# 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 27, 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

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:

- o 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)
- 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))

## TABLE OF CONTENTS

Item 7.01. Regulation FD Disclosure
Item 9.01. Financial Statements and Exhibits
SIGNATURE
EXHIBIT INDEX
EX-99.1

#### **Table of Contents**

#### Item 7.01. Regulation FD Disclosure.

Brian M. Culley, Chief Business Officer of ADVENTRX Pharmaceuticals, Inc. ("ADVENTRX"), and other ADVENTRX executives will present the information reflected in the slides attached as Exhibit 99.1 to this Current Report on Form 8-K (this "Report") commencing October 27, 2008 at various investor and analyst conferences and meetings.

The information in this Report, including the slides attached hereto as Exhibit 99.1, is being furnished pursuant to this Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933 or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Report.

By filing this Report and furnishing this information and the information included in the slides attached hereto, ADVENTRX makes no admission as to the materiality of any information in this Report or such slides. The information contained in the slides is summary information that is intended to be considered in the context of the discussion in which such information is presented and/or ADVENTRX's filings with the Securities and Exchange Commission (the "SEC") and other public announcements that ADVENTRX makes, by press release or otherwise, from time to time, as applicable. ADVENTRX does not intend and undertakes no duty or obligation to publicly update or revise the information contained in this Report or the attached slides, although it may do so from time to time as its management believes is appropriate. Any such updating or revision may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

ADVENTRX cautions you that statements information included in this Report and the slides attached hereto as Exhibit 99.1 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 that ADVENTRX will be unable to raise sufficient capital to fund the projects necessary to meet its goals; the risk that preclinical results are not indicative of the success of subsequent clinical trials and the results of pending clinical trials; the risk the FDA determines ADVENTRX's product candidates are not bioequivalent to the applicable reference product; difficulties or delays in developing, manufacturing, obtaining regulatory approval for and marketing ADVENTRX's product candidates; the potential for regulatory authorities to require additional preclinical work or other clinical requirements to support regulatory filings; the scope and validity of patent protection for ADVENTRX's product candidates; patent and non-patent exclusivity covering Navelbine® and Taxotere®; 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 http://www.sec.gov.

#### **Table of Contents**

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 update any forward-looking statement included in this Report or the slides attached hereto as Exhibit 99.1 to reflect events or circumstances arising after the date on which it was made. This caution is made under the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934.

#### 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.

#### **Table of Contents**

#### **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: October 27, 2008 By: /s/ Patrick Keran

Name: Patrick Keran

Title: Vice President, Legal

#### EXHIBIT INDEX

99.1 Presentation Slides



Refining therapies for life

## Safe Harbor Statement

ADVENTRX cautions you that statements included in this presentation 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 that ADVENTRX will be unable to raise sufficient capital to fund the projects necessary to meet its goals; the risk that preclinical results are not indicative of the success of subsequent clinical trials and the results of pending clinical trials; the risk the FDA determines ADVENTRX's product candidates are not bioequivalent to the applicable reference product; difficulties or delays in developing, manufacturing, obtaining regulatory approval for and marketing ADVENTRX's product candidates; the potential for regulatory authorities to require additional preclinical work or other clinical requirements to support regulatory filings; the scope and validity of patent protection for ADVENTRX's product candidates; patent and non-patent exclusivity covering Navelbine® and Taxotere®; 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 <a href="http://www.sec.gov">http://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 update any forward-looking statement as set forth in this presentation to reflect events or circumstances arising after the date on which it was made.

## **ADVENTRX Overview**

# Oncology-focused specialty pharmaceutical company (AMEX:ANX)

## **Developing late-stage product candidates**

- New formulations of approved products
- Two launches anticipated in 2010

## Lower cost, lower risk approach

- Bioequivalence trials
- High margin products
- Markets addressable with small sales force

## Innovative approach reduces cost & risk

# Unlike other companies' drugs, ADVENTRX formulations are designed to enhance safety rather than efficacy

Designed to be bioequivalent (BE) to the reference product

## New Drug Application (NDA) approvals via bioequivalence trials

- Single, small (~30 patient) BE studies; FDA affirmed
- Pharmacokinetic (PK) endpoint reduces risk
- > File under Section 505(b)(2) (not an ANDA)
- Obtain a unique J-code for Medicare reimbursement

## Share-shifting commercialization strategy

- Leverages an established market
- Small sales team to target oncology Group Purchasing Organizations (GPO's) and large individual practices
- Awareness campaigns (fixed properties, pharmacoeconomics, CME)
- Post-approval differentiation & label change (promotion)
  - Obtain approval prior to investment in differentiation
  - · Label-change trial paid for with profits rather than with dilution



## **ADVENTRX Formulation Technology**

#### **Features**

- A stable lipid-in-water emulsion
- Active drug is dissolved in homogeneous lipid microspheres
- Manipulation of emulsifiers and stabilizers prevents aggregation; unique to each molecule
- Non-toxic ingredients (GRAS, NOAEL, other approved drugs)

### **Advantages**

- Plasma enzymes rapidly degrade lipid spheres; distribution and pharmacokinetics aren't altered
- Provides a chemical <u>buffer</u> between active drug and surrounding cells
- <u>Dissolution</u> of non-water-soluble molecules
- Technology applicable to many molecules





# **Development Overview**

Product Development Steps	ANX-530	ANX-514
Preclinical Studies	/	/
File IND	/	
Initiate Bioequivalence Trial	/	
Complete Bioequivalence Trial	/	
Scale-Up Manufacturing		
Pre-NDA Meeting with FDA		
Submit NDA		
FDA Approval		
		ADVENT

## **ANX-530 - Vinorelbine Emulsion**

## **New formulation of Navelbine**

- Indicated for NSCLC (& Breast, EU)
- Generic as of 2003
- \$200M world-wide sales
- Inadequate launch; under-utilized
- ➤ Injection site reactions in ~30% of patients\*

## **ADVENTRX product (ANX-530)**

- 1. Delivers same serum levels of drug
- 2. Designed to reduce injection site reactions
- 3. "Re-launch" with proper pricing & promotion
- 4. Can leverage recent clinical studies

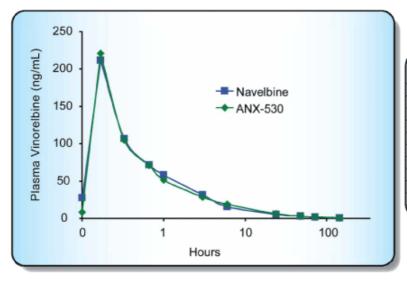
\*Source: Navelbine package insert





## ANX-530 Bioequivalence Study Positive Results – Endpoint Met

# Statistically equivalent pharmacokinetics observed between ANX-530 & Navelbine



Hours	Plasma Vinorelbine (ng/mL)			
Hours	ANX-530	Navelbine		
0	8.52	27.9		
0.17	221	212		
0.33	105	107		
0.67	71.2	71.8		
1	51.4	58.3		
3	28.5	31.6		
6	18.6	15.6		
24	6.26	5.42		
48	3.05	2.97		
72	1.84	1.78		
144	0.79	0.746		



## ANX-530 Bioequivalence Study Positive Safety Results

In Post-Hoc Analyses, ANX-530 Demonstrated Statistically Significant Reduction in Injection Site Reactions

	ANX-530	Navelbine	P value
Injection Site Reactions	1	9	<0.01
Infusion Site Phlebitis	1	7	0.03
Infusion Site Irritation	0	1	-
Infusion Site Pruritis	0	1	-



## **ANX-530 U.S. Commercial Strategy**

## **Current U.S. Market Overview:**

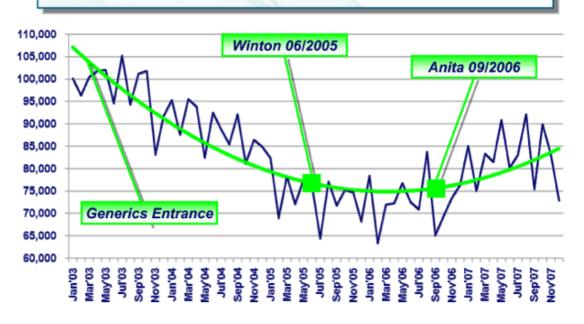
- > ~\$20M in sales (Navelbine & generic equivalents)
- Growing demand despite lack of promotion

## **ADVENTRX's Strategy**

- Leverage clinical benefits & provide favorable practice economics (pricing/discounting)
- Deploy a focused, business-to-business sales team
- Remove payer & reimbursement barriers to adoption
  - · Obtain separate J-code
  - Address coverage issues, if identified, using health economics benefits
- Invest in further clinical differentiation & expansion of demand
- Outlicense Ex.-U.S.

# Increasing U.S. Vinorelbine Demand Recent growth driven by large randomized studies

U.S. Oncology Vinorelbine Trend of Use (mgs 2003-2007)



## **ANX-530 Market Research & Forecast**

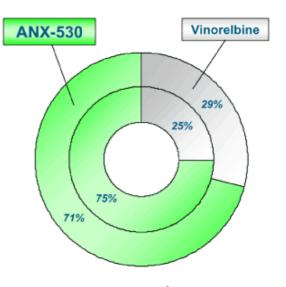
Third Party Conjoint Study of 70 U.S.-Based Medical Oncologists

Oncologist Preference for ANX-530 at 10x Generic Pricing
Prior to J-code Assignment

Share preference unaffected by reimbursement code even at 10x generic pricing

NSCLC Preference Share					
Therapy	Misc. J-code WAC +6%	Unique J-code ASP+6%, 0% disc.	Δ		
ANX-530	74.6% ±9.3	70.9% ±9.3	+1.3%		
Vinorelbine	25.4% ±9.3	29.1% ±9.3	-1.3%		

Conjoint derived (N = 70)



ADVENTRX ANX-530 Pricing Evaluation: Oct. 2008 ADVENTRX 12

## **ANX-530 Product Review**

- ANX-530 is an opportunity to re-launch vinorelbine with an improved formulation
- U.S. market opportunity can be significantly enlarged through premium pricing and non-generic reimbursement strategy
- Small, affordable, business-to-business focused national accounts sales force to target existing users
- > Market research predicts high penetration
- Long patent protection (U.S.; 2024)
- Estimated out of pocket expense from preclinical to NDA submission: ~\$10MM

## **ANX-514 (Docetaxel Emulsion)**

### **New formulation of Taxotere**

- Indicated in 5 cancer types
- Established patent-protected product (2010)
- \$3B world-wide sales
- Polysorbate-80 in formulation associated with hypersensitivity
  - Steroid premedication may reduce hypersensitivity, but introduces new side effects

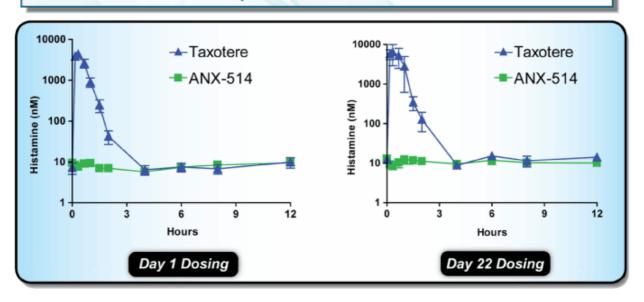
## **ADVENTRX Product (ANX-514)**

- Single-vial, lyophilized presentation
- Designed to eliminate hypersensitivity, edema, and other side effects caused by detergent
- Equivalent PK in 2 animal models
- Can be launched (2010) before generics come to market (2012)
- > Can retain premium pricing and adoption after generic introduction



# ANX-514 Preclinical Results Plasma Histamine Levels

Statistically lower hypersensitivity observed following ANX-514 administration compared to Taxotere in an animal model



Dose Level = 1 mg/kg. Duration of Infusion = 5 minutes. Crossover Study Design. (n= 4 animals per group) ADVENTRX data on file



# **ANX-514 U.S. Commercial Strategy**

## **Current U.S. Market Overview:**

- ~\$1 Billion in U.S. sales
- Competitors seeking 2010 launch expected to contain polysorbate-80

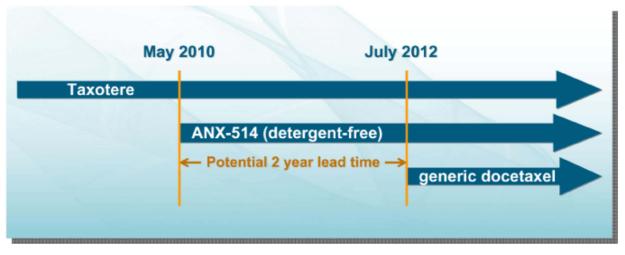
## **ADVENTRX's Strategy**

- Leverage patient benefits & provide favorable practice economics (pricing/discounting)
- Expand business-to-business sales team
- Reduce payer & reimbursement barriers to adoption
  - · Strong health economic story to ANX-514 vs. Taxotere
- Entrench detergent-free formulation to minimize impact of detergent-containing generics in 2012

## **ANX-514 Patent Opportunity**

Potential 2-year lead time in U.S. over generic Taxotere

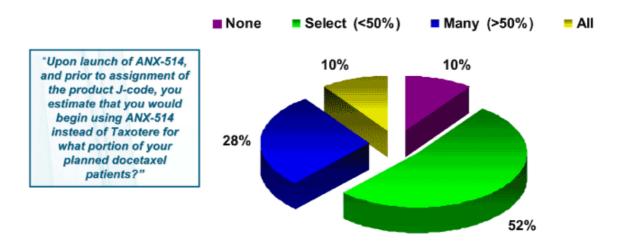
- Docetaxel composition patent expires May 14, 2010
- > Taxotere formulation patents begin to expire July 3, 2012



# **ANX-514 Market Research & Forecasting**

Oncologist's Willingness to Switch Patients to ANX-514

Prior to J-code Assignment

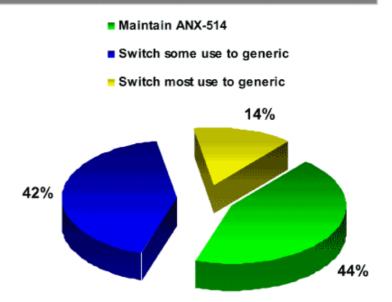


ADVENTRX ANX-514 Web-based Survey of 100 Oncologists: Oct. 2008 ADVENTRX 18

## **ANX-514 Market Research & Forecasting**

# Oncologist's Willingness to Remain with Premium-Priced ANX-514 After Generic Availability

"In 2012, once generic Taxotere is available, assume that for a year there is a large spread between the quickly-falling acquisition price of generic Taxotere, being driven down by competing generic manufacturers and the payor reimbursement rates due to the lag time (assume that ANX-514 pricing and reimbursement remains the same with no impact due to generics), what would your planned use of ANX-514 be?"



ADVENTRX ANX-514 Web-based Survey of 100 Oncologists: Oct. 2008 ADVENTRX 19

## **ANX-514 Product Review**

- Life-cycle extension away from the innovator
- Long patent protection (U.S.; 2027)
- Significant lead time over generics
- > Anticipated clinical advantage post-generic entrants
- > \$1B existing U.S. market opportunity
- Estimated out of pocket expense from preclinical to NDA submission: ~\$11MM

# **Investment Opportunity**

Develop drugs in less time, with less money & risk, while achieving high rates of return on invested capital

## Sustainable business model

- Reproducible, scalable, and physician-driven
- Technology-agnostic

## Late-stage product candidates

- Two products anticipated to be generating sales in 2010

## **Near Term Regulatory Milestones**

## Q1 2009

Complete enrollment in BE study of ANX-514 (docetaxel emulsion)

## Q2 2009

Submit New Drug Application for ANX-530 (vinorelbine emulsion)
Announce results from BE study of ANX-514 (docetaxel emulsion)

## Q3 2009

Submit New Drug Application for ANX-514 (docetaxel emulsion)

## **ADVENTRX Team**

#### Mark N. K. Bagnall, Executive Vice President & Chief Financial Officer

Metabolex Inc.; Metrika, Inc.; Progenitor, Inc.; Somatix Therapy Corp.; Hana Biologics, Inc.

#### Brian M. Culley, M.S., M.B.A., Chief Business Officer & SVP Business Development

Immusol; UCSD Technology Transfer and Intellectual Property Dept.; Neurocrine Biosciences

#### Mark Erwin, Senior Vice President, Operations

Centric Health Finance, LLC ;Ligand Pharmaceuticals; IDEC Pharmaceuticals; Eli Lilly & Co.

#### Michele L. Yelmene, Vice President, Regulatory Affairs & Quality Assurance

Perlan Therapeutics, Genzyme Corp., Mallinckrodt

#### Jose R. Hechavarria, Vice President, Manufacturing

HechTech Pharma Consult; Bristol Myers Squibb; DuPont Pharmaceuticals

#### Patrick L. Keran, J.D., General Counsel

Isis Pharmaceuticals; Heller Ehrman; Brobeck, Phleger & Harrison

### Brandi Roberts, C.P.A., M.B.A., Vice President, Finance

Artes Medical; Strategene; Pfizer, Inc.

## **ADVENTRX Board of Directors**

Jack Lief, Chairman President, CEO, Cofounder and Director,

**Arena Pharmaceuticals** 

Evan M. Levine Former CEO & President, ADVENTRX

Pharmaceuticals, Inc.

Mark N. K. Bagnall Chief Financial Officer & Executive Vice President,

**ADVENTRX Pharmaceuticals** 

Alex J. Denner, Ph.D. Icahn Partners LP, Icahn Partners Master

Fund LP; Director, ImClone Systems

Michael M. Goldberg, M.D. Partner, Montaur Capital Partners

Mark J. Pykett, V.M.D., Ph.D. President and COO, Alseres Pharmaceuticals

Inc.; Cofounder, Cytomatrix

Eric K. Rowinsky, M.D. Chief Medical Officer, ImClone Systems Inc.



Refining therapies for life