# 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 15, 2016**

# RESPIRERX PHARMACEUTICALS INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **1-16467** | **33-0303583** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(I.R.S Employer Identification No.)** |

| **126 Valley Road, Suite C**<br>**Glen Rock, New Jersey** | |
|---|---|
| **(Address of principal executive offices)** | **07452**<br>**(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))

**Item 7.01 Regulation FD Disclosure.**

On December 15, 2016, RespireRx Pharmaceuticals Inc. (the "Company") issued a press release announcing analysis of safety and efficacy data from a Phase 2A clinical trial of the Company's proprietary ampakine compound, CX1739, that was recently concluded at the Duke Clinical Research Unit of the Duke Clinical Research Institute. The press release is attached as exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

A list of exhibits required to be 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.

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 15, 2016

RESPIRERX PHARMACEUTICALS INC.

By: */s/ James S. Manuso*

James S. J. Manuso
President and Chief Executive Officer

**EXHIBIT INDEX**

| Exhibit Number | Exhibit Description |
|---|---|
| 99.1 | Press Release dated December 15, 2016* |

* Furnished herewith.

**RespireRx Pharmaceuticals Inc.**
**Announces Data for CX1739 Clinical Study in Opioid Induced Respiratory Depression**

Glen Rock, N.J., December 15, 2016 /Globe Newswire – RespireRx Pharmaceuticals Inc. (OTCQB: RSPI) ("RespireRx" or the "Company"), a leader in the development of medicines for respiratory disorders, including sleep apneas and drug-induced respiratory depression announces data for its CX1739 clinical study in opioid induced respiratory depression.

**Comments by the Executive Chairman and Chief Scientific Officer**

Arnold Lippa, Ph.D., Executive Chairman and Chief Scientific Officer commented, "We are pleased with the positive results of our recent Phase 2A study which encourages us to take CX1739 forward in additional studies. We look forward to conducting additional studies investigating the effects of CX1739 on opioid induced respiratory depression in post-surgical patients self-administering opioids in a hospital setting as well as on central sleep apnea in out-patients taking oral opioids chronically for pain management."

**Background**

Opioid analgesics are now the most commonly prescribed class of medicines in the United States, where chronic pain is estimated to affect around 68 million people each year. In 2014 alone, U.S. retail pharmacies dispensed 245 million prescriptions for opioid pain relievers. Opioids are useful and effective analgesics but produce several unwanted side effects, including episodes of potentially life-threatening respiratory depression, which resulted in over 30,000 deaths in 2014. While some of these deaths are from abuse of opioids, a large number are accidental deaths by patients who require opioids for pain management, in both an acute and chronic setting.

The respiratory depression produced by opioids is most sensitively detected during sleep and is manifested as apnea/hypopnea or central sleep apnea (CSA). Opioid induced sleep apneas are observed with intravenous opioid infusions in a post-surgical hospital setting, where approximately 2 - 4% of the 51 million U.S. patients undergoing in-hospital surgery present with opioid induced CSA. Furthermore, patients chronically taking oral opioids for pain relief also present with CSA. In fact, approximately 40 – 50% of patients diagnosed with CSA are taking chronic, oral opioids. Overall, sleep apnea is the major risk factor for mortality and morbidity in opioid overdose. Clearly, preventing or reducing the respiratory depressive effects of opioids will save lives.

In short, there is very substantial unmet medical need and very large market potential in treating respiratory depression/sleep apnea in patients who require short term or long term treatment with opioids to manage their pain. CX1739 belongs to a class of drugs called ampakines that the Company is developing to be taken in conjunction with opioids in order to reduce respiratory depression without altering analgesia.

**Summary of Clinical Trial Results**

In order to understand the relevance of the data in this study, it is important to understand the conditions under which opioids are used. The preponderance of opioid use is for the treatment of pain. Regardless of whether the opioid is taken orally or intravenously, either acutely or chronically, the treatment of pain requires stable opioid blood levels that also can produce respiratory depression/sleep apnea. Alternatively, some opioid users consume a large acute dose of opioid, whether orally or intravenously, intentionally or accidentally, that also can produce potentially fatal respiratory depression. While opioid antagonists, such as Narcanâ, are the gold standard for the treatment of acute opioid overdose, their use is inappropriate for patients taking the opioids for pain relief because they antagonize the analgesic effects of the opioids at the same time that they antagonize respiratory depression.

The recently completed Phase IIa clinical trial evaluated the ability of CX1739 to overcome the respiratory depression induced by the powerful, yet short-acting opioid, remifentanil, in two models of opioid use: During REMI-INFUSION, respiration, pain, and other parameters were measured during a 30 minute intravenous infusion of remifentanil in order to produce stable blood levels resulting in approximately 50% declines in respiratory rate over this period. During REMI-BOLUS, a model of acute opioid overdose, a single, intravenous bolus injection of remifentanil was administered at a dose calculated to achieve approximately 50% respiratory depression;

During REMI-INFUSION, CX1739 treatment antagonized the respiratory rate depression produced by remifentanil, with statistically significant effects observed at 300mg ($p<.005$) and 900mg ($p<.001$). The antagonism produced by the 600mg dose did not achieve statistical significance. This lack of a linear, dose response effect is not unusual in early stage clinical trials. During this period, CX1739 did not significantly alter the analgesic and sedative effects of reminfentanil.

During REMI-BOLUS, CX1739 treatment did not prevent respiratory depression, nor improve time to recovery at any of the doses tested.

Overall, CX1739 was found to be safe and well tolerated, both prior to and during administration of remifentanil. Treatment-related adverse events (AEs) for the various doses of CX1739 were mild, with an incidence comparable to that reported for placebo. The great majority of AEs occurred after remifentanil administration.

**Description of the Study Design**

The study consisted of two separate stages. Stage 1 was a randomized, double-blind, crossover study comparing 300 mg CX1739 to placebo and Stage 2 was an open-label, ascending dose study to assess 600 and 900 mg of CX1739. Subjects were tested once a week over a four-week period. Statistical comparisons were performed for Stage 1 alone as well as for Stage 1 and Stage 2 combined.

On each study day, REMI-BOLUS was initiated with an intravenous, bolus injection of remifentanil 3 hours after subjects received either placebo or CX1739. Respiration was measured for 20 minutes and then compared to the baseline respiration recorded 5 minutes prior to the bolus injection. REMI-INFUSION was initiated 3.5 hours after placebo or CX1739, with an intravenous infusion protocol designed to maintain stable remifentanil blood levels and calculated to produce approximately 50% respiratory depression.

The study was conducted at the Duke Clinical Research Unit of the Duke Clinical Research Institute. The ClinicalTrials.gov identifier is NCT02735629.

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

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.

**Ampakines.** One 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.

**Cannabinoids.** The other 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. In a double-blind, placebo-controlled, dose-ascending Phase 2A clinical study conducted by the Company, dronabinol produced a statistically significant reduction in the Apnea-Hypopnea Index, the primary therapeutic end-point, and was observed to be safe and well-tolerated in a group of patients with OSA.

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

**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.*

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*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.*

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