# 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): February 4, 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.)

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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 February 4, 2016, RespireRx Pharmaceuticals Inc. (the "Company") announced that the Company's President & CEO and Vice Chairman of the Board of Directors, James S. Manuso, Ph.D., will present at the 18<sup>th</sup> Annual BIO CEO & Investor Conference on Monday, February 8, 2016 at 10:00 AM Eastern Standard Time. The Conference is sponsored by the Biotechnology Innovation Organization (BIO) and will be held at the Waldorf Astoria Hotel, New York, NY on February 8 and 9, 2016.

The slide presentation that Dr. Manuso will be using at the conference 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) and following the links and instructions or by going to:

http://www.veracast.com/webcasts/bio/ceoinvestor2016/83109575564.cfm

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.

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.

#### $RESPIRERX\ PHARMACEUTICALS\ INC.$

Date: February 4, 2016

By: /s/ Robert N. Weingarten
Robert N. Weingarten
Vice President and Chief Financial Officer

#### EXHIBIT INDEX

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**Exhibit Description** Number

99.1

Slide Presentation\* Press Release dated February 4, 2016\* 99.2

\* Furnished herewith.





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

BIO CEO & INVESTOR CONFERENCE FEBRUARY 8, 2016, NEW YORK, NY

Medicines for Respiratory Diseases

### Forward Looking Statements



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**



"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

### The RespireRx Story: Innovative Medicines for Respiratory Diseases



- Two drug platforms
- Three Phase 2 or Phase 2-ready programs
- Three pre-clinical programs
- Blockbuster markets
- IP protection with the ability to add additional IP
- Multiple opportunities for strategic collaborations
- Non-dilutive financing from NHLBI and NIDA
- Experienced management team

## **Company Focus**



- 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
- More than \$5 million in NIH grants supporting two programs

# **Respiratory Diseases Product Pipeline**





# 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

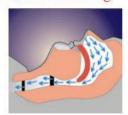


## **Obstructive Sleep Apnea (OSA)**

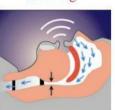


- Obstructive Sleep Apnea (OSA): a decrease or complete halt in airflow during sleep
  - Induced by relaxation of muscles during sleep
  - Soft tissue in back of throat collapses and obstructs upper airway
- Significant morbidity due to stroke, hypertension, heart failure, diabetes, and other cardiovascular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

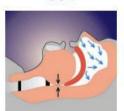
Normal Breathing



Snoring



OSA



# CPAP Efficacy is Severly 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



### Dronabinol: a BreakthroughTreatment for OSA



#### Mechanism of Action

Dronabinol is (delta 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

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

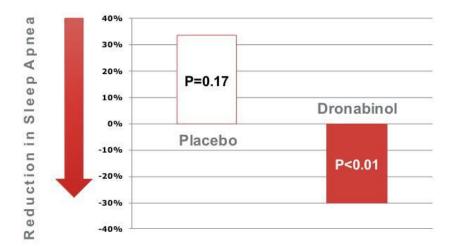
### **Completed Phase 2A Trial of Dronabinol in OSA**



- 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
- o FDA-accepted Efficacy tests:
  - Apnea-Hypopnea Time (AHT)
  - Apnea-Hypopnea Index (AHI)
  - Stanford Sleepiness Scale (SSS)

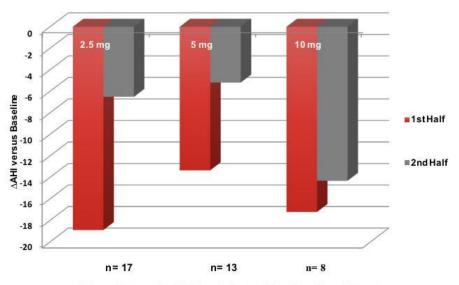
# Dronabinol Proven to Reduce Apnea in OSA Subjects





## **Apnea Suppression as a Function of Dose and Time**





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

### Ongoing Dronabinol Phase 2B Clinical Trial in OSA



- Sponsored and led by U of Illinois
- 4 major centers, fully funded by NIH
- Potentially pivotal for an NDA submission
- 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 and manufacturing protection

# **The Dronabinol Opportunity**



Impact on Patient	Commercial Opportunity
First medicine 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

## **Central Sleep Apnea**

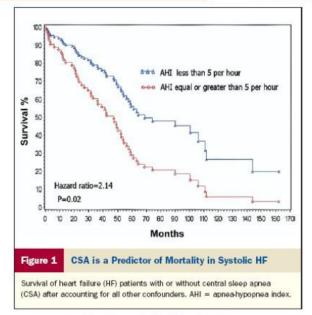


- Caused by a lack of drive from the brain to breathe during sleep
- Manifestations of CSA
  - 70% of chronic narcotic users
  - Up to 40% of heart failure patients
  - 5% of sleep apnea patients are idiopathic
- No medicine or device is approved for the indication

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



Reducing Central Sleep Apnea May Reduce Mortality in Heart Failure Patients



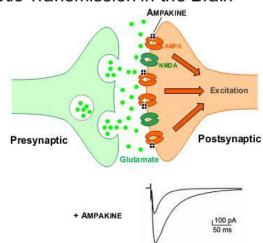
Javaheri et al, J. Amer. Coll. Cardiology 49:20, 2007

### AMPAKINES – A NOVEL CLASS OF DRUGS



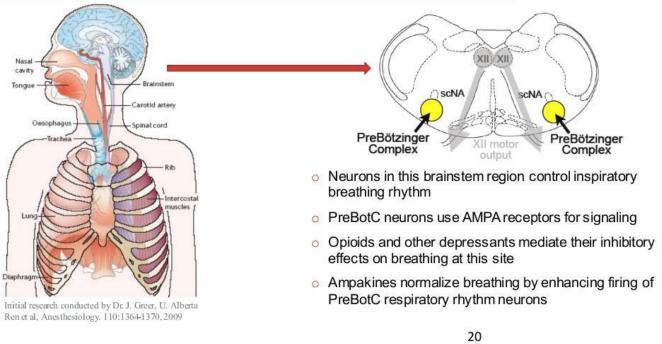
AMPA Receptors Mediate Synaptic Transmission in the Brain

- 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



### **AMPAKINES – Novel Treatment for Respiratory Depression**





### CX1739: A Third Generation, Oral Ampakine in Phase 2



#### 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
- Efficacy signals observed in CSA
- Pre-IND cardio-tox and Neuro-tox research was negative
- IND for Phase 2 trial in opioid-induced RD submitted to FDA

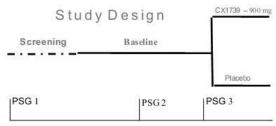
#### Intellectual Property Protection (owned and licensed)

- Issued Composition-of-Matter Patent (expires 2028), filed worldwide
- Method-of-use patent (expires 2030)

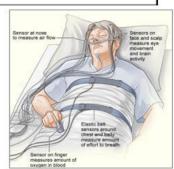
# CX1739: Completed Phase 2A in Sleep Apnea



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 single 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)

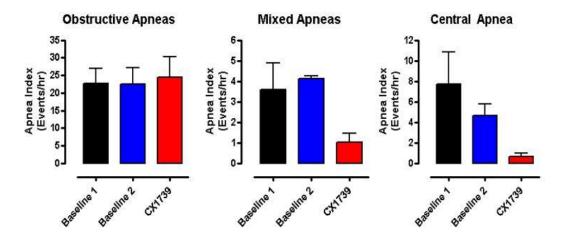






### Patient Selection: CX1739 Was More Effective in Treating Mixed and Central Sleep Apneas





## **Drug-induced Respiratory Depression**



### 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

# **Ampakines Prevent Opioid-induced Respiratory Depression in Humans**



- 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
- o Respiratory and analgesia end-points were measured

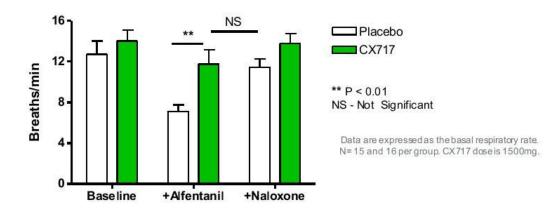
Oral CX717 prevented and reversed the Respiratory

Depression without impacting the pain-relieving

properties of the opioid

### CX717 Prevents Opioid-induced Respiratory Depression in Humans





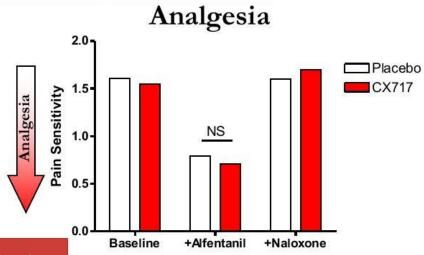
- Alfentanil reduced breathing rate & produced Respiratory Depression
- CX717 maintains respiratory rate in the presence of Alfentanil

# CX717 Maintains the Analgesic Properties of Opioids Without Affecting Rescue Therapy









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 1500 mg.

# **Respiratory Diseases Product Pipeline**





### Key Objectives for 2016 (Pending Financing)



Compound	Indication	Status	Estimated Start Date	Estimated Completion
Dronabinol	Obstructive Sleep Apnea	Phase 2B	Underway	3Q2016
074700	Opioid-induced RD	Phase 2A	1Q2016	2Q2016
CX1739	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

# **NIH-Supported Programs in Drug Abuse**



### Non-Core Programs in Drug Abuse and Addiction

- Cocaine and Amphetamines
- Research and development program with NIDA
- NIDA contracts with specialist labs and pays for animal studies
- Company provides compounds and retains all rights

# 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

	February 1, 2016
Closing price per share of Common Stock	\$0.017
Fully diluted market capitalization (\$ rounded)	\$16,208,000.00

# **Management and Directors**



President, CEO & Vice Chairman James Manuso

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

Chairman, Scientific Advisory Board Prof & Dir. Neuroscience Ctr., U. Alberta John Greer

### The RespireRx Story: Innovative Medicines for Respiratory Diseases



- Two drug platforms
- Three Phase 2 or Phase 2-ready programs
- One pre-clinical program
- Blockbuster markets
- o IP protection with the ability to add additional IP
- Multiple opportunities for strategic collaborations
- Non-dilutive financing from NHLBI and NIDA
- Experienced management team





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

BIO CEO & INVESTOR CONFERENCE FEBRUARY 8, 2016, NEW YORK, NY

Medicines for Respiratory Diseases



### RespireRx Pharmaceuticals Inc. to Present at 18<sup>th</sup> Annual BIO CEO & Investor Conference

GLEN ROCK, NJ--(Marketwired - Feb. 4, 2016) – RespireRx Pharmaceuticals Inc. (OTC QB: RSPI) ("RespireRx" or the "Company"), a leader in the development of medicines for respiratory disorders, including sleep apneas and drug-induced respiratory depression, announces that the Company's President & CEO and Vice Chairman of the Board of Directors, James S. Manuso, Ph.D., will present at the 18<sup>th</sup> Annual BIO CEO & Investor Conference (<u>info@bio.org</u>) in New York City on Monday, February 8, 2016 at 10:00 AM Eastern Standard Time. The Conference is sponsored by the Biotechnology Innovation Organization (BIO) and will be held at the Waldorf Astoria Hotel, New York, NY on February 8 and 9, 2016.

Stated Dr. Manuso, "The BIO CEO conference provides an excellent forum for updating investors on our ongoing research and development programs. I look forward to discussing the Company's January 29, 2016 submission to the FDA of a complete response to the Agency's request for additional information in connection with our IND application for the planned Phase 2A opoid-induced respiratory depression clinical study of the oral ampakine, CX-1739." Dr. Manuso will also describe the Company's new NIDA-funded program to explore the use of Ampakines in combating cocaine and methamphetamine addiction in animal models and will provide background information and descriptions of the Company's other product pipeline candidates, including dronabinol. Dr. Manuso stated, "We will continue to update shareholders and other stakeholders on the progress of RespireRx's scientific, clinical and regulatory development initiatives during 2016."

Dr. Manuso's presentation will be available by webcast, with replays available one hour after the presentation at <a href="http://www.veracast.com/webcasts/bio/ceoinvestor2016/83109575564.cfm">http://www.veracast.com/webcasts/bio/ceoinvestor2016/83109575564.cfm</a> and will be archived and remain available until May 8, 2016. The webcast may be accessed on the BIO website as well as on RespireRx's website at <a href="http://www.respirerx.com">www.respirerx.com</a>, by clicking on the investors tab and following the links and instructions. 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.

#### 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 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 Pharmaceuticals Inc., 126 Valley Road, Suite C, Glen Rock, NJ 07452 <a href="https://www.RespireRx.com">www.RespireRx.com</a>



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 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, which 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 Pompé Disease, spinal cord damage and perinatal respiratory distress, it has been demonstrated that certain 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.

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 U.S. Securities and Exchange Commission on EDGAR at <a href="www.sec.gov">www.sec.gov</a>.

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.

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 <u>www.RespireRx.com</u>