

**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): September 8, 2015

CORTEX PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

1-16467
(Commission
File Number)

33-0303583
(I.R.S Employer
Identification No.)

126 Valley Road, Suite C
Glen Rock, New Jersey
(Address of principal executive offices)

07452
(Zip Code)

Registrant's telephone number, including area code: (201) 444-4947

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the 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 September 8, 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 Rodman & Renshaw 17th Annual Global Investment Conference at The St. Regis Hotel, New York, New York. Dr. Manuso is currently scheduled to present at 4:40 p.m. Eastern Time on Thursday, September 10, 2015.

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

The slide presentation that the Company 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 at <http://wsw.com/webcast/rrshq25/corx>. A replay also will be archived at <http://wsw.com/webcast/rrshq25/corx>.

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: September 8, 2015

CORTEX PHARMACEUTICALS, INC.

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

EXHIBIT INDEX

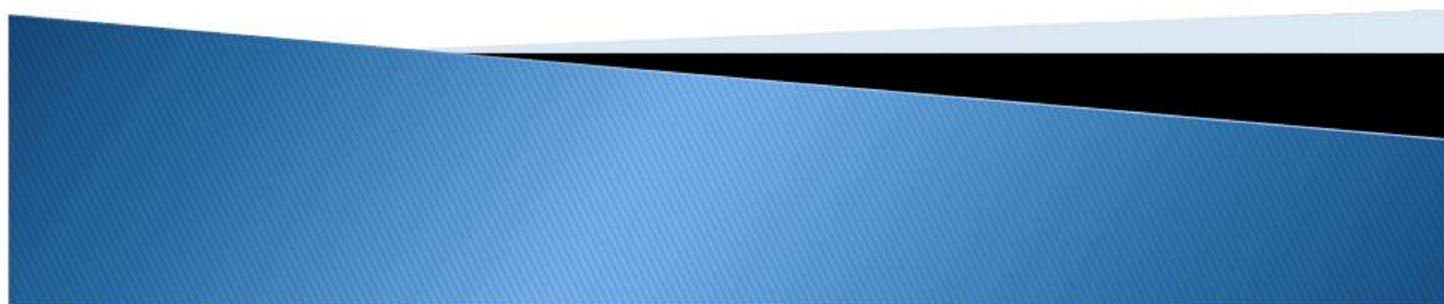
Exhibit Number	Exhibit Description
99.1	Slide Presentation*
99.2	Press Release dated September 8, 2015*
* Furnished herewith.	



Cortex Pharmaceuticals, Inc.

Rodman & Renshaw
17th Annual Global Investment Conference
September 10, 2015

James S. J. 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

- ▶ Two drug platforms for breathing disorders
- ▶ 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 (OTC QB:CORX): Medicines for breathing disorders

The Cortex of today was created by new management, financing and the combination of two clinical-stage companies:

- ▶ Pier Pharmaceuticals: a private company with rights to dronabinol, the lead, Phase 2B medicine for Sleep Apneas.
- ▶ Cortex Pharmaceuticals: a public company with a portfolio of Phase 2 and Phase 2-ready Ampakines for Sleep Apneas and Respiratory Depression.



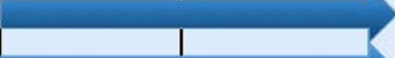
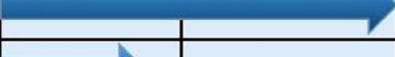



Cortex is a leader in the discovery and development of innovative pharmaceuticals for the treatment of breathing disorders

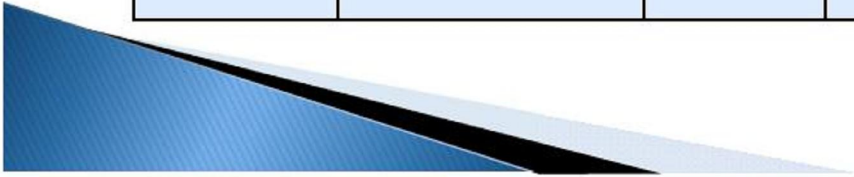
- ▶ **Sleep Apnea**
 - Dronabinol for Obstructive Sleep Apnea (OSA)
 - Ampakines for Central Sleep Apnea (CSA)
- ▶ **Drug-induced Respiratory Depression (RD) - Ampakines**
 - Semi-acute use – post-surgical pain management with opiates
 - Acute use – surgical anesthesia with propofol
 - Chronic use – Outpatient pain management with opiates
- ▶ **Two drug platforms with positive Phase 2A efficacy results in RD as well as OSA and CSA**
- ▶ **Commercial and IP protection for compounds and uses**
- ▶ **Over \$5 million in NIH grants supporting drug development**



Advanced Product Pipeline Targeting Respiratory Disorders

Stage of Development

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



Sleep Apnea: A Large Market Opportunity

▶ **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 apnea
- Market potential for sleep apnea is \$3 - 9 Billion/Year

▶ **Current Treatments**

- CPAP device
- Surgery; dental devices

▶ **Clear Market Need**

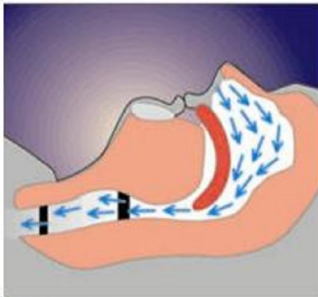
- Poor compliance with CPAP
- No drug treatment available



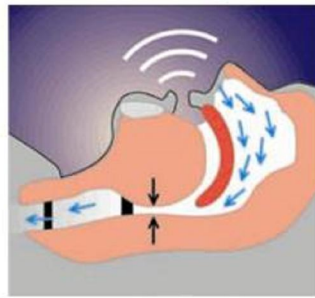
Obstructive Sleep Apnea (OSA)

- ▶ **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**

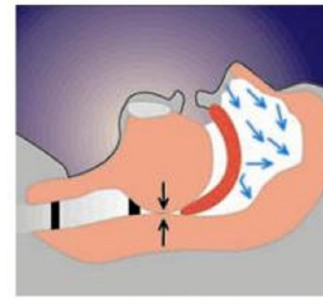
Normal Breathing



Snoring



OSA



CPAP Efficacy is 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

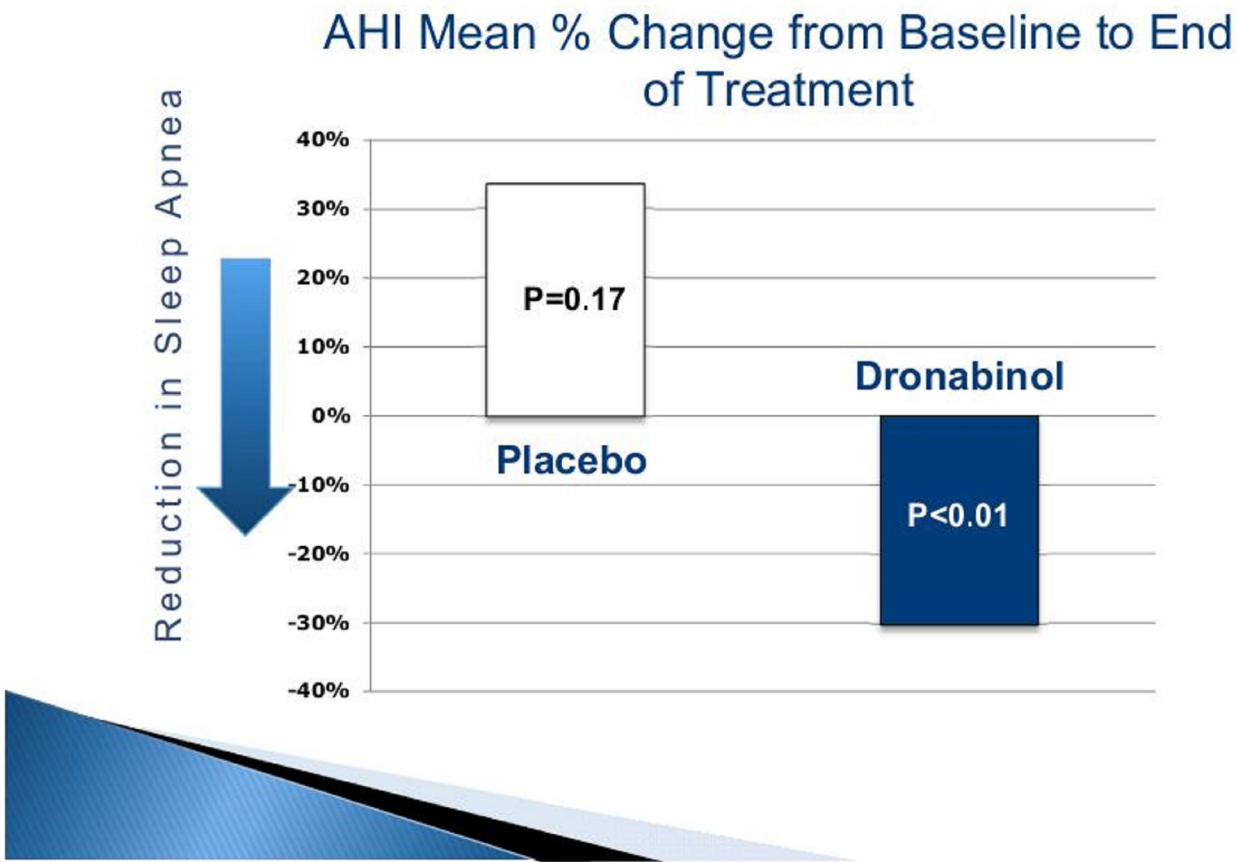
- NIH funded \$5MM grant for Phase 2B study in OSA

Completed Dronabinol Phase 2A Trial in OSA

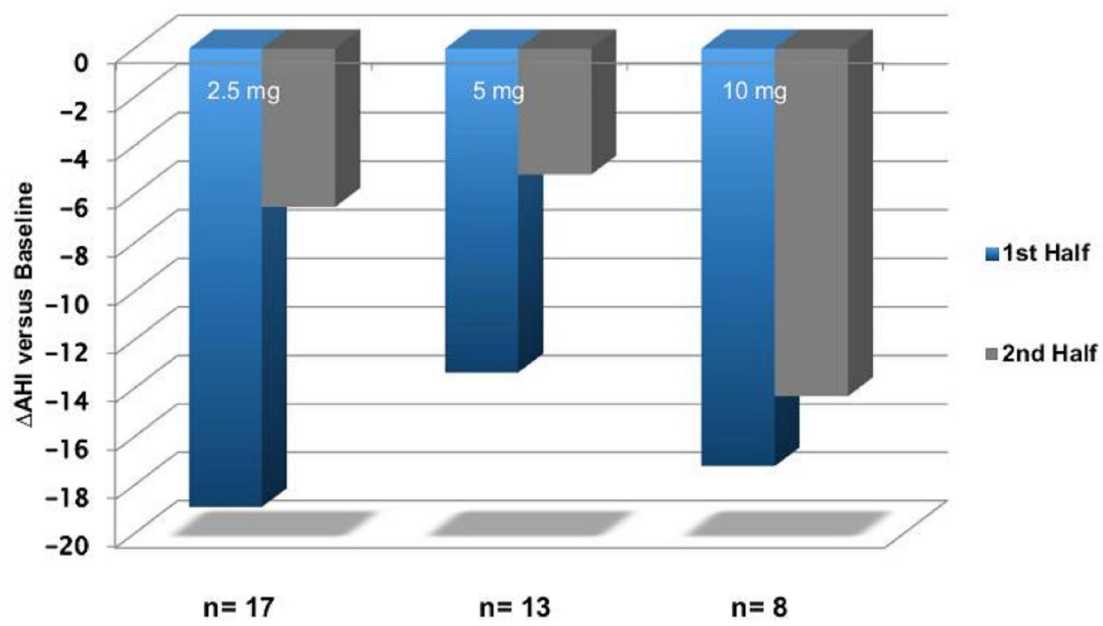
- ▶ **Randomized, double-blind, placebo-controlled dose escalation study in 22 patients with OSA**
- ▶ **Placebo (N=5) or dronabinol (N=17) for 21 days**
 - 2.5, 5 and 10 mg/night studied with weekly dose escalation
- ▶ **Overnight polysomnogram (PSG) at baseline, and after 7, 14 and 21 days of treatment**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



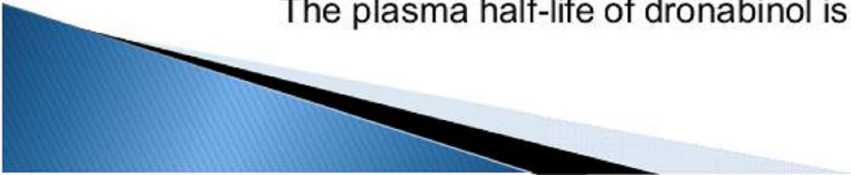
Dronabinol Reduced the AHI in OSA Subjects



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**
- ▶ **Potentially pivotal for an accelerated NDA**
- ▶ **120 subjects (40/group, 6 wks dosing)**
- ▶ **Doses: Placebo, 2.5 mg, 10 mg qd**
- ▶ **\$5 MM NIH Grant**
- ▶ **Completion by Q3/2016**
- ▶ **Initiate FDA Filing in Q4/2016**



Protecting Dronabinol in the Marketplace

- ▶ **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

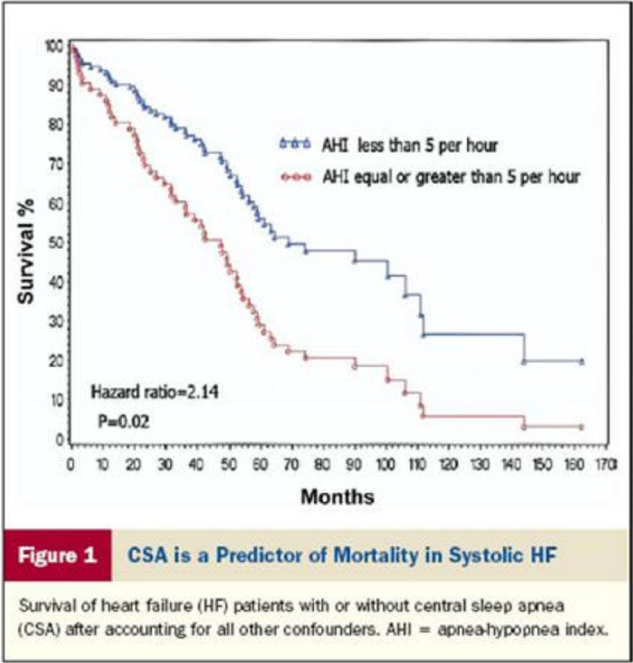
Central Sleep Apnea

- ▶ **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**



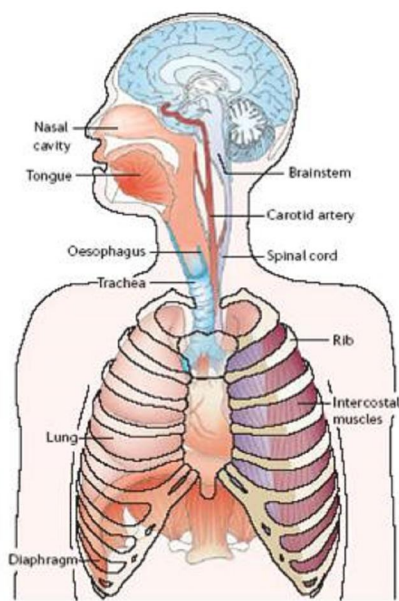
The Severity of CSA is Correlated with Increased Mortality in HF Patients

Reducing Central Sleep Apnea May Reduce Mortality in Heart Failure Patients

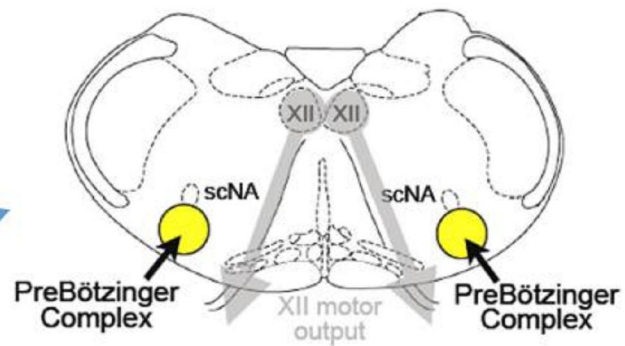


Javaheri et al, J. Amer. Coll. Cardiology 49:20, 2007

AMPAKINES – Novel Treatment for Respiratory Depression



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

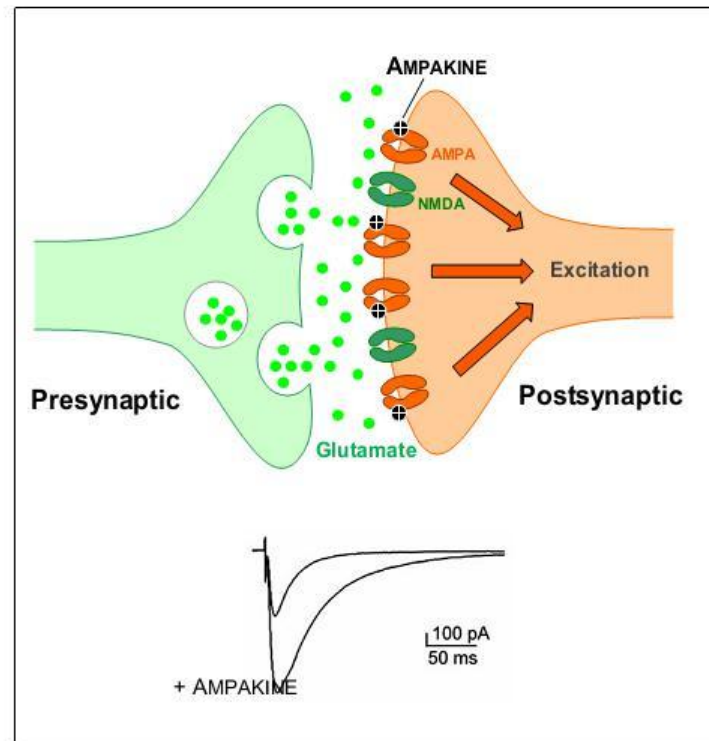


- Neurons in this brainstem region control inspiratory breathing rhythm
- PreBotC neurons use AMPA receptors for signaling
- Opiates and other depressants mediate their inhibitory effects on breathing at this site
- Ampakines normalize breathing by enhancing firing of PreBotC respiratory rhythm neurons

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



CX1739: A Second Generation, Oral Ampakine in Phase 2

▶ **Stage of Development**

- Completed Phase 1 in healthy volunteers and Phase 2A in Central Sleep Apnea
- IND-Ready for Phase 2 trials in opiate and propofol-induced Respiratory Depression

▶ **Targeted Indications**

- Oral therapy for opiate and propofol induced Respiratory Depression
- Oral therapy for Central Sleep Apnea
- Combination oral formulation with an opiate for treatment of chronic pain

▶ **Intellectual Property**

- Protected by an issued Composition-of-Matter Patent (expires 2028), filed worldwide; a method-of-use patent (expires 2030)

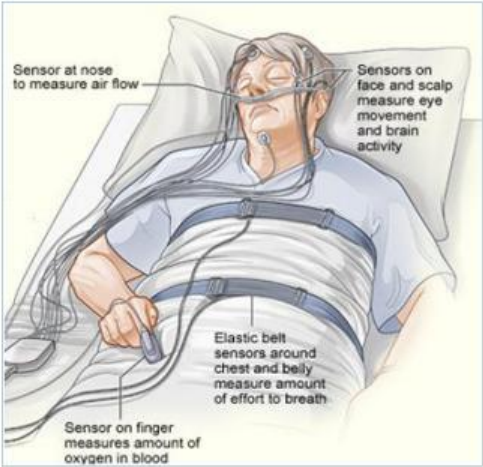
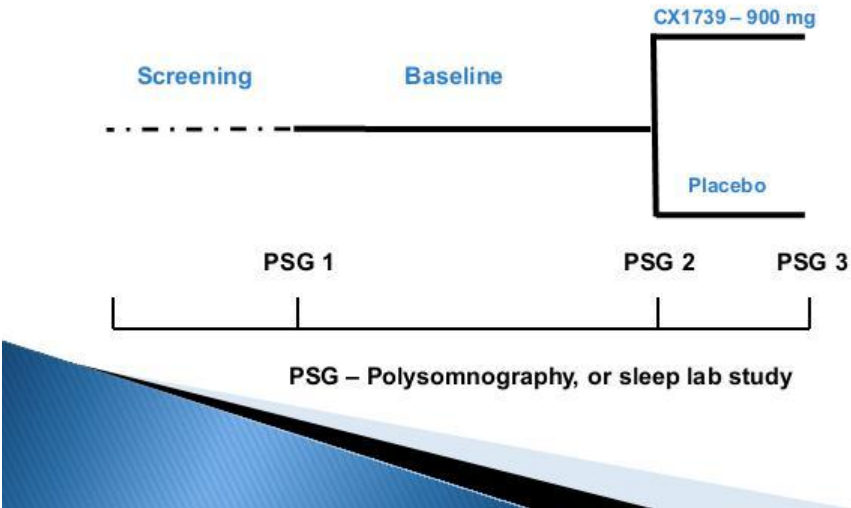
▶ **Strong Preclinical Pharmacology**

- Broad-spectrum reversal and prevention of drug-induced respiratory depression

CX1739: Completed Phase 2A in Central 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)

Study Design



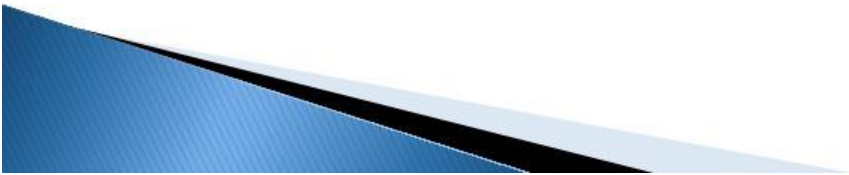
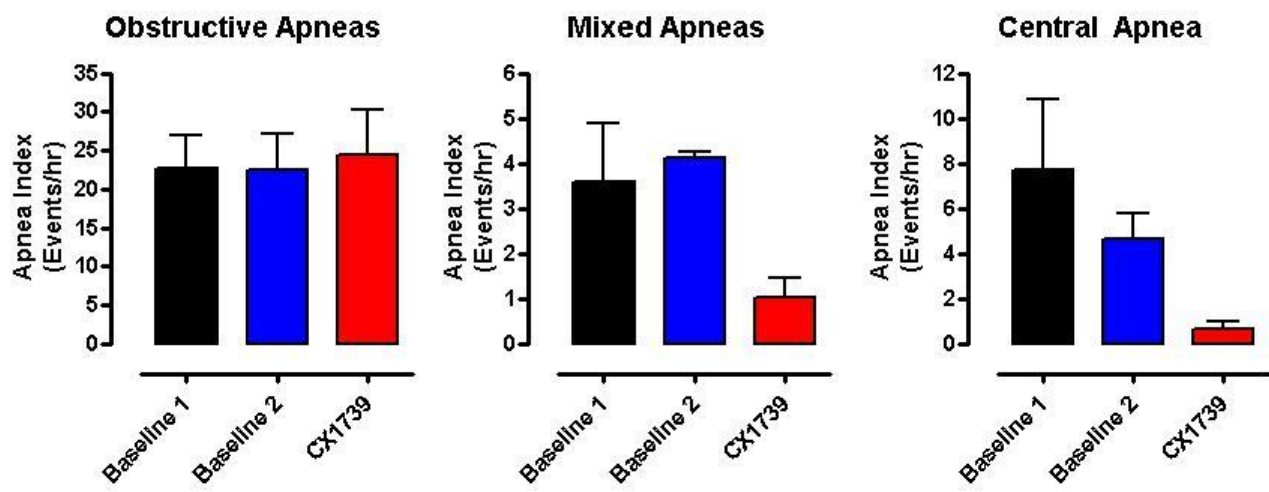
Apnea-Hypopnea Response to CX1739

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**



CX1739 Was More Effective on 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**

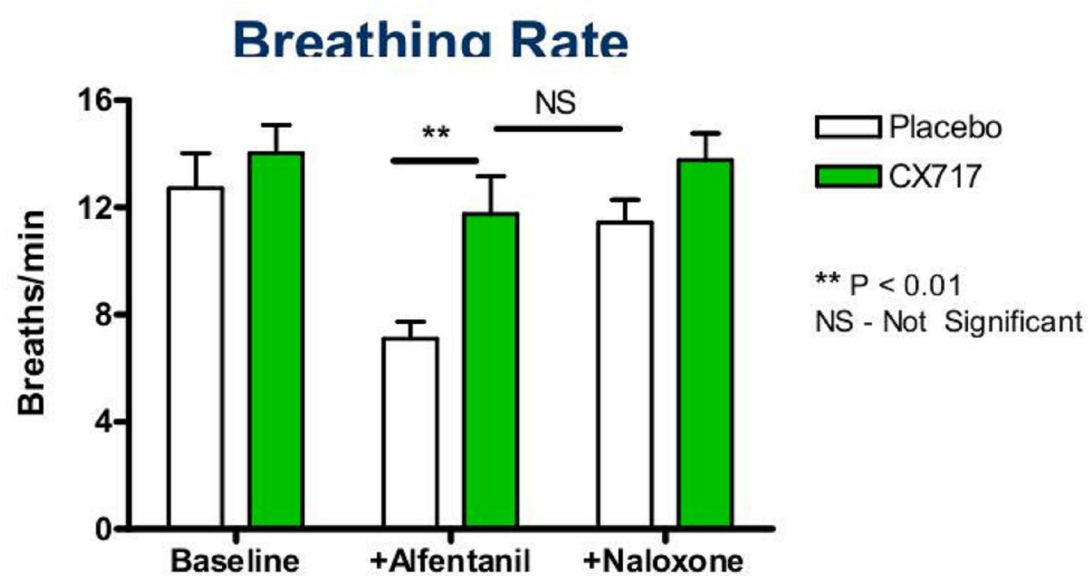


Ampakines Prevent Opioid-induced Respiratory Depression in Humans

- ▶ Two clinical studies were run in normal, healthy volunteers with CX717, a first-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

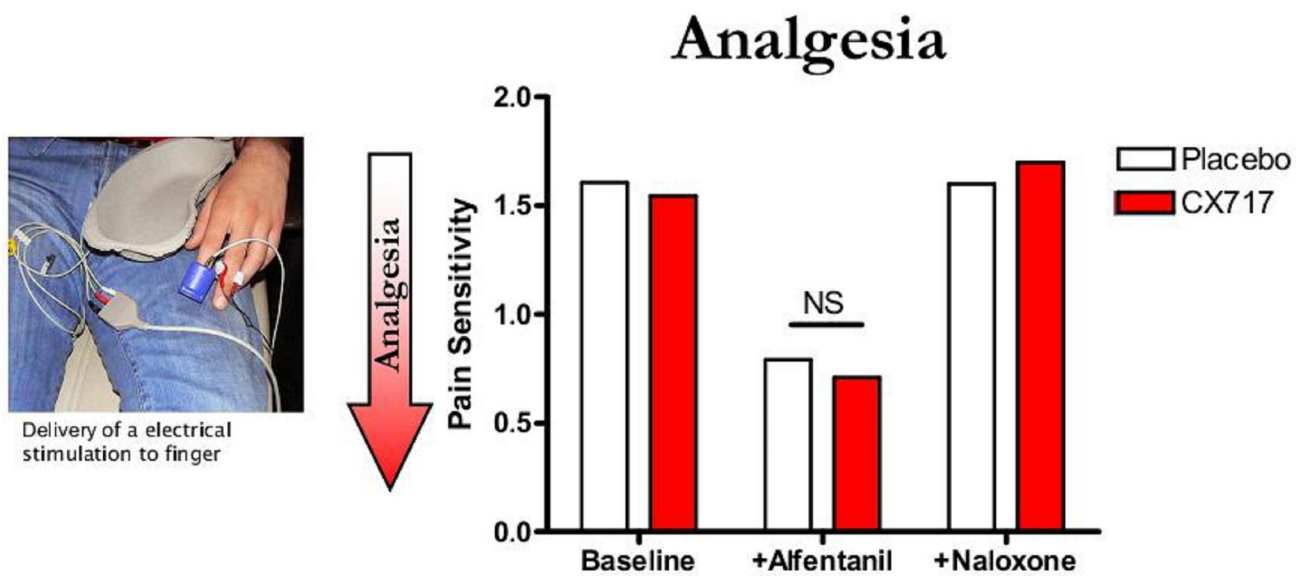
CX717 Prevents Opiate-induced Respiratory Depression in Humans



- 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.

CX717 Maintains the Analgesic Properties of Opioids Without Effecting Rescue Therapy



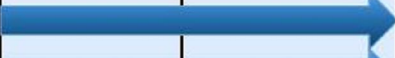
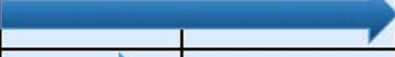

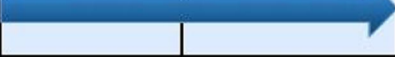



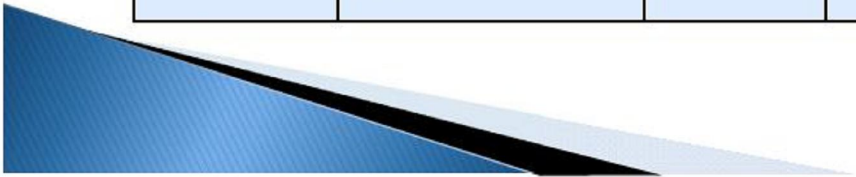
- Alfentanil reduced the pain sensitivity (produced analgesia)
- Analgesia was unaffected by CX717

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

Advanced Product Pipeline Targeting Respiratory Disorders

Stage of Development

Compound	Indication	Pre-clinical	Phase 1	Phase 2
<i>Dronabinol</i>	Obstructive Sleep Apnea			
<i>CX1739</i>	Central Sleep Apnea			
	Opiate-induced RD			
	Spinal Damage/Pompe			
<i>CX717</i>	Combination Formulation with Opiates for Reduced RD			
				
<i>CX1942</i>	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	4Q2015	1Q2016
	Central Sleep Apnea	Phase 2A	2Q2016	3Q2016
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 30 th Transactions	Total
Common Stock	413,477	34,293	447,770
Common Stock Equivalents of all Convertibles	112,602		112,602
Common Stock Equivalents of all Options and Warrants	144,991	215,811	360,802
	671,070	250,104	921,174



Management and Directors

James Manuso	President, CEO & Vice Chairman
Arnold Lipka	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

The Cortex Story

- Two drug platforms for breathing disorders
- 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

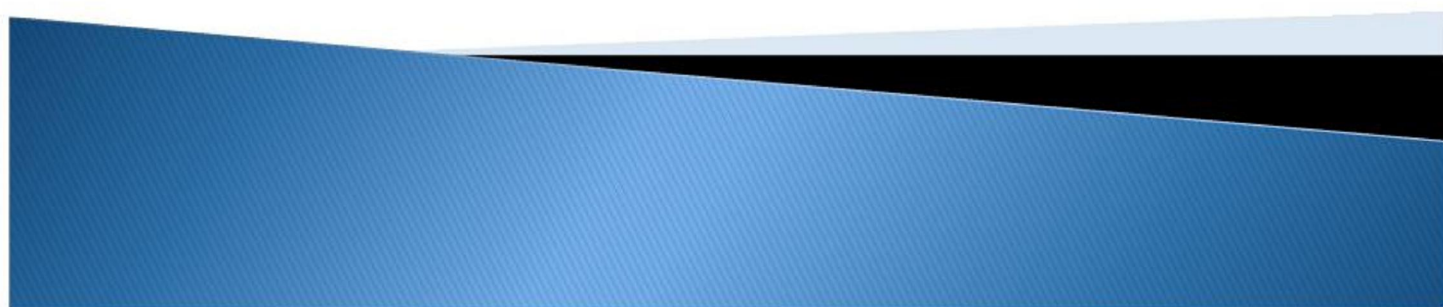




Cortex Pharmaceuticals, Inc.

Rodman & Renshaw
17th Annual Global Investment Conference
September 10, 2015

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





**Cortex Pharmaceuticals, Inc. to Present at
Rodman & Renshaw 17th Annual Global Investment Conference**

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

Glen Rock, N.J., September 8, 2015/Globe Newswire - Cortex Pharmaceuticals, Inc. (OTC: CORX) ("Cortex" or the "Company"), a leader in developing drugs for respiratory disorders, particularly obstructive sleep and central apneas and drug-induced respiratory depression, announces that it will be presenting at the Rodman & Renshaw 17th Annual Global Investment Conference (www.rodman.com). The conference is being sponsored by H.C. Wainwright & Co. and is being held on September 8 – 10, 2015 at The St. Regis Hotel, New York, New York. The Company's CEO, James S. J. Manuso, Ph.D. is currently scheduled to present at 4:40 p.m. Eastern Time on Thursday, September 10, 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 available by live webcast. To access the live audio webcast, please go to <http://www.cortexpharm.com/webcast/rrshq25/corx>. For those who are not available to listen to the live webcast, a replay will be archived at <http://www.cortexpharm.com/webcast/rrshq25/corx>. 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 CX-1739 (oral) for central sleep apnea (Phase 2B) and opiate induced respiratory depression (Phase 2A), and also will provide additional program and background information.

About Cortex Pharmaceuticals, Inc.

Cortex is a leader in developing drugs for respiratory disorders, particularly sleep apneas and drug-induced respiratory depression, and 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, 120 patient, double-blind, placebo-controlled Phase 2B clinical trial in 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 involved in the management or funding of 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 Pompe 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 displayed by earlier versions.

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.*

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