# 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): January 4, 2010

# **ADVENTRX Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware** (State or Other Jurisdiction of Incorporation) **001-32157** (Commission File No.)

**84-1318182** (IRS Employer Identification No.)

6725 Mesa Ridge Road, Suite 100 San Diego, CA 92121

(Address of Principal Executive Offices and Zip Code)

N/A

(Former name or former address if changed since last report)

Registrant's telephone number, including area code: (858) 552-0866

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)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

### Item 8.01. Other Events.

On January 4, 2010, ADVENTRX Pharmaceuticals, Inc. issued a press release announcing that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its product candidate ANX-530 (vinorelbine injectable emulsion). 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.

#### **SIGNATURE**

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: Vice President, Legal

# INDEX TO EXHIBITS

99.1 Press release, dated January 4, 2010

Dated: January 4, 2010



#### ADVENTRX PHARMACEUTICALS SUBMITS ANX-530 NEW DRUG APPLICATION

**SAN DIEGO (January 4, 2010)** – ADVENTRX Pharmaceuticals, Inc. (NYSE Amex: ANX) announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its product candidate ANX-530 (vinorelbine injectable emulsion).

"I congratulate our development team for achieving this important milestone on schedule in December, as planned. ANX-530 has the potential to offer important benefits to cancer patients, and we look forward to working with FDA towards its approval," said Brian M. Culley, Principal Executive Officer of ADVENTRX. "The ANX-530 NDA submission is a key step in our strategy to create valuable products that improve the performance of currently approved drugs."

The Company is seeking approval of ANX-530 for the same indications as Navelbine®, a branded formulation of vinorelbine, including non-small cell lung cancer. ADVENTRX submitted the NDA as a 505(b)(2) application, which relies in part on the FDA's findings of safety and effectiveness of a reference drug. The Company's 505(b)(2) NDA submission includes data from one clinical bioequivalence study designed to assess the pharmacokinetic equivalence of ANX 530 and Navelbine, the reference drug.

ANX-530 is ADVENTRX's proprietary emulsion formulation of vinorelbine. Vinorelbine is a vesicant and venous irritant, and these adverse effects can limit its tolerability. ANX-530 was designed to be bioequivalent to the reference drug while reducing the incidence and severity of vein irritation associated with intravenous delivery of the drug. In a clinical bioequivalence study, ANX 530 and the reference drug were determined to be bioequivalent.

ADVENTRX acquired ANX-530 in 2006 and retains exclusive worldwide rights to ANX-530, other than in China, Hong Kong, Macau and Taiwan.

#### **About ADVENTRX Pharmaceuticals**

ADVENTRX Pharmaceuticals is a specialty pharmaceutical company whose product candidates are designed to improve the performance of existing cancer treatments by addressing limitations associated principally with their safety and use. More information can be found on the Company's web site at <a href="https://www.adventrx.com">www.adventrx.com</a>.

#### **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 involve risks and assumptions that, if they materialize or do not prove to be accurate, could cause ADVENTRX's results to differ materially from historical results or those expressed or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: ADVENTRX's dependence on the success of ANX-530, and uncertainty as to whether ANX-530 will receive regulatory approval or be commercialized successfully; the potential that FDA may not accept the ANX-530 NDA for review, or that the bioequivalence data and other information included in the ANX-530 NDA may not adequately support bioequivalence with Navelbine, including as a result of performing pharmacokinetic equivalence analyses based on a patient population other than the population on which ADVENTRX based its analysis; the potential that changes made in transferring the manufacturing process for ANX-530 may result in a lack of comparability between the commercial product and the material used in clinical trials, and that FDA may require ADVENTRX to perform additional non-clinical or clinical studies; the potential for FDA to impose other requirements to

be completed before or after approval of the ANX-530 NDA; ADVENTRX's reliance on third parties to assist with its bioequivalence trials, regulatory submissions, manufacturing and other important aspects of the ANX-530 development program, and the risk that FDA approval may be delayed if their performance is found to have been substandard; the possibility that patent claims covering ANX-530 will not issue or, if they do, that such claims, which likely will be limited to a specific intravenous emulsion formulation of vinorelbine, will not be sufficient to preclude development of other formulations of vinorelbine by competitors; the risk of investigator bias in reporting adverse events as a result of the open-label nature of the ANX-530 bioequivalence study, including bias that increased the reporting of adverse events associated with Navelbine and/or that decreased the reporting of adverse events associated with ANX-530; the risk that ADVENTRX will have insufficient capital to support its operations during the FDA review of the ANX-530 NDA, including as a result of FDA requesting or ADVENTRX providing additional information or clarification with respect to such submission or the FDA not completing its review by the ANX-530 "PDUFA date;" the risk that ADVENTRX will pursue development activities at levels or on timelines, or will incur unexpected expenses, that shortens the period through which its operating funds will sustain it; the risk that ADVENTRX will be unable to raise sufficient additional capital to commercialize ANX-530, if the ANX-530 NDA is approved; and other risks and uncertainties more fully described in ADVENTRX's press releases and periodic filings with the Securities and Exchange Commission are available at <a href="https://www.sec.gov">www.sec.gov</a>.

You are cautioned not to place undue reliance on these 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 on which it was made.

Company Contact: ADVENTRX Pharmaceuticals Brian Culley, Principal Executive Officer 858-552-0866 Investor Contact: Lippert/Heilshorn & Associates, Inc. Don Markley (dmarkley@lhai.com) 310-691-7100

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