



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 3, 2005

**ADVENTRX Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**001-32157**

(Commission File Number)

**84-1318182**

(IRS Employer Identification No.)

**6725 Mesa Ridge Road, Suite 100  
San Diego, California 92121**

(Address of principal executive offices) (Zip Code)

**(858) 552-0866**

(Company's telephone number, including area code)

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 1.01 Entry into A Definitive Material Agreement

The Company and SD Pharmaceuticals, Inc. ("SD Pharma") entered into a License Agreement effective April 29, 2005 (the "License Agreement"). Pursuant to the terms of the License Agreement, SD Pharma granted to the Company an exclusive license under certain patent rights and other intellectual property rights to make, use, sell, offer for sale or import any vinca alkaloid drug composition or product (a "Licensed Product") that is covered by the intellectual property rights licensed under the License Agreement within the United States of America. The License Agreement can be terminated by the Company with 30-days' written notice to SD Pharma.

Subsequent to entering into the License Agreement, the Company evaluated the prospects of developing a Licensed Product for commercial use, including conducting pre-clinical tests and evaluating the feasibility of manufacturing Licensed Products. After conducting this evaluation, the Company corresponded with the United States Food and Drug Administration ("FDA") with respect to the prospects of developing a Licensed Product. On October 3, 2005, the Company received confirmation from the FDA that the FDA would hold a pre-IND (Investigational New Drug) meeting with the Company with respect to the Company's proposed development of a Licensed Product, referred to as ANX-530, and the clinical trial design for ANX-530. The Company is currently scheduled to meet with the FDA in December 2005.

Because the FDA has agreed to meet with the Company with respect to the Company's proposed development of ANX-530 and the clinical trial design for ANX-530, the Company has determined that it may in the future reasonably expend significant resources to develop ANX-530. As a result, the Company believes that as of October 3, 2005, the License Agreement may be deemed a "material definitive agreement" for purposes of Form 8-K.

The Company is obligated pursuant to the License Agreement to pay to SD Pharma various set milestone payments and, if Licensed Products are ultimately developed and approved for commercial sale, royalty payments on net sales of vinca alkaloid drug compositions or products that are covered by the intellectual property rights. The License Agreement also provides that the Company pay to SD Pharma a percentage of any fee the Company may receive from sublicensing the Company's rights under the License Agreement. In addition, the Company is obligated under the License Agreement to reimburse SD Pharma for certain patent prosecution fees related to the intellectual property rights licensed under the License Agreement.

### Item 8.01. Other Events.

On October 4, 2005, the Company announced it had acquired rights to an oncology drug through an exclusive license agreement with SD Pharma.

The press release issued by the Company on October 4, 2005 with respect to this matter is included with this report as an exhibit.

### Item 9.01. Financial Statements and Exhibits.

(99) (c) The exhibit list required by this item is incorporated by reference to the Exhibit Index filed as part of 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/ Carrie E. Carlander

**Name:** Carrie E. Carlander

**Title:** Chief Financial Officer, Vice President Finance, and  
Treasurer

October 7, 2005

**EXHIBIT INDEX**

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release of the Company dated October 4, 2005.

## ADVENTRX ACQUIRES ADDITIONAL ONCOLOGY DRUG THROUGH EXCLUSIVE LICENSE AGREEMENT

SAN DIEGO--(BUSINESS WIRE)--Oct. 4, 2005--ADVENTRX Pharmaceuticals, Inc. (AMEX:ANX - News) and privately held SD Pharmaceuticals Inc. (SD Pharma) today announced SD Pharma's grant to ADVENTRX of an exclusive license of certain rights to ANX-530, a novel emulsion formulation of vinorelbine tartrate. In preclinical testing, ANX-530 demonstrated markedly reduced vein irritation following repeated IV injections compared with Navelbine(R), GlaxoSmithKline's U.S. Food and Drug Administration (FDA)-approved form of vinorelbine. Severe phlebitis is a known complication of standard vinorelbine therapy. Vinorelbine is currently used as a monotherapy or in combination with other chemotherapeutic agents for the treatment of non-small-cell lung, breast, ovarian and other cancers.

ADVENTRX currently plans to pursue a 505(b)(2) regulatory path for ANX-530 and has initiated discussions with the FDA for the clinical trial design. The Company is preparing for its pre-Investigational New Drug (IND) meeting with the FDA scheduled for December 2005.

Section 505(b)(2) of the U.S. Food, Drug & Cosmetic Act allows the FDA to approve a follow-on drug on the basis of data in the scientific literature or data used by the FDA in the approval of other drugs. This procedure potentially makes it easier for drug manufacturers to obtain rapid approval of new forms of drugs based on proprietary data of the original drug manufacturer.

"We view the development of this novel formulation of vinorelbine as a valuable improvement in a well-established cancer therapy," said Brian M. Culley, vice president of business development for ADVENTRX. "Furthermore, ANX-530 is an excellent fit with our strategy to broaden our product pipeline and to commercialize treatments that improve upon the safety and performance of currently marketed therapies."

"We recognized a significant advantage in developing vinorelbine in a delivery vehicle that prevents direct contact with cells lining the vein as a means of reducing tissue damage at the injection site in patients suffering from cancer," said Paul J. Marangos, Ph.D., chairman and CEO of SD Pharma. "I am confident in ADVENTRX's ability to efficiently advance this compound through the regulatory process."

Vinorelbine works by disrupting microtubule formation and is a member of the class of antineoplastic drugs known as vinca alkaloids, agents that inhibit cellular replication and ultimately cause cellular death. Vinorelbine and other drugs in the vinca alkaloid category are classified as vesicants and may cause severe injection site reactions. Vinorelbine can cause both irritant and vesicant types of injection site reactions. Irritants cause an acute and limited irritation to the vein while vesicants cause an injection site reaction. Studies have shown injection site reactions, including erythema, pain at injection site, and vein discoloration, occur in approximately one-third of non-small-cell lung cancer (NSCLC) patients treated with vinorelbine.

The license agreement between ADVENTRX and SD Pharma grants ADVENTRX exclusive U.S. rights to ANX-530 and all future intellectual property related to vinca alkaloid formulations, including compositions for delivering highly water-soluble drugs such as vinca alkaloids and methods of using such compositions.

According to the American Cancer Society, approximately 80% of the more than 173,000 Americans diagnosed with lung cancer each year have NSCLC. Lung cancer is the leading cause of cancer death and more than 160,000 people in the U.S. will die each year from the disease. Breast cancer is the most common non-skin cancer and second leading cause of cancer-related death in women with more than 200,000 new cases diagnosed in the U.S. annually. Additionally, each year there are more than 20,000 new cases of ovarian cancer diagnosed and more than 16,000 deaths from the disease.

## About ADVENTRX

ADVENTRX Pharmaceuticals is a biopharmaceutical research and development company focused on introducing new technologies for anticancer and antiviral treatments that improve the performance and safety of

existing drugs by addressing significant problems such as drug metabolism, toxicity, bioavailability, and resistance. The Company's lead compound, CoFactor, is a biomodulator of 5-fluorouracil (5-FU), a widely used cancer chemotherapy. CoFactor is currently being tested with 5-FU in a U.S.-based Phase II and an EU-based Phase IIB clinical trial as a first-line treatment of metastatic colorectal cancer. In addition, CoFactor has received clearance under a special protocol assessment from the FDA to begin a Phase III pivotal clinical trial for metastatic colorectal cancer. More information can be found on the Company's Web site at [www.adventrx.com](http://www.adventrx.com).

#### About SD Pharmaceuticals Inc.

SD Pharmaceuticals Inc. is a privately-held formulation innovation company that targets approved drugs that display formulation-related safety and efficacy constraints sufficient to warrant Black Box safety warnings with the goal of improving these parameters through novel reformulation technology. The Company has a portfolio of patent-protected reformulated cancer and infectious disease drugs that it believes can be developed utilizing the 505(b)2 regulatory path. Further information can be found at [www.sdpharma.com](http://www.sdpharma.com).

#### Forward-Looking Statements Regarding ADVENTRX

This press release contains forward-looking statements, within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, regarding ADVENTRX. Such statements are made based on management's current expectations and beliefs. Actual results may vary from those currently anticipated based upon a number of factors, including uncertainties inherent in the drug development process, the timing and success of clinical trials, the validity of research results, and the receipt of necessary approvals from the FDA and other regulatory agencies. For a discussion of such risks and uncertainties, which could cause actual results to differ from those contained in the forward-looking statements regarding ADVENTRX, see the section titled "Risk Factors" in ADVENTRX's last quarterly report on Form 10-Q, as well as other reports that ADVENTRX files from time to time with the Securities and Exchange Commission. All forward-looking statements regarding ADVENTRX are qualified in their entirety by this cautionary statement. ADVENTRX undertakes no obligation to release publicly any revisions, which may be made to reflect events or circumstances after the date hereof.

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