

ADVENTRX PHARMACEUTICALS INC
Form 8-K
January 07, 2011

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 6, 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.

ADVENTRX Pharmaceuticals, Inc. ("ADVENTRX") has signed a term sheet to acquire a private company that holds certain rights and know-how to poloxamer-based therapeutics. The term sheet is non-binding on both ADVENTRX and the target company.

The target company's lead product candidate, or the TPC, is a purified form of a nonionic block copolymer surfactant that is believed to adhere to hydrophobic surfaces that develop when cells are damaged. The TPC is designed to restore hydration lattices and minimize the cascade of adhesive, inflammatory and coagulation responses that cause adhesion of cells, impaired blood flow and tissue ischemia. Improving blood flow in the microvasculature may benefit patients with sickle cell disease in acute crisis, which is associated with microvascular occlusion. A phase 3 study in this indication previously was initiated by a prior sponsor of the TPC, but was discontinued primarily due to inadequate capital being available to continue.

Current discussions with the target company contemplate an all-stock acquisition by merger. Other than an upfront issuance of approximately 19% of ADVENTRX's currently outstanding common stock (of which only 6.5% would be fully-vested upon issuance and 12.5% would vest subject to successfully attaining the initial development milestone), the acquisition consideration would be issued based on the TPC successfully attaining development milestones, such as first patient dosing in a pivotal trial, acceptance by the FDA of a New Drug Application, or NDA, for the TPC and NDA approval. Based on current discussions, of the total acquisition consideration that could be paid, approximately 71% is tied to NDA acceptance and NDA approval. If all development milestones are achieved, including NDA approval, stockholders of the target company would own approximately 47% of ADVENTRX (based on ADVENTRX's currently outstanding shares of common stock but including the shares issued to the target company's stockholders). If ADVENTRX's stockholders do not approve the issuance of shares beyond the upfront issuance, as required by NYSE Amex listing standards, ADVENTRX expects to pay the target company's stockholders in cash the value of the shares it otherwise would have issued in excess of the 19% upfront issuance described above, with the NDA acceptance and NDA approval milestone payments payable based on net sales of the TPC and all milestone payments payable in quarterly installments. The target company has no employees, but in connection with a transaction ADVENTRX expects to retain the services of certain members of the target company's management team who have been involved in the development of the TPC.

If a transaction is consummated, ADVENTRX expects to conduct a phase 3 clinical trial of the TPC for the treatment of sickle cell crisis. Prior to initiating this study, ADVENTRX would discuss the design and analytical methodologies of the study with the FDA. Based on its evaluation to-date, ADVENTRX believes the out-of-pocket cost to submit an NDA covering the TPC would be approximately \$15 million to \$25 million over 3 years. ADVENTRX expects to agree to commit approximately \$1.5 million to conduct particular activities during the first 12 months following consummation of the acquisition. The principal source of market exclusivity for the TPC for the sickle cell disease indication is expected to be based on orphan drug exclusivity. The FDA has granted an orphan drug designation for the TPC for the treatment of sickle cell crisis.

The foregoing is based on ADVENTRX's current discussions with the target company. There is no guarantee that definitive agreements will be entered into or that ADVENTRX will consummate a transaction with the target company or that any transaction ADVENTRX ultimately may consummate will be on the terms described above.

Forward Looking Statements

ADVENTRX cautions you that statements included in this current report 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 the terms and conditions of an acquisition transaction with the target company, retaining services of members of the target company's management team following the transaction, use of the TPC to treat patients with sickle cell disease in acute crisis, initiation of a phase 3 clinical trial of the TPC for the treatment of sickle cell crisis, the amount and timing of out-of-pocket cost to ADVENTRX to submit an NDA covering the TPC, and orphan drug designation for the TPC for the treatment of sickle cell crisis. Actual events or results may differ materially from those expressed or implied by the forward-looking statements in this current report due to a number of risks and uncertainties, including, without limitation: the risk that ADVENTRX does not enter into definitive agreements or consummate a transaction with the target company on a timely basis, or at all; the potential for the definitive agreements, if any, to reflect terms and conditions that are materially different from the terms described in this current report; the risk that ADVENTRX may

not be able to integrate the target company successfully into its operations or that it may incur unexpected costs and disruptions to its business as a result of such integration; the potential for the FDA to require ADVENTRX to perform additional nonclinical, or clinical studies prior to initiating or following completion of the currently contemplated phase 3 clinical trial of the TPC for the treatment of sickle cell crisis; the risk that subsequent nonclinical or clinical study results do not support the safety and efficacy or the commercial viability of the TPC or any other product candidate developed using technology acquired from the target company; the risk that the neither the FDA nor any other regulatory agency approves a product based on the TPC or any other product candidate developed using technology acquired from the target company on a timely basis, or at all; the potential for the out-of-pocket cost to ADVENTRX and the time required for development of the TPC necessary to support an NDA submission are greater than ADVENTRX's current expectations; the risk that the TPC loses its orphan drug designation for the treatment of sickle cell crisis or that a third party's product candidate is shown to be clinically superior and is approved by the FDA during the TPC's market exclusivity period; the risk that individuals previously involved in the development of the TPC will not assist ADVENTRX in further development of the TPC and that ADVENTRX may be unable to retain the services of other qualified individuals on a timely basis, or at all; ADVENTRX's planned reliance on third parties to assist with its nonclinical and clinical studies, regulatory submissions, manufacturing and other important aspects of the TPC development program, if it consummates a transaction with the target company, and the risk that FDA approval may be delayed if their performance is found to be substandard; the potential that ADVENTRX may require substantial additional funding in order to obtain FDA approval for and commercialize the TPC, and the risk that ADVENTRX may not be able to raise sufficient capital when needed, or at all; and other risks and uncertainties more fully described in ADVENTRX's 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 current report to reflect events or circumstances arising after the date hereof, except as may be required by law.

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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.

January 7, 2011

ADVENTRX Pharmaceuticals, Inc.

By: */s/ Patrick L. Keran*

Name: Patrick L. Keran

Title: President and Chief Operating Officer