# 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): May 20, 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)
- 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))

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#### Item 7.01. Regulation FD Disclosure.

Evan M. Levine, Chief Executive Officer and President of ADVENTRX Pharmaceuticals, Inc. ("ADVENTRX"), and other executive officers will present the information reflected in the slides attached as Exhibit 99.1 to this Current Report on Form 8-K (this "Report") commencing May 20, 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, ADVENTRX makes no admission as to the materiality of any information in this Report. The information contained in the slides is summary information that is intended to be considered in the context of 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. ADVENTRX does not intend and undertakes no duty or obligation to publicly update or revise the information contained in this Report, 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 and information included in 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 anticipated or stated goals and milestones; 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.

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 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.

#### **Table of Contents**

#### 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.

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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.

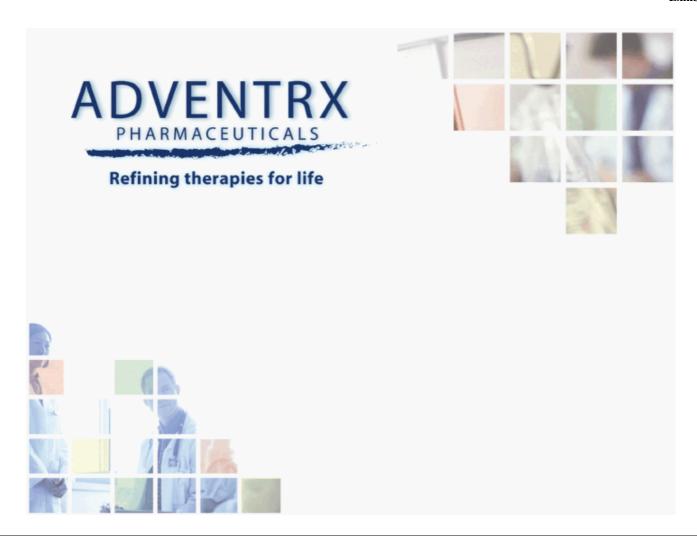
Dated: May 20, 2008 By: /s/ Patrick Keran

Name: Patrick Keran

Title: Vice President, Legal

#### INDEX TO EXHIBITS

99.1 Presentation Slides



#### 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 anticipated or stated goals and milestones; 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.

## **Corporate Overview**

Two novel formulations of currently marketed chemotherapy drugs potentially on the market by 2010

Represent combined market opportunity in excess of \$3 Billion Two New Drug Applications (NDA's) potentially on file in 2009



ANX-530 (vinorelbine emulsion)



ANX-514 (docetaxel emulsion)

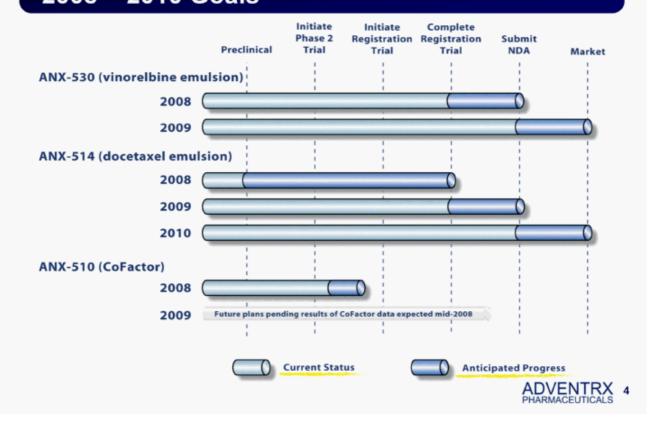
Third oncology product candidate, CoFactor®, addresses market opportunity in excess of \$500 Million



ANX-510 (CoFactor®)

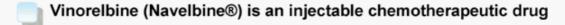
ADVENTRX 3

# **ADVENTRX Lead Product Candidates** 2008 – 2010 Goals



## ANX-530 (vinorelbine emulsion)

ANX-530 is a novel formulation of vinorelbine, designed to reduce the incidence and severity of injection site reactions



Despite narrow label & generic pricing, worldwide sales in excess of \$200 million



Based on recent clinical data, we believe the market for vinorelbine-based treatments both in the U.S. & abroad will increase

Vinorelbine has several side effects and limitations

- Injection site reactions occur in one-third of patients
- Reactions cause administration challenges for nurses and patients

ADVENTRX 5

## ANX-530 (vinorelbine emulsion)

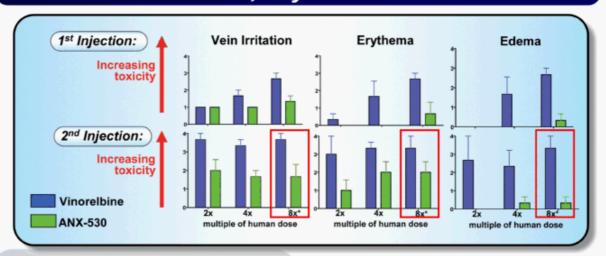
ANX-530 is a novel formulation of vinorelbine, designed to reduce the incidence and severity of injection site reactions

- Registrational bioequivalence clinical study complete
  - Primary endpoint met, pharmacokinetic equivalence observed between ANX-530 & Navelbine
  - In post-hoc analyses, ANX-530 showed a statistically significant reduction in injection site reactions (when compared to Navelbine)
- NDA submission anticipated around end of 2008; potential market launch in 2009
- Market research indicates a preference for a formulation of vinorelbine that reduces or eliminates injection site reactions while providing comparable efficacy
- Premium pricing strategy could substantially increase existing market opportunity



ADVENTRX 6

#### **ANX-530 Preclinical Results** Lower Vein Irritation, Erythema & Edema



Vinorelbine: Due to the severity of toxicity, some of the animals could not receive either the second or third injections at certain doses, but were still analyzed for toxicity after each injection period.

\*High dose Vinorelbine group received 1st injection only.

Low and medium dose Vinorelbine group could not receive the  $3^{\rm rd}$  injection.





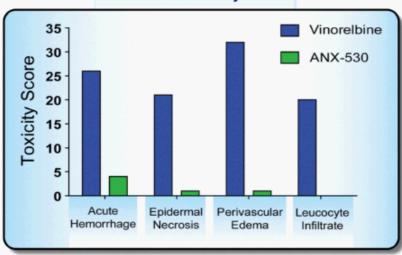


Vinorelbine ADVENTRX 7

# ANX-530 Preclinical Results Ear Vein Histopathology

ANX-530 exhibited markedly less ear vein histopathological toxicity in preclinical studies

#### **Cumulative Toxicity Score**



Following intravenous treatment in rabbits, ear vein tissue sections were scored for severity of symptoms

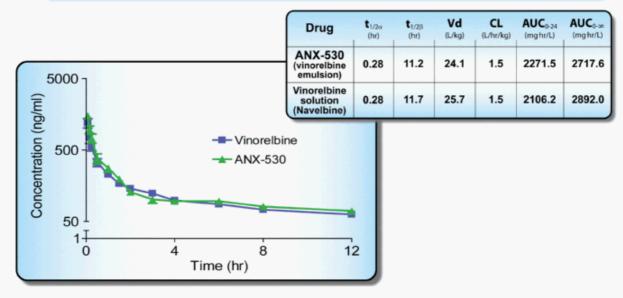
> (0 to 3 scale - no observable event to marked severity).

Toxicity score represents the summation of scores from seven separate vein sections/rabbit.

ADVENTRX 8 PHARMACEUTICALS

# ANX-530 Preclinical Results Pharmacokinetics

Pharmacokinetics statistically equivalent for ANX-530 in a rat pK model



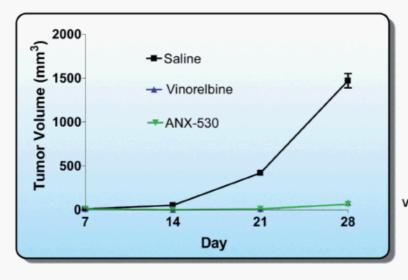
Source: Cantwell, MJ, Robbins, JM, Chen, AX; A novel emulsion formulation of vinorelbine attenuates venous toxicity while maintaining antitumor efficacy; AACR 2006

n= 12/group

ADVENTRX 9

# ANX-530 Preclinical Results Breast Tumor Xenograft

ANX-530 exhibits statistically equivalent antitumor activity compared to Navelbine in a mouse xenograft model



Similar results observed in a lung tumor model in mice

Saline Sa

**Day 28 Excised Tumors** 

ANX-530

Dose level = 8 mg/kg (24 mg/m² human equivalent dose), qdx6 intravenous treatment n=12 (saline group); n=6/group (Navelbine & ANX-530 groups)

**ADVENTRX 10**PHARMACEUTICALS

# ANX-530 Registrational Bioequivalence Clinical Study

Clinical Design: Open Label, Crossover comparison of ANX-530

and Navelbine

Dosing Regimen: Crossover study design, beginning with

either a single dose of ANX-530 (30mg/m²) administered via a 10 min. infusion in the first

week, and a single dose of Navelbine

(30mg/m²) administered via a 10 min. infusion

in the following week (or vice versa)

Primary Objective: Demonstrating pharmacokinetic equivalence of

ANX-530 and Navelbine

Secondary Objective: Determining the safety of a single dose of

ANX-530

Study Population: 31 patients with various advanced cancers

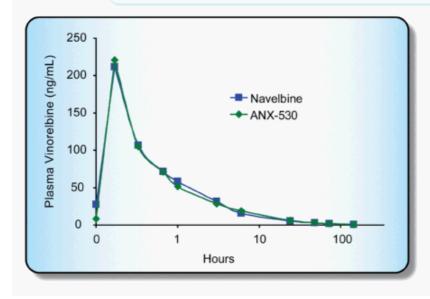
Clinical Sites: 7 (South America)

**ADVENTRX 11**PHARMACEUTICALS

#### ANX-530 Registrational Bioequivalence Clinical Study Positive Results

Primary endpoint met in registrational bioequivalence clinical study of ANX-530

Statistically equivalent pharmacokinetics observed between ANX-530 and Navelbine

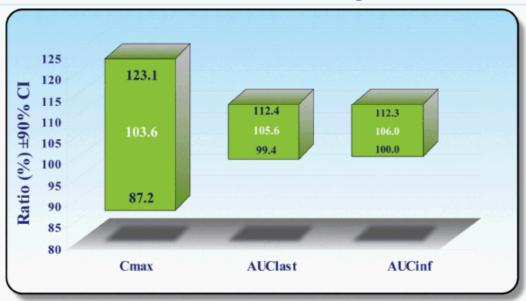


| Hours | Plasma Vinorelbine (ng/mL) |           |  |
|-------|----------------------------|-----------|--|
|       | ANX-530                    | Navelbine |  |
| 0     | 8.52                       | 27.9      |  |
| 0.17  | 221                        | 212       |  |
| 0.33  | 105                        | 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     |  |

ADVENTRX 12 PHARMACEUTICALS

# ANX-530 Registrational Bioequivalence Clinical Study Positive Results

ANX-530 and Navelbine are considered to have equivalent pharmacokinetics if the upper and lower bounds of the AUC ratio's and the Cmax ratio's 90% confidence interval ranged from 80 to 125%



**ADVENTRX 13**PHARMACEUTICALS

#### ANX-530 Registrational Bioequivalence Clinical Study Positive Safety Results

In Post-hoc Analyses ANX-530 Demonstrates Statistically Significant Reduction in Injection Site Reactions

| Injection Cite Depotions |                                                  |                                                      |                                                          |
|--------------------------|--------------------------------------------------|------------------------------------------------------|----------------------------------------------------------|
| Injection Site Reactions | 1                                                | 9                                                    | <0.01                                                    |
| Infusion Site Phlebitis  | 1                                                | 7                                                    | 0.03                                                     |
| Infusion Site Irritation | 0                                                | 1                                                    | -                                                        |
| Infusion Site Pruritis   | 0                                                | 1                                                    | -                                                        |
|                          | Infusion Site Phlebitis Infusion Site Irritation | Infusion Site Phlebitis 1 Infusion Site Irritation 0 | Infusion Site Phlebitis 1 7 Infusion Site Irritation 0 1 |

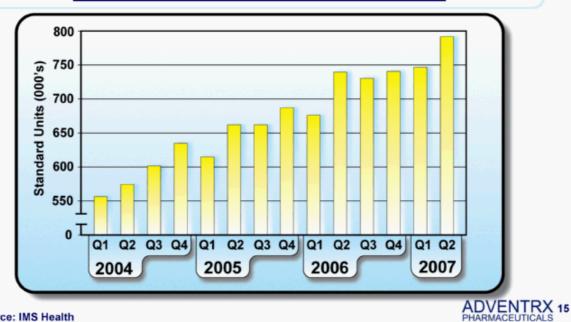
Injection site reactions consist of all grades of investigator-reported phlebitis, irritation and pruritus, in each case at the site of injection. Adverse events were graded based on the investigator's assessment of severity.

Safety data published in the 2008 Proceedings of the American Society of Clinical Oncology (ASCO)

**ADVENTRX 14**PHARMACEUTICALS

## Vinorelbine Market

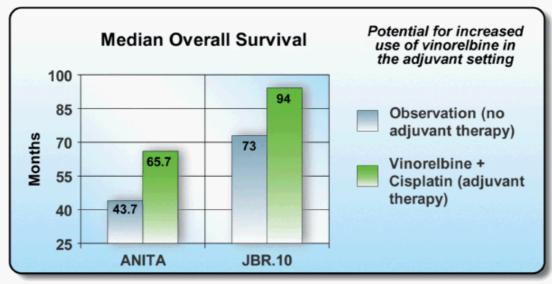
Generic Vinorelbine Unit Sales (2004-2007) Global annual sales in excess of \$200M



Source: IMS Health

#### **Vinorelbine Market Growth Opportunity**

Two independent clinical studies demonstrated that vinorelbine + cisplatin prolongs survival in patients with completely resected NSCLC<sup>1,2</sup>



1. ANITA Study, Lancet Oncology 7:719-727, 2006

2. JBR.10 Study, New England Journal of Medicine 352:258902597, 2005

**ADVENTRX 16** PHARMACEUTICALS

## **ANX-530 Key Milestones**

#### 2008

- Present PK Results from ANX-530 Registrational Bioequivalence Study at AACR
- Announce Safety Results from ANX-530 Registrational Bioequivalence Study at ASCO
- Submit and Plan to Present Safety Results from ANX-530
  Registrational Bioequivalence Study Breast Cancer Patient Subset at the San Antonio Breast Cancer Symposium
- Submit U.S. New Drug Application (NDA)

#### 2009

- FDA Acceptance of NDA for Filing
- Approval of NDA
- Market Launch

**ADVENTRX 17**PHARMACEUTICALS

## ANX-514 (docetaxel emulsion)

ANX-514 is a novel formulation of docetaxel, formulated without polysorbate 80 or other detergents and is designed to reduce the incidence and severity of hypersensitivity reactions

Docetaxel (Taxotere®) is an injectable chemotherapeutic agent approved for treatment of breast, non-small cell lung, and neck & gastric cancers



- One of the top-selling anti-cancer agents in the world, with sales in 2007 totaling approx \$2.9 billion
- Taxotere has certain side effects and limitations
  - Formulated with polysorbate 80, a toxic detergent
  - Can cause acute hypersensitivity reactions
    - Patients must be pre-medicated to address these reactions; premedication with steroids has side effects
  - Administration and compatibility limitations
  - Stability limitations

**ADVENTRX 18**PHARMACEUTICALS

# ANX-514 (docetaxel emulsion)

ANX-514 is a novel formulation of docetaxel, formulated without polysorbate 80 or other detergents and is designed to reduce the incidence and severity of hypersensitivity reactions

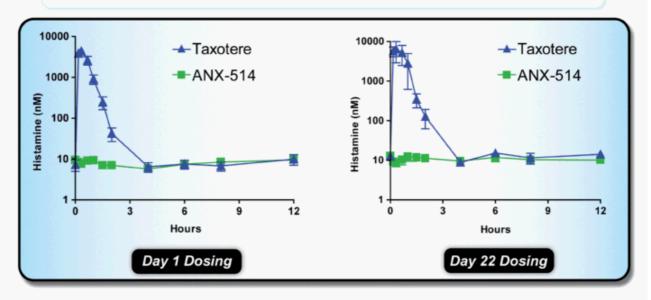
- FDA affirmed 505(b)(2) clinical/regulatory path
  - Patient enrollment in registrational bioequivalence clinical study of ANX-514 initiated
- Preclinical testing with ANX-514 indicated reduced hypersensitivity reactions without impact on pharmacokinetics or anti-tumor activity when compared to Taxotere
- Improved administration and compatibility with common supplies as well as improved stability
- Potential 2 year lead time over generic Taxotere
  - Docetaxel patent expires May 14, 2010
  - Taxotere patents expire July 3, 2012
- Market research indicates a preference for a docetaxel formulation that reduces hypersensitivity reactions



ADVENTRX 19
PHARMACEUTICALS

# ANX-514 Preclinical Results Plasma Histamine Levels

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

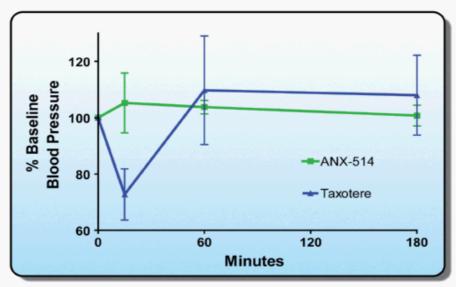


Dose Level = 1 mg/kg. Duration of Infusion = 5 minutes. Crossover Study Design. (n= 4 animals per group) ADVENTRX data on file

**ADVENTRX 20** PHARMACEUTICALS

# ANX-514 Preclinical Results Blood Pressure Changes

Systolic blood pressure drops following Taxotere treatment compared to ANX-514 in an animal model

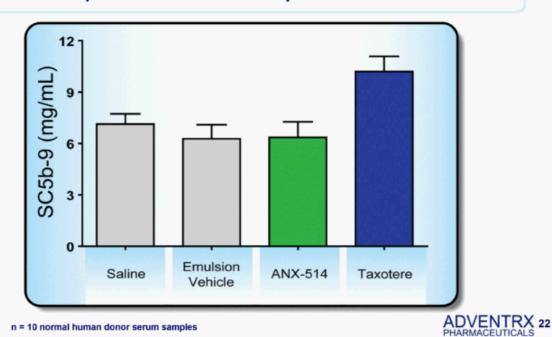


Dose Level = 1 mg/kg. Duration of Infusion = 5 minutes. Crossover Study Design. (n= 4 animals per group) ADVENTRX data on file

**ADVENTRX 21** PHARMACEUTICALS

# ANX-514 Preclinical Results Complement Activation

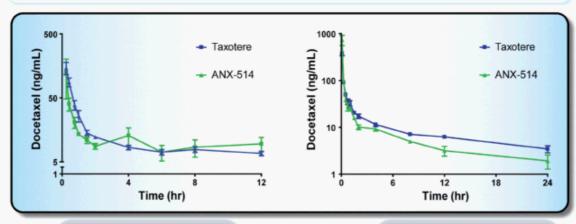
Taxotere induces statistically significant increase in serum complement activation compared to ANX-514



# **ANX-514 Preclinical Results**

#### **Pharmacokinetics**

Pharmacokinetics statistically equivalent for ANX-514 in two separate animal models



|      | Taxotere | ANX-<br>514 |
|------|----------|-------------|
| AUC  | 242      | 246         |
| Cmax | 183      | 157         |

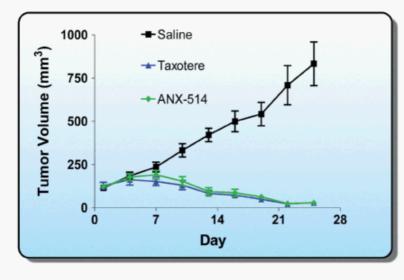
n = 4 animals/group

|      | Taxotere | ANX-<br>514 |
|------|----------|-------------|
| AUC  | 358      | 354         |
| Cmax | 374      | 739         |

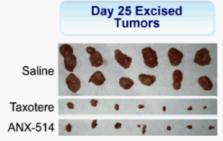
n = 6 animals/group ADVENTRX 23 PHARMACEUTICALS

# ANX-514 Preclinical Results Breast Tumor Xenograft

ANX-514 exhibits statistically equivalent antitumor activity compared to Taxotere in a mouse xenograft model



Similar results observed in liver and sarcoma tumor xenograft models in mice

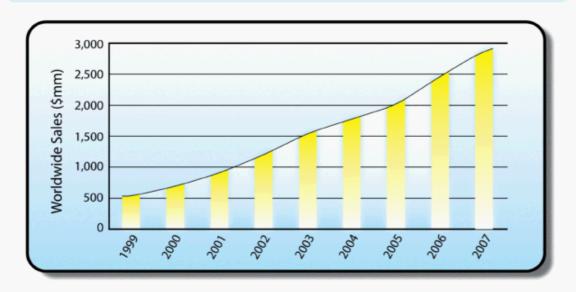


Dose level = 10 mg/kg (30 mg/m² human equivalent dose), q3dx4 intravenous treatment; n=12 (saline group); n=6 (Taxotere & ANX-514 groups)

**ADVENTRX 24**PHARMACEUTICALS

### **Docetaxel Market**

Worldwide Taxotere market approx \$2.9 billion in 2007 U.S. Sales of ~ \$920 Million



Source: Sanofi Aventis

**ADVENTRX 25** PHARMACEUTICALS

## **ANX-514 Key Milestones**

# Initiate Patient Enrollment in Registrational Bioequivalence Study Complete Patient Enrollment in Registrational Bioequivalence Study Announce PK Results from Registrational Bioequivalence Study 2009 Submit and Plan to Present PK and Safety Results from Registrational Bioequivalence Study at Oncology Conferences Submit U.S. New Drug Application (NDA) FDA Acceptance of NDA for Filing 2010 Approval of NDA Market Launch ADVENTRX 26 PHARMACEUTICALS

## ANX-510, CoFactor®

CoFactor is a folate-based biomodulator designed to replace leucovorin as the preferred method to enhance the activity and reduce the associated toxicity of the widely used cancer chemotherapeutic agent 5-FU

- Leucovorin/Isovorin® is a folate-based biomodulator that can be used to enhance the anti-cancer effect of 5-FU chemotherapy or to protect healthy cells from chemotherapy
- Indicated for use in metastatic colorectal and other cancers as well as in high dose methotrexate rescue
- Global market in excess of \$500 million
- Leucovorin has several limitations
  - Requires multiple metabolic steps to become the active form of folate
  - Commonly administered as a 2 hour infusion

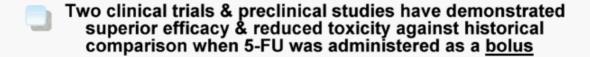
**ADVENTRX 27**PHARMACEUTICALS

## ANX-510 (CoFactor)

CoFactor is a folate-based biomodulator designed to replace leucovorin as the preferred method to enhance the activity and reduce the associated toxicity of the widely used cancer chemotherapeutic agent 5-FU







**ADVENTRX 28**PHARMACEUTICALS

## **CoFactor Clinical Development**

Finishing and collecting data from four CoFactor clinical trials

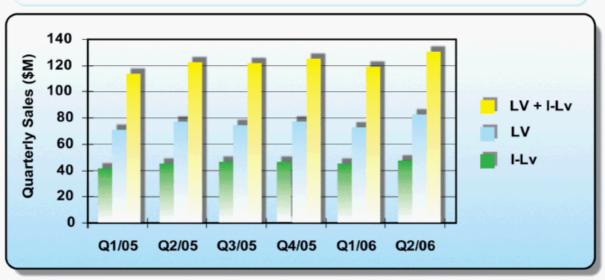
- reliminary data from Phase 2 clinical trial of CoFactor in advanced breast cancer, in which 5-FU was administered as a bolus;
- Sults relating to overall survival in Phase 2b clinical trial of CoFactor in first-line metastatic colorectal cancer, in which 5-FU was administered as an infusion;
- CoFactor in first-line metastatic colorectal cancer, in which 5-FU was administered as a bolus; and
- ta from a CoFactor pharmacokinetic bridging study.

On track to provide update on CoFactor program mid-2008

**ADVENTRX 29** PHARMACEUTICALS

## Leucovorin/Isovorin Market

# Global Market > \$500M for Leucovorin & Calcium Levofolinate (*I*-Lv)\*



\* all intravenous and oral forms included

Sources: IMS Health, Oncology, Inc.

**ADVENTRX 30** PHARMACEUTICALS

# **CoFactor Key Milestones**

#### 2008

- Announce Results Relating to the Primary Endpoint from CoFactor Phase 2 Breast Cancer study at ASCO
- Analyze Results Relating to Overall Survival from CoFactor Phase 2b mCRC study
- Analyze Available Results from CoFactor Phase 3 mCRC study
- Analyze Results from CoFactor Pharmacokinetic Bridging Study
- Provide Update on CoFactor Program

**ADVENTRX 31**PHARMACEUTICALS

#### **ADVENTRX Team**

Evan M. Levine, Chief Executive Officer & President, Director

Brown Simpson Asset Management; Dillon Read; Hambrecht & Quist

Mark N. K. Bagnall, C.P.A., Chief Financial Officer

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

Joan M. Robbins, Ph.D., Chief Scientific Officer

Immusol; Chiron; NCI/NIH Laboratory of Tumor Immunology & Biology

Brian M. Culley, M.S., M.B.A., Chief Business Officer

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

Joachim P. H. Schupp, M.D., Vice President, Medical Affairs

ProSanos Corp.; Novartis AG; CIBA-GEIGY AG

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

Isis Pharmaceuticals; Heller Ehrman; Brobeck, Phleger & Harrison

Mark J. Cantwell, Ph.D., Vice President, Research & Development

Tragen Pharmaceuticals; UCSD

Mark Erwin, Vice President, Commercialization

Centric Health Finance, LLC ;Ligand Pharmaceuticals; IDEC Pharmaceuticals

Michele L. Yelmene, Vice President, Regulatory Affairs

Perlan Therapeutics, Genzyme Corp., Mallinckrodt

Jose R. Hechavarria, Vice President, Manufacturing

HechTech Pharma Consult; Bristol Myers Squibb; DuPont Pharmaceuticals.

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#### **ADVENTRX Board of Directors**

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

**Arena Pharmaceuticals** 

Evan M. Levine Chief Executive Officer & President,

**ADVENTRX Pharmaceuticals** 

Mark N. K. Bagnall, C.P.A. 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.

ADVENTRX 33 PHARMACEUTICALS



Refining therapies for life



