

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. ☐

**Item 7.01. Regulation FD Disclosure.**

Beginning on or after March 9, 2020, RespireRx Pharmaceuticals Inc. will participate in meetings with third parties in which a corporate slide presentation will be presented. The presentation includes certain forward-looking information. A copy of the presentation materials is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 and the document attached as Exhibit 99.1 are being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), nor otherwise subject to the liabilities of that section, nor incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	<a href="#">RespireRx Pharmaceuticals Inc. Corporate Presentation</a>

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: March 9, 2020

RESPIRERX PHARMACEUTICALS INC.  
(Registrant)  
  
By: /s/ Jeff E. Margolis  
Jeff E. Margolis  
SVP, CFO, Secretary and Treasurer

---



March 9, 2020

OTC QB: RSPI

**Newco:  
A New Pharmaceutical Cannabinoid  
Company**

## Forward Looking Statements



This progress 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 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 "anticipates," "believes," "intends," "estimates," "expects," "plans," "contemplates," "targets," "continues," "budgets," "may," and similar expressions 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 proposed products, (iv) reorganization plans, and (v) 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, 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 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 as of December 31, 2018.

For more current information about the Company, see the Company's Quarterly Report on Form 10-Q as of September 30, 2019. 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-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.

The commercialization of pharmaceutical cannabinoids has opened the door to a potentially large, expanding pharmaceutical cannabinoid market opportunity. In order to capitalize on this opportunity, RespireRx is creating a new clinical-stage biopharmaceutical company (“Newco”, official name not yet determined) with its own management team and board of directors, focused on developing and commercializing proprietary pharmaceutical cannabinoids.

\* See <http://respirerx.com/wp-content/uploads/2020/02/Progress-and-Status-Report-02122020-final.pdf>

**1. Development of Pharmaceutical Cannabinoids** - refers to the development of cannabinoids according to FDA and other foreign accepted regulatory pathways by which a company receives approval to market and sell a new drug.

**2. Clinical Validation** - two Phase 2 clinical trials have been completed demonstrating the ability of dronabinol to significantly reduce the symptoms of obstructive sleep apnea (“OSA”), a sleep-related breathing disorder that afflicts an estimated 60 million people in the US, Germany and UK combined.

**3. Intellectual Property** – issued and pending patents claiming cannabinoid compositions and methods for treating cannabinoid-sensitive disorders, including sleep apnea and other conditions, as well as novel dosage and controlled release compositions.

**4. Defined Regulatory Route to Commercialization** - 505(b)(2) NDA in US creates expedited path to market by allowing publicly available safety data.

**5. Business Plan** – business plan in place with new CEO.

\* See <http://respirerx.com/wp-content/uploads/2020/02/Progress-and-Status-Report-02122020-final.pdf>

## ***1. Pharmaceutical Cannabinoids***

- Cannabinoids are pharmacologically active substances found in the marijuana plant
- The FDA has not recognized or approved the marijuana plant as medicine and it is not legal to sell products that contain cannabinoids as drugs or dietary supplements, other than those already approved
- Whether extracted from plants or synthetically manufactured, medical claims and uses of cannabinoids must be approved by FDA
- Scientific study has focused on the two major cannabinoids,  $\Delta^9$ -tetrahydrocannabinol (THC) and cannabidiol (CBD), and led to several commercial products approved by regulatory authorities
- The commercialization of these pharmaceutical cannabinoids has opened the door to a greatly expanding market sector



## 1. Pharmaceutical Cannabinoids



**Marinol**® (dronabinol) - synthetically manufactured THC formulated as a soft gel capsule was the first pharmaceutical cannabinoid approved by the FDA in 1986. Sold as a Schedule 3 drug for the treatment of HIV/AIDS related anorexia and chemotherapy induced nausea and vomiting.

**Syndros**® (dronabinol) - proprietary, liquid formulation of dronabinol. Sold as a Schedule 2 drug for the treatment of HIV/AIDS related anorexia and chemotherapy induced nausea and vomiting.

**Cesamet**® (nabilone) - synthetic analogue of THC. Sold as a Schedule 2 drug for the treatment of chemotherapy induced nausea and vomiting.

**Epidiolex**® - GW Pharma's lead cannabinoid product is a proprietary oral solution of highly purified plant-derived CBD approved by the FDA and sold as a Schedule 5 drug for the treatment of certain rare, treatment-resistant forms of epilepsy.

**Sativex**® (Nabiximols® in the US) - is an oromucosal spray of a formulated extract of the cannabis sativa plant containing primarily THC and CBD in a 1:1 ratio. GW Pharma is planning to seek FDA approval for Nabiximols in the U.S. Sativex® is approved and sold in 25 countries outside the U.S. for the treatment of multiple sclerosis.

## 2. *Dronabinol for Obstructive Sleep Apnea*

### **Sleep Apnea**

- Repetitive episodes of airflow cessation (apnea) or reduction (hypopnea) for more than 10 seconds during sleep
- Three types: Obstructive, Central & Mixed

### **The Sleep Apnea Market is Large**

- Approximately 30 million U.S. adults suffer from OSA
- Market potential for OSA is \$3 to \$9 Billion per Year

### **Current Treatments**

- CPAP device
- Surgery
- Dental devices

### **Clear Market Need**

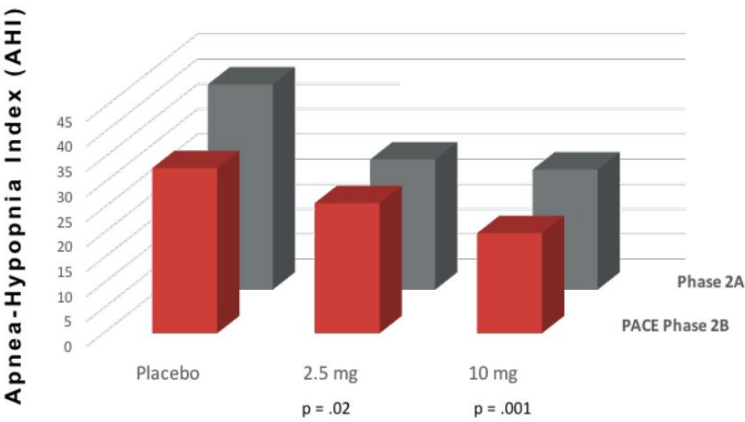
- Poor compliance with CPAP
- No FDA-Approved drug treatment available



***Dronabinol: Two Successful Phase 2 Studies***



**Two Phase 2 Clinical Trials Demonstrated a Statistically Significant, Dose Related Improvement in the Apnea Hypopnea Index (AHI) the “Gold Standard” Primary Endpoint needed for FDA Approval**

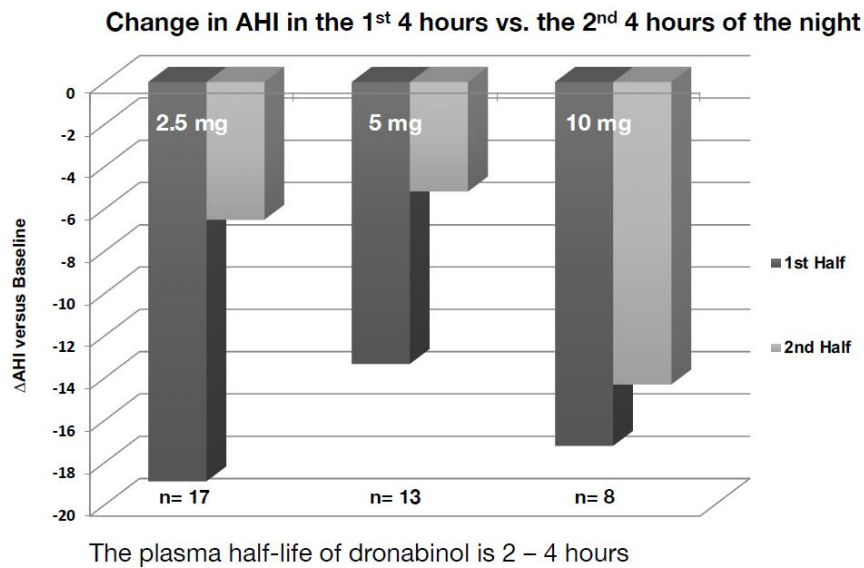


### ***3. Proprietary Intellectual Property***



Patents in the United States, Germany and the United Kingdom claiming a method of treating sleep apnea by administering cannabinoids, including dronabinol, when administered either alone or in combinations.

- Poor and erratic absorption, 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 3 – 4 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.



- Low-dose dronabinol is as effective as the high dose in the first half of the night
- Effectiveness diminishes in the second half of the night
- Opportunities for controlled release formulations

### ***3. Proprietary Intellectual Property***



- US and foreign pending patents claim cannabinoid compositions and methods for treating cannabinoid-sensitive disorders, with specific low dosage strengths and controlled release formulations for attaining a therapeutic window of cannabinoid blood levels that produces the desired therapeutic effect(s) for a controlled period of time, while minimizing undesirable side effects.
- To the extent that new technologies result in lower doses and/or controlled release, they would infringe on our pending patents once issued, not only for use in the treatment of OSA but potentially for a wide variety of other indications as well.
- We believe that this intellectual property will give us a major position in the burgeoning pharmaceutical cannabinoid business sector.



- Under the 505(b)(2) NDA regulatory pathway in the US, the requirements for FDA approval are substantially reduced.
- 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.
- Possibility of only one Phase 3 Needed for FDA Approval.



## ***5. NEWCO Business Plan in Place***



1. New, highly experienced senior executive identified as CEO
2. Regulatory plan developed with Camargo Pharmaceutical Services, pre-eminent advisory firm for 505(b)(2) filings, greatly reducing the requirements for FDA approval
3. Joint development agreement with Noramco Inc./Purisys, a leading dronabinol manufacturer, in which Noramco will provide in-kind funding for all API supplies prior to NDA approval in exchange for an exclusive purchase agreement and limited participation in the success of the product
4. In discussions with several firms for the development of a proprietary dronabinol formulation covered by our existing patents, providing market exclusivity until at least 2031
5. Clinical plan developed with Clinilabs Drug Development Corporation, a full-service CRO, which will oversee a Phase 3 trial. The draft clinical protocol, budget and timeline have been completed.
6. Clinical advisory panel composed of the major Key Opinion Leaders in OSA

***Upon completion of additional financing:***

1. Finalize discussions and enter into development agreement with formulation company for new proprietary formulation
2. Acquire preclinical PK data on new formulation and have pre-IND meeting with FDA
3. Upon IND allowance, conduct PK/PD clinical trial in OSA patients and “likeability” clinical study in chronic cannabis users
4. With human PK/PD data, have end-of Phase 2 meeting with FDA to approve development program and seek breakthrough status and fast track designation
5. Conduct Phase 3 clinical trial in 120 – 300 OSA patients



**RespireRx**  
Pharmaceuticals Inc

OTC QB: RSP1

Contact:  
Jeff Margolis, CFO  
jmargolis@respirerx.com  
917-834-7206

