

CORTEX PHARMACEUTICALS INC/DE/
Form 8-K
July 01, 2014

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): June 27, 2014

CORTEX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

| | | |
|---|-------------------------------------|--|
| Delaware | 1-16467 | 33-0303583 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (I.R.S Employer Identification No.) |

126 Valley Road, Suite C

07452

Glen Rock, New Jersey

(Address of principal executive offices) (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 1.01 Entry into a Material Definitive Agreement.

On June 27, 2014, Cortex Pharmaceuticals, Inc. (the “Company”) entered into an Exclusive License Agreement (the “License Agreement”) with the Board of Trustees of the University of Illinois (the “University”), which shall become effective upon the completion of certain conditions set forth in the License Agreement including (i) the payment by the Company of a \$25,000 licensing fee, (ii) the payment by the Company of certain outstanding patent costs (not to exceed \$16,000), and (iii) the assignment to the University of certain rights the Company holds in certain patent applications. The Company expects the License Agreement to become effective within the next several weeks. In exchange for certain milestone and royalty payments, the License Agreement grants the Company (i) exclusive rights to several issued and pending patents in numerous jurisdictions and (ii) the non-exclusive right to certain technical information that is generated by the University in connection with certain clinical trials as specified in the License Agreement, all of which relate to the use of cannabinoids for the treatment of sleep related breathing disorders. The Company is developing dronabinol (D9-tetrahydrocannabinol), a cannabinoid, for the treatment of obstructive sleep apnea (OSA), the most common form of sleep apnea.

The Company previously conducted a 21 day, randomized, double-blind, placebo-controlled dose escalation Phase 2 clinical study in 22 patients with OSA, in which dronabinol produced a statistically significant reduction in the Apnea-Hypopnea Index (AHI), the primary therapeutic end-point, and was observed to be safe and well tolerated. Dronabinol is currently under investigation, at the University of Illinois and other centers, in a pivotal Phase 2 OSA clinical trial, fully funded by the National Institutes of Health.

Dronabinol is a Schedule III, controlled generic drug with a relatively low abuse potential that is approved by the FDA for the treatment of AIDS related anorexia and chemotherapy induced emesis. The use of dronabinol for the treatment of OSA is a novel indication for an already approved drug and, as such, would only require approval by the FDA of a supplemental new drug application (sNDA).

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the License Agreement, a copy of which is attached hereto as Exhibit 10.1 and is incorporated herein by reference.

Item 8.01 Other Events

On July 1, 2014, the Company issued a press release announcing its entry into the License Agreement. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

A list of exhibits required to be 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: July 1, 2014 CORTEX PHARMACEUTICALS, INC.

By: */s/ Arnold S. Lippa*
Arnold S. Lippa
President and Chief Executive Officer

EXHIBIT INDEX

| Exhibit Number | Exhibit Description |
|-----------------------|---|
| 10.1 | Exclusive License Agreement, dated as of June 27, 2014, by and between the Board of Trustees of the University of Illinois, a body corporate and politic of the State of Illinois, and Cortex Pharmaceuticals, Inc. |
| 99.1 | Press Release dated July 1, 2014. |

