potential stakeholders, are encouraged not to place undue reliance on forward-looking statements. You should read this document completely. Other than as required by law, we undertake no obligation to update or revise these forward-looking statements, even though our situation may change in the future.

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 described in the 2021 Form 10-K and in this documnt, as well as others 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, including those described in the 2021 Form 10-K and in this document. 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.

For more information about the risks and uncertainties the Company faces, see "Item 1A. Risk Factors" in our 2021 Form 10-K. Forward-looking statements speak only as of the date they are made. The Company does not undertake and specifically declines any obligation to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments. We advise investors, as well as potential collaborators and other potential stakeholders, to consult any further disclosures we may make on related subjects in our annual reports on Form 10-K and other reports that we file with or furnish to the SEC.