
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):

October 26, 2011

ADVENTRX Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

001-32157

84-1318182

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(I.R.S. Employer
Identification No.)

12390 El Camino Real, Suite 150, San Diego,
California

92130

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

858-552-0866

Not Applicable

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 8.01 Other Events.

On October 26, 2011, ADVENTRX Pharmaceuticals, Inc. issued a press release announcing its meeting with the U.S. Food and Drug Administration regarding its clinical development plans for ANX-514 (docetaxel for injectable emulsion) and the outcome of that meeting. The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The list of exhibits called for by this Item is incorporated by reference to the Exhibit Index filed with this report.

SIGNATURES

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.

ADVENTRX Pharmaceuticals, Inc.

October 26, 2011

By: /s/ Patrick L. Keran

Name: Patrick L. Keran

Title: President and Chief Operating Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated October 26, 2011

ADVENTRX AND FDA REACH AGREEMENT ON PIVOTAL STUDY FOR ANX-514

- **Approved product will not require corticosteroid premedication**
- **Single study will support NDA submission as early as 2014**

SAN DIEGO (October 26, 2011) – ADVENTRX Pharmaceuticals, Inc. (NYSE Amex: ANX) announced today that it met with the U.S. Food and Drug Administration (FDA) to discuss a single clinical study to support approval of ANX-514 (docetaxel for injectable emulsion), a detergent-free reformulation of Taxotere (docetaxel).

ADVENTRX proposed a non-inferiority study (Study 514-02) with a primary objective of comparing fluid retention following treatment with ANX-514, administered without corticosteroid premedication, and Taxotere®, administered with corticosteroid premedication, which would enroll approximately 400 patients. The FDA agreed that the proposed study would generate sufficient clinical data to support approval of ANX-514 without requiring corticosteroid premedication.

Eric K. Rowinsky, M.D., principal clinical advisor to ADVENTRX, said, “Eliminating the high-dose corticosteroid premedication required with Taxotere would represent a significant benefit to cancer patients. Corticosteroids expose cancer patients to otherwise unnecessary and costly complications, such as hyperglycemia, immunosuppression and insomnia. ANX-514 has the potential to improve the tolerability and safety of docetaxel treatment while eliminating toxicities caused by the polysorbate 80 detergent and complications associated with the Taxotere premedication regimen.”

Brian M. Culley, Chief Executive Officer of ADVENTRX, said, “We are very pleased to have reached agreement with the FDA on a reasonable path to approval for ANX-514. Our focus is on initiating Study 514-02 as soon as possible and submitting an NDA in 2014.”

Mr. Culley continued: “The high-dose steroids required with Taxotere are problematic for all cancer patients, and in particular those who have diabetes or a predisposition to hyperglycemia, who we estimate constitute one-third of the patients who receive Taxotere.”

About Study 514-02

Study 514-02 will be a randomized, open-label, multicenter, non-inferiority study comparing ANX-514, administered without corticosteroid premedication, and Taxotere, administered with corticosteroid premedication, in the treatment of non-small cell lung cancer after failure of prior platinum-based therapy. Approximately 400 patients will be enrolled and treated until evidence of progressive disease, unacceptable toxicity, withdrawal of consent or other withdrawal criteria are met. The primary objective will be to compare the incidence of fluid retention between study arms. The secondary objectives will be to compare ANX-514 and Taxotere in terms of overall safety profile, objective response rate, duration of response, progression-free survival and overall survival.

About ADVENTRX Pharmaceuticals

ADVENTRX Pharmaceuticals is a specialty pharmaceutical company focused on developing proprietary product candidates. The Company’s current lead product candidates are ANX-188, a novel, purified, rheologic and antithrombotic compound initially being developed as a first-in-class treatment for pediatric patients with sickle cell disease in acute crisis, and ANX-514, a detergent-free formulation of the blockbuster drug Taxotere®, which recently went off-patent. The Company is seeking a partner or outside investor for its Exelbine program. More information can be found on the Company’s web site at www.adventrx.com.

Forward Looking Statements

ADVENTRX cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements that are based on ADVENTRX’s current expectations and assumptions. Such forward-looking statements include, but are not limited to, statements regarding the design for, and timing and feasibility of, Study 514-02, the timing of submission of an NDA for ANX-514, the prospects for ultimate approval of an NDA for ANX-514 without clinical studies in addition to Study 514-02, the prospects for elimination of the high-dose corticosteroid premedication required with Taxotere and the potential for ANX-514 to improve the tolerability and safety of docetaxel treatment. Actual events or results may differ materially from those expressed or implied by the forward-looking statements in this press release due to a number of risks and uncertainties, including, without limitation: the risk that ADVENTRX is unable to raise sufficient capital to fund development of its product candidates, including ANX-514; the risk that the primary endpoint in Study 514-02 is not met; the risk that, to demonstrate non-inferiority in Study 514-02, the rate of fluid retention in the ANX-514 arm must be lower than the rate in the Taxotere arm; uncertainty regarding the relative contribution of polysorbate 80 versus docetaxel or other factors on the incidence and severity of fluid retention and other adverse events; uncertainty regarding the impact of removing corticosteroid premedication from the ANX-514 arm on the incidence and severity of adverse events; the risk that, even if ANX-514 meets the primary endpoint in Study 514-02, it may not demonstrate comparable overall safety to Taxotere and, accordingly, may not be sufficient to support an NDA or eliminate corticosteroid premedication without additional clinical studies; the risk that the results of an additional bioequivalence study, if required by FDA, will cause the FDA to require additional nonclinical and/or clinical studies in addition to Study 514-02 prior to the submission or approval of an NDA for ANX-514; the risk that the FDA does not grant market approval of ANX-514 on a timely basis, or at all; the potential for difficulties or delays in completing manufacturing process development activities and manufacturing material for Study 514-02 and any other clinical studies; ADVENTRX’s reliance on third parties to assist in the conduct of important aspects of its product candidates’ development programs, including manufacture of clinical trial material, conduct of Study 514-02 and other clinical trials and regulatory submissions related to product approval, and that such third parties may fail to perform as expected; and other risks and uncertainties more fully described in ADVENTRX’s press releases and periodic filings with the Securities and Exchange Commission. ADVENTRX’s public filings with the Securities and Exchange Commission are available at www.sec.gov.

You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date when made. ADVENTRX does not intend to revise or update any forward-looking statement set forth in this press release to reflect events or circumstances arising after the date hereof, except as may be required by law.

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