# 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 23, 2016

## 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 followin 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))
. 1	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 8.01 Other Events.

On December 23, 2016 the Company issued a press release announcing unblinded data, received from the University of Illinois at Chicago, regarding the Phase 2B PACE (Pharmacotherapy of Apnea by Cannabimimetic Enhancement) trial. That press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The PACE trial was conducted by the University of Illinois at Chicago and Northwestern University. This was a six week, placebo-controlled Phase 2B clinical trial investigating the effects of dronabinol in patients with moderate to severe obstructive sleep apnea. The Company has licensed from the University of Illinois certain patent rights pertaining to the use of cannabinoids, including dronabinol, for the treatment of sleep-related breathing disorders such as obstructive sleep apnea. The Company did not manage or fund this clinical trial, which was fully funded by grant number 5UM1HL112856 from the National Heart, Lung and Blood Institute of the National Institutes of Health ("NIH") and was managed by University of Illinois at Chicago researchers.

On November 1, 2016, the Company filed a Current Report on Form 8-K attaching the Final Progress Report (the "Project Report") to the NIH, which contained blinded data for the PACE trial. The Project Report indicated that the principal investigators anticipated submitting an abstract for presentation at the *Sleep 2017* international conference of the Associated Professional Sleep Societies, as well as a peer-review manuscript detailing the findings in the winter of 2017.

The Company is providing the press release, to update investors and shareholders with respect to the information available on this Phase 2B clinical trial, which the Company has discussed in its periodic filings with the Securities and Exchange Commission, including its most recently filed Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2016, as amended.

## **Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

A list of exhibits furnished 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

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 23, 2016

## RESPIRERX PHARMACEUTICALS INC.

(Registrant)

By: /s/ James S. Manuso

James S. Manuso

President and Chief Executive Officer

## EXHIBIT INDEX

Exhibit

Number Exhibit Description

Press Release dated December 23, 2016



# RespireRx Pharmaceuticals Inc. Announces Positive Results from Phase 2B PACE Study Conducted by the University of Illinois Dronabinol Reduces Symptoms of Obstructive Sleep Apnea

Glen Rock, N.J., December 23, 2016 /Globe Newswire – RespireRx Pharmaceuticals Inc. (OTCQB: RSPI) ("RespireRx" or the "Company"), is pleased to announce positive results of the PACE (Pharmacotherapy of Apnea by Cannabimimetic Enhancement) trial conducted by Dr. David Carley and colleagues at the University of Illinois at Chicago and Northwestern University. The PACE trial, a Phase 2B study of dronabinol for the treatment of obstructive sleep apnea ("OSA"), clearly demonstrates that dronabinol significantly improves the primary outcome measures of Apnea Hypopnea Index ("AHI"), daytime sleepiness as measured by the Epworth Sleepiness Scale ("ESS") and overall patient satisfaction as measured by the Treatment Satisfaction Questionnaire for Medications ("TSQM").

In a dose dependent fashion, treatment with 2.5 mg and 10 mg dronabinol once a day at night significantly reduces the Apnea Hypopnea Index ("AHI"), a measure of breathing abnormalities during sleep, in 56 patients with moderate to severe OSA who completed the study. Of these, 17 received placebo, 19 received the 2.5 mg dose and 20 received the 10 mg dose. Compared to average baseline AHI values of  $26 \pm 12$ , six weeks of dronabinol administration to moderate to severe OSA patients reduced AHI values, compared to placebo, by  $9.7 \pm 4$  for the 2.5 mg dose and  $13.2 \pm 4$  for the 10 mg dose (p=.02 and p=.001, respectively, compared to control). Furthermore, treatment with 10 mg dronabinol significantly improved daytime sleepiness as measured by the ESS (p = 0.0001, compared to placebo) and achieved the greatest overall patient satisfaction with treatment (p=.02) as measured by the TSQM.

Arnold Lippa, Ph.D., Chief Scientific Officer and Executive Chairman commented, "We congratulate Dr. Carley and his colleagues at both the University of Illinois at Chicago and Northwestern University for the successful completion of the PACE trial. These positive results clearly demonstrate the potential for dronabinol to treat OSA, a serious condition affecting millions of people with very few viable treatment options. We plan to move forward with the development of dronabinol in OSA, and plan to meet with the FDA for a Special Protocol Assessment ("SPA") to finalize the Phase 3 study required for approval using both fast track and breakthrough designations from the FDA to facilitate the development path."

James S. Manuso, Ph.D., President, Chief Executive Officer and Vice Chairman stated, "We are very excited with the possibility of bringing to market the first drug treatment for OSA. We can now envision a small molecule, easy to use, oral medicine for OSA patients as an alternative to CPAP (continuous positive airway pressure) devices, surgery and other methods used to treat this underappreciated disease, which has such enourmous costs to society."

"We look forward to discussing with investors the results of this trial at upcoming conferences."

RespireRx Pharmaceuticals Inc., 126 Valley Road, Suite C, Glen Rock, NJ 07452 www.RespireRx.com



### **Background**

Obstructive Sleep Apnea is the most common form of sleep apnea and affects 29.4 million Americans according to Frost & Sullivan. 5.9 million adults are diagnosed (23.5 million are undiagnosed). OSA, besides causing next day sleepiness which is a major cause of motor vehicle and industrial accidents, is also comorbid with cardiovascular disease, type 2 diabetes and other conditions. Treatment options are limited and the most effective treatment, the CPAP device has an extremely high non-compliance rate. The overall cost to the U.S. economy of the diagnosed and undiagnosed portions of the OSA market are estimated to be \$12.4 billion and \$149.6 billion respectively for a total cost of \$162.0 billion in 2015. There is no drug therapy approved for OSA. While certain stimulants such as modafinil and methylphenidate are FDA approved for next day sleepiness in certain OSA patients, they do not treat OSA itself. Dronabinol, currently formulated as a capsule, is believed to be much more user friendly than the current devices, should have a higher patient compliance rate, should work well in the moderate to mild patient segment, which represents approximately 50% of the overall OSA patient population, and may result in more of the currently undiagnosed patient population getting diagnosed.

Dronabinol is synthetic  $\Delta 9$ -THC (delta 9-tetrahydrocannabinol), one of the active cannabinoids found in marijuana. It is approved in the United States in 2.5mg, 5mg and 10mg capsules for the treatment of anorexia associated with AIDS and chemo-therapy induced nausea and vomiting. It is a schedule III drug meaning there is a low abuse potential, but it is monitored by the United States DEA (drug enforcement agency). It is Medicare part B reimbursed for its current approved indications. Use of dronabinol for the treatment of OSA is novel.

### About RespireRx Pharmaceuticals Inc.

RespireRx Pharmaceuticals Inc. is a leader in the development of medicines for respiratory disorders, with a focus on sleep apneas 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.

RespireRx has a pipeline of medicines in Phase 2 clinical development focused on pharmaceutical treatments for a variety of breathing disorders. Clinical development in the area of respiratory disorders, particularly drug-induced respiratory depression and sleep apnea, has created opportunities for the development and commercialization of the Company's compounds.

**Cannabinoids.** One platform being developed by RespireRx is the class of compounds known as cannabinoids, including dronabinol. Under a license agreement with the University of Illinois, the Company has rights to patents claiming the use of cannabinoids for the treatment of sleep-related breathing disorders.

Ampakines. The other 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 disorders. In clinical studies, 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 orphan disorders, such as Pompe Disease, spinal cord injury and perinatal respiratory distress, it has been demonstrated that certain ampakines improve breathing function. The Company's compounds belong to a new class that does not display the undesirable side effects previously reported for other ampakines.

Additional information about the Company and the matters discussed herein can be obtained on the Company's web-site at <a href="www.RespireRx.com">www.RespireRx.com</a> or in the Company's filings with the Securities and Exchange Commission at <a href="www.sec.gov">www.sec.gov</a>.

RespireRx Pharmaceuticals Inc., 126 Valley Road, Suite C, Glen Rock, NJ 07452 www.RespireRx.com



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

This press release 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 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," 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, and (iv) 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, and market and general economic factors. This press release should be read in conjunction with the condensed consolidated financial statements (unaudited) and notes thereto included in Item 1 of the Company's recently filed Quarterly Report on Form 10-Q and the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, including the section entitled "Item 1A. Risk Factors." The Company does not intend to update or revise any forward-looking statements to reflect new information, future events or otherwise.

Company Contact:

Jeff Margolis Vice-President, Treasurer and Secretary Telephone: (917) 834-7206 E-mail: jmargolis@respirerx.com

RespireRx Pharmaceuticals Inc., 126 Valley Road, Suite C, Glen Rock, NJ 07452 www.RespireRx.com