

CORTEX PHARMACEUTICALS INC/DE/
Form 8-K
March 21, 2011

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): March 15, 2011

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
(IRS Employer
Identification No.)

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15241 Barranca Parkway, Irvine, California
(Address of principal executive offices)

92618
(Zip Code)

Registrant's telephone number, including area code:(949) 727-3157

N/A

(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.

(a) Asset Purchase from Biovail Laboratories International SRL

As previously reported on a Current Report on Form 8-K, in March 2010 Cortex Pharmaceuticals, Inc., a Delaware corporation (the Company), entered into an asset purchase agreement (the 2010 Agreement) with Biovail Laboratories International SRL, an international society with restricted liability organized under the laws of Barbados (Biovail). Pursuant to the 2010 Agreement, Biovail acquired the Company's interests in certain pharmaceutical compounds and related intellectual property (the Asset Sale) for use in the field of respiratory depression or vaso-occlusive crises associated with sickle cell disease (the Field). The assets acquired by Biovail in the Asset Sale included: (i) the Phase II compound CX717, the preclinical compounds CX1763 and CX1942, and the injectable dosage form of CX1739 (collectively, the primary AMPAKINE® compounds), (ii) certain other AMPAKINE® compounds, specifically, the molecules disclosed in, claimed in or otherwise covered by the patent families acquired pursuant to the 2010 Agreement (other than the primary AMPAKINE® compounds), which are being or may be developed, among other things, for use in the Field, and (iii) certain method of use patents and related assets (the Acquired Assets). In connection with the Asset Sale, Biovail agreed to assume certain liabilities and obligations of the Company related to the Acquired Assets. Pursuant to the terms of the 2010 Agreement, Biovail paid the Company the lump sum of \$9,000,000 upon the execution of the Agreement, and an additional \$1,000,000 upon the Company's completion of the specified transfer plan in September 2010. In addition, the 2010 Agreement provided that the Company would have the right to receive up to three milestone payments in an aggregate amount of up to \$15,000,000 plus the reimbursement of certain related expenses, each conditioned upon the occurrence of particular events relating to the clinical development of certain Acquired Assets.

In September 2010, Biovail's parent corporation, Biovail Corporation, combined with Valeant Pharmaceuticals International in a merger transaction and the combined company was renamed Valeant Pharmaceuticals International, Inc. (Valeant). Following the merger, Valeant and Biovail conducted a strategic and financial review of the product pipeline and, as a result, in November 2010, Biovail announced its intent to exit from the respiratory depression project acquired from the Company in March 2010. Following that announcement, the Company immediately entered into discussions with Biovail regarding the future of the respiratory depression project.

On March 15, 2011, the Company entered into a new asset purchase agreement with Biovail (the 2011 Agreement) to reacquire the Acquired Assets that Biovail acquired from the Company in March 2010. In connection with the transactions contemplated by the 2011 Agreement, the Company agreed to assume certain liabilities and obligations of Biovail related to the Acquired Assets. The 2011 Agreement includes an upfront payment by the Company of \$200,000 and potential future payments to Biovail of up to \$15,150,000 based upon the achievement of certain development and New Drug Application submission and approval milestones. Biovail is also eligible to receive additional payments of up to \$15,000,000 based upon the Company's net sales of an intravenous dosage form of the compounds for respiratory depression.

In addition, at any time following the completion of Phase I clinical studies and prior to the end of Phase IIa clinical studies, Biovail retains an option to co-develop and co-market intravenous dosage forms of an AMPAKINE compound as a treatment for respiratory depression and vaso-occlusive crises associated with sickle cell disease. In such an event, the Company would be reimbursed for certain development expenses to date and Biovail would share in all such future development costs with the Company. If Biovail makes the co-marketing election, the Company would owe no further milestone payments to Biovail and the Company would be eligible to receive a royalty on net sales of the compound by Biovail or its affiliates and licensees.

Effective March 15, 2011, the 2010 Agreement was terminated (with the exception of certain indemnification obligations) by the terms of the 2011 Agreement. Following the execution of the 2011 Agreement, Biovail was renamed Valeant International (Barbados) SRL.

On March 16, 2011, the Company issued a press release describing this transaction. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K.

The foregoing summary of the 2011 Agreement is qualified in its entirety by reference to such Agreement, a copy of which will be filed as an exhibit to the Company's Form 10-Q for the quarterly period ended March 31, 2011. The Company intends to submit a FOIA confidential treatment request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, requesting that it be permitted to redact certain portions of the 2011 Agreement. The omitted material will be included in the request for confidential treatment.

(b) Amendment to License Agreement with the Regents of the University of California

On March 15, 2011, the Company entered into a Fifth Amendment (the Amendment) to License Agreement between Cortex and the Regents of the University of California (the License Agreement) in order to, among other things, clarify the current scope of patent coverage of the License Agreement following the consummation of the transactions contemplated by the 2011 Agreement described above as well as to extend the required date for filing regulatory approval of an AMPAKINE compound covered by the License Agreement to October 11, 2015.

The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Amendment, a copy of which is attached hereto as Exhibit 10.121 and is incorporated herein by reference. The Amendment is not intended as a document for investors and the public to obtain factual information about the current state of affairs of the Company. Rather, investors and the public should look to other disclosures contained in the Company's reports filed with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934, as amended.

Item 1.02 Termination of a Material Definitive Agreement.

See the disclosure set forth in Item 1.01(a), which is incorporated by reference into this Item 1.02.

Item 2.01 Completion of Acquisition or Disposition of Assets.

See the disclosure set forth in Item 1.01(a), which is incorporated by reference into this Item 2.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| <i>Exhibit No.</i> | <i>Description</i> |
|--------------------|---|
| 10.121 | Fifth Amendment to the License Agreement between the Company and The Regents of the University of California, dated as of March 15, 2011. |
| 99.1 | Press Release dated March 16, 2011. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Current Report to be signed on its behalf by the undersigned, hereunto duly authorized.

CORTEX PHARMACEUTICALS, INC.

Dated: March 21, 2011

By: /s/ Maria S. Messinger
Maria S. Messinger, Vice President and Chief

Financial Officer

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EXHIBIT INDEX

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