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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 8-K**

Current Report

Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 10, 2018

**RESPIRERX PHARMACEUTICALS INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

1-16467  
(Commission  
File Number)

33-0303583  
(I.R.S Employer  
Identification No.)

126 Valley Road, Suite C  
Glen Rock, New Jersey  
(Address of principal executive offices)

07452  
(Zip Code)

Registrant's telephone number, including area code: (201) 444-4947

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)  
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)  
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))  
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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**Item 7.01 Regulation FD Disclosure**

On December 10, 2018, RespireRx Pharmaceuticals Inc. (the “Company”) announced that the Company’s Senior Vice President of Research and Development, Richard Purcell and its Senior Vice President, Chief Financial Officer, Treasurer and Secretary, Jeff E. Margolis, each will be presenting at the International Cannabinoid Derived Pharmaceuticals Summit at the Revere Hotel in Boston, Massachusetts. Mr. Purcell is scheduled to co-lead a pre-conference workshop on “Financial Planning and Commercial Strategy” on Monday, December 10, 2018. Mr. Purcell is also scheduled to present “Using Cannabis to Treat Previously Untreatable Diseases” on Wednesday, December 12, 2018. Mr. Margolis is scheduled to participate on a panel on Wednesday, December 12, 2018 entitled “The Funding Challenges Associated with Cannabis-Derived Pharmaceuticals.”

The slide presentations that the Company will be using at the conference are attached as Exhibits 99.1, 99.2 and 99.3. The press release announcing the Company’s participation in the conference is attached as Exhibit 99.4. These exhibits are being furnished and not filed pursuant to Item 7.01 of Form 8-K

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

A list of exhibits that are furnished and filed as part of this report is set forth in the Exhibit Index, which is presented elsewhere in this document, and is incorporated herein by reference.

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## EXHIBIT INDEX

Exhibit Number	Exhibit Description
99.1	<a href="#">Slide Presentation*</a>
99.2	<a href="#">Slide Presentation*</a>
99.3	<a href="#">Slide Presentation*</a>
99.4	<a href="#">Press Release dated December 10, 2018*</a>

\* Furnished herewith.

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Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 10, 2018

RESPIRERX PHARMACEUTICALS INC.

By: /s/ Jeff E. Margolis

Jeff E. Margolis

Senior Vice President, Chief Financial Officer, Treasurer and Secretary

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## Pharmaceutical Development of Cannabinoid Medicines: Opportunities and Challenges

Richard Purcell  
SVP R&D  
RespireRx Pharmaceuticals

December 10, 2018

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## Forward Looking Statements & Disclaimer



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In some cases, forward-looking statements may be identified by words including "anticipates," "believes," "intends," "estimates," "expects," "plans," "contemplates," "targets," "continues," "budgets," "may" and similar expressions 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 proposed products, (iv) reorganization plans, (v) clinical development, regulatory review and commercialization process and (vi) the need for, and availability of, additional financing.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties. 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 and competitive conditions, 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 the Company believes that the assumptions underlying the forward-looking statements are reasonable, actual results may differ materially from those set forth in the forward-looking statements. In light of the significant uncertainties inherent in the forward-looking information included herein, the inclusion of such information should not be regarded as a representation by the Company or any other person that the Company's objectives or plans will be achieved.

Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies or changes thereto, available cash, research and development results, competition from other similar businesses, interest of third parties in collaborations with us and market and general economic factors.

For more information about the risks and uncertainties the Company faces, see "Item 1A. Risk Factors" of the RespireRx Pharmaceuticals Inc. Annual Report on 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.

- ❖ This presentation has been compiled from publicly available information. It is designed to provide a general overview on the state of development of cannabinoid products in the U.S. and is not intended to be a comprehensive nor definitive guide to cannabinoid development. RespireRx makes no guarantee as to the accuracy of the information contained herein.

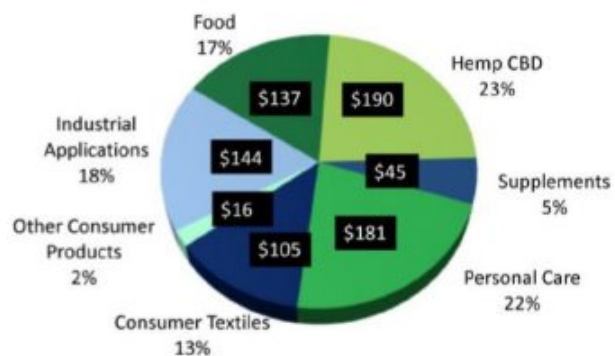
## The Market for Cannabinoid Products is Exploding



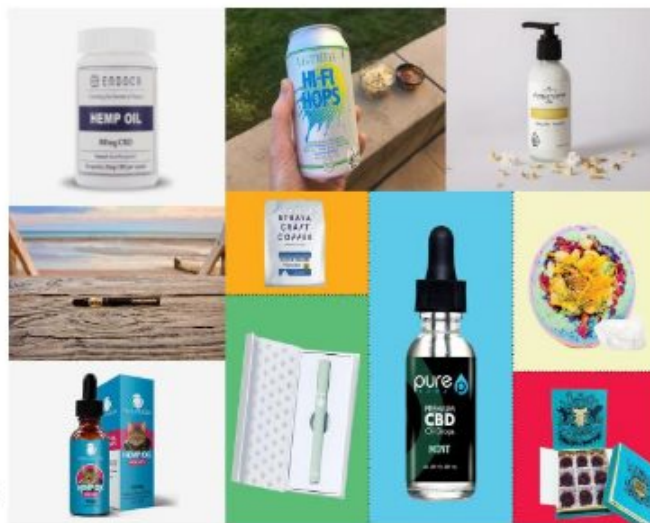
- Consumer cannabis sales = \$9.5 billion in 2017<sup>1</sup>
- The global cannabis market is estimated to reach \$32 billion by 2022 and \$57 Billion by 2027<sup>1</sup>
- The global hemp-CBD market alone could hit \$22 billion by 2022<sup>2</sup>

# CBD Products are Everywhere!

## \$820 Million U.S. Hemp-Based Product Sales by Category in 2017



Source: Hemp Business Journal estimates (\$mil., consumer sales)





## The Laws and Regulations for Cannabinoids are Confusing

**Example: In California Marijuana is Legal as per Prop 64 But CBD is Illegal!!!**

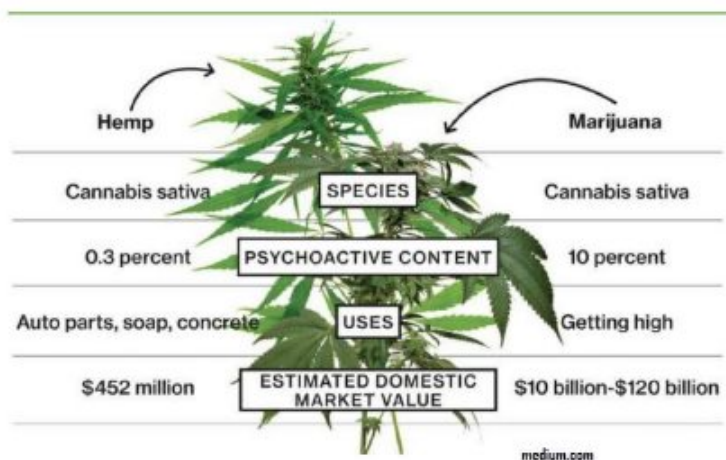
Until the FDA rules that industrial hemp-derived CBD oil and CBD products can be used as a food or California makes a determination that they are safe to use for human and animal consumption, CBD products are not an approved food, food ingredient, food additive, or dietary supplement (California Department of Health, Food & Drug Branch 7/6/18)



\* Industrial Hemp can Only be Grown with State License per 2014 Farm Bill

# Cannabinoids From Hemp vs Cannabis

Federal Law Prohibits the Growing, Sale, and Distribution of Cannabis, Hemp & Their Derivatives



Hemp		Marijuana
Cannabis sativa	SPECIES	Cannabis sativa
0.3 percent	PSYCHOACTIVE CONTENT	10 percent
Auto parts, soap, concrete	USES	Getting high
\$452 million	ESTIMATED DOMESTIC MARKET VALUE	\$10 billion-\$120 billion

medium.com

- The DEA considers both marijuana and hemp and their derivatives (including THC and CBD) to be Schedule I drugs
- THC is separately listed as a Schedule I drug
- The 2014 Farm Bill allowed for the growing of industrial hemp by licensed state authorities and research facilities

## CBD Manufacturers are Ramping up Production to Meet Growing Demand

### The 2018 Farm Bill Holds the Key to the Future of CBD

If passed, the 2018 Hemp Farming Act will:

1. Legalize the cultivation of industrial hemp across the USA, making CBD products legal in all 50 states
2. Remove hemp and CBD from the list of Schedule Class I Substances
3. Enable the banking system to conduct business with hemp producers and CBD product manufacturers



Purified Cannabinoid Extracts Including CBD are Still Subject to FDA Regulation of Drug Products



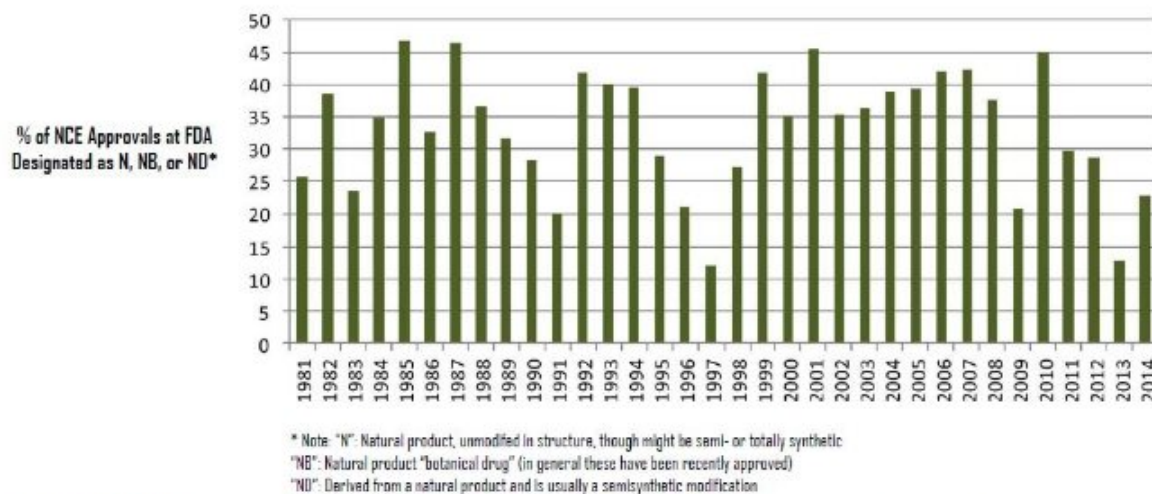
## The FDA Oversees the Regulatory Approval of Cannabinoids as Drugs

As per the FDA, the Path to Development of Cannabinoid Pharmaceutical & Medicinal Products is the Same as the Normal Development Path for any Pharmaceutical Drug Product

Development Phase	Pre-clinical	Phase I "safety"	Phase II "efficacy"	Phase III "pivotal"
Typical time for phase (Cumulative Time)	6-18 months	6-24 months (1-2 years cumulative)	12-36 months (2-5 years cumulative)	36-72 months (5-12 years cumulative)
Study subjects	Animals	Humans	Patients 20-200	Patients 500 – 5,000
Costs	~\$1 - 3 Million	~\$3 – 5 Million	~\$10 – 50 Million	~\$200 - 500 Million
Objectives of Phase	<ul style="list-style-type: none"> <li>• Safety/Toxicology</li> <li>• Pharmacokinetics</li> <li>• Pharmacology</li> <li>• Teratogenicity (i.e., does it cause cancer)</li> </ul>	<ul style="list-style-type: none"> <li>• Safety/Toxicology</li> <li>• Pharmacokinetics</li> <li>• Pharmacology</li> <li>• Preliminary Efficacy</li> </ul>	<ul style="list-style-type: none"> <li>• Safety/Toxicology</li> <li>• Pharmacokinetics</li> <li>• Pharmacology</li> <li>• Efficacy</li> </ul>	<ul style="list-style-type: none"> <li>• Safety/Toxicology</li> <li>• Pharmacokinetics</li> <li>• Pharmacology</li> <li>• Efficacy</li> <li>• Dosing</li> </ul>
Regulatory Filings	IND			NDA
	Pre-clinical studies lead to filing of Investigational New Drug (IND) with FDA for human study permission			Phase III clinical studies lead to filing of New Drug Application (NDA) with FDA for initial marketing and Phase IV studies

## Many Medicines are Derived from Plants and Microbes

Over the last 34 years, the 33% of All Drugs Approved by FDA are Derived from Natural Products and Botanicals



## June 25, 2018 FDA Approves 1<sup>st</sup> Marijuana Derived Medicine



Approved for Dravet syndrome and Lennox-Gestaut syndrome, two rare forms of childhood epilepsy

Derived from CBD extracted from Cannabis grown in the U.K.

Oral solution that has undergone rigorous clinical testing & regulatory review

Sativex (CBD:THC) approved ex-US for spasticity in MS; Nabiximols in development for U.S. market



## Wide Ranging Therapeutic Opportunities for Cannabinoids

Clinicaltrials.gov lists 139 clinical trials of cannabidiol and 282 trials for cannabinoids\*

- ADHD
- Anxiety
- Appetite
- Autism
- Bipolar Disorder
- Cancer
- Cerebral Palsy
- Cervical Dystonia
- COPD
- Crohn's Disease
- Depression
- Epilepsy & Seizure disorders
- Fragile X disorder
- Huntington's
- Inflammatory Bowel Disease
- Irritable Bowel Syndrome
- Multiple Sclerosis
- Neuropathy
- OCD
- Osteoarthritis
- Pain
- Parkinson's
- Psychosis
- PTSD
- Retinitis Pigmentosa
- Schizophrenia
- Spasticity
- Substance abuse disorders

*\*Completed or in progress: partial list*



## FDA Regulatory Pathways for Cannabinoid Drugs

As per the FDA, the Path to Development of Cannabinoid Pharmaceutical & Medicinal Products is the Same as the Normal Development Path for any Pharmaceutical Drug Product

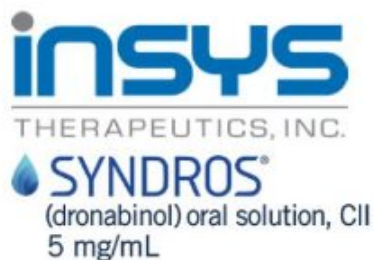
FDA has Stated that THC and CBD Products are Excluded from the Dietary Supplement Definition Under Sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act

505(b)(1) NDA	505(b)(2) NDA	505(j) ANDA
Full application – Data Predominantly from sponsor studies	Hybrid between an ANDA and Full NDA	Pathway for drug products that are the same as approved (generic)



## The FDA Regulatory Path for Generic Products

### The Abbreviated New Drug Application - ANDA



**SYNDROS<sup>®</sup>** FDA-approved liquid dronabinol

- fast absorption
- flexible dosing

**4.2 mg of SYNDROS<sup>®</sup> = 5 mg Dronabinol gel cap (Marinol<sup>®</sup>)**

Oral formulation provides comparable systemic exposure (C<sub>max</sub> and AUC)

**Schedule II Drug – Abuse Potential for “Likeability”**

### ○ Dronabinol Overview

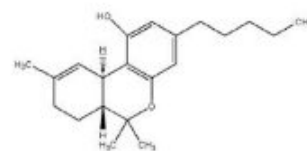
- Dronabinol is a synthetic form of delta-9-THC, the psychoactive molecule in cannabis
- Rx drug approved for the treatment of anorexia in AIDS patients and nausea and vomiting in cancer patients undergoing chemotherapy
- Marinol® & Generic Manufacturers Market 2.5, 5, 10 mg gel caps in sesame oil
- Dronabinol API is Schedule I and finished formulation gel caps are Schedule III

### ○ Intellectual Property

- Translational research program with Dr. David Carley at the U of Illinois – Chicago
- License to issued method-of-use patent in the US for the use of dronabinol for treating OSA (expires 2025)
- Additional patent applications filed
- Positive Phase 2A & 2B studies in the treatment of OSA

### ○ Funding

- NIH grants at the University of Illinois – Chicago
- Private investors – Steady State Rx & Pier Pharmaceuticals
- ~\$5MM NHLBI-funded grant to Univ. of IL at Chicago (D. Carley) for Phase 2B study in OSA
- Public investors – RespireRx Pharmaceuticals



### **RespireRx Believes that Dronabinol is Eligible for the 505(b)(2) NDA Regulatory Pathway**

With the 505(b)(2) regulatory approach, existing labelling information of an approved Listed Drug (Marinol®) and/or published literature may be relied upon to meet certain regulatory requirements for product approval.

# Protect Your Intellectual Property with Patents

**RespireRx Holds the Patents for Cannabinoids in the Treatment of Sleep Related Breathing Disorders**

## **Dronabinol for OSA is Patent Protected**

- **Issued Method-of-Use Patents:**

"Functional Role for Cannabinoids in Autonomic Stability During Sleep" - Patent 7,705,039 (see Attachment 6) . issued in the U.S., Germany and Great Britain and claiming the use of cannabinoids (including dronabinol, cannabidiol, etc.) for the treatment of sleep-related disorders, including apneas

- **Additional Patent Applications Filed**

## Secure the API Supply Chain

### Dronabinol API is a Schedule I Drug with Manufacturing and Import Quotas

Dronabinol API Suppliers	Form	Location
Noramco*	20% Sesame Oil or Ethanol	Switzerland USA
Norac (Alkem/SGB Pharma)	Resin	USA
Johnson-Matthey	Oil or Ethanol	UK
Rhodes Technologies	10% Sesame Oil	USA
Insys	Resin	USA

\*RespireRx Development & Supply Partner

## Formulation of Cannabinoid Products & Differential Routes of Administration\*

Technology	Advantage	Examples
Sesame Oil Gel Caps	Approved as Schedule III drug	Marinol® from AbbVie Generic Dronabinol
Buccal Film/Tablet	Bypass 1 <sup>st</sup> Pass Metabolism	VersaFilm Dronabinol IntelGenX/Tetra
Oral Solution	Rapid Onset of Action Ease of Use	Syndros® (Dronabinol Oral Solution) from Insys
Buccal Spray	Bypass 1 <sup>st</sup> Pass Metabolism Metered Dosing	RapidMist® CBD Buccal Spray Scientus Pharma
Transdermal Patches	Rapid Onset of Action Ease of Use	Mary's Medicinals Papa & Barkley CBD
Topical Creams, Salves & Balms	Localized Application Non-Systemic	Charlotte's Web AnandaHemp: Spectrum Salve 125

# PACE: A Phase 2B Clinical Trial: Pharmacotherapy of Apnea by Cannabimimetic Enhancement

## Principle Investigators

- Dr. David Carley at University of Illinois - Chicago & Dr. Phyllis Zee at Northwestern University

## Study Design

- Randomized, Placebo-controlled, Parallel Groups, Multi-site Trial in Patients with Moderate to Severe OSA (n = 73 subjects enrolled; 57 completers)

## Study Drug

- Dronabinol (Overencapsulated Marinol®); 2.5 mg or 10 mg QD - 60 minutes before bedtime

## Inclusion Criteria

- Age 21 – 64; AHI 15 – 50; Epworth Sleepiness Scale (ESS)  $\geq 7$ ; Body Mass Index (BMI)  $\leq 45$

## Exclusion Criteria

- Shift Work or OSA treatment within 1 month; Medical Co-morbidity; Psychiatric Dx; CNS Active Meds

## Results

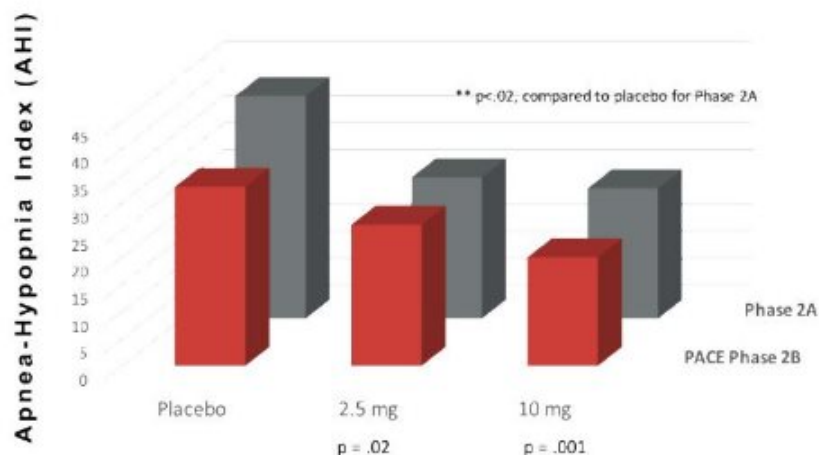
- Statistically significant reduction in apnea hypopnea index (AHI) and scores on the Epworth Sleepiness Scale (ESS) with 10 mg dose
- Clean safety profile & significant improvement of patient satisfaction with therapy

**PACE** enhancement  
cannabimimetic

## The Pace Trial Replicates the Phase 2A Study<sup>1</sup>



The Published Literature Can be used to Support a 505(b)2 NDA for Dronabinol in OSA



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

\* Double blind, placebo controlled dose-ascending study in patients with OSA. 2a n=19 2b n=57

<sup>1</sup>Published in Frontiers in Psychiatry January 2013 | Volume 4 | Article 1

## FDA Expedited Approval Opportunities & RespireRx\* Dronabinol for OSA

<b>Breakthrough Therapy Designation</b>	Preliminary clinical data	Substantial improvement on clinically significant endpoint(s) over available therapies  <i>No Drug Therapy for OSAS*</i>	More frequent meetings with FDA More frequent FDA communication Rolling review Intensive guidance on an NDA FDA help to expedite development
<b>Accelerated Approval Pathway</b>	Not specified. Sponsor should make justification of alternate endpoint based scientific support	Generally provides a meaningful advantage over available therapies AND demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or a clinical endpoint that can be measured earlier than irreversible morbidity or mortality  <i>Cannot or Will Not Use C-PAP*</i>	Approval based on a surrogate or intermediate endpoint (often allows for shorter development time) Note: FDA requires clinical trials to be conducted post-approval to confirm clinical benefit  <i>AHI &amp; ESS Endpoints*</i>
<b>Priority Review Designation</b>	Data contained in the final NDA submission	Significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition. <i>OSAS Health &amp; Economic Impact*</i>	Review of application in 6 months



\*There are no assurances that expedited approvals will be granted by FDA



## Developing Cannabinoids: Topics for Discussion

- ❖ Federal & state laws
- ❖ Hemp & cannabis products
- ❖ FDA requirements for Rx development
- ❖ DEA constraints on supply
- ❖ Extracts vs purified compounds
- ❖ OTC supplements outlook
- ❖ Intellectual property & patents
- ❖ Therapeutic indications & marketing claims



**RespireRx**  
Pharmaceuticals Inc.

OTC QB: RSPX

December 10th - 12th 2018 | Boston, USA  
[international-icdp.com](http://international-icdp.com)



## **Pharmaceutical Development of Cannabinoid Medicines: Opportunities and Challenges**

**Richard Purcell**  
SVP R&D  
RespireRx Pharmaceuticals

December 10, 2018

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RespireRx Pharmaceuticals is focused on the development of medicines that modulate neuronal signaling in diseases and disorders of neuronal dysfunction



OTC QB: RSPi

**Using Cannabis to Treat Previously Untreatable Diseases**

International Cannabinoid Pharmaceuticals Summit  
December 12, 2018

## Forward Looking Statements



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## Breath

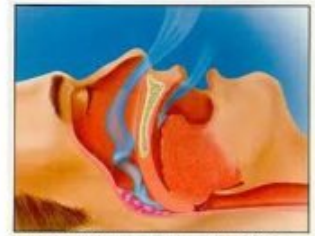
"Breath is the universal factor of life. We are born the first time we inspire, and we die the last time we expire. Breath is life itself. In Sanskrit the same word means both breath and life."

.....Abbot George Burke

# Sleep Apnea: A National Health Epidemic

## 3 Types of Sleep Apnea

- **Obstructive** (OSA) - a peripheral phenomenon that occurs when throat muscles intermittently relax and block airway during sleep
  - May be accompanied by snoring
- **Central** (CSA) – a brain-mediated phenomenon that occurs when breathing control centers in the brain reduce activity
  - Frequently caused by opioid consumption
- **Mixed** - a combination of OSA and CSA



During sleep apnea, air flow is completely blocked.



~ 30 million Americans Stop Breathing Every Night  
5-50 Times per Hour!

**SLEEP APNEA IS NOT MERELY SNORING**

## Obstructive Sleep Apnea is a National Epidemic



Disease State	Estimated US Prevalence	Annual Estimated Cost to Society	Annual Indicated Drug Therapy Expenditures
OSA <sup>1-5</sup>	29.4 MM	\$162.0 Billion	\$ 0
Asthma <sup>6,7</sup>	16.4 MM	\$18.3 Billion	\$13.5 Billion
Hypertension <sup>8-10</sup>	43.2 MM	\$73.4 Billion	\$48.5 Billion
Diabetes <sup>11,12</sup>	23.5 MM	\$174 Billion	\$20.6 Billion

1 Obstructive sleep apnea and sleep. National Sleep Foundation Web site.

2 Manufacturer Recommendations

3 Qualitative Market Research, Physician / Patient interviews, 2010

4 CPAP Supply USA,

5 American Sleep Apnea Association, 2010

6 Asthma & Allergy Foundation of America

7 Espicom Business Intelligence's New Drug Futures, 2008

8 Burt, V., et al., Hypertension, 2005

9 Lloyd-Jones, D., et al., Circulation 119(3):e21-101, 2009

10 Acorn Market Intelligence, 2008

11 Arrowhead, Global Diabetes Market, 2006

12 American Diabetes Assoc., 2007



# There are No Drug Therapies for OSA

## Current Approved Treatments Include Devices and Surgery

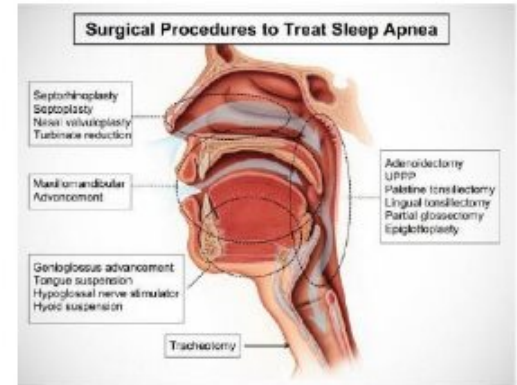
### CPAP device



### Dental devices



### Surgery



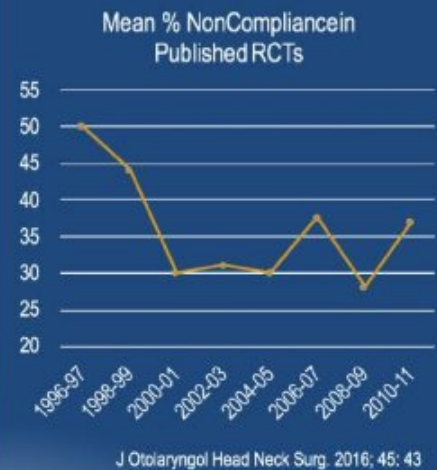
Source: American Sleep Association

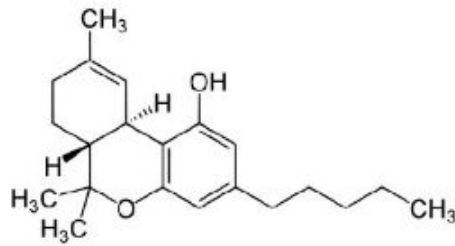
In addition to the above, there are also exercises and stimulant drugs for next day sleepiness



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

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





- **Dronabinol is Δ-9-THC**
- Oral, small molecule
- Cannabinoid receptor agonist
- Reduces apnea by acting on nodose ganglia controlling muscle tone in throat
- Positive Phase 2A and 2B clinical trials in OSA

- **Dronabinol Background**

- FDA approved for the treatment of anorexia in AIDS patients and nausea and vomiting in cancer patients undergoing chemotherapy (Marinol®)
- Schedule III drug available by prescription, with a low risk of addiction

- **Intellectual Property**

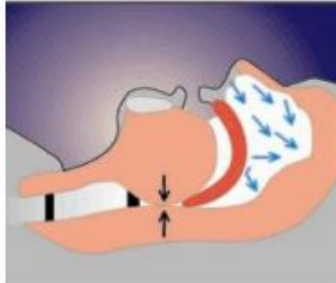
- RespireRx exclusive worldwide license from the University of Illinois - Chicago
- RespireRx licensed from University of Illinois – Chicago, issued U.S. patent for the use of dronabinol in the treatment of OSA
- New patents pending that are also part of the University of Illinois – Chicago license

- **NIH Support**

- ~\$5MM NIH-funded grant to Univ. of IL at Chicago (D. Carley) for PACE Phase 2B trial in OSA

## IDENTIFY TARGET SITE: The Vagus Nerve Controls Upper Airway Muscles

### Obstructive Sleep Apnea



#### Pharyngeal plexus

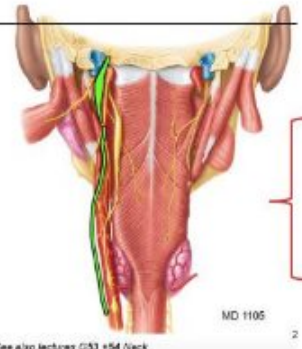
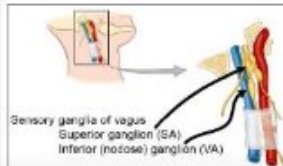
##### Vagus (CN X)

Via jugular foramen

In pharynx:

Sensory (SA) to laryngopharynx  
(VA) to taste buds

Motor (SE) to pharyngeal muscles  
except stylopharyngeus

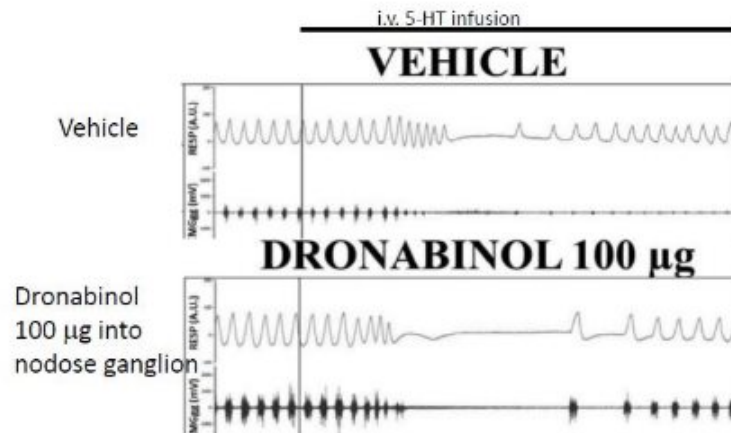


*Serotonin (5-HT)  
stimulation of vagus  
nerve afferents induces  
reflex apnea*

Illustration by Notter - <https://www.memorangapp.com/>

### Animal Model of OSA: Serotonin (5HT)-induced Reflex Apnea in Rats

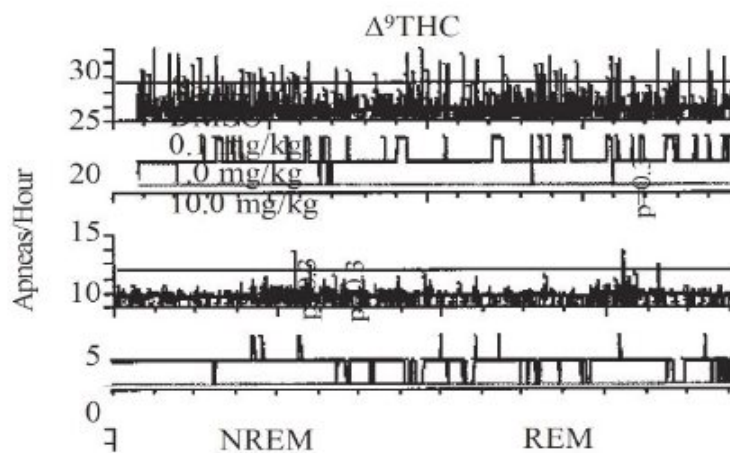
Dr. David Carley at the University of Illinois – Chicago Discovered the Mechanism of Action for Dronabinol in the Treatment of OSA



Data from Calik *et al*, *Respir Physiol Neurobiol*, 2013

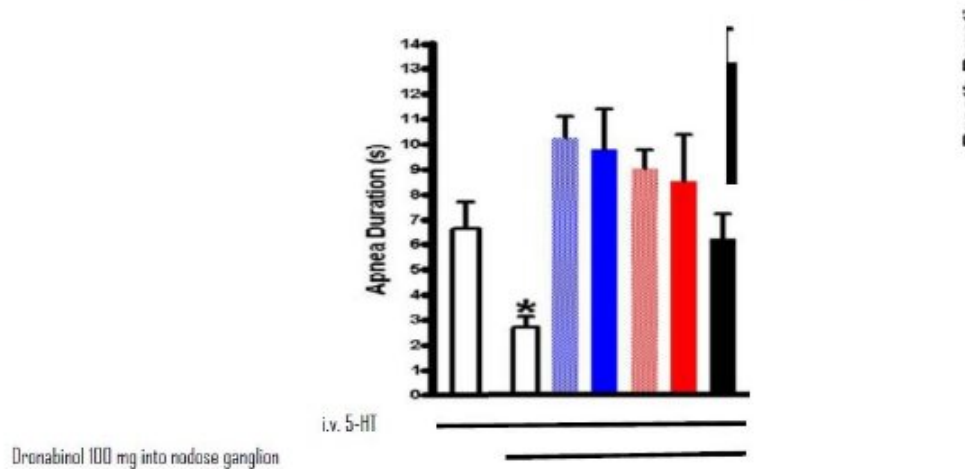
## Polysomnographic recording of spontaneous sleep apneas in rats

IP Injection of Dronabinol Attenuates 5HT-Induced Reflex Apnea



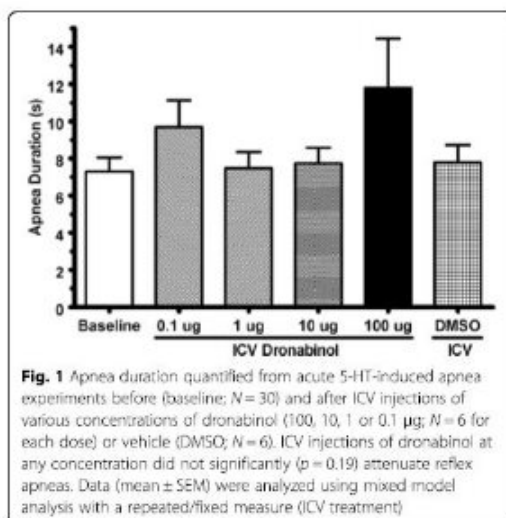
Data from Carley *et al. Sleep*, 2002

**CB1 (AM251) and CB2 (AM630) Antagonists Block the Effects of Dronabinol on Serotonin-Induced Apnea**



Data from Calik and Carley, *PLoS One*, 2013

### Direct Injection of Dronabinol into the Brain Does Not Alter 5-HT Induced Reflex Apnea



Data from Calik and Carley, *Plos One*, 2016

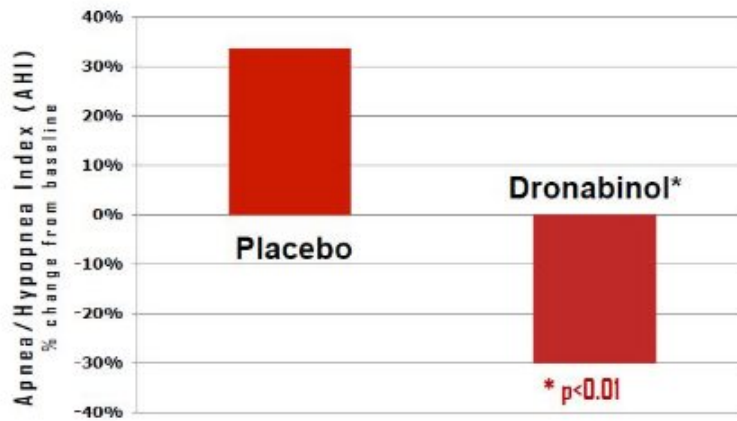


## Dronabinol Proven to Reduce Apnea in OSA Subjects



### Phase 2a Proof of Concept Trial of Dronabinol in OSA

David Carley, University of Illinois at Chicago



- 3-Week Dose-ascending Study
- Statistical Analysis Across All Doses & Times

## THE PACE Clinical Trial: Pharmacotherapy of Apnea by Cannabimimetic Enhancement – A Phase 2B Study



- Randomized, Placebo-controlled, Parallel Groups, Multi-site Trial in Patients with Moderate to Severe OSA
- Study Drug: Dronabinol (Overencapsulated Marinol®): 2.5 mg or 10 mg QD
- Dose Administration: 60 minutes before bedtime
- Inclusion: Age 21 – 64; AHI 15 – 50; Epworth Sleepiness Scale (ESS) > 7; Body Mass Index (BMI) < 45
- Exclusion: Shift Work or OSA Tx within 1 mo; Medical Co-morbidity; Psych Dx; CNS Active Meds



**PACE** enhancement  
apnea by  
cannabimimetic  
pharmacotherapy of  
Clinical Trial

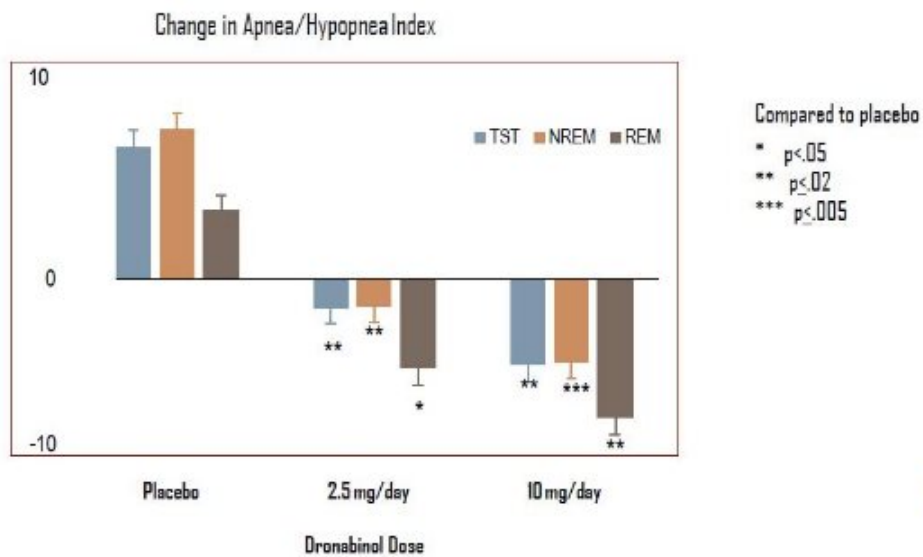
## Statistically significant improvement in Primary Outcome Measures

- Apnea-Hypopnea Index (AHI) (2.5 and 10 mg)
- ESS Sleepiness Scale (10 mg)
- Overall Patient Satisfaction (10 mg)

## Results of 6-Week Treatment: Dronabinol Reduces AHI

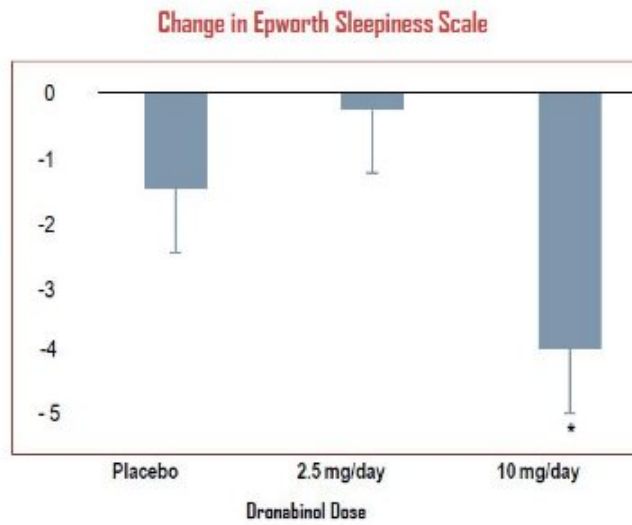


Positive Effects of Dronabinol vs. Placebo in TOTAL, REM & NREM Sleep Demonstrate Efficacy



**PACE** enhancement  
of cannabinimetic  
sleep by  
pharmacotherapy of  
Clinical Trial

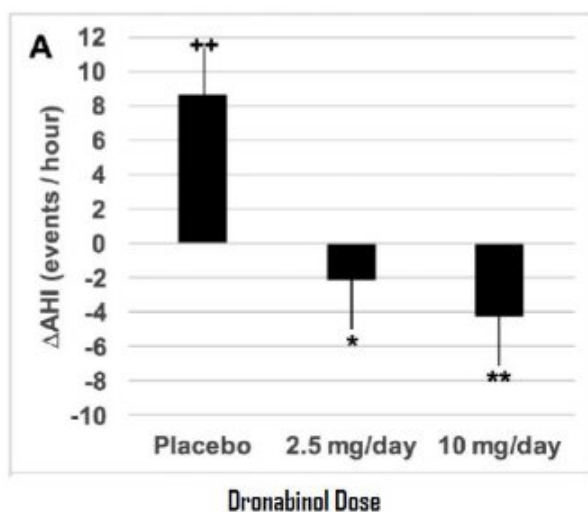
## Dronabinol Reduces Daytime Sleepiness



\*  $p < 0.05$ , compared to placebo

**PACE** enhancement  
of cannabinimimetic  
prea by  
pharmacotherapy of  
Clinical Trial

### Change in Mean Wakefulness Testing (MWT)



**PACE** enhancement  
of cannabinimetic  
pressure by  
pharmacotherapy of  
Clinical Trial

## Patients are Highly Satisfied With Treatment

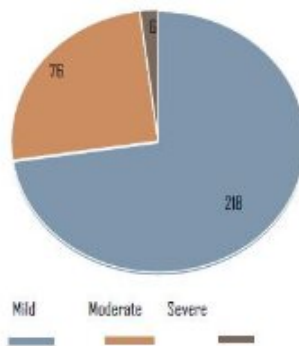


### TSQM Response, End of Treatment \*

Tx Response	Placebo	2.5 mg/day	10 mg/day
Extremely Dissatisfied	3	2	1
Very Dissatisfied	1	2	0
Dissatisfied	0	3	0
Somewhat Satisfied	5	6	4
Satisfied	1	4	4
Very Satisfied	5	1	5
Extremely Satisfied	1	1	6
Total	16	19	20

\* p=0.04 for Treatment Effect

Great Majority of AEs were mild to moderate



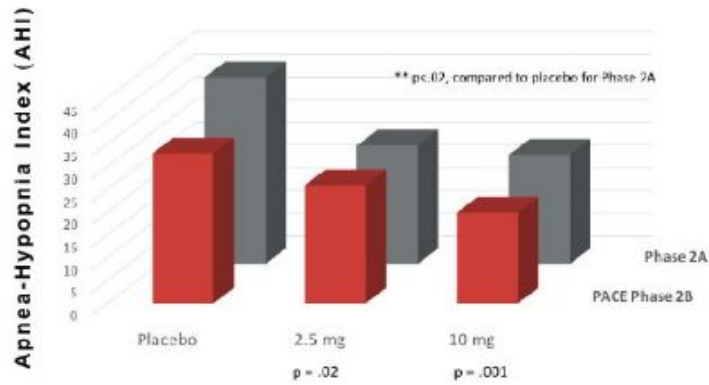
- Average Number of AEs =  $4.1 \pm 4.0$
- AEs did not differ by treatment group
- Most Frequent Verbatim AEs Reported Were:
  - Sleepiness/Drowsiness (N=25)
  - Headache (N=24)
  - Nausea/Vomiting (N=23)



## Two Successful Phase 2 Studies – Phase 3 Ready



Two Phase 2 Clinical Trials Have Shown That Dronabinol Treatment Results in Statistically Significant, Dose Related Improvements in AHI, a Primary Endpoint for FDA Approval



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

- Meet with FDA during Q1/2019
- Finalize the Phase 3 trial plan required for approval
- Position dronabinol as a breakthrough medicine
- Seek fast track designation
- Facilitate and hasten the development path

\* Subject to available financing, of which no assurance can be provided

- **Dronabinol Overview**
  - Rx drug approved for the treatment of anorexia in AIDS patients and nausea and vomiting in cancer patients undergoing chemotherapy
  - Marinol® & Generic Manufacturers Market 2.5, 5, 10 mg gel caps in sesame oil
  - Dronabinol API is Schedule I and finished formulation gel caps are Schedule III
- **Intellectual Property**
  - Translational research program with Dr. David Carley at the U of Illinois – Chicago
  - License to issued method-of-use patent in the US for the use of dronabinol for treating OSA (expires 2025)
  - Additional patent applications pending
- **Multiple Funding Sources to Date**
  - NIH grants to the University of Illinois – Chicago
  - Private investors – Steady State Rx & Pier Pharmaceuticals
  - ~\$5MM NHLBI-funded grant to Univ. of IL at Chicago (D. Carley) for Phase 2B study in OSA
  - Public investors – RespireRx Pharmaceuticals
- **Development Status**
  - Positive Phase 2A & 2B studies in the treatment of OSA
  - Using the 505(b)(2) regulatory approach, existing labelling information of an approved Listed Drug (Marinol®) and/or published literature may be relied upon to meet certain regulatory requirements for product approval.



RespireRx Pharmaceuticals is focused on the development of medicines that modulate neuronal signaling in diseases and disorders of neuronal dysfunction



OTC QB: RSPI

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917-834-7206



OTC QB: RSPH

## **The Funding Challenges Associated with Cannabis-Derived Pharmaceuticals**

Presented December 12, 2018

Jeff Margolis  
SVP CFO etc  
RespireRx Pharmaceuticals



## Forward Looking Statements & Disclaimer



This presentation contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act") and the Company intends that such forward-looking statements be subject to the safe harbor created thereby. These forward-looking statements 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 are all forward-looking statements.

In some cases, forward-looking statements may be identified by words including "anticipates," "believes," "intends," "estimates," "expects," "plans," "contemplates," "targets," "continues," "budgets," "may" and similar expressions 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 proposed products, (iv) reorganization plans, (v) the clinical, regulatory review and commercialization process and (vi) the need for, and availability of, additional financing.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties. 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 and competitive conditions, 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 the Company believes that the assumptions underlying the forward-looking statements are reasonable, actual results may differ materially from those set forth in the forward-looking statements. In light of the significant uncertainties inherent in the forward-looking information included herein, the inclusion of such information should not be regarded as a representation by the Company or any other person that the Company's objectives or plans will be achieved.

Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies or changes thereto, available cash, research and development results, competition from other similar businesses, interest from third parties in collaborations with us and market and general economic factors.

This presentation has been compiled from publicly available information. It is designed to provide a general overview on the state of development of cannabinoid products in the U.S. and is not intended to be a comprehensive nor definitive guide to cannabinoid development. RespireRx makes no guarantee as to the accuracy of the information contained herein.

For more information about the risks and uncertainties the Company faces, see "Item 1A, Risk Factors" of the RespireRx Pharmaceuticals Inc. Annual Report on Form 10-K for the year ended December 31, 2017 and subsequent reports we file from time to time with the Securities and Exchange Commission. 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.

## Need to Distinguish Cannabinoids from Cannabis

*We think of Cannabinoids as following a federally regulated drug development pathway*

- Often synthetic - dronabinol is  $\Delta^9$ -THC
- Can be plant derived – Epidiolex®
- Can be plant derived and modified

*We think of Cannabis as being associated with the plant itself and not following a regulated drug development pathway*

- Consumer products such as marijuana cigarettes, vapes, CBD oils, edibles, etc
- Industrial products – but then we also have to distinguish between hemp and marijuana
- Grow facilities, processing, packaging

*We believe that many investors currently do not make the distinction of Cannabinoids from Cannabis, nor hemp from marijuana*



## Investor (and Regulator/Lawmaker) Education Needed

*In the Cannabinoid market, rationalization will make education easier*

- Drug development and commercialization, which are federally regulated with products that are federally legal, represents an infrastructure with which drug developers and investors are familiar
- Risks and uncertainties are generally known and somewhat measurable
- Similar process as non-cannabinoid drug development
- This is true in the United States and many developed non-U.S. markets



## Investor (and Regulator/Lawmaker) Education Needed

*In the United States, the Cannabis universe is more difficult to understand*

- State laws vary from state to state, enforcement varies and almost nothing is federally legal
- Cole Memorandum added some rationalization and predictability
- Rescinding of the Cole Memorandum by US Dept of Justice in January 2018 created significant unpredictability
- If finally enacted, 2018 Farm Act may bring back some predictability

## Commercial Banking Firms

*In the United States, commercial banks find it difficult if not impossible to provide traditional banking services to Cannabis companies.*

*We believe that:*

- this is due to the federal illegality
- the anti-money laundering laws, rules and regulations play a role
- the rescission of the Cole Memorandum plays a role

We believe that, if passed, the 2018 Farm Act, will have a positive impact, at least with respect to hemp

## Securities Clearing Firms

- At least some securities clearing firms have refused to hold and clear securities transactions, particularly private securities transactions in Cannabis companies.
- This situation makes trading in the stock of such companies more difficult and therefore capital formation more expensive, more time consuming and more difficult
- We have been told that the rescission of the Cole Memorandum may have a lot to do with this
- Also, anti-money laundering laws, rules and regulations
- Less problematic for Cannabinoid companies adhering to federal regulatory pathways companies than for Cannabis companies

## Canada and the U.S. and Israel

### *Canada*

- Recreational marijuana now legal in Canada
- At present, Canadian financial markets, particularly in Toronto, are receptive
- According to Forbes (Sept 26, 2018), there are about 120 Cannabis companies listed on Canadian exchanges of which approximately 100 are on the Canadian Securities Exchange and the aggregate value of the top 5 Cannabis companies trading in Canada rose from \$4 billion to \$40 billion in one year
- Straw poll survey of several Canadian investment banks seems to indicate that Canadian financial markets are more receptive to Cannabis than Cannabinoids (diametrically opposite of what we believe is the US market)

## Canada and the U.S. and Israel

### *United States*

- Difficult financial market regulatory market, especially after the rescission of the Cole Memorandum.
- More difficult for Cannabis because Cannabis is still federally illegal.
- Less difficult for Cannabinoid-derived pharmaceuticals due to FDA and federal legality.
- Not impossible - Tilray, Aurora Cannabis

### *Israel*

- Hot-bed of research



OTC QB: RSPX

## The Funding Challenges Associated with Cannabis-Derived Pharmaceuticals

Presented December 12, 2018

Jeff Margolis  
SVP CFO etc  
RespireRx Pharmaceuticals





**RespireRx Pharmaceuticals Inc. Executives Presenting at the  
International Cannabinoid Derived Pharmaceuticals Summit**

**December 11 – 12, 2018  
Workshops, December 10, 2018  
The Revere Hotel  
200 Stuart St., Boston, MA**

- SVP R&D leading workshop on Financial Planning and Commercial Development
- SVP R&D to present A Translational R&D Program with Dronabinol for OSA
- CFO participating on panel on Funding the Commercial Development of Pharmaceutical Cannabinoids

Glen Rock, N.J., December 10, 2018 /Globe Newswire – RespireRx Pharmaceuticals Inc. (OTCQB: RSPI) (“RespireRx” or the “Company”), a clinical stage pharmaceutical company, focused on the development of medicines that promote neuronal signaling in diseases and disorders of neuronal dysfunction, is pleased to announce that the Company and members of its executive management team are highlighted speakers at the International Cannabinoid Derived Pharmaceuticals Summit at the Revere Hotel, 200 Stuart St. Boston, MA (<http://international-cdp.com/>).

Richard Purcell, RespireRx Senior Vice President of Research & Development will co-lead a workshop on December 10<sup>th</sup> on “Financial Planning and Commercial Strategy” for cannabinoids. <http://international-cdp.com/whats-on/workshops/>

On December 12<sup>th</sup>, Richard Purcell is scheduled to present “Using Cannabis to Treat Previously Untreatable Diseases” and will provide a detailed scientific talk on the dronabinol translational research program – from in vitro through animal models to clinic trials – that demonstrate the mechanism of action and clinical effectiveness of dronabinol for the treatment of obstructive sleep apnea, a condition that affects nearly 30 million Americans, and for which there are no drug therapies. [http://international-cdp.com/whats-on/agenda/?curr\\_day=194](http://international-cdp.com/whats-on/agenda/?curr_day=194)

Also, on December 12<sup>th</sup>, Jeff Margolis, RespireRx Senior Vice President, Chief Financial Officer, Treasurer and Secretary, is scheduled to participate in a panel discussion entitled “The Funding Challenges Associated with Cannabis-Derived Pharmaceuticals.” [http://international-cdp.com/whats-on/agenda/?curr\\_day=194](http://international-cdp.com/whats-on/agenda/?curr_day=194)

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[www.respirerx.com](http://www.respirerx.com)

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“RespireRx is at the forefront of developing cannabinoids for the treatment of disease, because we are focused on science and medicine”, said Dr. Lippa, Executive Chairman, Chief Scientific Officer, Interim CEO and Interim President. “By understanding the neurologic mechanisms of how and why cannabinoids effect their therapeutic properties, we have demonstrated that dronabinol works to improve breathing in OSA patients through a well-defined neuronal signaling pathway involving receptors for serotonin, CB1 and CB2 in specific neurons that control the muscles in the upper airway. Rich Purcell will be presenting our translational research, through which we have shown that dronabinol modulates the serotonin pathway to overcome the cessation of breathing that we see in OSA. Through our research efforts, which include two Phase II clinical trials, as well as our partnership with Noramco, Inc. for clinical and commercial supply of dronabinol, and in conjunction with our regulatory consultants, we are preparing a package for FDA to initiate our pivotal trial in OSA. We are excited as a management team to participate in the important conference to advance the commercial development of pharmaceutical cannabinoids.”

#### **About RespireRx Pharmaceuticals Inc.**

RespireRx Pharmaceuticals Inc. is a leader in the development of medicines for respiratory disorders and CNS indications, with a focus on obstructive sleep apnea, attention deficit hyperactivity disorder (ADHD), spinal cord injury, other neurological conditions and drug-induced respiratory depression. The Company holds exclusive licenses and owns patents and patent applications or rights thereto for certain families of chemical compounds that claim the chemical structures and their uses in the treatment of a variety of disorders, as well as claims for novel uses of known drugs.

**Cannabinoids.** RespireRx is developing dronabinol, a synthetic derivative of a naturally occurring substance in the cannabis plant, for the treatment of OSA, a serious respiratory disorder that impacts an estimated 29.4 million people in the United States according to the American Academy of Sleep Medicine (“AASM”), published in August 2016. OSA has been linked to increased risk for hypertension, heart failure, depression, and diabetes, and has an annual economic cost in the United States of \$162 billion according to the AASM. There are no approved drug treatments for OSA.

RespireRx believes, pending the outcome of an intended meeting with the FDA, that it will be able to commence a Phase 3 clinical study for the treatment of OSA with dronabinol. The Company further believes that it would only require approval by the FDA of a 505(b)(2) new drug application (“NDA”), an efficient regulatory pathway.

RespireRx believes that the most direct route to commercialization is to proceed directly to a Phase 3 pivotal trial using the currently available dronabinol formulation (2.5, 5 and 10 mg gel caps) and to then commercialize a RespireRx branded dronabinol capsule (“RBDC”).

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RespireRx also believes that there are numerous opportunities for reformulation of dronabinol to produce a second-generation proprietary, branded product for the treatment of OSA with an improved profile. Therefore, simultaneous with the development of the RBDC, RespireRx plans to develop a proprietary dronabinol formulation to optimize the dose and duration of action for treating OSA.

**Ampakines.** The second platform of proprietary medicines being developed by RespireRx are ampakines, which act to enhance the actions of the excitatory neurotransmitter glutamate at AMPA glutamate receptors. Several ampakines, in both oral and injectable forms, are being developed by the Company for the treatment of a variety of breathing and CNS disorders. In clinical studies of respiratory function, select ampakines have shown preliminary efficacy in central sleep apnea and in the control of respiratory depression produced by opioids, without altering the opioid analgesic effects. In animal models of certain orphan disorders, such as Pompe Disease, Rett's Syndrome and perinatal respiratory distress, certain ampakines have been shown to improve breathing function.

Ampakines also have shown potential as possible therapeutic agents for the treatment of certain neuropsychiatric and neurological disorders. Ampakines have demonstrated positive activity in animal models of ADHD, results that have been extended translationally into statistically significant improvement of symptoms observed in a Phase 2 clinical trial of CX717 in adults with ADHD. At present, the major pharmacotherapies available for ADHD are made up of two types of drugs. Stimulants, such as amphetamine, rapidly produce robust effects, but suffer from side effects typical of stimulants, including tolerance, dependence, withdrawal and abuse. For these reasons, stimulants are scheduled by the FDA. Non-stimulants, such as Strattera® (atomoxetine) tend to be less effective than stimulants, with a much longer (approximately 4 – 8 week) latency to onset of action. In a number of animal and human studies, CX717 and other ampakines did not display any stimulant properties typically associated with drugs like amphetamine. In the Phase 2 ADHD clinical trial, statistically significant therapeutic effects were observed within one week. Therefore, we believe ampakines may represent a novel, non-stimulant treatment for ADHD with a more rapid onset of action than alternative non-stimulant treatment options.

RespireRx owns certain composition of matter and use patents and patent applications with respect to ampakines CX1739, CX717 and other amakines. The Company has received notice from the University of Alberta that purports to terminate the Company's license in respect of patents associated with respiratory applications of ampakines. RespireRx has been in contact with the University of Alberta and anticipates engaging in a dispute resolution process with respect to its license with the University of Alberta in respect to use patents associated only with respiratory applications of ampakines.

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Additional information about the Company and the matters discussed herein can be obtained on the Company's web-site at [www.RespireRx.com](http://www.RespireRx.com) or in the Company's filings with the Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov).

### **Cautionary Note Regarding Forward-Looking Statements**

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#### **Company Contact:**

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