
**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 4, 2014

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 September 4, 2014, Cortex Pharmaceuticals, Inc. (the “Company”) announced that the Company’s Executive Chairman and CEO, Arnold S. Lippa, will be presenting at the Rodman & Renshaw 16th Annual Global Investment Conference at the New York Palace Hotel. Mr. Lippa is currently scheduled to present at 3:45 p.m. Eastern time on September 10, 2014. 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 presentation will be available by live webcast that can be accessed by clicking on the investors tab on the Company’s web-site (www.cortexpharm.com) and following the links and instructions or by going to <http://www.wsw.com/webcast/rshq24/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.

CORTEX PHARMACEUTICALS, INC.

Date: September 4, 2014

By: /s/ Arnold S. Lippa

Arnold S. Lippa
President and Chief Executive Officer

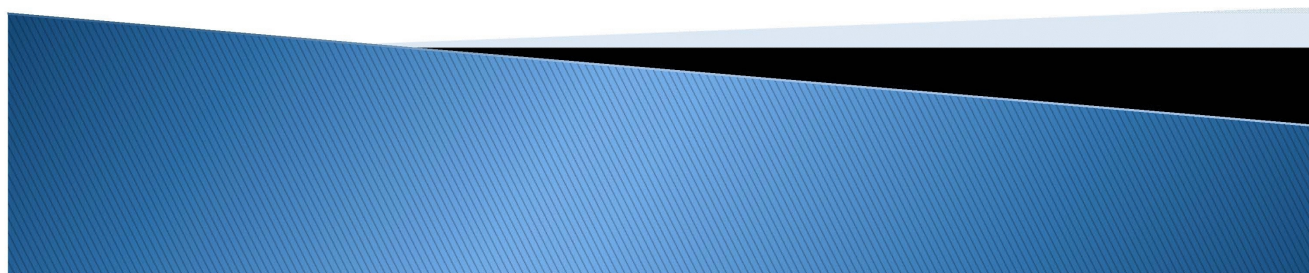
EXHIBIT INDEX

Exhibit Number	Exhibit Description
99.1	Slide Presentation (furnished herewith)
99.2	Press Release dated September 4, 2014



Cortex Pharmaceuticals, Inc.

Rodman and Renshaw
16th Annual Global Investment Conference
September 10, 2014

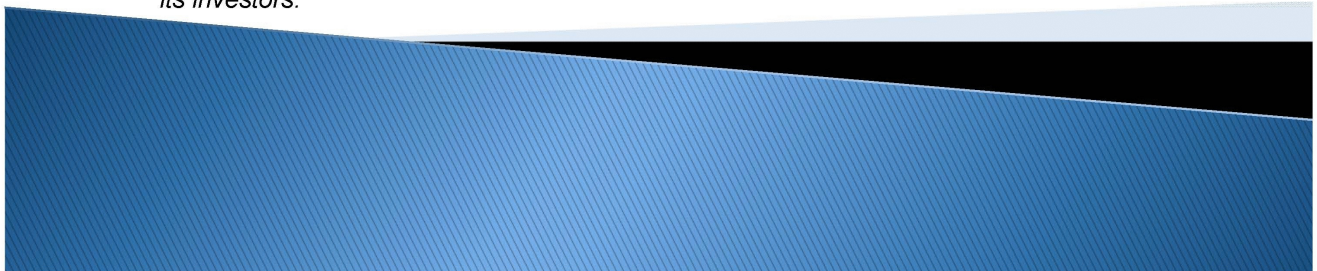


Forward Looking Statements



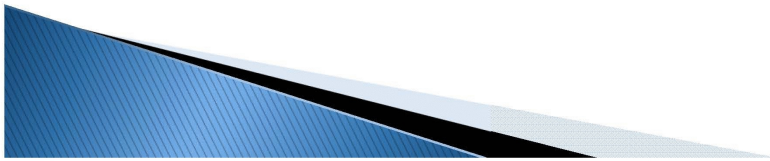
The matters discussed in this presentation that are not historical facts are "forward-looking statements." Forward-looking statements include, but are not limited to, statements containing the words "believes," "anticipates," "intends," "expects," "projects" and words of similar import. Readers are cautioned 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.



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

- ▶ **Drug-induced respiratory depression (RD) - ampakines**
 - Acute use – surgical anesthesia with propofol
 - Semi-acute use – post-surgical pain management with opiates
 - Chronic use – Outpatient pain management with opiates
- ▶ **Sleep Apnea**
 - Central sleep apnea (CSA) - ampakines
 - Obstructive sleep apnea (OSA) - dronabinol
- ▶ **Two drug platforms with positive Phase2A efficacy results in RD as well as CSmA and OSA**
- ▶ **Strong IP protection for compounds and uses**
- ▶ **Over \$5 million in NIH grants supporting drug development**



Cortex Drug Platforms

Ampakines

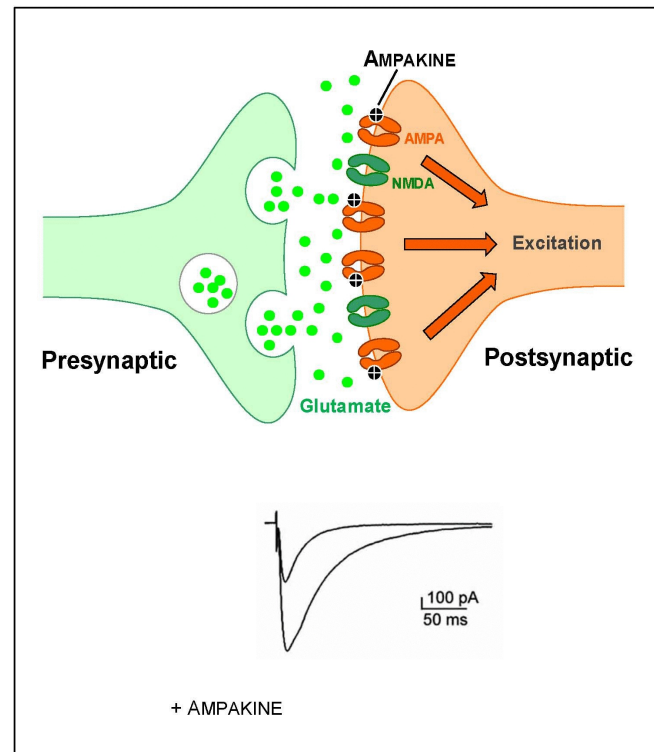
- Positive allosteric modulators of AMPA glutamate receptors
- Positive effects for treatment of central sleep apnea in Phase 2A study
- Positive effects for treatment of drug-induced respiratory depression in Phase 2A study

Cannabinoids

- Dronabinol (D9-THC) is a generic FDA-approved drug
- Positive Phase 2A data for treatment of obstructive sleep apnea
- Phase 2B clinical trial in progress
- Method patent licensed from U. Illinois for the treatment of sleep related breathing disorders

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
- ▶ Early ampakines
 - accelerate channel opening, attenuate desensitization and slow channel closing
 - Preclinical data suggested potential treatment for various disorders
 - Convulsant activity



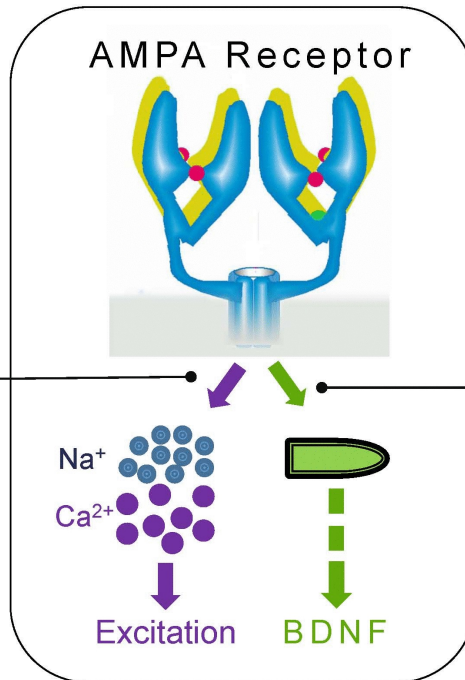
Cortex's AMPAKINE Technology

Low and High Impact Platforms

Low Impact AMPAKINES

- Stimulate one pathway
- Enhance synaptic transmission
- Reverse RD
- No convulsant activity
- CX717, CX1739, CX1942, CX1763

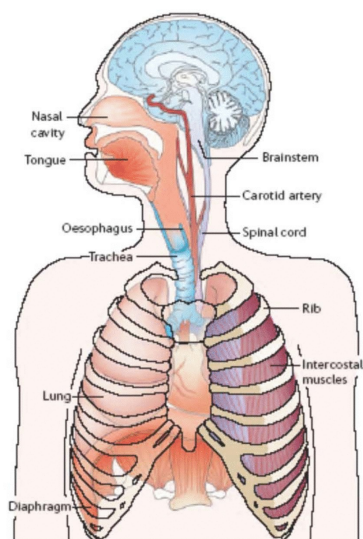
AMPA Receptor



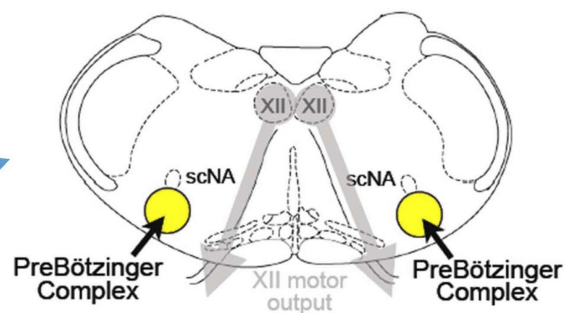
High Impact AMPAKINES

- Stimulate both pathways
- Enhance synaptic transmission
- Reverse RD
- Increase growth factors in the brain
- Convulsant activity
- CX1837, LY451395

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

Respiratory Failure: A Very Serious Hospital Safety Problem

HealthGrades Patient Safety in American Hospitals Study 2010 - 28
Appendix E: Patient Safety Events and Attributable Mortality and Excess Charge

Appendix E: Patient Safety Events and Their Attributable Mortality and Excess Charge Among Medicare Beneficiaries by Patient Safety Indicator (2006 – 2008)

Patient Safety Indicator	Actual Number of National Events	Percentage of Total Number of Events	Attributable Mortality Rates**	Number of Deaths Attributable to PSI (Attributable Mortality**)	Attributable Charge**	Excess Charge Attributable to PSI** (Millions)	Excess Cost Attributable to PSI ^^ (Millions)
Decubitus ulcer	487,718	50.90%	7.23%	35,262	\$10,845	\$5,289.30	\$2,644.65
Post-operative pulmonary embolism or deep vein thrombosis	143,699	15.00%	6.56%	9,427	\$21,709	\$3,119.56	\$1,559.78
Accidental puncture or laceration	96,082	10.03%	2.16%	2,075	\$8,271	\$794.69	\$397.35
Post-operative respiratory failure	69,078	7.21%	21.84%	15,087	\$53,502	\$3,695.81	\$1,847.91
Selected infections due to medical care	50,165	5.24%	4.31%	2,162	\$38,656	\$1,939.18	\$969.59

Highest mortality rate
2nd highest attributable number of deaths
2nd largest overall excess cost to Medicare system

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 2 studies in opiate-induced respiratory depression and central sleep apnea

▶ **Targeted Indication**

- Oral therapy for opiate- and propofol-induced respiratory depression
- Oral therapy for central sleep apnea

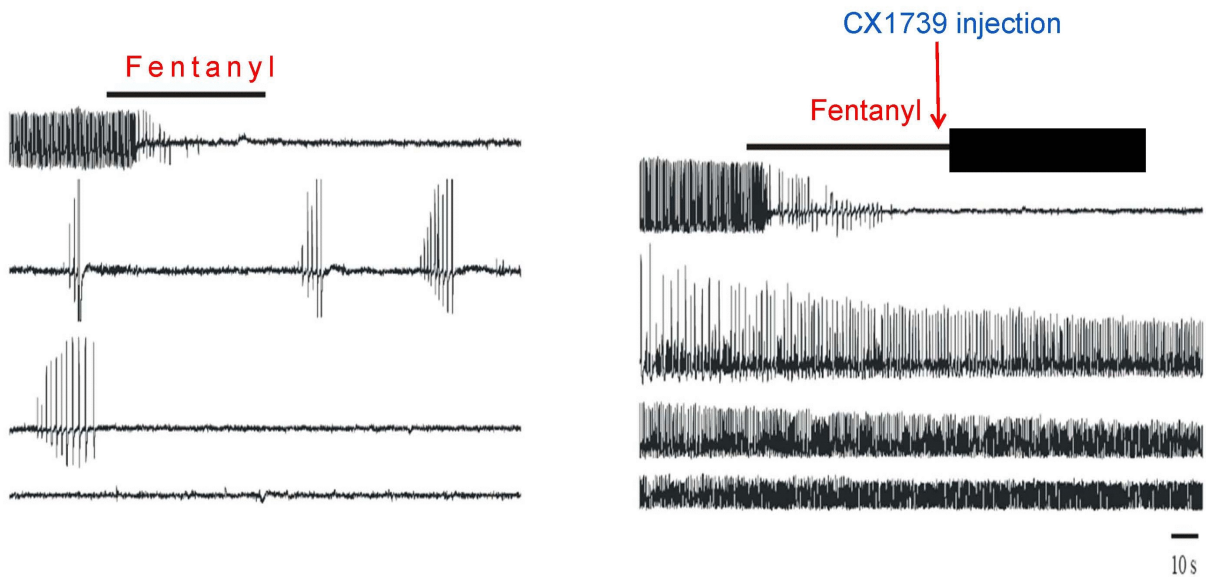
▶ **Intellectual Property**

- 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



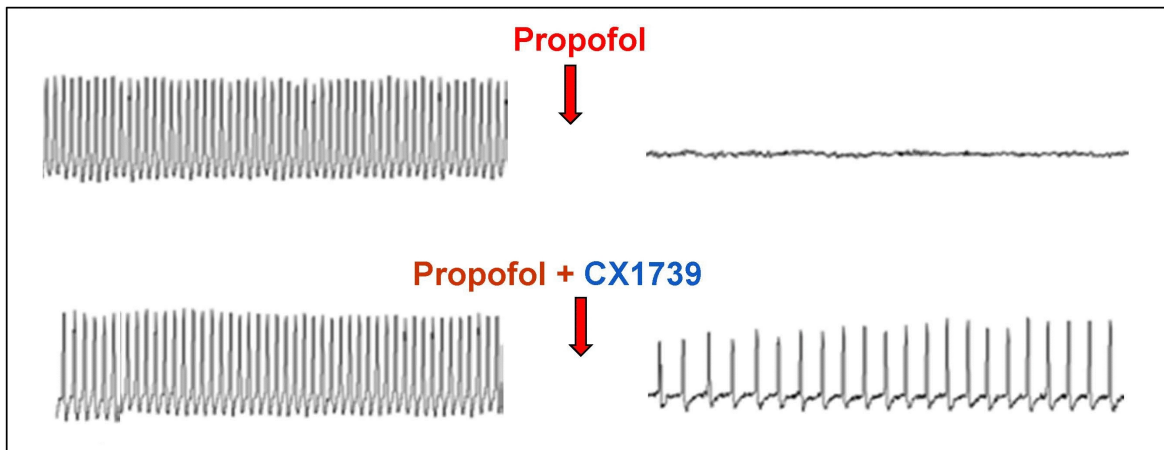
Prolonged opiate-induced respiratory depression leads to lethality

CX1739 reverses opiate-induced respiratory depression and prevents lethality

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

Experimental Design:

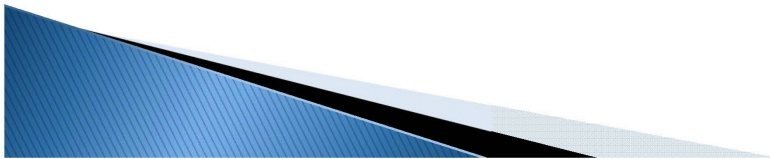
- Administer a lethal dose of propofol to rats
- Inject **CX1739** within 1 minute



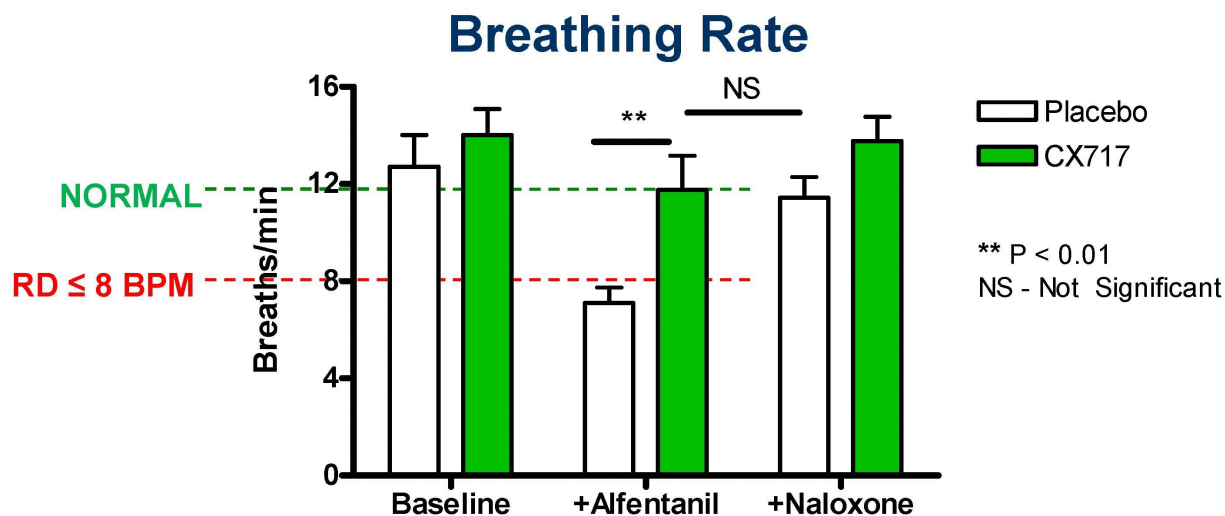
Ampakines Prevent Opioid-induced Respiratory Depression in Humans

- ▶ Two clinical studies were run in normal, healthy volunteers with **CX717** an older generation 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



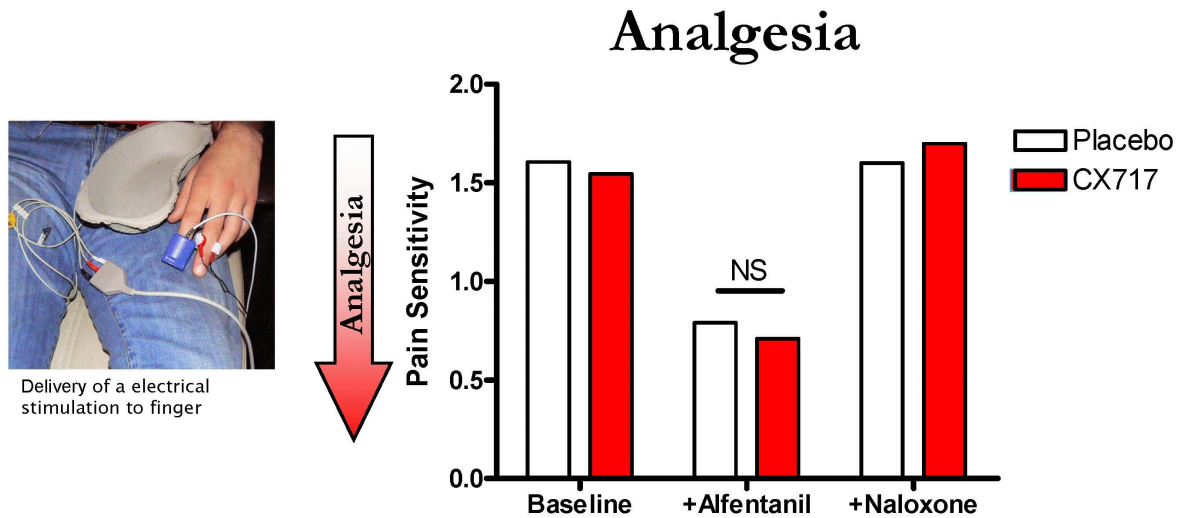
CX717 Prevents Opiate-induced Respiratory Depression in Humans



- 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



- 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.

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

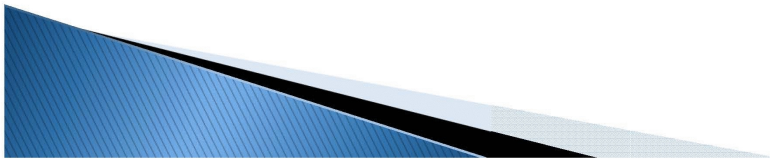
▶ **Clear Market Need**

- Poor compliance with CPAP
- No drug treatment available



Central Sleep Apnea

- ▶ **Characterized by a lack of drive from the brain to breathe during sleep – similar response as in treatment of RD**
- ▶ **Manifestations of CSA**
 - Narcotic-induced central apnea (70% chronic users)
 - Heart failure patients (up to 40%)
 - Idiopathic CSA (5% sleep apnea patients)
- ▶ **Standard CPAP therapy is not effective for central sleep apnea**



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

Reducing Central Sleep Apnea May Reduce Mortality in Heart Failure Patients

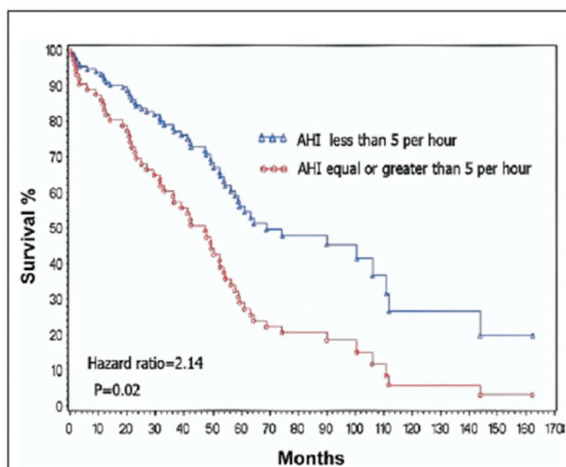


Figure 1 CSA is a Predictor of Mortality in Systolic HF

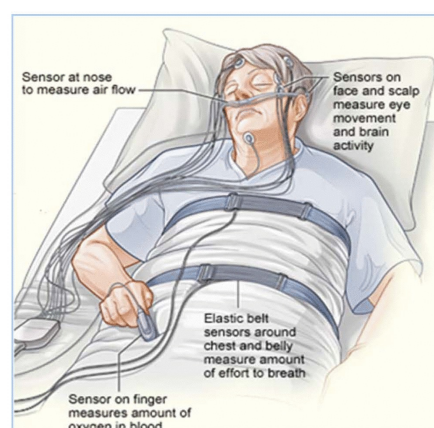
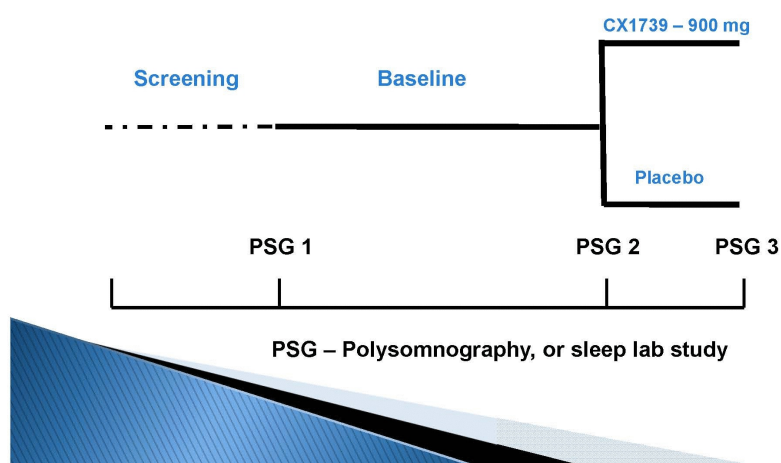
Survival of heart failure (HF) patients with or without central sleep apnea (CSA) after accounting for all other confounders. AHI = apnea-hypopnea index.

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

CX1739 Sleep Apnea Clinical Study Design

Design	Randomized, double-blind, placebo-controlled study
Population	20 adults with moderate to severe sleep apnea (16 given CX1739; 4 given Placebo)
Dosing	Each subject receives 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

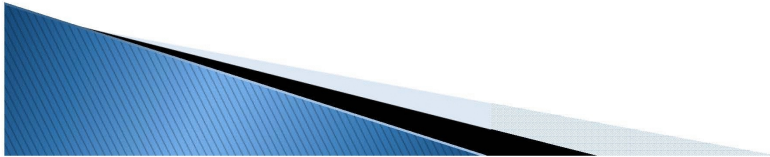


Apnea-Hypopnea Scores (Responders)

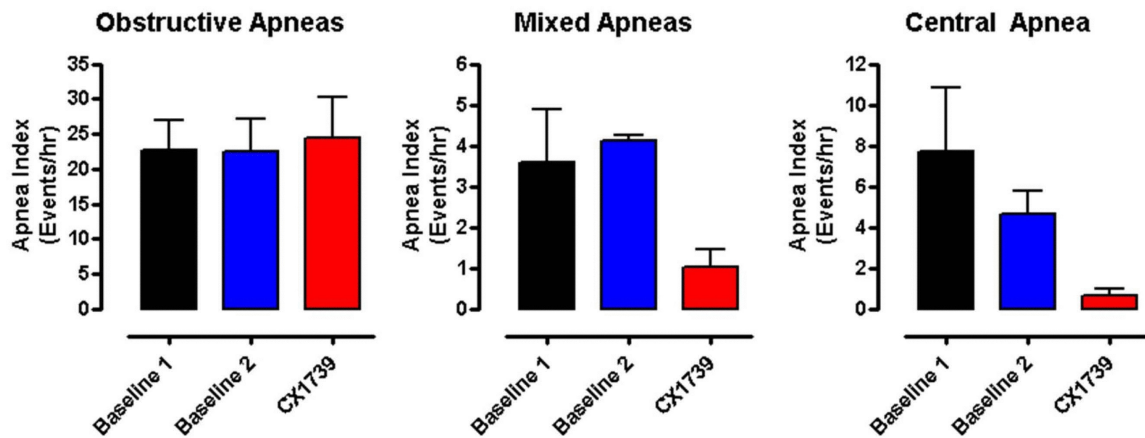
Measure	Group	No. Responders*
Apnea-Hypopnea Index (AHI)	CX1739	3 / 15
	Placebo	0 / 4
Apnea-Hypopnea Time (AHT)	CX1739	5 / 15
	Placebo	0 / 4

Why do some patients respond, and others not ?

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



CX1739 Was More Effective on Mixed and Central Sleep Apneas



CX1942: A Soluble Ampakine

- ▶ **Mechanism of Action**

- Low Impact Positive Allosteric Modulator of AMPA receptors
- 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 therapy for opiate and propofol-induced respiratory depression

- ▶ **Intellectual Property**

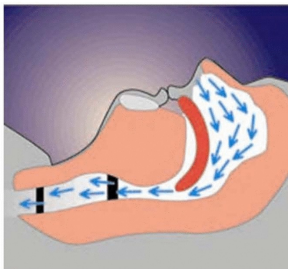
- Protected by an issued Composition-of-Matter Patent (expires 2028), filed worldwide; a method-of-use patent (expires 2030)

- ▶ **Strong Preclinical pharmacology package**

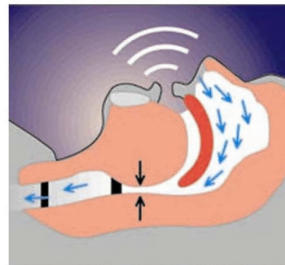
Obstructive Sleep Apnea (OSA)

- ▶ **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**

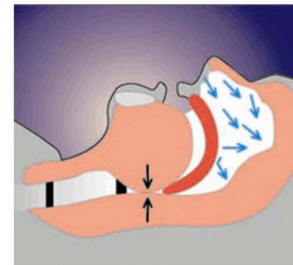
Normal Breathing



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

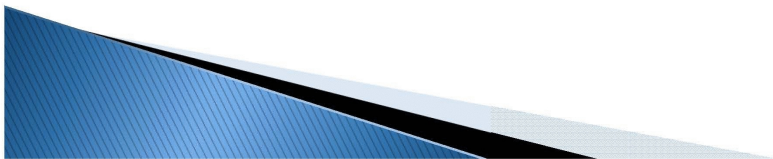
Works as an air splint to keep upper airway open during sleep

- ▶ 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



Obstructive Sleep Apnea

**Unmet Need:
Therapeutic drug treatment that can
significantly improve OSA and reduce
excessive daytime sleepiness (EDS)**



Dronabinol for Treatment of OSA: A Phase 2 Compound

▶ **Mechanism of Action**

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

▶ **Stage of Development**

- Schedule III drug available by prescription, 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 demonstrates clear signal of activity in OSA
- Phase 2B study in OSA initiated

▶ **Intellectual Property**

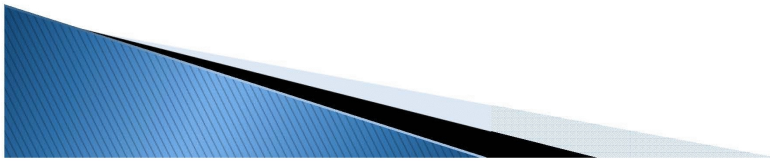
- Issued method-of-use patent in the US for the use of dronabinol for treating OSA (expires 2025) & pending patents on modified release formulations

▶ **Funding**

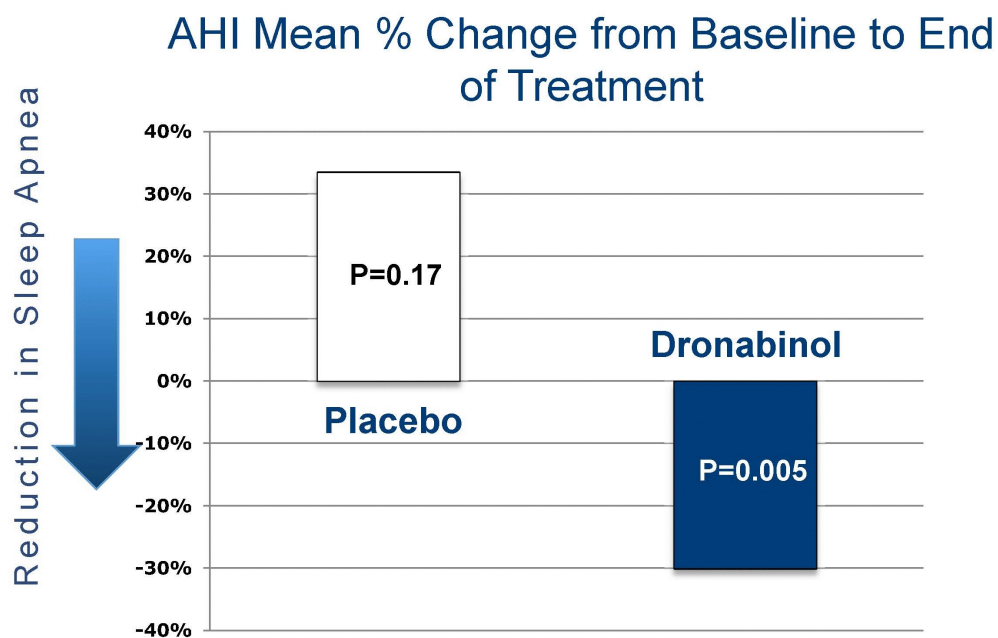
- NIH funded \$5MM grant for Phase 2B study in OSA

Dronabinol Phase 2A Clinical Study in OSA

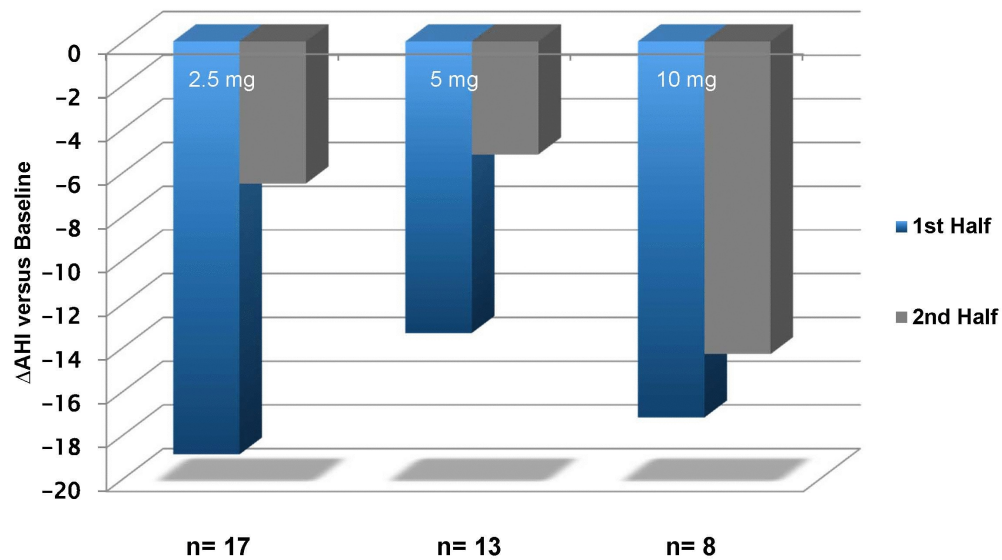
- ▶ **Randomized, double-blind, placebo-controlled dose escalation study in 22 patients with OSA**
- ▶ **Randomized to Placebo (N=5) or Dronabinol (N=17) for 21 days**
 - 2.5, 5 and 10 mg/night studied with weekly dose escalation
- ▶ **Overnight polysomnogram (PSG) at baseline, and after 7, 14 and 21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



Dronabinol Reduced the AHI in OSA Subjects



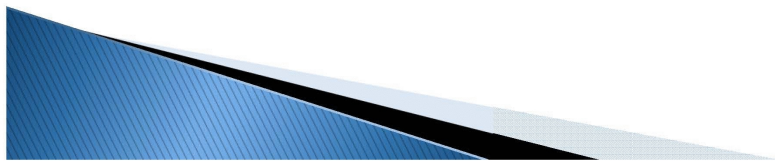
Apnea Suppression as a Function of Dose and Time



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

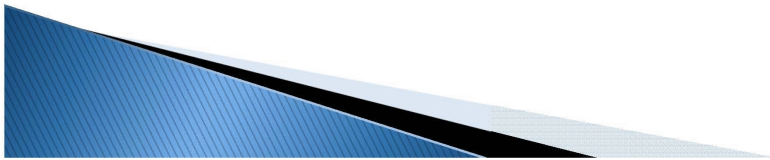
Dronabinol Phase 2B Trial in COA

- **Phase 2 study re-initiated January, 2014**
- **Top line data by 4Q2015**
- **120 subjects (40/group, 6 wks dosing)**
- **Doses: Placebo, 2.5 mg, 10 mg qd**
- **Study costs funded by NIH Grant for \$5 MM**







Protecting Dronabinol in the Marketplace

- ▶ **Issued Method-of-Use patent for dronabinol and OSA**
 - Expires in 2025
- ▶ **Proprietary dosage and pulse-dose formulation to provide efficacy over entire night**
 - Pending patent applications
- ▶ **Off-label use of generics and medical marijuana are not covered by third party payers**

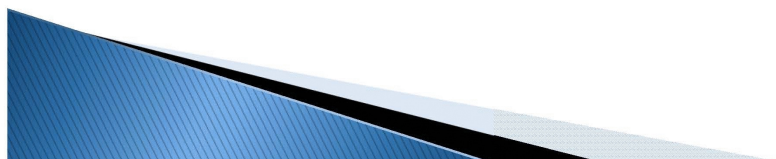


Respiratory Disorders

Indication	Compound	Drug Discovery	Pre-clinical	Phase 1	Phase 2
Obstructive Sleep Apnea	<i>Dronabinol</i>				
Central Sleep Apnea in CHF	<i>CX1739</i>				
Drug-induced Respiratory Depression (oral)	<i>CX1739</i>				
Drug-induced Respiratory Depression (injectable)	<i>CX1942</i>				

Key Objectives for the Next 16 Months

Compound	Indication	Status	Estimated Start Date	Estimated Completion
<i>Dronabino I</i>	Obstructive Sleep Apnea	Phase IIB	started	4Q2015
<i>CX1739</i>	Opiate-induced RD	Phase IIA	1Q2015	3Q2015
	Propofol-induced RD	Phase IIA	2Q2015	4Q2015
<i>CX1942</i>	Injectable for RD	Pre-clinical studies	3Q2014	2Q2015





Cortex Pharmaceuticals, Inc. to Present at Rodman & Renshaw 16th Annual Global Investment Conference

CEO to Present Strategic Initiatives in Respiratory Disorders and Key Objectives

September 4, 2014, 5:20pm EDT

Glen Rock, N.J. September 5, 2014/Globe Newswire - Cortex Pharmaceuticals, Inc. (OTC: CORX) ("Cortex" or the "Company"), a leader in developing drugs for respiratory disorders, particularly drug-induced respiratory depression as well as obstructive, central and mixed sleep apneas, announces that it will be presenting at the Rodman & Renshaw 16th Annual Global Investment Conference (www.rodman.com). The conference will be held September 8 – 10, 2014 at the New York Palace Hotel sponsored by H.C. Wainwright & Co., LLC. The Company's Executive Chairman and CEO, Arnold S. Lippa, Ph.D. is currently scheduled to present at 3:45pm EDT on Wednesday, September 10, 2014.

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 log onto Cortex's website (www.cortexpharm.com), click on the investors tab and follow the links and instructions or go to <http://www.wsj.com/webcast/rshq24/corx>. A copy of the slide presentation to be presented is being filed on a Current Report on Form 8-K and will also be available on Cortex's website in the investors section.

Dr. Lippa will present details of Cortex's initiatives with dronabinol for obstructive sleep apnea (Phase-II), CX-1739 (oral) for drug-induced respiratory depression and central sleep apnea (both Phase-IIa) and CX-1942 (injectable) for drug-induced respiratory depression (preclinical) as well as background data.

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.

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



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 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 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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