

# Cortex Pharmaceuticals, Inc. Files December 31, 2014 Annual Report on Form 10-K; Provides Update on Current Status and Activities

# Company Focusing on Strategic Initiatives Involving Respiratory Disorders

Glen Rock, N.J., April 6, 2015/Globe Newswire - Cortex Pharmaceuticals, Inc. (OTC: CORX) ("Cortex" or the "Company") is a leader in developing drugs for respiratory disorders, particularly sleep apneas and drug-induced respiratory depression.

#### **Corporate Overview**

With the timely filing of the Company's December 31, 2014 Annual Report on Form 10-K, Cortex has completed a transformation that began in March 2013, when a new Board of Directors and executive management team assumed control of the Company and initiated an out-of-bankruptcy restructuring and recapitalization. When the new Board of Directors and management assumed control, Cortex was insolvent, the prior Board of Directors had been considering liquidation through a filing under Chapter 7 of the U.S. Bankruptcy Code, the Company had essentially no ongoing operations and it was deficient in its periodic filings with the U. S. Securities and Exchange Commission ("SEC"). The Company had also lost its license agreement with the University of Illinois that granted it rights to patents claiming the use of dronabinol, a synthetic derivative of  $\Delta 9$ -THC,  $\Delta 9$ -tetrahydrocannabinol, the naturally occurring substance in the cannabis plant), for the treatment of respiratory disorders.

Due to the efforts of our new Board of Directors and management team, the Company has raised over \$1,500,000 of new equity and debt capital, reduced liabilities by over \$2,300,000 through various negotiated settlements, and is now current in its periodic SEC filings. In addition, the Company has entered into a new dronabinol license agreement with the University of Illinois, and the Company's newly-organized research group has developed and initiated a comprehensive clinical and pre-clinical research plan.

"The last twenty-four months have been a very dynamic period for the Company, one in which the Company has recovered from near-bankruptcy and is now poised to address the remaining issues to allow us to finish rebuilding the Company's operating infrastructure and research programs. In this regard, we are focusing our efforts on raising additional capital in the near-term to fund the Company's operations and clinical programs," commented Dr. Arnold S. Lippa, Ph.D., the Chairman and Chief Executive Officer of Cortex. "We believe that our efforts to date have now placed us on the threshold of being able to implement a substantial increase in the scope and depth of our research activities and clinical programs."

## **Research and Development Activities Overview**

Cortex is a biopharmaceutical company with a pipeline of compounds in Phase 2 clinical development focused on developing drug treatments for a variety of different breathing disorders. Clinical



development in the area of respiratory disorders, particularly drug-induced respiratory depression and sleep apnea, creates opportunities for the development and commercialization of our compounds. As a result of our scientific discoveries and the acquisition of strategic, exclusive license agreements, we believe we are now well-positioned to be a leader in the discovery and development of innovative pharmaceuticals for the treatment of respiratory disorders.

Recent key developments in the Company's ongoing research and development programs include:

- Entering into a new dronabinol license agreement with the University of Illinois, signed in June 2014, on terms substantially similar to those of the prior license agreement. This new license agreement gives the Company access to data from a potentially pivotal, six week, double blind, placebo controlled Phase 2B clinical trial in 120 patients with obstructive sleep apnea that is currently being conducted by the University of Illinois, with results expected sometime during the second half of 2015. This \$5 million study is fully funded by the National Institutes of Health.
- Expanding our research and development organization by hiring Richard Purcell as Senior Vice President and re-initiated clinical and pre-clinical operations.
- Appointing Dr. John Greer, Ph.D. as Chairman of our Scientific Advisory Board. Dr. Greer is the Director of the Neuroscience and Mental Health Institute of the University of Alberta and is the inventor of certain of the patents and patent applications licensed to the Company.
- Entering into a contract, in September 2014, with the National Institute on Drug Abuse (NIDA), a division of the National Institutes of Health, which resulted in an approximate \$150,000 Phase 1 grant under the Small Business Innovation Research Funding Program to study CX1942, our injectable ampakine, in animals as a potential rescue from drug induced respiratory depression.
- Developing plans for studying the ability of CX1739, our lead ampakine, to antagonize opiate and propofol induced respiratory depression in two Phase 2A clinical studies, pending additional financing.
- Developing preliminary plans for a Phase 2A study in patients with Pompe disease experiencing respiratory depression.

#### Financial Overview and Selected Financial Information

The Company is currently, and has for some time, been in financial distress.

The Company has incurred net losses of \$2,707,535 and \$1,201,457 for the years ended December 31, 2014 and 2013, respectively, negative operating cash flows of \$885,869 and \$182,435 for the years ended December 31, 2014 and 2013, respectively, and expects to continue to incur net losses and negative operating cash flows for several more years.

The Company incurred a net loss attributable to common stockholders of \$12,768,307 for the year ended December 31, 2014 (including adjustments related to the Series G 1.5% Convertible Preferred



Stock of \$10,060,772), reflecting a net loss per share of \$0.07, as compared to a net loss attributable to common stockholders of \$1,201,457 for the year ended December 31, 2013, reflecting a net loss per share of \$0.01.

At December 31, 2014, the Company had 232,145,326 shares of common stock outstanding, as compared to 144,041,556 shares of common stock outstanding at December 31, 2013. The conversion of all of the outstanding shares of Series G 1.5% Convertible Preferred Stock, inclusive of preferred dividends, at December 31, 2014 would have resulted in the issuance of an additional 264,464,990 shares of common stock, and the conversion of all of the 10% Convertible Notes and the exercise of all of the related warrants at December 31, 2014 would have resulted in the issuance of an additional 21,231,251 shares of common stock.

At December 31, 2014, the Company had a working capital deficit of \$2,280,035, as compared to a working capital deficit of \$4,188,424 at December 31, 2013, reflecting an increase in working capital of \$1,908,389 for the year ended December 31, 2014. At December 31, 2014, the Company had cash aggregating \$162,752, as compared to \$14,352 at December 31, 2013, reflecting an increase in cash of \$148,400 for the year ended December 31, 2014. The increase in cash during the year ended December 31, 2014 was primarily the result of the proceeds from the issuance of the Series G 1.5% Convertible Preferred Stock and the Convertible Note and Warrant Financing. The increase in working capital during the year ended December 31, 2014 was impacted by the increase in cash described above and the reduction in short-term liabilities resulting from the settlement agreements reached with four former executives, two former service providers and an obligation relating to a project advance.

The Company will need to continue to raise additional capital to be able to pay its obligations and fund its business activities going forward. As a result of the Company's current financial situation, the Company has limited access to external sources of debt and equity financing. Accordingly, there can be no assurances that the Company will be able to secure additional financing in the amounts necessary to fully fund its operating and debt service requirements. If the Company is unable to access sufficient cash resources on a timely basis, the Company may need to scale back its research and development efforts and could be forced to discontinue operations entirely.

Additional information with respect to the Company's financial condition, results of operations, cash flows, capital structure and other matters involving the business and operations of the Company is included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as filed with the SEC.

#### **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 in restoring 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 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 <a href="https://www.cortexpharm.com">www.cortexpharm.com</a> or in the Company's filings on EDGAR at <a href="https://www.sec.gov">www.sec.gov</a>.

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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