

☐ 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 January 11, 2016, RespireRx Pharmaceuticals Inc. (f/k/a Cortex Pharmaceuticals, Inc., the “Company”) announced that the Company’s President and Chief Executive Officer, James S. J. Manuso, Ph.D., will be presenting at The Biotech Showcase™ 2016 at The Parc 55 Wyndham San Francisco-Union Square Hotel, San Francisco, California. Dr. Manuso is scheduled to present at 10:30 a.m. Pacific Standard Time on Monday, January 11, 2016.

The slide presentation that the Company will be using at the forum is attached as Exhibit 99.1 and is being furnished and not filed pursuant to Item 7.01 of Form 8-K. The presentation will be available by live webcast that can be accessed by clicking on the investors tab on the Company’s web-site ([www.respirerx.com](http://www.respirerx.com)) and following the links and instructions or by going to <http://edge.media-server.com/m/p/9bge98ed>.

The press release announcing the Company’s participation in the conference is attached as Exhibit 99.2.

**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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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: January 11, 2016

RESPIRERX PHARMACEUTICALS INC.

By: /s/ James S. J. Manuso  
James S. J. Manuso  
President and Chief Executive Officer

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EXHIBIT INDEX

Exhibit Number	Exhibit Description
99.1	Slide Presentation*
99.2	Press Release dated January 11, 2016*
* Furnished herewith.	



OTC QB: RSPI

James S. Manuso, Ph.D., President and CEO

January 11, 2016

**BIOTECH**  
SHOWCASE 2016  
Medicines for Respiratory Diseases

The matters discussed in this presentation that are not historical facts are "forward-looking statements." Forward-looking statements include, but are not limited to, statements containing the words "believes," "anticipates," "intends," "expects," "projects" and words of similar import. Readers are cautioned not to place undue reliance on these forward-looking statements, which are based on the information available to management at this time and which speak only as of the date of this presentation. The Company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of the Company or its industry to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. All forward-looking statements should be evaluated with the understanding of their inherent uncertainty.

While the Company believes the information contained herein is reliable, the Company makes no representations or warranties regarding the accuracy or completeness of this information. In addition, any investment in the Company is subject to numerous risks. Investors must be able to afford the loss of their entire investment. Any such representations and warranties and further discussion of risk factors would be made solely in formal agreements executed by the Company with its investors.

"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

- Two drug platforms
- Three Phase 2 or Phase 2-ready programs
- One pre-clinical program
- Blockbuster markets
- IP protection with the ability to add additional IP
- Multiple opportunities for strategic collaborations
- Availability of non-dilutive financing
- Experienced management team



- **Sleep Apneas**
  - Dronabinol for Obstructive Sleep Apnea (**OSA**)
  - Ampakines for Central Sleep Apnea (**CSA**)
- **Drug-induced Respiratory Depression (RD) - Ampakines**
  - Semi-acute use – post-surgical pain management with opioids
  - Acute use – surgical anesthesia/sedation
  - Chronic use – outpatient pain management with opioids
- **Positive Phase 2A efficacy results in RD, OSA and CSA**
- **Commercial and IP protection for compounds and uses**
- **\$5 million in NIH grants supporting OSA drug development**

# Respiratory Diseases Product Pipeline



Compound	Indication	Pre-clinical	Phase 1	Phase 2
Dronabinol	Obstructive Sleep Apnea			
CX1739	Central Sleep Apnea			
	Opioid-induced RD			
	Spinal Damage/Pompe			
CX717	Combination Formulation with Opioids for Reduced RD			
CX1942	Drug-induced Respiratory Depression (injectable)			

# Sleep Apnea

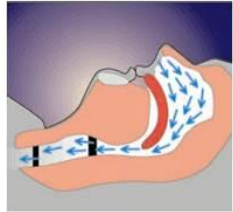
- **Sleep Apnea**
  - Repetitive episodes of airflow cessation (apnea) or reduction (hypopnea) for more than 10 seconds during sleep
  - Three types: Obstructive, Central & Mixed
- **The Sleep Apnea Market is Large**
  - 18 million U.S. adults suffer from moderate or severe sleep apneas
  - Market potential for sleep apneas is \$3 - 9 Billion/Year
- **Current Treatments**
  - CPAP device
  - Surgery; dental devices
- **Clear Market Need**
  - Poor compliance with CPAP
  - No drug treatment available



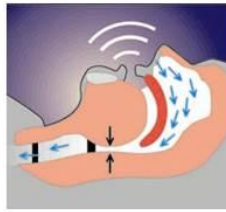
# Obstructive Sleep Apnea (OSA)

- **Obstructive Sleep Apnea (OSA):** a decrease or complete halt in airflow during sleep
  - Induced by relaxation of muscles during sleep
  - Soft tissue in back of throat collapses and obstructs upper airway
- **Significant morbidity due to stroke, hypertension, heart failure, diabetes, and other cardiovascular diseases**

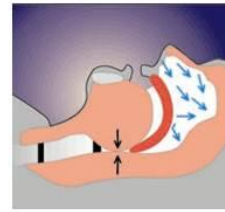
Normal Breathing



Snoring



OSA



## CPAP Efficacy is Severely Limited by Patient Compliance

- Works as an air splint to keep upper airway open during sleep
- 30% of diagnosed patients never initiate CPAP treatment when prescribed a machine
- Over 50% of patients stop using CPAP in the first year
- Many CPAP users wear the device for less than 4 hours per night, limiting efficacy



- **Mechanism of Action**

- Dronabinol is (D-9)THC, a cannabinoid agonist

- **Background**

- Schedule III drug available by prescription, with a low risk of addiction
- Approved for the treatment of anorexia in AIDS patients and nausea and vomiting in cancer patients undergoing chemotherapy
- Phase 2A data demonstrated clear signal of activity in OSA
- Phase 2B study in OSA in progress

- **Intellectual Property**

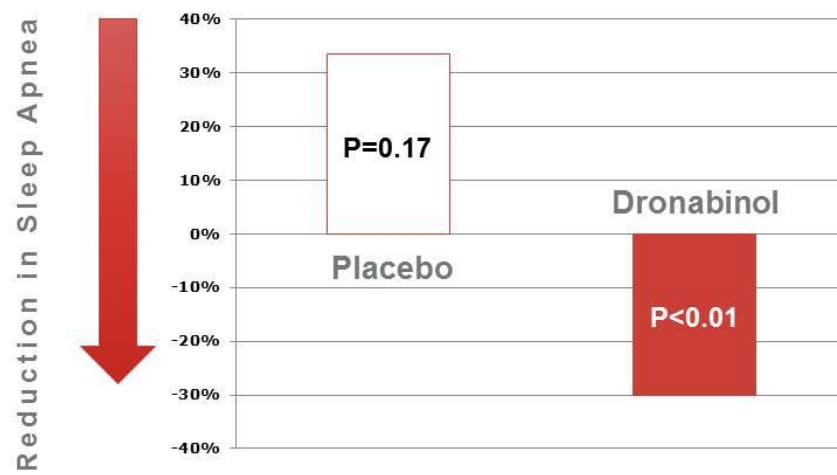
- License to issued method-of-use patent in the US for the use of dronabinol for treating OSA (expires 2025)
- Pending patents on modified release formulations

- **Funding**

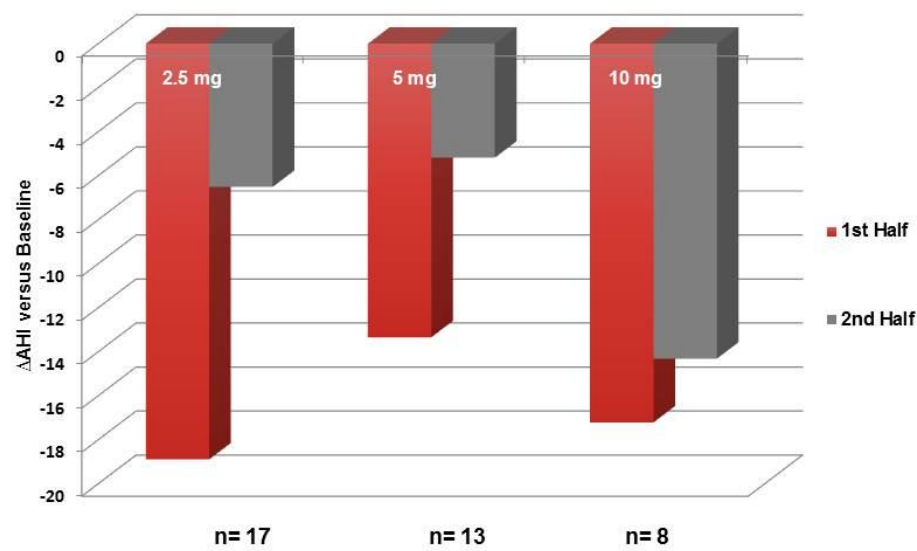
- NIH funded \$5MM grant for Phase 2B study in OSA

- **Randomized, double-blind, placebo-controlled dose escalation study in 22 patients with OSA**
- **Placebo (N=5) or dronabinol (N=17) for 21 days**
  - 2.5, 5 and 10 mg/night studied with weekly dose escalation
- **Overnight polysomnogram (PSG) at baseline, and after 7, 14 and 21 days of treatment**
- **FDA-accepted Efficacy tests:**
  - Apnea-Hypopnea Time (AHT)
  - Apnea-Hypopnea Index (AHI)
  - Stanford Sleepiness Scale (SSS)









The plasma half-life of dronabinol is 2 – 4 hours.

- Sponsored and led by U of Illinois
- 4 major centers, fully funded by NIH
- Potentially pivotal for an accelerated NDA
- 120 subjects (40/group, 6 wks dosing)
- Doses: Placebo, 2.5 mg, 10 mg qd
- Data expected Q3/2016
- Plan to meet with FDA after study completion to determine registration path forward

## Protecting Dronabinol in the Market



- License to issued Method-of-Use patent for dronabinol in OSA
  - Expires in 2025
- Schedule III drug: off-label use monitored by US government, discouraging generic manufacturers from selling off-label
- Off-label use of generics and medical marijuana are not covered by insurers
- Market pricing protection

# The Dronabinol Opportunity



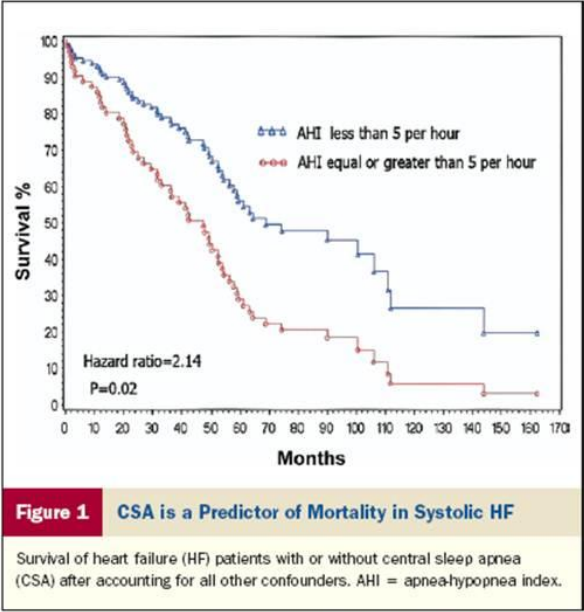
Impact on Patient	Commercial Opportunity
First pharmacotherapeutic available for OSA	Changes the nature of OSA treatment
Ease of Use/Better Patient Compliance	Broadly expands prescriber base from sleep specialists to include primary care physicians and cardiologists
Low cost	Recurring lifetime sales versus one time sale or ongoing rental of a device
Safe and effective	Market will expand into the currently undiagnosed/untreated population
Potential for better cardiovascular outcomes	Potential for reducing systemic healthcare costs by reduced cardiac re-hospitalizations

- **Caused by a lack of drive from the brain to breathe during sleep**
- **Manifestations of CSA**
  - 70% of chronic narcotic users
  - Up to 40% of heart failure patients
  - 5% of sleep apnea patients are idiopathic
- **No therapeutic or device is approved for the indication**

The Severity of CSA is Correlated with Increased Mortality in HF Patients



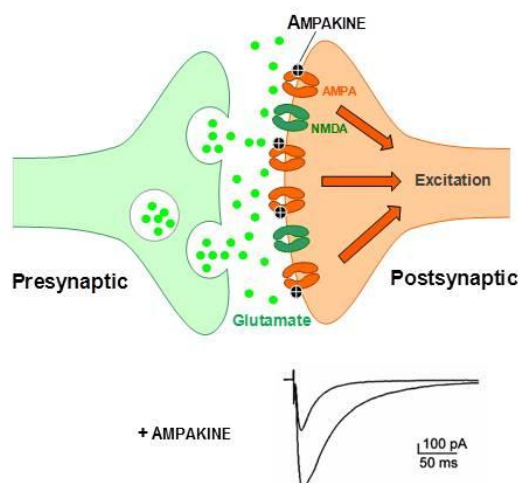
Reducing Central Sleep Apnea May Reduce Mortality in Heart Failure Patients



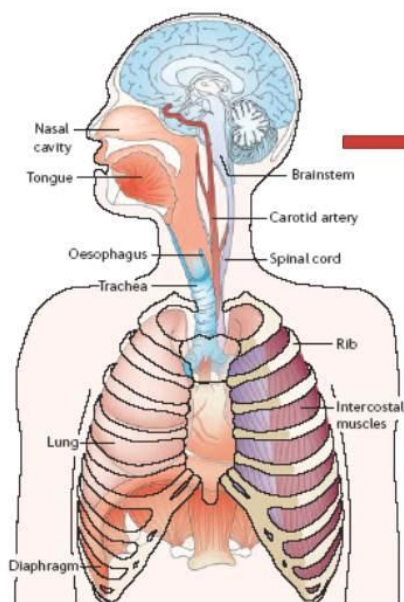
Javaheri et al, J. Amer. Coll. Cardiology 49:20, 2007

### AMPA Receptors Mediate Synaptic Transmission in the Brain

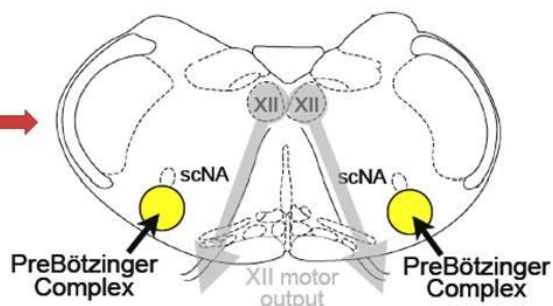
- Glutamate is the major excitatory neurotransmitter in the CNS
- Fast excitatory transmission is mediated by AMPA-type glutamate receptors
- Ampakines are positive, allosteric modulators of the AMPA-type glutamate receptor
- Prolong and strengthen synaptic transmission







Initial research conducted by Dr. J. Greer, U. Alberta  
Ren et al, Anesthesiology. 110:1364-1370, 2009



- Neurons in this brainstem region control inspiratory breathing rhythm
- PreBotC neurons use AMPA receptors for signaling
- Opioids and other depressants mediate their inhibitory effects on breathing at this site
- Ampakines normalize breathing by enhancing firing of PreBotC respiratory rhythm neurons



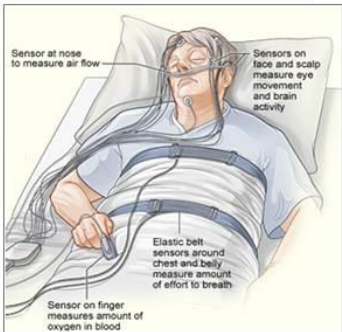
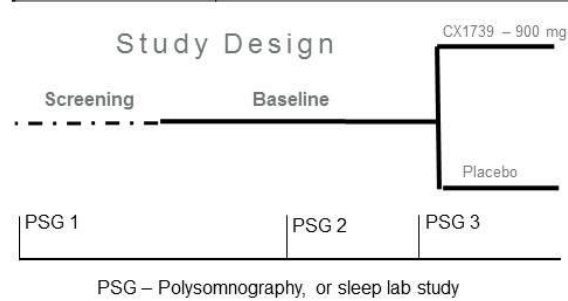
- **Targeted Indications**
  - Central Sleep Apnea (CSA)
  - Reversal and prevention of opioid-induced Respiratory Depression (RD)
  - Combination formulation with an opioid for treatment of chronic pain
- **Stage of Development**
  - Successfully completed four Phase 1 studies
  - Indications of efficacy in CSA
  - Phase 2 trial in opioid-induced RD planned
- **Intellectual Property Protection (owned and licensed)**
  - Issued Composition-of-Matter Patent (expires 2028), filed worldwide
  - Method-of-use patent (expires 2030)

- **IND**
  - Opioid induced respiratory depression study
  - Submitted to FDA on September 18, 2015
- **FDA noted two deficiencies**
  - Myocardial Histology
    - ✓ FDA requested tissue analysis for all rats at all doses
    - ✓ Analysis completed
    - ✓ No drug-related histopathology observed by two independent board certified pathologists
  - FDA requested an additional study of neuro-histopathology measured at 1, 3 and 14 days after single doses of 250, 750 and 1500 mg/kg
    - ✓ Prior studies showed no histopathology when CX1739 was dosed for 14 and 28 days
    - ✓ Top line results from the additional study show no histopathology
    - ✓ Independent pathologist report in preparation
- **Anticipate filing complete response to FDA within 30 days**

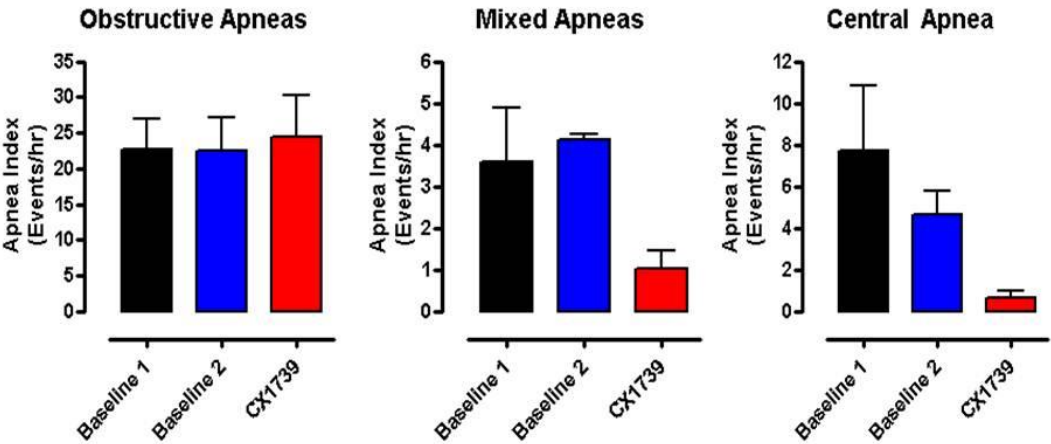
# CX1739: Completed Phase 2A in Sleep Apnea



Design	Randomized, double-blind, placebo-controlled study
Population	20 adults with all types of moderate to severe sleep apnea (16 given CX1739; 4 given Placebo)
Dosing	Each subject received either placebo or a <u>single</u> dose of 900mg CX1739 one hour before lights out
Primary Measures	Apnea-Hypopnea measures; Oxygen saturation; Sleep quality, measured by PSG (Apnea: no airflow for >10s; Hypopnea: reduced airflow for >10s)



Patient Selection: CX1739 Was More Effective in Treating Mixed and Central Sleep Apneas



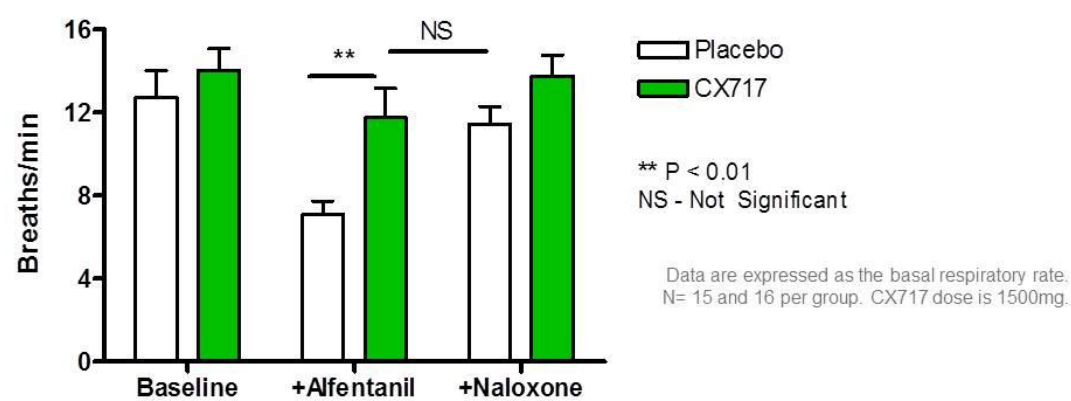
***RD is the most frequent lethal side effect of opioid use***

- **Acute and Semi-Acute Use of opioids**
  - ~25M patients/year at risk for RD (hospitalized, peri- and post-surgical opioid patients)
- **Chronic Opioid Use**
  - Use of Ampakines in combination with other drugs to prevent RD
- **Unmet Need: Medicine to counter or reduce RD without interfering with analgesia or anesthesia**
- **Large multi-\$ billion/year market potential**

- Two clinical studies in normal, healthy volunteers with CX717, a second-generation Ampakine
- Moderate Respiratory Depression was induced experimentally by infusion of the opioid, Alfentanil
- Respiratory and analgesia end-points were measured

**Oral CX717 prevented and reversed the Respiratory Depression without impacting the pain-relieving properties of the opioid**

# CX717 Prevents Opioid-induced Respiratory Depression in Humans



- Alfentanil reduced breathing rate & produced Respiratory Depression
- CX717 maintains respiratory rate in the presence of Alfentanil

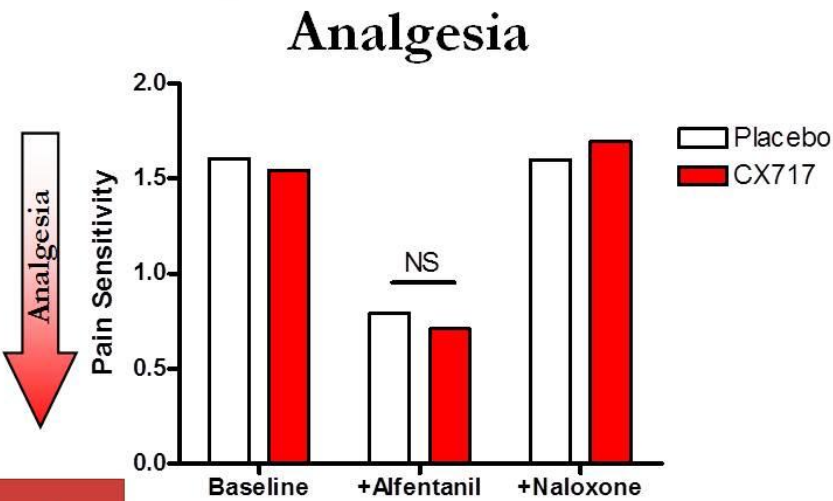


CX717 Maintains the Analgesic Properties of Opioids  
Without Affecting Rescue Therapy



Delivery of a electrical stimulation to finger

- Alfentanil reduced the pain sensitivity (produced analgesia)
- Analgesia was unaffected by CX717



Data are expressed as the pain sensitivity, normalized to the Baseline measurement.  
N = 15 and 16 per group. CX717 dose is 1500mg.



# Respiratory Diseases Product Pipeline



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Key Objectives for 2016  
(Pending Financing)



Compound	Indication	Status	Estimated Start Date	Estimated Completion
Dronabinol	Obstructive Sleep Apnea	Phase 2B	Underway	3Q2016
CX1739	Opioid-induced RD	Phase 2A	1Q2016	2Q2016
	Central Sleep Apnea	Phase 2A	3Q2016	2Q2017
CX1739 / CX717	Spinal Cord Injury, Pompe Disease, other	Phase 2A	3Q2016	1Q2017
CX717	Combination formulation with opioid	Pre-clinical studies	1Q2016	4Q2016
CX1942	Injectable for RD	Pre-clinical studies	3Q2016	4Q2017

Capital Structure (in thousands of shares) & Market Metrics



	Total As of September 30, 2015
Common Stock	477,221
Common Stock Equivalents of all Convertibles (Preferred Stock and Convertible Notes)	95,934
Common Stock Equivalents of all Options and Warrants	380,247
Total	953,402

	January 6, 2015
Closing price per share of Common Stock	\$0.0216
Fully diluted market capitalization (\$ rounded)	\$20,593,000

James Manuso	President, CEO & Vice Chairman
Arnold Lippa	CSO & Chairman
Jeff Margolis	VP, Secretary/Treasurer, Director
Robert Weingarten	CFO, Director
Richard Purcell	Senior VP, R&D
Katie MacFarlane	Director CCO Agile Therapeutics
James Sapirstein	Director CEO ContraVir Pharmaceuticals
John Greer	Chairman, Scientific Advisory Board Prof & Dir. Neuroscience Ctr., U. Alberta

- Two drug platforms
- Three Phase 2 or Phase 2-ready programs
- One pre-clinical program
- Blockbuster markets
- IP protection with the ability to add additional IP
- Multiple opportunities for strategic collaborations
- Availability of non-dilutive financing
- Experienced management team



OTC QB: RSPI

James S. Manuso, Ph.D., President and CEO

January 11, 2016

**BIOTECH**  
SHOWCASE 2016

Medicines for Respiratory Diseases

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## **RespireRx Pharmaceuticals Inc. to Present at 8<sup>th</sup> Annual Biotech Showcase™ 2016**

### **CEO to Review Initiatives in the Treatment of Respiratory Disorders and Provide Pipeline Update**

#### **RespireRx Announces Ticker Symbol Change**

Glen Rock, N.J., Jan. 11, 2016/Globe Newswire – RespireRx Pharmaceuticals Inc. (OTC QB: RSPI as of January 11, 2016; previously OTC QB: CORX) (“RespireRx” or the “Company”), a leader in developing drugs for respiratory disorders, particularly sleep apneas and drug-induced respiratory depression, announces that the Company’s President, Chief Executive Officer and Vice Chairman of the Board of Directors, James S. Manuso, Ph.D., will present at The Biotech Showcase™ on Monday, January 11, 2016 at 10:30 AM Pacific Standard Time ([www.biotechshowcase.com](http://www.biotechshowcase.com)). The Conference is co-sponsored by the EBD Group and Demy-Colton Life Sciences Advisors. Presentations will be held at the Parc 55 Wyndham San Francisco-Union Square Hotel in San Francisco, California from January 11 – 13, 2016.

Dr. Manuso will discuss RespireRx’s initiatives with dronabinol for obstructive sleep apnea (Phase - 2B) and CX-1739 (oral) for drug-induced respiratory depression and central sleep apnea (both Phase - 2A). He will also provide background information and descriptions of other product pipeline opportunities.

Dr. Manuso’s presentation will be available by live webcast streaming online. To access the live audio webcast, log onto the RespireRx website at [www.respirerx.com](http://www.respirerx.com), click on the investors tab and follow the links and instructions, or go to <http://edge.media-server.com/m/p/9bge98ed>. A copy of the slide presentation to be presented at the conference will be submitted in a filing by the Company with the U.S. Securities and Exchange Commission in a Current Report on Form 8-K prior to the presentation and will also be available in the investors section of the RespireRx website.

#### **New Ticker Symbol**

RespireRx will trade under the ticker symbol **RSPI** commencing on Monday, January 11, 2016.

#### **Clinical Trial Plans for 2016 - Phase 2A Clinical Trial for CX1739**

On December 17, 2015, RespireRx provided information in a press release and in a Form 8-K about its recently submitted Investigational New Drug Application, including two deficiencies noted by the Food and Drug Administration (“FDA”). An update of the Company’s progress with respect to addressing these deficiencies is presented below.

- The FDA cited a single incidence of mild necrosis in cardiac tissue from a rat in the highest dose group tested in a 4-week toxicology study. In that study, histopathology analysis was performed on the heart tissue only from rats that received placebo and the highest of three doses of CX1739. In its letter, the FDA requested that cardiac tissue from all animals in all dosage groups be analyzed. This analysis has been completed and, according to two independent, board-certified pathologists, results from the drug-treated animals did not differ from the vehicle-treated animals and, for this reason, they concluded that there does not appear to be any drug-related histopathology and that the original finding most likely was due to “progressive rodent cardiomyopathy,” a syndrome commonly observed in the subject strain of rats.
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- Despite prior studies showing no histopathology when CX1739 was dosed for 14 and 28 days, the FDA requested that the Company perform an additional study in which rats were to be given single doses of 250, 750 and 1500 mg/kg of CX1739, followed by neuro-histopathologic evaluations 1, 3 and 14 days after drug administration. The agreed upon single dose study has now been completed and no neuro-histopathology was observed at any dose. An independent pathologist review is in process.

The Company intends to submit a complete response with the FDA within the next 30 days.

**Comments by the Company’s President and Chief Executive Officer**

Dr. James S. Manuso, President and Chief Executive Officer, commented, “We look forward to advancing the many initiatives RespireRx is undertaking throughout the course of 2016. With three Phase 2 or Phase 2-ready programs in development, there are numerous strategic and operational milestones on the calendar. We intend to continue our focus in 2016 on the clinical and regulatory development of the Company’s two proprietary platforms for addressing unmet needs in the sleep apnea and respiratory depression markets. In addition, we will continue to support the scientific research and pre-clinical development upon which RespireRx is based. I look forward to reporting to you our progress in the months ahead.”

**About RespireRx Pharmaceuticals Inc.**

RespireRx Pharmaceuticals Inc. is a leader in the development of drugs 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 for certain families of chemical compounds that claim the chemical structures and their use in the treatment of a variety of disorders, as well as claims for novel uses of known drugs.

RespireRx’s pharmaceutical candidates in development are derived from two platforms, as described below.

The first platform is the class of compounds known as cannabinoids, in particular, 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 Obstructive Sleep Apnea (“OSA”). The University of Illinois and three other centers currently are investigating dronabinol in a potentially pivotal, six week, double-blind, placebo-controlled Phase 2B clinical trial in 120 patients with OSA. This study, which the University of Illinois has indicated that it expects to be completed during the second quarter of 2016, is fully funded by the National Heart, Lung and Blood Institute of the National Institutes of Health. The Company is not managing or funding this ongoing clinical trial.

The second platform of medicines being developed by RespireRx is a class of proprietary compounds known as ampakines that act to enhance the actions of the excitatory neurotransmitter glutamate at AMPA glutamate receptors. Several ampakines, in both oral and injectable form, 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 opiates, without altering their analgesic effects. In animal models of orphan disorders, such as Pompe Disease, spinal cord damage and perinatal respiratory distress, it has been demonstrated that the ampakines improve breathing function. The Company’s compounds belong to a new class of ampakines that do not display the undesirable side effects previously reported in animal models of earlier generations.

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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 U.S. Securities and Exchange Commission on EDGAR at [www.sec.gov](http://www.sec.gov).

***Special Note Regarding Forward-Looking Statements:*** Certain statements included or incorporated by reference in this news release, including information as to the future financial or operating performance of the Company and its drug development programs, constitute forward-looking statements. The words "believe," "expect," "anticipate," "contemplate," "target," "plan," "intend," "continue," "budget," "estimate," "may," "schedule" and similar expressions identify forward-looking statements. Forward-looking statements include, among other things, statements regarding future plans, targets, estimates and assumptions. Forward-looking statements are necessarily based upon a number of estimates and assumptions that, while considered reasonable by the Company, are inherently subject to significant business, economic and competitive uncertainties and contingencies. Many factors could cause the Company's actual results to differ materially from those expressed or implied in any forward-looking statements made by, or on behalf of, the Company. Due to these various risks and uncertainties, actual events may differ materially from current expectations. Investors are cautioned that forward-looking statements are not guarantees of future performance and, accordingly, investors are cautioned not to put undue reliance on forward-looking statements due to the inherent uncertainty therein. Forward-looking statements are made as of the date of this news release and the Company disclaims any intent or obligation to update publicly such forward-looking statements, whether as a result of new information, future events or results or otherwise.

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