# 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): October 19, 2015**

# CORTEX 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**<br>**(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 October 19, 2015, 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 14th Annual BIO Investor Forum, sponsored by the Biotechnology Industry Organization, at The Parc 55 Hotel, San Francisco, California. Dr. Manuso is scheduled to present at 11:30 a.m. West Coast Time on Tuesday, October 20, 2015.

Dr. Manuso will present details of the Company's clinical initiatives with respect to dronabinol for obstructive sleep apnea (Phase 2B) and the Ampakine CX-1739 (oral) for opiate induced respiratory depression (Phase 2A) and central sleep apnea (Phase 2B). Additional program and background information will also be provided.

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 at:

http://www.veracast.com/webcasts/bio/investorforum2015/48108124757.cfm.

A replay also will be archived at the same web address beginning one hour after the conclusion of the live presentation.

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.

Date: October 20, 2015

CORTEX PHARMACEUTICALS, INC.

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

**EXHIBIT INDEX**

| Exhibit Number | Exhibit Description |
|---|---|
| 99.1 | Slide Presentation* |
| 99.2 | Press Release dated October 19, 2015* |

* Furnished herewith.

Exhibit 99.1


CORTEX
PHARMACEUTICALS, INC.
Cortex Pharmaceuticals, Inc.
OTC QB:CORX
BIO Investor Forum
October 20, 2015
James S. Manuso, Ph.D., President & CEO

# 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 Cortex Story: Innovative Medicines for Respiratory Diseases

- Two drug platforms from two companies
- Four Phase 2 or Phase 2-ready programs
- Blockbuster markets
- IP protection with the ability to add additional IP
- Multiple opportunities for strategic collaborations
- Availability of non-dilutive financing
- 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 opiates
  - Acute use – surgical anesthesia
  - Chronic use – Outpatient pain management with opiates
- **Positive Phase 2A efficacy results in RD, OSA and CSA**
- **Commercial and IP protection for compounds and uses**
- **Over $5 million in NIH grants supporting OSA drug development**

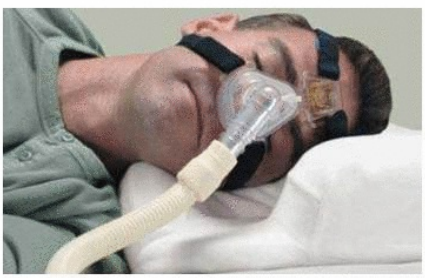
# Respiratory Diseases Product Pipeline

*Stage of Development*

| Compound | Indication | Pre-clinical | Phase 1 | Phase 2 |
|---|---|---|---|---|
| *Dronabinol* | Obstructive Sleep Apnea | | | |
| *CX1739* | Central Sleep Apnea<br>Opiate-induced RD<br>Spinal Damage/Pompe | | | |
| *CX717* | Combination Formulation with Opiates for Reduced RD | | | |
| *CX1942* | Drug-induced Respiratory Depression (injectable) | | | |

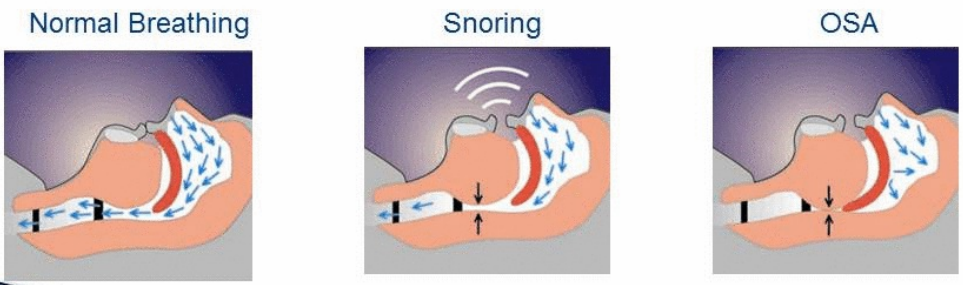
# Sleep Apnea

- **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**



# CPAP Efficacy is Greatly 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

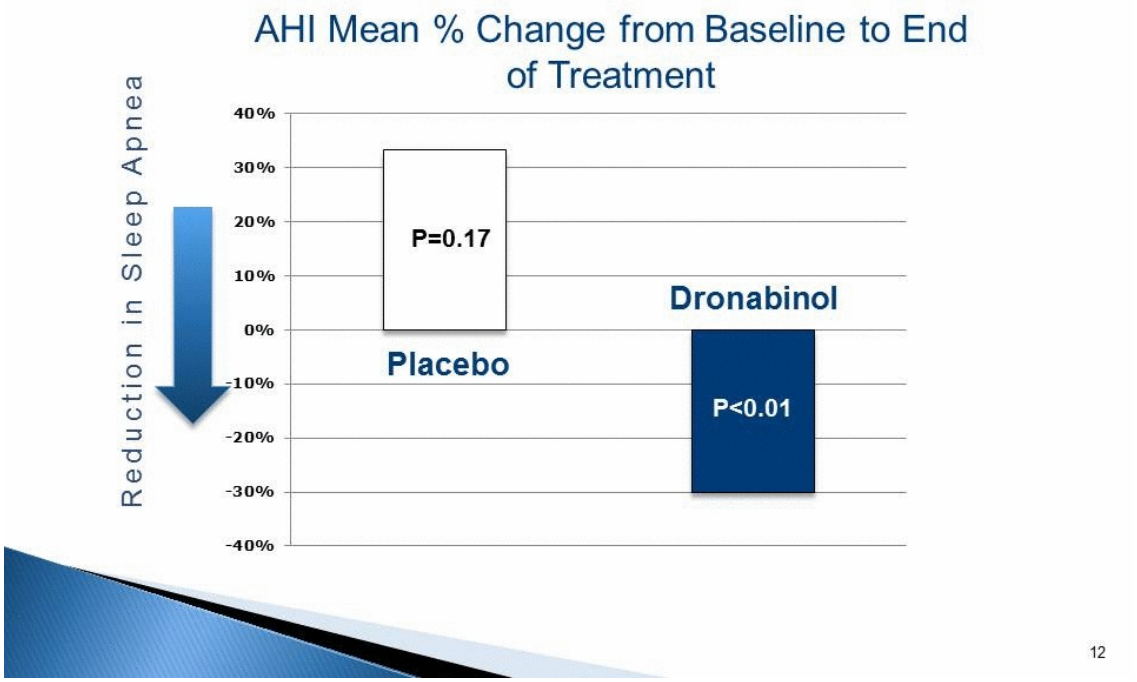
# Dronabinol: a Breakthrough Treatment for OSA

- **Mechanism of Action**
  - Dronabinol is (D-9)THC, a cannabinoid agonist
- **Stage of Development**
  - 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**
  - 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

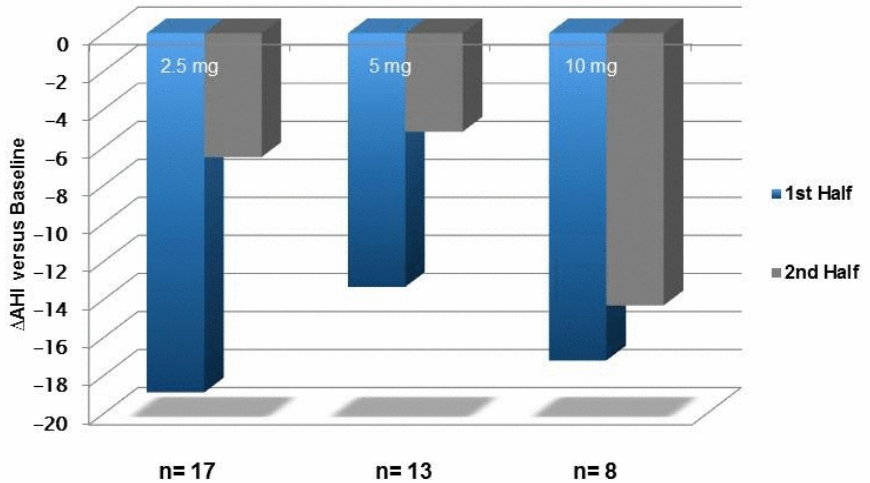
# Completed Phase 2A Trial of Dronabinol in OSA

- **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**
- **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

- 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
- Completion by Q3/2016
- Meet with FDA in Q4/2016 to determine registration path forward

# Protecting Dronabinol in the Market

- **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**

# The Dronabinol Opportunity

| Impact on Patient | Commercial Opportunity |
|---|---|
| First therapeutic 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 have 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

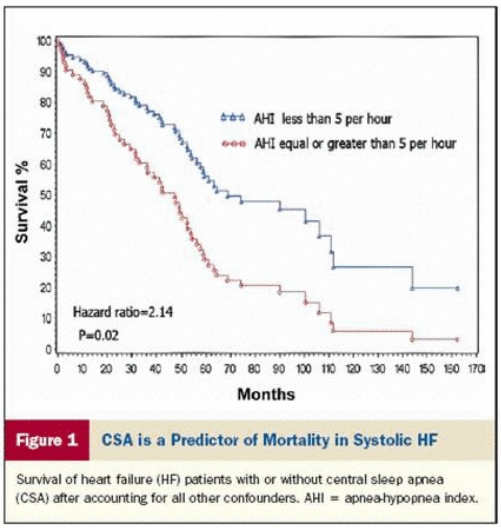



**Figure 1** CSA is a Predictor of Mortality in Systolic HF

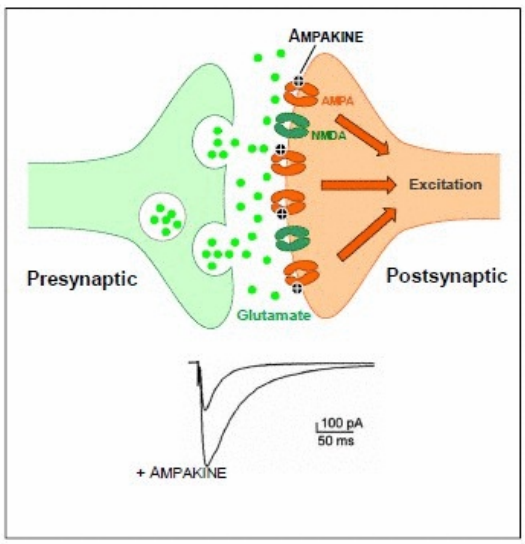
Survival of heart failure (HF) patients with or without central sleep apnea (CSA) after accounting for all other confounders. AHI = apnea-hypopnea index.

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

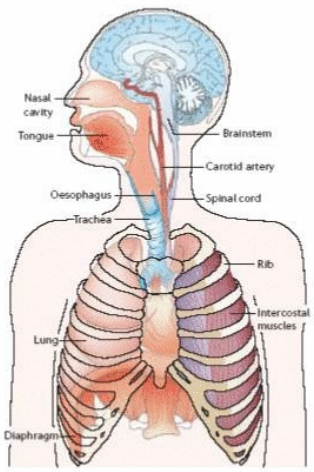
# AMPAKINES – A NOVEL CLASS OF DRUGS

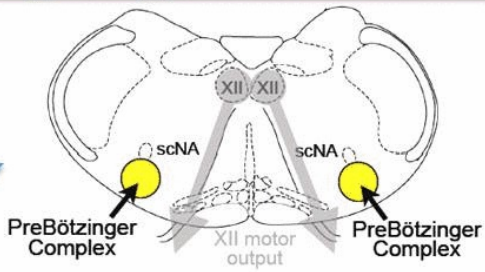
## AMPA Receptors Mediate Synaptic Transmission in the Brain

- 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




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
- Opiates and other depressants mediate their inhibitory effects on breathing at this site
- Ampakines normalize breathing by enhancing firing of PreBotC respiratory rhythm neurons

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

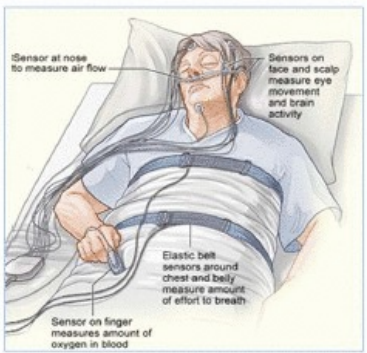
- **Targeted Indications**
  - Central Sleep Apnea (CSA)
  - Reversal and prevention of opiate-induced Respiratory Depression (RD)
  - Combination formulation with an opiate for treatment of chronic pain
- **Stage of Development**
  - Successfully completed Phase 1 in RD induced in healthy volunteers
  - Successfully completed Phase 2A in CSA and Opiate-induced RD
  - Phase 2 trial in opiate-induced RD being prepared
- **Intellectual Property Protection**
  - Issued Composition-of-Matter Patent (expires 2028), filed worldwide
  - Method-of-use patent (expires 2030)

# CX1739: Completed Phase 2A in CSA

| | |
|---|---|
| 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) |

## Study Design


PSG – Polysomnography, or sleep lab study

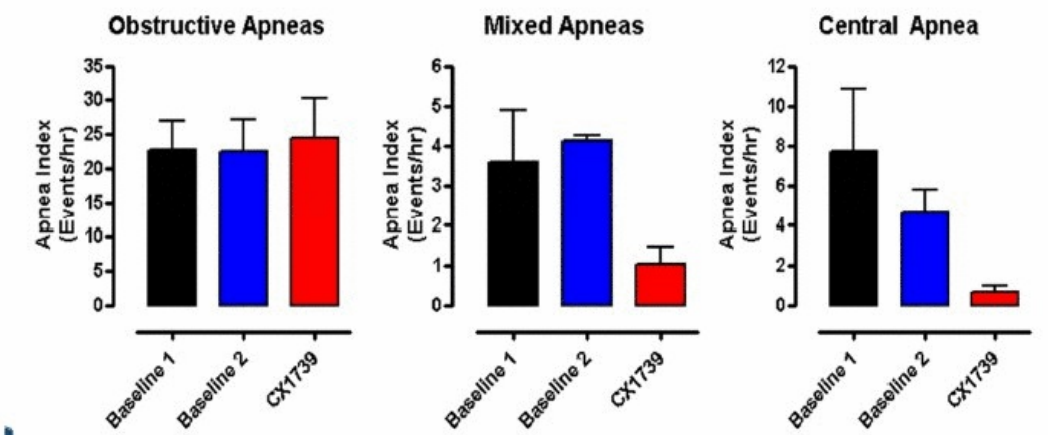


# Apnea-Hypopnea Response to CX1739

| Measure | Group | No. Responders* |
|---|---|---|
| **Apnea-Hypopnea Index (AHI)** | CX1739 | 3 / 15 |
| | Placebo | 0 / 4 |
| **Apnea-Hypopnea Time (AHT)** | CX1739 | 5 / 15 |
| | Placebo | 0 / 4 |

*** A responder has at least a 40% decrease in the respective parameter**

# 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 opiate use

- **Acute and Semi-Acute Use of opiates**
  - ~25M patients/year at risk for RD (hospitalized, peri- and post-surgical opiate patients)
- **Chronic Opiate Use**
  - Proprietary combination formulation for use in patients with chronic pain
- **Unmet Need: Medicine to counter or reduce RD without interfering with analgesia or anesthesia**
- **Large multi-$ billion/year market potential**

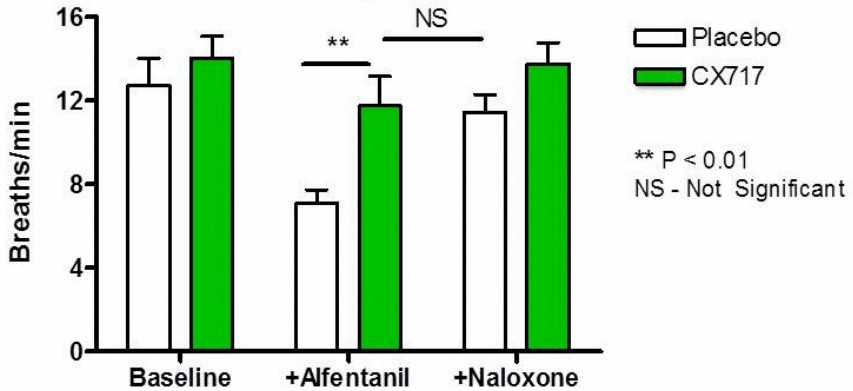
# Ampakines Prevent Opioid-induced Respiratory Depression in Humans

- Two clinical studies were run 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 Opiate-induced Respiratory Depression in Humans

## Breathing Rate




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

*Data are expressed as the basal respiratory rate.*
*N= 15 and 16 per group. CX717 dose is 1500mg.*

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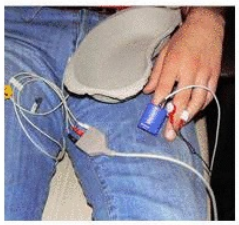
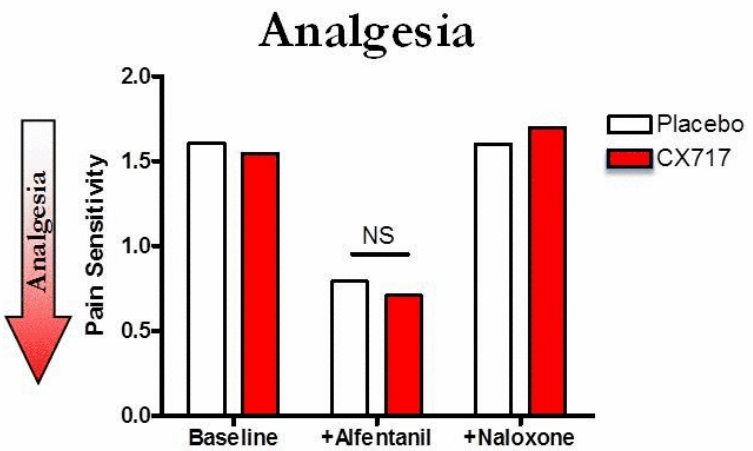
# CX717 Maintains the Analgesic Properties of Opioids Without Affecting Rescue Therapy



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

*Stage of Development*

| Compound | Indication | Pre-clinical | Phase 1 | Phase 2 |
|---|---|---|---|---|
| *Dronabinol* | Obstructive Sleep Apnea | | | |
| *CX1739* | Central Sleep Apnea<br>Opiate-induced RD<br>Spinal Damage/Pompe | | | |
| *CX717* | Combination Formulation with Opiates for Reduced RD | | | |
| *CX1942* | Drug-induced Respiratory Depression (injectable) | | | |

# Key Objectives for the Next 12 Months
(Pending Financing)

| Compound | Indication | Status | Estimated Start Date | Estimated Completion |
|---|---|---|---|---|
| **Dronabinol** | Obstructive Sleep Apnea | Phase 2B | Underway | 3Q2016 |
| **CX1739** | Opiate-induced RD | Phase 2A | 1Q2016 | 2Q2016 |
| | Central Sleep Apnea | Phase 2A | 2Q2016 | 4Q2016 |
| **CX1739 / CX717** | Spinal Cord Injury, Pompe Disease, other | Phase 2A | 1Q2016 | 3Q2016 |
| **CX717** | Combination formulation with opiate | Pre-clinical studies | 4Q2015 | 3Q2016 |
| **CX1942** | Injectable for RD | Pre-clinical studies | 4Q2015 | 3Q2016 |

# Capital Structure (in thousands of shares)

| | June 30, 2015 | Post June 30th Transactions | Total |
|---|---|---|---|
| Common Stock | 413,477 | 63,744 | 477,221 |
| Common Stock Equivalents of all Convertibles | 112,602 | (16,668) | 95,934 |
| Common Stock Equivalents of all Options and Warrants | 144,991 | 235,256 | 380,247 |
| | 671,070 | 282,332 | 953,402 |

# Management and Directors

| | |
|---|---|
| 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<br>CCO Agile Therapeutics |
| James Sapirstein | Director<br>CEO ContraVir Pharmaceuticals |
| John Greer | Chairman, Scientific Advisory Board<br>Prof & Dir. Neuroscience Ctr., U. Alberta |

# The Cortex Story: Innovative Medicines for Respiratory Diseases

- Two drug platforms from two companies
- Four Phase 2 or Phase 2-ready programs
- Blockbuster markets
- IP protection with the ability to add additional IP
- Multiple opportunities for strategic collaborations
- Availability of non-dilutive financing
- Experienced management team

# Cortex Pharmaceuticals, Inc.
# OTC QB:CORX

## BIO Investor Forum
## October 20, 2015

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

**Exhibit 99.2**

**Cortex Pharmaceuticals, Inc. to Present at the 14th Annual BIO Investor Forum**

**Cortex CEO James S. J. Manuso, Ph.D. to Present**

Glen Rock, N.J., October 19, 2015/Globe Newswire - Cortex Pharmaceuticals, Inc. (OTC: CORX) ("Cortex" or the "Company"), a leader in developing drugs for respiratory disorders, particularly obstructive and central sleep apneas and drug-induced respiratory depression, announces that it will be presenting at the 14th Annual BIO Investor Forum (www.bio.org). The conference is being sponsored by the Biotechnology Industry Organization and is being held on October 20 - 21, 2015 at the Parc 55 Hotel, San Francisco, California. The Company's CEO, James S. J. Manuso, Ph.D. is scheduled to present at 11:30 a.m. West Coast Time on Tuesday, October 20, 2015.

The conference is attended by public companies, institutional investors, industry executives, private equity firms, private companies, venture capitalists, business development executives and sophisticated private investors.

The presentation will be accessible by live audio webcast at http://www.veracast.com/webcasts/bio/investorforum2015/48108124757.cfm. A replay of the live audio webcast will be archived at the same website address and will be available one hour after the conclusion of the live event. A copy of the slide presentation to be presented by the Company is being furnished as an exhibit to a Current Report on Form 8-K being filed with the U.S. Securities and Exchange Commission and also will be accessible in the investors section of the Cortex web-site.

Dr. Manuso will present details of Cortex's clinical initiatives with respect to dronabinol for obstructive sleep apnea (Phase 2B) and the Ampakine CX-1739 (oral) for opiate induced respiratory depression (Phase 2A) and central sleep apnea (Phase 2B). Additional program and background information will also be provided.

**About Cortex Pharmaceuticals, Inc.**

Cortex is a leader in developing drugs for respiratory disorders, particularly sleep apneas and drug-induced respiratory depression. The Company owns patents and patent applications for certain families of chemical compounds that claim the chemical structures and their use in the treatment of these and other disorders.

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

Drug candidates are currently 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 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 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 Cortex for the treatment of a variety of breathing disorders. In clinical studies, such drugs have shown preliminary efficacy in central sleep apnea and in antagonizing respiratory depression produced by opiates without altering their analgesic effects. Ampakines also have improved breathing in animal models of orphan disorders such as Pompé Disease, spinal cord damage and perinatal respiratory distress. The Company's compounds belong to a new generation of ampakines that do not display the undesirable side effects of earlier versions observed in animal models.

Additional information about Cortex and the matters discussed herein can be obtained on the Company's web-site at www.cortexpharm.com or in the Company's filings on EDGAR at 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.*

Company Contact:

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