



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 14, 2008

**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**

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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 January 14, 2008, ADVENTRX Pharmaceuticals, Inc. issued a press release announcing safety results from its marketing-enabling bioequivalence clinical study of ANX-530 (vinorelbine emulsion) and that it intends to submit to the U.S. Food and Drug Administration (FDA) a Section 505(b)(2) New Drug Application (NDA) for ANX-530 in the fourth quarter of 2008, as well as hold a pre-NDA meeting with the FDA in the second quarter of 2008. 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 Index to Exhibits filed with this report.

#### Forward-Looking Statements

Certain statements in this Form 8-K and the attached press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the safety of ANX-530 and the timeframe in which it intends to submit to the FDA a Section 505(b)(2) NDA for ANX-530. Actual events or results may differ materially from our expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to: the risk of investigator bias in reporting adverse events as a result of the study's open-label nature, 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 the FDA will determine that ANX-530 and Navelbine are not bioequivalent, including as a result of performing pharmacokinetic equivalence analysis based a patient population other than the population on which ADVENTRX based its analysis; difficulties or delays in manufacturing, marketing and obtaining regulatory approval for ANX-530, including validating commercial manufacturers and suppliers and the potential for automatic injunctions regarding FDA approval of ANX-530 and other challenges by patent holders during the Section 505(b)(2) process; the risk that ADVENTRX will be unable to raise sufficient capital to fund the projects necessary to meet its goals, including funding the continued development and commercialization of ANX-530; the potential for regulatory authorities to require additional preclinical work or other clinical requirements to support regulatory filings; patent and non-patent exclusivity covering Navelbine; ADVENTRX's lack of long-term agreements with suppliers of ANX-530 components and contract manufacturers of ANX-530, including its inability to timely secure commercial quantities of ANX-530 or its components on commercially reasonable terms, or at all; uncertainty under Section 505(b)(2) resulting from legal action against the FDA and the potential that future interpretations of Section 505(b)(2) could delay or prevent the FDA from approving any Section 505(b)(2) NDA; 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 <http://www.sec.gov>.

You are cautioned not to place undue reliance on these forward-looking statements, which speak

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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.

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**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.**

Dated: January 14, 2008

By: /s/ Evan M. Levine

Name: Evan M. Levine

Title: Chief Executive Officer

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99.1 Press release, dated January 14, 2008

**ADVENTRX ANNOUNCES ANX-530 SAFETY DATA AND PROVIDES NDA SUBMISSION GUIDANCE*****ANX-530 Demonstrates Statistically Significant Reduction in Injection Site Reactions***

**SAN DIEGO – January 14, 2008-** ADVENTRX Pharmaceuticals, Inc. (Amex: ANX) today announced safety results from its marketing-enabling bioequivalence clinical study of ANX-530 (vinorelbine emulsion). ANX-530 demonstrated a statistically significant reduction in injection site reactions when compared to Navelbine® ( $p < 0.05$ ). The incidence of injection site reactions attributed to Navelbine was consistent with its product label. Furthermore, ANX-530 was determined to be safe and well-tolerated with no significant differences observed in any other safety parameters. In November 2007, ADVENTRX announced that it met the primary endpoint in this study, with pharmacokinetic equivalence observed between ANX-530 and Navelbine. Full results from this study have been submitted for presentation at an upcoming oncology conference.

ADVENTRX also announced that it intends to submit to the U.S. Food and Drug Administration (FDA) a Section 505(b)(2) New Drug Application (NDA) for ANX-530 in the fourth quarter of 2008. In December 2007, ADVENTRX met with the FDA to discuss its commercial manufacturing plans for ANX-530. The Company reached agreement with the FDA regarding commercial manufacturing requirements for ANX-530, as well as requisites for the Chemistry Manufacturing and Controls (CMC) section of the NDA. As a follow up, ADVENTRX anticipates holding a pre-NDA meeting with the FDA in the second quarter of 2008.

“We are extremely encouraged by these data, and pleased that our goal to improve the safety of vinorelbine was observed in the clinic. Particularly compelling is that even in a small study we were able to observe a statistical difference in injection site reactions,” stated Evan M. Levine, chief executive officer of ADVENTRX. “We are excited by the continued progress of ANX-530 and look forward to our NDA submission later this year.”

ANX-530 is a novel emulsion formulation of vinorelbine. Vinorelbine, marketed under the brand name Navelbine and available in generic versions, is an anti-cancer agent approved to treat advanced non-small cell lung cancer as a single agent or in combination with cisplatin. Worldwide sales of Navelbine and generic vinorelbine in 2006 were in excess of \$200 million.

The bioequivalence study of ANX-530 was an open-label crossover comparison of ANX-530 and Navelbine in 31 patients, with a primary objective of demonstrating the pharmacokinetic equivalence of ANX-530 and Navelbine. Determining the safety of a single dose of ANX-530 was a secondary objective. In the first week, patients were dosed with either ANX-530 or Navelbine, and after a washout period, were dosed with the opposite drug during the second week of treatment. The FDA has indicated that this single clinical study, should it demonstrate pharmacokinetic equivalence between ANX-530 and Navelbine, would provide sufficient clinical data to support a Section 505(b)(2) NDA.

Adverse events in the study were analyzed by logistic regression models with factors for treatment (ANX-530 vs. Navelbine), phase (days 1-7 vs. days 8-14), sequence (ANX-530 followed by Navelbine vs. Navelbine followed by ANX-530) and subject within a sequence. The most common adverse events were neutropenia, leucopenia, injection site phlebitis, and constipation. Injection site reactions were the only adverse events that were statistically different between the control arm and the study arm.

**About ANX-530 (vinorelbine emulsion)**

ANX-530 is designed to reduce the incidence and severity of injection site reaction from intravenous-delivery of vinorelbine tartrate. Vinorelbine tartrate works by disrupting microtubule formation and is a member of the vinca alkaloid class of antineoplastic agents. Vinorelbine is indicated as a single agent or in combination with cisplatin for treatment of advanced non-small cell lung cancer and has also shown activity in breast, ovarian, and other cancers.

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## **About Section 505(b)(2)**

Section 505(b)(2) of the U.S. Food, Drug & Cosmetic Act (FDCA) allows the FDA to approve a follow-on drug on the basis of data in the scientific literature or conclusions regarding safety or effectiveness made by the FDA in the approval of other drugs. This regulatory pathway potentially makes it easier for drug manufacturers to obtain rapid approval of new forms of drugs based on the FDA's approval of the original drug. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs that have a new dosage form, strength, route of administration, formulation or indication. Upon approval, a drug may be marketed only for the FDA-approved indications in the approved dosage forms. Further clinical trials are necessary to gain approval for the use of the product for any additional indications or dosage forms. To the extent a Section 505(b)(2) applicant is relying on the FDA's findings for an already-approved drug, the applicant is required to certify to the FDA concerning any patents listed for the approved drug in the FDA's Orange Book publication, which may include a certification that listed patents are invalid or will not be infringed by the manufacture, use or sale of the new drug.

## **About ADVENTRX Pharmaceuticals**

ADVENTRX Pharmaceuticals is a biopharmaceutical research and development company focused on commercializing proprietary product candidates for the treatment of cancer and infectious diseases. The Company seeks to improve the performance and safety of existing treatments by addressing significant problems such as drug metabolism, bioavailability, excessive toxicity and treatment resistance. More information can be found on the Company's web site at <http://www.adventrx.com>.

## **Forward Looking Statement**

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: the risk of investigator bias in reporting adverse events as a result of the study's open-label nature, 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 the FDA will determine that ANX-530 and Navelbine are not bioequivalent, including as a result of performing pharmacokinetic equivalence analysis based a patient population other than the population on which ADVENTRX based its analysis; difficulties or delays in manufacturing, marketing and obtaining regulatory approval for ANX-530, including validating commercial manufacturers and suppliers and the potential for automatic injunctions regarding FDA approval of ANX-530 and other challenges by patent holders during the Section 505(b)(2) process; the risk that ADVENTRX will be unable to raise sufficient capital to fund the projects necessary to meet its goals, including funding the continued development and commercialization of ANX-530; the potential for regulatory authorities to require additional preclinical work or other clinical requirements to support regulatory filings; patent and non-patent exclusivity covering Navelbine; ADVENTRX's lack of long-term agreements with suppliers of ANX-530 components and contract manufacturers of ANX-530, including its inability to timely secure commercial quantities of ANX-530 or its components on commercially reasonable terms, or at all; uncertainty under Section 505(b)(2) resulting from legal action against the FDA and the potential that future interpretations of Section 505(b)(2) could delay or prevent the FDA from approving any Section 505(b)(2) NDA; 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 <http://www.sec.gov>.

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.

## **Investor Contact:**

### **ADVENTRX Pharmaceuticals**

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858-552-0866

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