
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):

August 9, 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 August 9, 2011, ADVENTRX Pharmaceuticals, Inc. issued a press release announcing that it received a complete response letter from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) 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.

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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.

By: */s/ Patrick L. Keran*

Name: Patrick L. Keran
Title: President and Chief Operating Officer

August 10, 2011

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated August 9, 2011



ADVENTRX RECEIVES COMPLETE RESPONSE LETTER FOR EXELBINE NDA

- **Conference call scheduled for 8:30 a.m. Eastern time Wednesday, August 10**

SAN DIEGO (August 9, 2011) – ADVENTRX Pharmaceuticals, Inc. (NYSE Amex: ANX) announced today that it received a complete response letter from the U.S. Food and Drug Administration (FDA) regarding the Company's New Drug Application (NDA) for Exelbine™ (vinorelbine injectable emulsion) for the treatment of non-small cell lung cancer.

The FDA determined that it could not approve the Exelbine NDA in its present form. In particular, the complete response letter noted that, based on inspections at clinical sites, the authenticity of the drug products used in the pivotal bioequivalence trial (Study 530-01) could not be verified, which placed the results of the trial into question. The letter stated that the bioequivalence trial will need to be repeated to address this deficiency.

In addition, the FDA requested information regarding product quality, or CMC matters. All CMC information requests in the complete response letter were the subject of FDA inquiries from earlier in the review cycle, and the Company had submitted responses to each request prior to receipt of the complete response letter.

"We are disappointed with the FDA's determination and, next week, plan to request a type A meeting to discuss its response. Following that meeting, we will be in a better position to comment on the future of our Exelbine program. However, we believe the authenticity of the drug products used in the pivotal study is verifiable and plan to discuss FDA's concerns in this regard. We also will inquire whether FDA has comments to our previously submitted responses," said Brian M. Culley, Chief Executive Officer of ADVENTRX.

"In the meantime, our resources and focus are on ANX-188 and ANX-514, which we believe are the long-term value drivers for our company. Our cash and equivalents of \$40.7 million at July 31, plus cost savings from delaying or potentially discontinuing the Exelbine program, will provide us the capital to continue to advance both of these programs," Mr. Culley added.

The Company believes that FDA's concern over drug product authenticity stems from the procedures used to select testing and reserve samples in Study 530-01 and the availability of testing and reserve samples for inspection. The Company believes the procedures used to select testing and reserve samples in Study 530-01 were adequate to verify the authenticity of the drug products. Of note, Exelbine and the reference product come in different package presentations, require different preparation procedures and have different physical characteristics. Based on the different characteristics between the study drugs, the Company believes it is unlikely that study sites would confuse the two study drugs or fail to recognize which drug was being administered to a patient.

Conference Call and Webcast

ADVENTRX will hold a conference call on Wednesday, August 10, 2011 beginning at 8:30 a.m. Eastern time to review the developments discussed in this news release and answer questions. Individuals interested in listening to the conference call may do so by dialing (800) 860-2442 for domestic callers, (412) 858-4600 for international callers and requesting the ADVENTRX Pharmaceuticals Update Call, or, from the webcast on the investor relations section of the Company's Web site at www.adventrx.com. A telephone replay will be available for five days approximately one hour after the conclusion of the call by dialing (877) 344-7529 for domestic callers, or (412) 317-0088 for international callers, and entering conference number 10003222. The webcast will be available on the Company's Web site for 30 days following the completion of the call.

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 reformulation of the blockbuster drug Taxotere®, which recently went off-patent. The Company is evaluating its Exelbine program following the complete response letter it received from the FDA. 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 belief that the authenticity of the drug products used in Study 530-01 is verifiable; the adequacy of ADVENTRX's responses to FDA requests; whether ANX-188 and/or ANX-514 will be the long-term value drivers for ADVENTRX; the basis for the complete response letter; whether ADVENTRX will delay or discontinue its Exelbine program and related cost savings; and whether its cash at July 31, 2011, with or without cost savings from delaying or discontinuing its Exelbine program, will provide the capital to advance 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 the procedures used to select testing and reserves samples in Study 530-01 are not adequate to verify the

authenticity of the drug products used in Study 530-01; the risk that ADVENTRX will not continue to seek approval of the Exelbine NDA; the risk that ADVENTRX's previously submitted responses to FDA requests are not satisfactory to FDA; the risk that ADVENTRX cannot satisfy future FDA requests, or future comments to prior requests; the risk that, should ADVENTRX continue to seek approval of the Exelbine NDA, the FDA will impose requirements to be completed before or after any such approval; 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; investor reaction to the complete response letter and its impact on the ability of ADVENTRX to raise additional capital to fund development of ANX-188 and ANX-514, and/or Exelbine; difficulties or delays in reaching agreement with the FDA on the clinical development of ANX-188 and ANX-514; the potential for the FDA to require significant additional clinical and/or nonclinical studies of ADVENTRX's lead product candidates, in addition to its planned clinical trials of ANX-188 and ANX-514, and that ADVENTRX consequently determines to discontinue one or more of those development programs; 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, 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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