



## **Cortex Pharmaceuticals, Inc. Announces Name Change and Symbol Change**

### **Provides 2015 Year-End Update and Outlines Clinical Trial Plans for 2016**

Glen Rock, N.J., December 17, 2015/Globe Newswire - Cortex Pharmaceuticals, Inc. (OTC: CORX) (the "Company") is providing investors and shareholders with a 2015 year-end update and a summary overview of the Company's clinical trial plans for 2016.

#### **Name Change and Symbol Change**

In keeping with its focus on respiratory disorders, the Company announced that it has changed its name to RespireRx Pharmaceuticals Inc. effective as of December 16, 2015. The Company's trading symbol is in the process of being changed and the new trading symbol requested is "RSRX", or alternatively "RSPI". The URL for the Company's web-site has been changed to [www.RespireRx.com](http://www.RespireRx.com).

The Company is addressing significant and growing markets for respiratory disorders, where current treatment options are limited or inadequate. The Company's product candidate portfolio includes two clinical stage compounds, dronabinol, which is being developed for obstructive sleep apnea ("OSA"), and CX1739, which is being developed for multiple respiratory indications, including central sleep apnea and drug-induced respiratory depression.

#### **Executive Management Changes in 2015**

In August 2015, Dr. James S. J. Manuso, Ph.D., 66, was appointed as the Company's President and Chief Executive Officer, as well as Vice Chairman and a member of the Board of Directors. Dr. Manuso invested \$250,000 in the August 2015 closing of the common stock and warrant financing discussed below. Dr. Manuso is the former Chairman of the Board of Directors and Chief Executive Officer of Astex Pharmaceuticals, Inc. ("Astex") (NASDAQ: ASTX), having served in such positions from July 2011 through October 2013, at which time he successfully concluded efforts to sell Astex to Otsuka Pharmaceuticals, Inc. for \$886 million. Dr. Manuso replaced Dr. Arnold S. Lippa, Ph.D., who is continuing as Executive Chairman of the Board of Directors and has assumed the position of Chief Scientific Officer.

#### **Ongoing Phase 2B Clinical Trial of Dronabinol**

As described in more detail below, the Company anticipates reporting the results of an ongoing 120 patient, double-blind, placebo-controlled clinical trial of dronabinol ( $\Delta^9$ -THC), a synthetic cannabinoid, for use in the treatment of OSA during the third quarter of 2016.

#### **Clinical Trial Plans for 2016 - Phase 2A Clinical Trial for CX1739**

The Company recently disclosed that it had filed an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration ("FDA") to conduct a double-blind, placebo-controlled, dose-ascending Phase 2A clinical trial in approximately 18 subjects to determine the ability of orally administered CX1739, the Company's lead ampakine, to prevent the respiratory depression produced by remifentanyl, a strong opiate, without altering remifentanyl's analgesic properties. The clinical protocol is



designed to evaluate the safety and efficacy of three escalating doses of CX1739 versus placebo when administered prior to remifentanyl, with respiration, analgesia and a number of other clinical measures being taken after administration of both drugs. The clinical trial, to be conducted at Duke University, is ready for initiation; clinical supplies have been prepared, a protocol has been written, and the IRB submission has been prepared.

The commencement of this clinical trial is subject to resolution of two deficiencies raised by the FDA in its recent clinical hold letter, as follows:

- The FDA cited a single incidence of mild necrosis in cardiac tissue from a rat in the highest dose group tested in a 4-week toxicology study. In that study, histopathology analysis was performed on the heart tissue only from rats that received placebo and the highest of three doses of CX1739. In its letter, the FDA requested that cardiac tissue from all animals in all dosage groups be analyzed. This analysis has been completed and, according to two independent, board-certified pathologists, there does not appear to be any drug-related histopathology and the original finding most likely was due to "progressive rodent cardiomyopathy", a syndrome commonly observed in this strain of rats.
- The FDA requested that the Company perform an additional study in which rats are to be given a single administration of three dosages of CX1739, followed by neuro-histopathology evaluation 1, 3 and 14 days after drug administration. In two previous studies, no neuropathology had been observed after 14 or 28 days of CX1739 administration at very high doses. The agreed upon single dose study has begun and is scheduled to be completed by year end.

The Company intends to utilize the data from the two studies described above to address and resolve, in early 2016, the two deficiencies raised by the FDA. Subsequent to such formal submission, if no further comments are received from the FDA, and subject to the availability of sufficient working capital resources, the Company expects to initiate the clinical trial at the Duke University Clinical Research Unit in the first quarter of 2016 or shortly thereafter, and to complete it in approximately four months, at an expected cost of approximately \$750,000.

The Company will consider expanding its 2016 clinical trial program based on the availability of additional working capital resources and the further development of the Company's clinical stage compounds.

### **Comments by the Company's President and Chief Executive Officer**

Dr. James S. J. Manuso, the Company's President, Chief Executive Officer and Vice Chairman of the Board of Directors commented, "We are extremely pleased with the progress that we have achieved on all fronts over the course of this past year. In 2016 we will continue to focus on the clinical and regulatory development of the Company's two proprietary platforms for addressing unmet needs in the sleep apnea and opioid-induced respiratory depression markets. In order to reflect our refined research efforts and clinical focus, we are rebranding Cortex Pharmaceuticals, Inc. as RespireRx Pharmaceuticals Inc."

### **Financing Matters**

Since August 28, 2015, the Company has raised \$1,194,710 in three closings of an offering of units priced at \$0.02103 per unit. Each unit was comprised of one share of the Company's common stock and a five-year warrant to purchase an additional two shares of common stock at a price of \$0.02103 per share. This financing is currently scheduled to conclude on or before December 31, 2015.



As of September 15, 2015, the maturity date of the notes in a previous note and warrant financing was extended to September 15, 2016. In order to effect the extension, the Company issued 8,903,684 additional warrants, exercisable at \$0.035 per share of common stock, to those note holders. Additionally, at that time, the Company extended the maturity date of the existing 16,557,142 warrants from that note and warrant offering until September 15, 2016.

### **Investor and Industry Conferences**

The Company presented at several investor and industry conferences in 2015. Most recently, the Company presented at the 14<sup>th</sup> Annual BioInvestor Conference in San Francisco, California on October 20, 2015. Prior to that, the Company presented at the Rodman & Renshaw 17<sup>th</sup> Annual Global Investment Conference, in New York City, on September 10, 2015, and at the New York BIO 25<sup>th</sup> Anniversary Conference in New York City, on May 4, 2015. The Company is currently scheduled to present at the Biotech Showcase 2016 in San Francisco, California on January 11, 2016. It is the Company's intention to present at similar conferences in 2016.

### **About RespireRx Pharmaceuticals Inc.**

The Company 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.

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 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 the Company 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 of earlier versions observed in animal models.

Additional information about the Company and the matters discussed herein can be obtained on the Company's web-site at [www.RespireRx.com](http://www.RespireRx.com) or in the Company's filings with the U.S. Securities and Exchange Commission on EDGAR at [www.sec.gov](http://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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