
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):

September 30, 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 September 30, 2011, ADVENTRX Pharmaceuticals, Inc. (the "Company") issued a press release announcing the results of its meeting with the U.S. Food and Drug Administration (the "FDA") regarding the FDA's complete response letter to the Company's New Drug Application for Exelbine (vinorelbine injectable emulsion) for the treatment of non-small cell lung cancer. 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.

September 30, 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 September 30, 2011



ADVENTRX ANNOUNCES RESULTS OF FDA MEETING TO DISCUSS EXELBINE NDA

SAN DIEGO (September 30, 2011) – ADVENTRX Pharmaceuticals, Inc. (NYSE Amex: ANX) announced today that it held a Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss the complete response letter (CRL) it received in August from the FDA regarding the Company's New Drug Application (NDA) for Exelbine™ (vinorelbine injectable emulsion) for the treatment of non-small cell lung cancer. During the meeting, ADVENTRX discussed with FDA staff all of the items outlined in the CRL, including responses previously submitted by the Company to the FDA during the NDA review and information the Company believes demonstrates the authenticity of the study drugs used in the pivotal bioequivalence study of Exelbine (Study 530-01).

As previously announced, the CRL stated that the authenticity of the study drugs used in Study 530-01 could not be verified. During the meeting, FDA staff indicated that the clinical sites, which were selected in 2006 by a third-party contract research organization, failed to randomly select and retain reserve samples of the test article (Exelbine) and reference standard (Navelbine®) and this deficiency could not be overcome by alternative methods of verifying authenticity and reiterated that the bioequivalence study would need to be repeated.

Additionally, FDA staff commented that no clinical deficiencies were noted with Study 530-01 and that there were no comments regarding the Company's conclusion that Exelbine and Navelbine are bioequivalent based on Study 530-01 data.

"Although we are pleased with the Agency's assessment of the clinical data, we are disappointed it could not exercise discretion in our case to consider other methods of verifying the authenticity of the study drugs," stated Brian M. Culley, Chief Executive Officer of ADVENTRX. "The Agency's assessment of the clinical data gives us confidence that a repeat study would be successful and that Exelbine can be approved. However, although the third-party costs to conduct an additional bioequivalence study and to launch Exelbine are relatively modest, we believe our stockholders are best served by focusing our capital on ANX-188 and ANX-514, which reflect larger market opportunities, and we intend to seek a partner or outside investor for the Exelbine program."

"Our cash and equivalents of \$40.7 million at July 31, plus cost savings from discontinuing the Exelbine program, will provide us the capital to advance both our ANX-188 and ANX-514 programs into their respective pivotal clinical studies next year. Additionally, we have taken and will continue to take measures to ensure that our contractors have the qualifications and experience needed to bring new therapies successfully through pivotal studies and make them available to patients," Mr. Culley added.

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 ADVENTRX's beliefs that a single, additional bioequivalence study could support FDA approval of Exelbine and that the third-party costs of such a repeat study and to launch Exelbine are relatively minor, the extent to which ADVENTRX's cash position and cash savings from discontinuing its Exelbine program will enable it to advance its other development programs, and the qualifications, experience and performance of third parties that ADVENTRX engages to assist in the development of product candidates, including ANX-188 and ANX-514. 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 any future bioequivalence study of Exelbine and Navelbine fails to demonstrate the same clinical results as Study 530-01 or that, even if any such study does demonstrate substantially similar results, the FDA does not agree that it demonstrates Exelbine is bioequivalent to Navelbine; the risk that, in addition to an additional bioequivalence study, the FDA will impose other requirements, including further clinical studies, before or after approval of an Exelbine NDA; the potential that the costs of a repeat study and to launch Exelbine are significantly greater than ADVENTRX currently believes; the risk that the FDA does not grant market approval of Exelbine on a timely basis, or at all; the risk that ADVENTRX is not able to partner or obtain outside investment for its Exelbine program on satisfactory terms or on a timely basis or at all; the potential for difficulties or delays in reaching agreement with the FDA on the clinical development of ANX-188 and/or ANX-514; the potential for the FDA to require significant additional clinical and/or nonclinical studies of ANX-188 and/or ANX-514, in addition to ADVENTRX's planned pivotal studies for those product candidates, and that ADVENTRX consequently determines to discontinue one or more of those programs; the risk that ADVENTRX will pursue development activities at levels on timelines, or will incur unexpected expenses, that shorten the period through which its operating funds will sustain it; the risk that investor reaction to discontinuation of the Exelbine program will negatively impact ADVENTRX's ability to raise additional capital to fund development of ANX-188 and ANX-514; difficulties or delays in manufacturing material for clinical studies; ADVENTRX's reliance on third parties to assist in the conduct of important aspects of its product candidates' development programs, including the conduct of clinical trials, and that such third parties may fail to perform as expected; the potential for ADVENTRX to raise additional capital to acquire new technologies, product candidates or products and/or to fund development and/or commercialization activities for current and/or future product candidates; 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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