
**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): May 1, 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))
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Item 7.01 Regulation FD Disclosure

On May 1, 2015, Cortex Pharmaceuticals, Inc. (the “Company”) announced that the Company’s Executive Chairman and CEO, Dr. Arnold S. Lippa, Ph.D., will be presenting at the New York BIO 25th Anniversary Conference (the “Conference”) at 10 on the Park @ Time Warner Center. Dr. Lippa is currently scheduled to present at 10:30 a.m. Eastern Time on Monday, May 4, 2015. 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.

Item 8.01 Other Events

The information provided in Item 7.01 is incorporated herein by reference. 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: May 1, 2015

CORTEX PHARMACEUTICALS, INC.

(Registrant)

By: /s/ *ARNOLD S. LIPPA*

Arnold S. Lippa

President and Chief Executive Officer

EXHIBIT INDEX

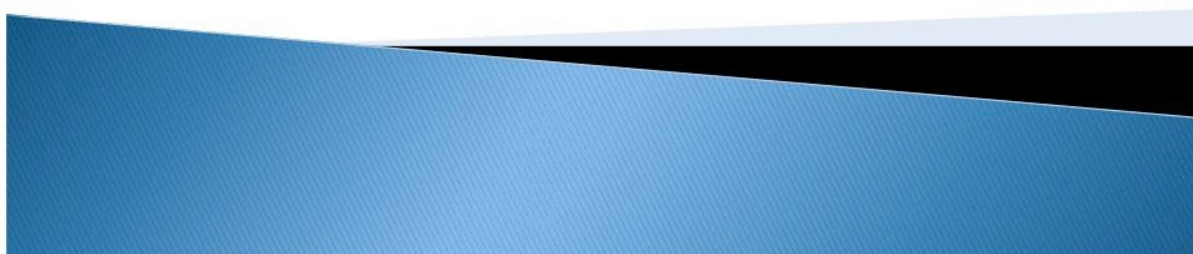
Exhibit Number	Exhibit Description
99.1	Slide Presentation*
99.2	Press Release dated May 1, 2015*

*Furnished herewith.



Cortex Pharmaceuticals, Inc.

May 4, 2015



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.



Background

2013

- Insolvent & near bankruptcy
- No ongoing operations
- Lost dronabinol license
- Deficient in SEC reporting
- Approx. \$3M market cap

Today

- Non-bankruptcy reorganization
- New capital raised
- Re-gained dronabinol license
- Current in SEC reporting
- Approx. \$25M market cap
- Newly organized research program
- Phase 2B dronabinol clinical trial to be completed mid-year
- Phase 2A ampakine clinical trial to begin 3Q, pending financing
- Committed management team and board of directors

Management and Directors

Arnold Lippa

Chairman, CEO

Jeff Margolis

VP, Sec/Treas, Director

Robert Weingarten

CFO, Director

Richard Purcell

Senior VP R&D

John Greer

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

Katie MacFarlane

Director, CCO Agile Therapeutics

James Sapirstein

Director, CEO ContraVir Pharm



Cortex Drug Platforms

Ampakines

- Positive allosteric modulators of AMPA glutamate receptors
- Positive effects for treatment of drug-induced respiratory depression in Phase 2A studies
- Positive effects for treatment of central sleep apnea in Phase 2A study
- Positive effects for treatment of ADHD in Phase 2A study
- Positive preclinical results in Pompe disease, neonatal apnea and spinal disorders

Cannabinoids

- Dronabinol (Δ^9 -THC) is a generic FDA-approved drug
- Positive Phase 2A data for treatment of obstructive sleep apnea
- Phase 2B clinical trial in progress
- Use patent for the treatment of sleep related breathing disorders

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

Key Company Highlights

- ▶ **Drug-induced respiratory depression (RD) - ampakines**
 - **Acute use – surgical anesthesia with propofol**
 - **Semi-acute use – post-surgical pain management with opiates**
 - **Chronic use – in conjunction with opiates**
- ▶ **Sleep Apnea**
 - **Obstructive sleep apnea (OSA) – dronabinol**
 - **Central sleep apnea (CSA) - ampakines**
- ▶ **Orphan Diseases – Pompe & Perinatal Apnea**
- ▶ **Strong IP protection for compounds and uses**
- ▶ **Over \$5 million in NIH grants supporting drug development**

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

Large Market with Unmet Need

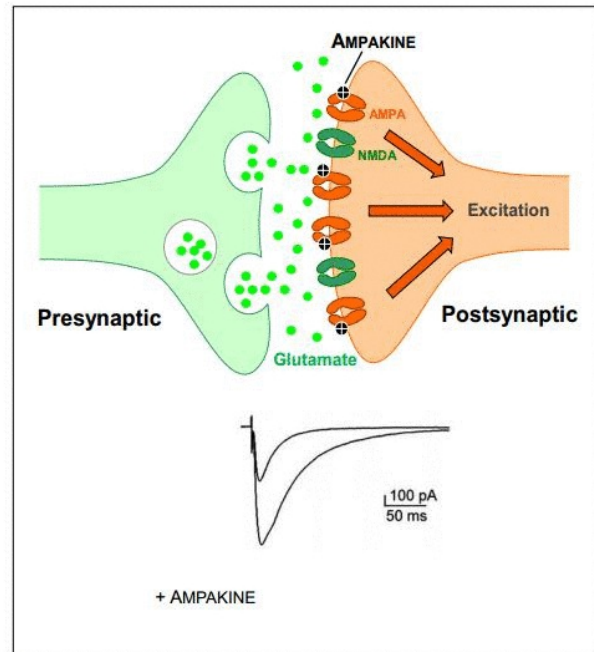
- **Drug-Induced Respiratory Depression (RD)**
 - Patients treated with anesthetic, analgesic and/or sedatives in association with surgery (12 million/yr) or medical procedures (17 million/yr) are at risk for RD, which can be lethal (cardio-respiratory arrest) or require intubation & longer hospital stay
- **Obstructive Sleep Apnea**
 - 18 million patients in the US
 - CPAP is very problematic due to high non-compliance
 - Associated morbidity (hypertension, heart disease) and mortality issues
- **Central Sleep Apnea**
 - Affects > 5 million heart failure patients in the US with high morbidity and mortality
 - Approx 40% of heart failure patients have CSA, which promotes heart disease progression and increases the risk of mortality. No current therapy for treatment of CSA in CHF



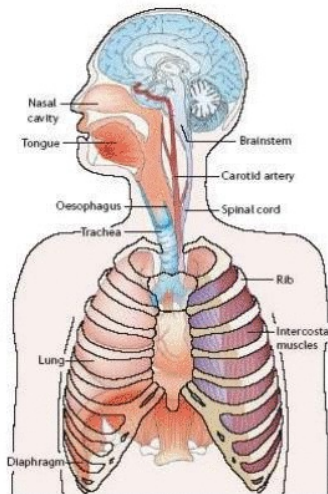
AMPAKINES – Positive Allosteric Modulators at AMPA Glutamate Receptors

AMPA Receptors Mediate Synaptic Transmission in the Brain

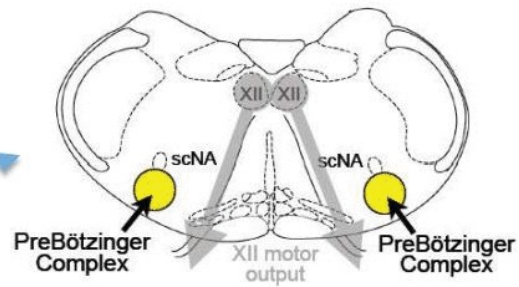
- ▶ Glutamate is the major excitatory neurotransmitter in the CNS
- ▶ Fast excitatory transmission is mediated by AMPA-type glutamate receptors
- ▶ Ampakines are positive, allosteric modulators of the AMPA-type glutamate receptor
- ▶ Prolong and strengthen synaptic transmission



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
- AMPA-PAMs normalize breathing by enhancing firing of PreBotC respiratory rhythm neurons

Acute Drug-induced Respiratory Depression

- **Most frequent lethal side effect of opiate use is respiratory depression (RD)**
- **In-patient, post-surgical opiate use (~12M patients/year) increases risk for RD**
- **RD also occurs during anesthetic procedures (e.g. colonoscopy) with propofol (20 MM procedures/year)**
- **Large market potential in excess of \$1 Billion/year in the US**
- **Unmet Need : Therapeutic drug treatment that can counter and reduce respiratory depression without interfering with analgesia or anesthesia**
- **Short-term studies that can be conducted rapidly and inexpensively**

CX1739: An Oral Phase 2 Ampakine

▶ **Stage of Development**

- Completed Phase 1 in healthy volunteers and Phase 2a in central sleep apnea
- Ready for Phase 2A studies in opiate- and propofol-induced respiratory depression and central sleep apnea

▶ **Targeted Indication**

- Prevention of propofol-induced respiratory depression during surgery
- Post-surgical prevention of opiate-induced respiratory depression

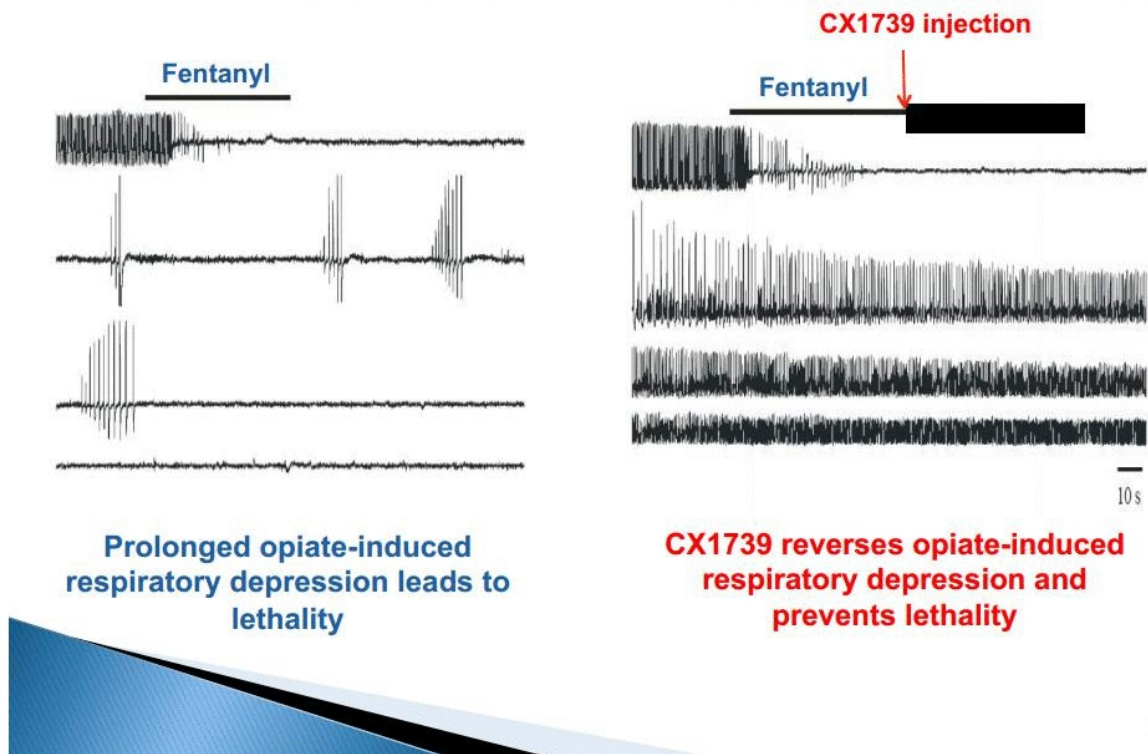
▶ **Intellectual Property**

- 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 & prevention of drug-induced respiratory depression

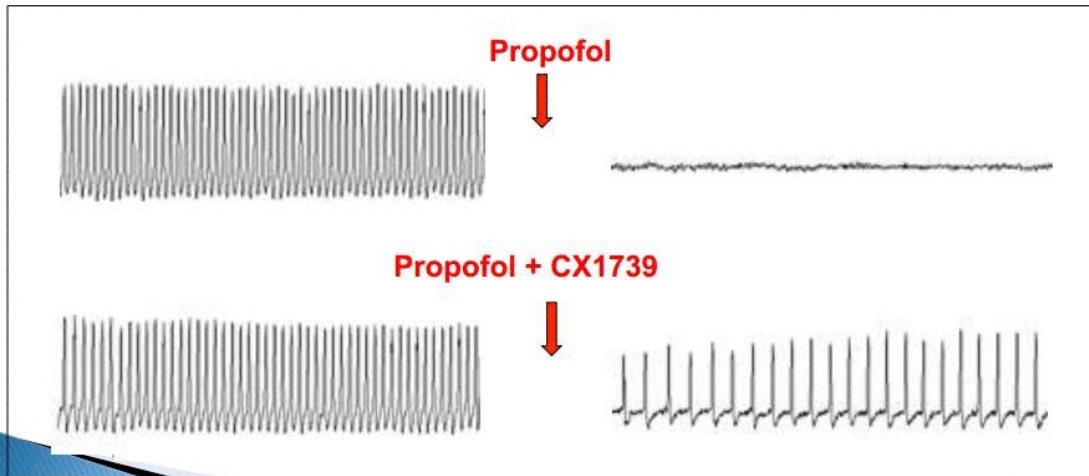
Reversal of Opioid-induced Respiratory Depression with an Ampakine in Rats



Reversal of Propofol-induced RD With an Ampakine in the Rat

Experimental Design:

- Administer a lethal dose of propofol to rats
- Inject CX1739 within 1 minute

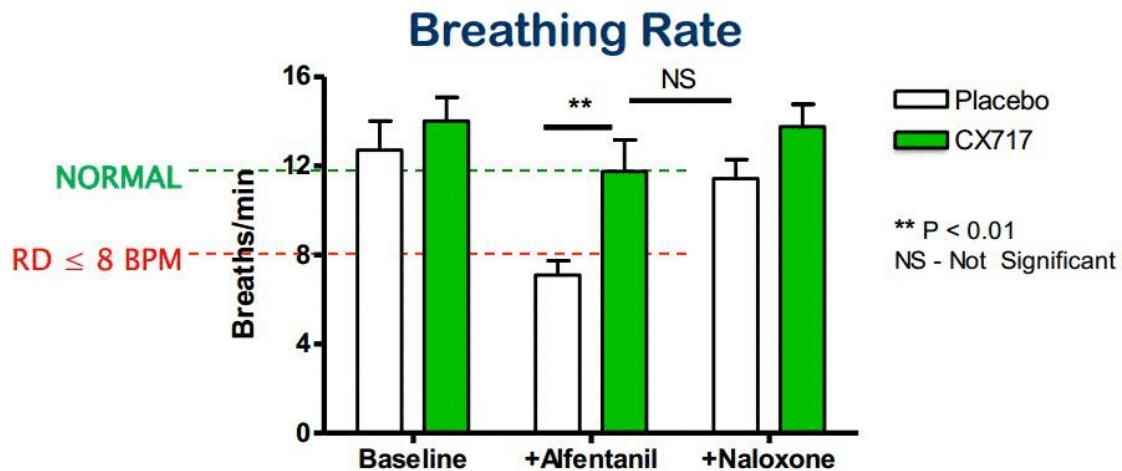


Ampakines Prevent Opioid-induced Respiratory Depression in Humans

- ▶ **Two clinical studies were run in normal, healthy volunteers with CX717, an earlier Ampakine**
- ▶ **Moderate respiratory depression was induced experimentally by infusion of the opioid, Alfentanil**
- ▶ **Respiratory and analgesia end-points were measured**

Oral CX717 prevented the onset of respiratory depression without impacting the pain-relieving properties of the opioid

CX717 Prevents Opiate-induced Respiratory Depression in Humans



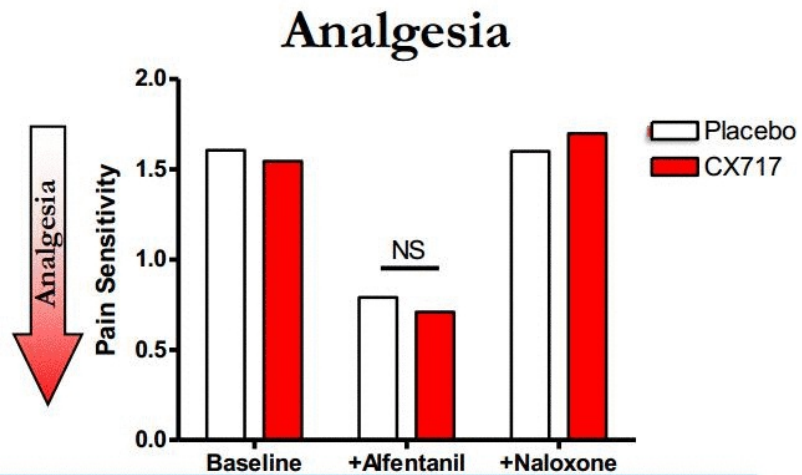
- Alfentanil reduced breathing rate & produced respiratory depression
- CX717 maintains respiratory rate in the presence of Alfentanil

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



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.

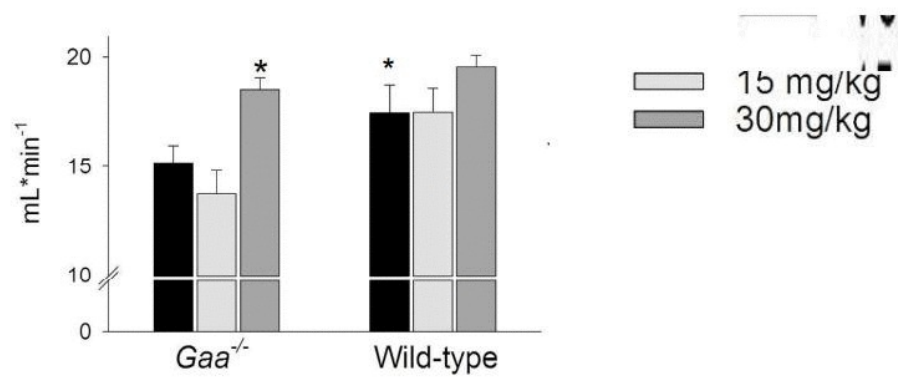
N = 15 and 16 per group. CX717 dose is 1500mg.

POMPE DISEASE

- Autosomal recessive metabolic disorder caused by an accumulation of lysosomal glycogen due to a deficiency of alpha glucosidase
- Damages muscle and nerve cells throughout the body
- Respiratory failure is the most common cause of death
- Replacement enzyme therapy

MOUSE MODEL OF POMPE DISEASE

Effects of Ampakine on Minute Volume



* p<.05, compared to vehicle
** p<.05, compared to mutant

Elmallah *et al*, in press

CX1942: A Soluble AMPA-PAM

▶ **Mechanism of Action**

- A Positive Allosteric Modulator of AMPA receptors (AMPA-PAM)
- Water-soluble for injectable dosage forms

▶ **Stage of Development**

- Injectable routes being studied in animal models of respiratory depression
- Supported by SBIR contract

▶ **Targeted Indication**

- Injectable rescue treatment for opiate and propofol-induced respiratory depression

▶ **Intellectual Property**

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

▶ **Strong Preclinical pharmacology package**

Sleep Apnea: A Large Market Opportunity

▶ Sleep Apnea

- Repetitive episodes of airflow cessation (apnea) or reduction (hypopnea) for more than 10s during sleep
- Three types: Obstructive, Central & Mixed

▶ The Sleep Apnea Market is Large

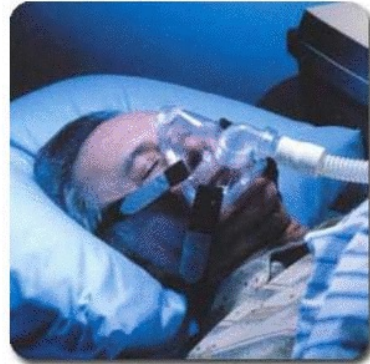
- 18 million U.S. adults with moderate or severe sleep apnea
- Market potential for sleep apnea is \$3 - 9 Billion/Year

▶ Current Treatments

- CPAP device
- Surgery; dental devices

▶ Clear Market Need

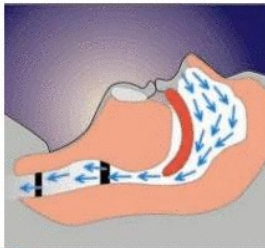
- Poor compliance with CPAP
- No drug treatment available



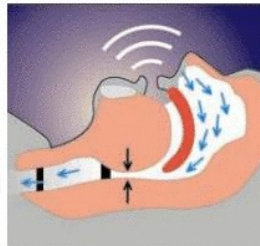
Obstructive Sleep Apnea (OSA)

- ▶ **Obstructive sleep apnea (OSA) involves a decrease or complete halt in airflow despite an ongoing effort to breathe during sleep**
 - Occurs when the muscles relax during sleep
 - Soft tissue in back of throat collapses and obstructs upper airway
- ▶ **Affects 18 MM adults in the U.S.; no current drug treatment available**
- ▶ **Significant morbidity due to stroke, hypertension, heart failure, diabetes, and other cardiovascular diseases**

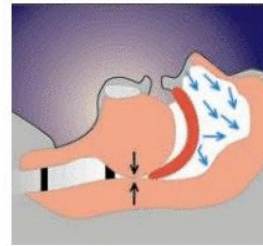
Normal Breathing



Snoring



OSA



Obstructive Sleep Apnea

Scope of the Problem in the US

Disease State	Estimated US Prevalence	Annual Estimated Cost to Society	Annual Indicated Drug Therapy Expenditures
OSA ¹⁻⁵	18.0 MM	\$75.0 Billion	\$ 0
Asthma ^{6,7}	16.4 MM	\$18.3 Billion	\$13.5 Billion
Hypertension ⁸⁻¹⁰	43.2 MM	\$73.4 Billion	\$48.5 Billion
Diabetes ^{11,12}	23.5 MM	\$174 Billion	\$20.6 Billion

1 Obstructive sleep apnea and sleep. National Sleep Foundation Web site.
2 Manufacturer Recommendations
3 Qualitative Market Research, Physician / Patient interviews, 2010
4 CPAP Supply USA,
5 American Sleep Apnea Association, 2010
6 Asthma & Allergy Foundation of America

7 Espicom Business Intelligence's New Drug Futures, 2006
8 Burt, V., et al., Hypertension, 2005
9 Lloyd-Jones, D., et al., Circulation 119(3):e21-181, 2009
10 Acmite Market Intelligence, 2008
11 Arrowhead, Global Diabetes Market, 2006
12 American Diabetes Assoc., 2007

CPAP Efficacy is Greatly Limited by Patient Compliance

- ▶ Works as an air splint to keep upper airway open during sleep
- ▶ 30% of patients prescribed CPAP never initiate treatment when prescribed a machine
- ▶ Over 50% of patients stop using CPAP in the first year of use ; may only wear 3-4h/night



Dronabinol for Treatment of OSA: A Phase 2 Compound

▶ **Mechanism of Action**

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

▶ **Commercial Status**

- FDA approved for the treatment of anorexia in AIDS patients and nausea and vomiting in cancer patients undergoing chemotherapy
- Schedule III drug available by prescription, low risk of addiction

▶ **Stage of Development**

- Phase 2A data demonstrates statistically significant improvement in OSA
- Phase 2B study in OSA is in progress with completion in 3Q2015

▶ **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**

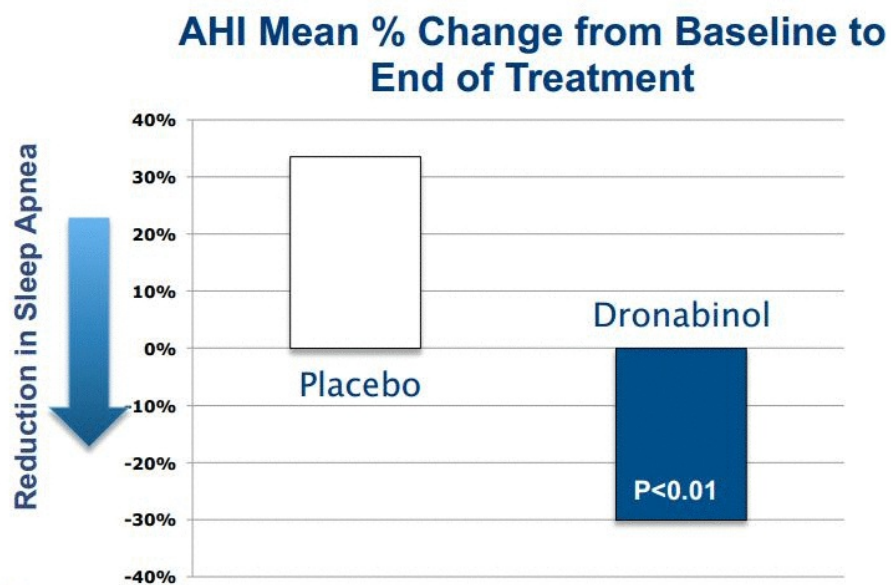
- NIH funded \$5MM grant for Phase 2B study in OSA

Dronabinol Phase 2A Clinical Study in OSA

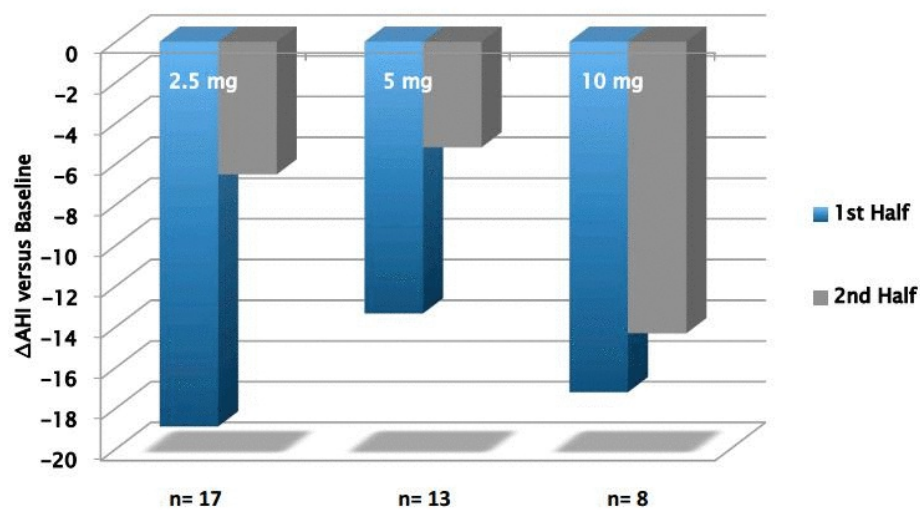
- ▶ **Randomized, double-blind, placebo-controlled dose escalation study in 22 patients with OSA**
- ▶ **Randomized to Placebo (N=5) or Dronabinol (N=17) for 21 days**
 - 2.5, 5 and 10 mg/night studied with weekly dose escalation
- ▶ **Overnight polysomnogram (PSG) at baseline, and after 7, 14 and 21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



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.

Dronabinol Phase 2B Trial in Chronic, Obstructive Sleep Apnea

- **Phase 2B study in progress at University of Illinois**
- **120 subjects (40/group, 6 wks dosing)**
- **Doses: Placebo, 2.5 mg, 10 mg qd**
- **Study costs funded by NIH Grant for \$5 MM**
- **Top line data by 3Q2015**



Protecting Dronabinol in the Marketplace

- ▶ **Issued Method-of-Use patent for dronabinol and OSA**
 - Expires in 2025
- ▶ **Potential proprietary dosage and pulse-dose formulation to provide efficacy over entire night**
 - Pending patent applications
- ▶ **US government maintains close oversight on off-label dronabinol sales due to its Schedule III status**
- ▶ **Generics and medical marijuana are not covered for this use by third party payers**
 - Off-label prescriptions unlikely



Key Objectives for the Next 12 Months

Compound	Indication	Status	Estimated Start Date	Estimated Completion
Dronabinol	Obstructive Sleep Apnea	Phase IIB	started	3Q2015
CX1739	Opiate-induced RD	Phase IIA	2Q2015	3Q2015
	Propofol-induced RD	Phase IIA	3Q2015	4Q2015
CX1739/ CX717	Pompe Disease	Phase IIA	4Q2015	2Q2016
CX1942	Injectable for RD	Pre-clinical studies	3Q2014	2Q2015



**Cortex Pharmaceuticals, Inc. to Present at
NewYorkBIO 25th Anniversary Conference**

Glen Rock, N.J., May 1, 2015/Globe Newswire – Cortex Pharmaceuticals, Inc. (CORX) (“Cortex” or the “Company”), a leader in developing drugs for respiratory disorders, particularly sleep apneas and drug-induced respiratory depression, announces that it will be presenting at the NewYorkBIO 25th Anniversary Conference (<http://conference.newyorkbio.org>). The conference will take place on May 4 – 5, 2015 at 10 on the Park @ Time Warner Center.

The Company’s Executive Chairman and CEO, Dr. Arnold S. Lippa, Ph.D., is currently scheduled to present at 10:30 a.m. Eastern Time on Monday, May 4, 2015, in what is referred to as a “Pitch & Partner Forum.” Dr. Lippa will present details of Cortex’s initiatives with dronabinol for obstructive sleep apnea (Phase 2B), CX-1739 (oral) for drug-induced respiratory depression and central sleep apnea (both Phase 2A), and CX-1942 (injectable) for drug-induced respiratory depression (preclinical), as well as background data.

NewYorkBIO is an organization that advocates for the New York life science industry, “helping to define the industry, protect its interests and grow its opportunities.” The conference will have more than 660 attendees, 65% of which are Managers, Directors, C-level or Executive Management, with one-third from outside New York State. In addition to the “Pitch & Partner Forums,” there will be three major symposia, more than 24 panels and major keynote speakers.

A copy of this press release and a copy of the slide presentation to be presented at the conference are being submitted as Exhibits to a Current Report on Form 8-K and will also be available in the investors section of Cortex’s website (www.cortexpharm.com).

About Cortex Pharmaceuticals, Inc.

Cortex Pharmaceuticals, Inc. is a biopharmaceutical company currently engaged in the discovery and development of drugs for the treatment of respiratory disorders. Drug candidates are currently derived from two platforms, as described below.

The first platform is a class of compounds known as ampakines that act as positive allosteric modulators of AMPA glutamate receptors. Several ampakines in both oral and injectable form are being developed by Cortex for the treatment of drug induced respiratory depression caused by opiates and anesthetics. In preclinical and clinical studies, such drugs have shown preliminary efficacy in central sleep apnea and restored normal respiration without altering the analgesic effects of opiates or the anesthetic effects of drugs such as propofol. The Company’s compounds belong to a new generation of ampakines that do not display the undesirable side effects displayed by previous compounds.

The second platform is the class of compounds known as cannabinoids, in particular, dronabinol. In a double-blind, placebo-controlled, dose-ascending Phase 2A clinical study conducted by the Company, dronabinol significantly improved measures of sleep apnea in a group of patients with obstructive sleep apnea. A larger 120 patient, double-blind, placebo-controlled Phase 2B clinical study is currently being conducted by the University of Illinois and is being funded by the National Institutes of Health.

Additional information about Cortex and the matters discussed herein can be obtained on the Company's website 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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E-mail: jmargolis@cortexpharm.com
