ADVENTRX PHARMACEUTICALS INC
Form 10-K
March 27, 2009

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2008

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File No. 001-32157

ADVENTRX Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
6725 Mesa Ridge Road, Ste 100 San Diego, CA	**92121**
(Address of principal executive offices)	*(Zip Code)*

(858) 552-0866

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Name of each exchange on which registered:
Common Stock, par value $0.001 per share	NYSE Amex

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter periods that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES þ NO o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer o Smaller Reporting Company þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO þ

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2008 was approximately $30,087,567 based upon the closing price on the NYSE Amex (formerly the American Stock Exchange) reported for such date. Shares of common stock held by each officer and director and by each person or entity who is known to own beneficially 5% or more of the registrant s outstanding common stock have been excluded in that such persons and entities may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

90,252,572 shares of the registrant s common stock were issued and outstanding as of March 2, 2009.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant s definitive proxy statement, which will be filed with the Securities and Exchange Commission in connection with the registrant s 2009 Annual Meeting of Stockholders.

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Forward-Looking Statements

This Annual Report on Form 10-K, particularly in Item 1 Business, and Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations, and the documents incorporated by reference, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements regarding our business strategy, expectations and plans, our objectives for future operations, including product development and strategic transactions, and our future financial position. When used in this report, the words believe, may, could, will, estimate, continue, anticipate, intend, expect, indicate and similar expressio identify forward-looking statements.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs, including our ability to consummate a strategic transaction or otherwise satisfy our immediate need for additional capital. These forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from those reflected in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: the risk that we will be unable to consummate a strategic or partnering transaction or otherwise raise sufficient capital on a timely basis, or at all, to continue as a going concern; the risk that our recent cost-containment measures, including the discontinuation of substantially all of our development activities and fundamental business operations and reduction in force to five full-time employees, will negatively impact our ability to consummate a strategic transaction; the risk that the departure of our former Chief Executive Officer and President and our former Executive Vice President and Chief Financial Officer and/or our reduced workforce and leadership by officers who do not have substantial previous experience in executive leadership roles will negatively impact our ability to attract a strategic or other partner, raise capital or maintain effective disclosure controls and procedures or internal control over financial reporting; the risk the FDA will determine that ANX-530 and Navelbine® are not bioequivalent, including as a result of performing pharmacokinetic equivalence analysis based on a patient population other than the population on which we based our analysis; the risk that the bioequivalence study of ANX-514 does not demonstrate pharmacokinetic equivalence or bioequivalence to Taxotere®; the risk of investigator bias in reporting adverse events as a result of the open-label nature of the ANX-530 bioequivalence study, 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; difficulties or delays in manufacturing, obtaining regulatory approval for and marketing ANX-530 and ANX-514, including validating commercial manufacturers and suppliers and the potential for automatic injunctions regarding FDA approval of ANX-514; the potential for regulatory authorities to require additional preclinical work or other clinical requirements to support regulatory filings, including prior to the submission or the approval of a New Drug Application for ANX-530 and ANX-514; the risk that the performance of third parties on whom we rely to conduct our studies or evaluate the data, including clinical investigators, expert data monitoring committees, contract laboratories and contract research organizations, may be substandard, or they may fail to perform as expected; and other risks and uncertainties discussed in other reports and documents we file with the Securities and Exchange Commission. Except as required by law, we do not intend to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

In light of these risks and uncertainties and our assumptions, the forward-looking events and circumstances discussed in this report and in the documents incorporated in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in such forward-looking statements. Accordingly, you are cautioned not to place undue reliance on such forward-looking statements.

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Item 1. Business

Overview

We are a development-stage biopharmaceutical company whose fundamental business is focused on in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. We seek to improve the performance and commercial potential of existing treatments by addressing limitations associated principally with their safety and use. We have not yet marketed or sold any products or generated any significant revenue.

Our lead product candidates, ANX-530 and ANX-514, are novel emulsion formulations of currently marketed chemotherapy drugs. We believe ANX-530 and ANX-514 may improve the safety of and have greater commercial potential than the currently marketed reference products, Navelbine and Taxotere, respectively, by:

Reducing the incidence and severity of adverse effects; and

Increasing their pharmacoeconomics and convenience to healthcare practitioners and patients.

Currently, we are focused primarily on evaluating strategic options, including the sale or exclusive license of one or more of our product candidate programs, a strategic business merger and other similar transactions. In October 2008, we announced a restructuring designed to reduce operating costs while continuing advancement towards our near-term goals and that we had discontinued active work on all product candidates other than ANX-530 and ANX-514, including our ANX-510, or CoFactor, program. With respect to ANX-530 and ANX-514, we announced that, until we secured additional funding, we would focus primarily on those activities relating to submitting New Drug Applications, or NDAs, to obtain the approval of the United States Food and Drug Administration, or FDA, for marketing ANX-530 and ANX-514 in the U.S., and that we may delay or significantly reduce spending on other work, including activities related to product launches. In December 2008, we announced that we were exploring a range of strategic options, including the sale or disposition of one or more of our product candidate programs, a strategic business merger and other similar transactions that maximize the value of our assets. In January 2009, we announced further cost-cutting measures in an effort to extend our remaining cash as we continued to evaluate strategic options, as well as conduct activities related to submitting an NDA for ANX-530 and continue our bioequivalence trial of ANX-514. In February 2009, we announced that we had received written indications of interest from numerous companies representing a range of strategic transactions and currently are evaluating all proposals and options. We also indicated that continued cost-containment measures could impact the timeline of our regulatory filings.

In March 2009, we announced that, effective April 3, 2009, we will reduce our full-time workforce to five employees consisting of our chief business officer, our general counsel, our senior vice president of operations, our vice president of regulatory affairs and quality and our manager of accounting. In addition, we announced that we will discontinue substantially all of our development activities and fundamental business operations to provide additional time to consummate a strategic transaction or otherwise obtain financing. If we are unable to consummate a strategic transaction on a timeline that we believe is acceptable, we may divest our assets on best-available terms, entirely wind-down our operations and distribute any remaining cash to our stockholders. However, based on our current working capital and the estimated costs associated with seeking approval for and implementing a liquidation plan, we expect our remaining cash, if any, to be insignificant.

We are unable to predict when, if ever, we will consummate a strategic transaction, or the form, structure or terms of any potential strategic transaction, including whether we will continue as a going concern. As a result, our future plans and strategy are uncertain.

Throughout 2008, we experienced substantial turn-over in our executive and management ranks. In January and April 2008, our employment relationship with our former president and chief medical officer and former chief financial officer and senior vice president, respectively, ended. In April 2008, Mark N.K. Bagnall, the former chair of the audit committee of our board of directors, who was also a member of the compensation and nominating and governance committees of our board of directors, joined our management team as executive vice president and chief financial officer and, in December 2008, Mr. Bagnall stepped down as executive vice president and chief financial officer and resumed his role as solely a member of our board of directors but also serves as a consultant to us. In October 2008, as part of a reduction in our workforce, we ended our employment

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relationship with our former chief scientific officer and senior vice president, our former vice president of medical affairs and our former vice president of research and development and promoted our former vice president of commercialization to senior vice president of operations. At the same time, our former chief executive officer and president resigned his management positions, though remained on our board of directors until December 2008, at which time he resigned his position on our board of directors. In January 2009, as part of an additional reduction in our work force, we ended our employment relationship with our vice president of manufacturing. Beginning in October 2008, our company was led by a committee of executive officers. In February 2009, our board of directors appointed Brian M. Culley, our chief business officer and senior vice president, to additionally serve as our principal executive officer and appointed Mr. Bagnall to additionally serve as our principal financial officer and principal accounting officer. It is unclear whether the departure of our former executives and management personnel, including specifically our former chief executive officer and president and our former executive vice president and chief financial officer and/or our reduced workforce, or our leadership by officers who do not have substantial previous experience in executive leadership roles, will negatively impact our ability to execute our business plan or to maintain effective disclosure controls and procedures or internal control over financial reporting.

Our business was incorporated in Delaware in December 1995. In October 2000, we merged our wholly-owned subsidiary, Biokeys Acquisition Corp., with and into Biokeys, Inc. and changed our name to Biokeys Pharmaceuticals, Inc. In May 2003, we merged Biokeys, Inc., our wholly-owned subsidiary, with and into us and changed our name to ADVENTRX Pharmaceuticals, Inc. In July 2004, we formed a wholly-owned subsidiary, ADVENTRX (Europe) Ltd., in the United Kingdom primarily to facilitate conducting clinical trials in the European Union and to obtain favorable pricing for discussions with the European Medicines Agency. In April 2006, we acquired SD Pharmaceuticals, Inc. as a wholly-owned subsidiary. Our executive offices are located at 6725 Mesa Ridge Road, Suite 100, San Diego, California 92121, and our telephone number is (858) 552-0866. Our corporate website is located at www.adventrx.com.

Our trademark CoFactor® is registered in the United States Patent and Trademark Office (in the Supplemental Register) under Registration No. 2,946,934, for use in connection with chemotherapy modulators derived from folic acid. We are developing commercial names for our other product candidates. All other trademarks, service marks or trade names appearing in this report, including but not limited to Navelbine®, Taxol® and Taxotere® are the property of their respective owners. Use or display by us of other parties trademarks, service marks, trade names, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark, trade name, trade dress or product owners.

Oncology Focus

Our lead product candidates are designed to improve treatments for cancer patients. Each year, almost 11 million people worldwide are diagnosed with and nearly 7 million people die from cancer. According to the American Cancer Society, cancer is the second most common cause of death in the U.S., accounting for 1 of every 4 deaths. It is estimated that over 1.4 million new cancer cases were diagnosed and over 550,000 people died from cancer in the U.S. in 2007.

Treatment choices for cancer patients depend on the type, stage and progression of the cancer, along with the number and types of prior therapies, if any. Treatment options include surgery, radiation, chemotherapy, hormone therapy and immunotherapy, both alone and in combination with each other. Treatment of cancer with chemicals is referred to as chemotherapy. Adjuvant therapy refers to additional treatment, typically chemotherapy or radiation, following removal of detectable cancerous growths, typically by surgery. In 2006, cancer chemotherapies generated over $40 billion in revenues.

Our Lead Product Candidates (ANX-530 and ANX-514)

Opportunities for New Formulations

Reformulating existing pharmaceutical products is an increasingly common product lifecycle-management technique. Between 2002 and 2005, nearly 40% of the products launched by the top 50 pharmaceutical manufacturers were reformulations. Finding new markets for and ways to modify and improve existing products is often an essential element of pharmaceutical companies efforts to maintain or grow revenues in the face of patent expirations and competitive pressures.

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Navelbine and Taxotere are intravenously-injected chemotherapy drugs commonly used to treat solid tumors. We believe the current formulations of these drugs have limitations that present opportunities for improvement. We are developing novel ways to formulate the active ingredient underlying each of these drugs that we believe may improve their safety profiles without adversely affecting efficacy. In addition, we believe our formulations may provide benefits to patients and practioners that do not manifest themselves in traditional measures of safety or efficacy.

Regulatory Strategy

The regulatory strategy for our lead product candidates has been to demonstrate the bioequivalence of each of ANX-530 and ANX-514 to the currently marketed reference product. The bioequivalence of two drugs can be demonstrated in a single trial of as few as 28 patients, typically in an open-label, single-dose, cross-over comparison of the drugs. For each of ANX-530 and ANX-514, the FDA has indicated that data from a single study of approximately 28 patients that demonstrates the bioequivalence of our product candidates to the reference product may be sufficient to support a Section 505(b)(2) NDA. Accordingly, we view these bioequivalence trials as registrational studies in that they have the potential to support a marketing application. If approved, the drug prescribing information, or label, for our products may reflect data generated during the bioequivalence trials, including comparative adverse event information.

The relatively low number of required patients and the single-dose treatment cycles associated with these bioequivalence trials can decrease study timelines and costs relative to typical pivotal studies. Accordingly, with relatively modest financial investment, we are able to assess the pharmacokinetic equivalence of each of our product candidates to the reference product in as little as 12 to 18 months from initiation of the trial, which information should provide the data necessary to support an NDA. By securing in advance clarity from the FDA regarding our planned regulatory pathway, as we have done for ANX-530 and ANX-514, we mitigate aspects of the regulatory risk associated with drug development. Furthermore, after we obtain marketing approval, we can conduct clinical studies while marketing our products to expand product labels in ways that might increase their commercial value.

Furthermore, if any clinical studies we conduct, in addition to our bioequivalence studies, are essential to the FDA s approval of an application to use our products or product candidates to treat a new indication, or to support a label change in product use, the product may be eligible for three years of marketing exclusivity for that indication or use. Marketing exclusivity means that the FDA will not approve an abbreviated NDA, or ANDA (an ANDA is for a generic drug product) or Section 505(b)(2) NDA during the exclusivity period based on the conditions of approval of our product.

Commercialization Strategy

HCPCS Product Codes and Reimbursement

In the U.S. and elsewhere, healthcare providers, including hospitals, nursing homes and physician offices, typically purchase and administer to patients the drugs that patients are restricted from self-administering and then seek reimbursement, primarily from third party payors such as Medicare, Medicaid and private insurance companies. As a result, sales of physician-administered prescription pharmaceuticals are dependent in large part on the availability and rate of reimbursement to healthcare providers from third party payors.

The Healthcare Common Procedure Coding System, or HCPCS, was established to identify and provide unique codes for healthcare goods and procedures, including codes for injectable oncology drugs such as ANX-530 and ANX-514, should they be approved. Ultimately, the Centers for Medicare and Medicaid Services, or CMS, is responsible for reviewing and approving applications for new HCPCS codes for healthcare goods. Generic equivalents of drugs are assigned the same HCPCS code as the original drug. Virtually all U.S. payors, including Medicare and private insurance plans, use the Healthcare Common Procedure Coding System, including the product codes assigned by CMS.

In determining a specific reimbursement rate for a drug, CMS publishes an average sales price for the drug based on manufacturer-reported sales data for all drugs within the same HCPCS product code, including applicable discounts and rebates, as well as a reimbursement rate, expressed as a percentage of the average sales price. Because generic equivalents of drugs are assigned the same HCPCS code as the original drug, generic competition can be expected to decrease the level of reimbursement for all drugs with the same HCPCS product code (both the original drug and its generic equivalents) until price equilibrium is reached. Most private payors use similar methods for determining

reimbursement rates, sometimes based on average wholesale prices or CMS published average sales price.

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Our fundamental commercial strategy in the U.S. for ANX-530 and ANX-514 has been to seek HCPCS product codes that are distinct from those for Navelbine and Taxotere, respectively. If our products are provided unique HCPCS codes, they will be reimbursed based on their own sales prices, without including sales prices of the applicable reference product or its generic competition. We believe this would provide greater freedom to price our products at a premium to competitive products, thereby enhancing their value, and our plans included pricing ANX-530 at a premium to competitive products. If we are successful in consummating a strategic transaction, we cannot be certain whether or how our reimbursement and pricing strategy may change.

Group Purchasing Organizations

Group purchasing organizations, or GPOs, including provider networks, are entities that help health care providers, such as hospitals, nursing homes and physician offices, realize savings and efficiencies by aggregating purchasing volume and using that scale to negotiate discounts with manufacturers and other vendors. The U.S. healthcare industry spends more than $200 billion annually in medical and non-medical products, with more than 70% allocated through GPOs.

We believe up to 80% of the U.S. markets for ANX-530 and ANX-514 are concentrated within eight to ten GPOs and that a focused, specialized sales force may be able to effectively market and sell our products, if approved, through these organizations. As consolidation within the industry and attempts to further enhance economies of scale and marketing advantages continue, we believe these markets will concentrate further. If our products demonstrate equivalent efficacy and superior tolerability or pharmacoeconomic benefits relative to the reference product, we believe the well-established utility of the reference product should enable GPOs to enact broad and rapid shifts among their constituents from the reference product to our novel emulsion formulations.

In October 2008, we announced that, until we secured additional funding, we may delay or significantly reduce spending on activities related to product launches. Since then, we have deferred conducting most activities related to further acquiring or developing sales, marketing and distribution capabilities and building the associated regulatory compliance infrastructure. If we are successful in consummating a strategic transaction, we cannot be certain whether or how our sales and marketing strategy may change.

ANX-530 (vinorelbine emulsion)

Background; Limitations of Current Formulations

ANX-530 is a novel emulsion formulation of the chemotherapy drug vinorelbine. Navelbine, a branded formulation of vinorelbine, is approved in the U.S. to treat advanced non-small cell lung cancer as a single agent or in combination with cisplatin, and approved in the European Union, or EU, to treat non-small cell lung cancer and advanced or metastatic breast cancer. Since February 2003, generic equivalents of Navelbine have been available in the U.S.

Navelbine and its generic equivalents are often associated with injection site reactions, including phlebitis, erythema and pain at the site of injection. Studies have shown these reactions occur in approximately one-third of patients, with 5% of the reactions categorized as severe.

ANX-530 is designed to reduce the incidence and severity of these injection site reactions. Our formulation emulsifies vinorelbine into a homogeneous suspension of nanoparticles that is designed protect the venous endothelium during administration into a peripheral vein, thereby reducing irritation associated with administration of the drug.

Clinical and Regulatory Developments

In November 2007, we announced positive results from a bioequivalence study of ANX-530. Pharmacokinetic equivalence, the primary endpoint of the study, was observed between ANX-530 and Navelbine. Based on federal regulations and FDA guidance regarding bioequivalence studies, pharmacokinetic equivalence was demonstrated by a statistical comparison of both the areas under the curve (AUC) and maximum plasma concentrations (Cmax).

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In January 2008, we announced safety results from the study. In post hoc analyses, relative to Navelbine, ANX-530 demonstrated a statistically significant reduction in injection site reactions. Notably, 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.

Throughout 2008, we conducted various activities related to our ANX-530 NDA submission. In particular, we engaged a new contract manufacturer and met with the FDA regarding our NDA submission. At this meeting, the FDA requested additional information regarding our new contract manufacturer and material manufactured by our new contract manufacturer. In February 2009, we announced that our continued cost-containment measures could impact the timeline of our regulatory filings. Currently, because of the uncertainty surrounding our ability to consummate a strategic transaction and the form, structure and terms of any potential strategic transaction, including whether we will continue as a going concern, as well as uncertainty surrounding our plans if we are unable to consummate a strategic transaction on a timeline that we believe is acceptable, we cannot predict if or when an NDA for ANX-530 may be filed.

Market and Opportunity

Worldwide sales of Navelbine and generic formulations of vinorelbine in 2006 were in excess of $200 million, with approximately 13% of these revenues generated in the U.S. Between 2004 and 2007, U.S. unit sales of Navelbine and its generic equivalents grew at a compounded annual rate of approximately 9%. If ANX-530 is granted a separate HCPCS code and is sold at a price-premium to Navelbine and its generic equivalents, the potential dollar value of this market could increase substantially.

Additionally, based in part on recent clinical studies, we believe the market for vinorelbine-based treatments, both in the U.S. and abroad, will grow in the coming years. In 2005, the New England Journal of Medicine published a study reporting a statistically significant improvement in overall survival among patients with early-stage lung cancer who received adjuvant therapy consisting of vinorelbine plus cisplatin following tumor resection relative to patients receiving no adjuvant therapy. In addition, a second study presented at the 2005 annual meeting of the American Society of Clinical Oncology reported similarly positive results. Research involving vinorelbine to treat other cancer types, including breast and ovarian cancer, is ongoing. We believe that if ongoing research yields additional positive results, demand may increase for vinorelbine-based treatments, including ANX-530.

We believe ANX-530 is well-positioned as an alternative to Navelbine and its generic equivalents. In post hoc analyses, relative to Navelbine, ANX-530 demonstrated a statistically significant reduction in injection site reactions in our registrational bioequivalence study while maintaining comparable pharmacokinetics. We believe an improved safety profile of ANX-530 will be compelling to healthcare practitioners and patients.

Our market research, conducted among practicing oncologists and oncology nurses, suggests that healthcare practitioners prefer and would use a formulation of vinorelbine that reduced or eliminated injection site reactions while providing comparable efficacy, provided the financial impact to the practitioner of using such a formulation, relative to alternative formulations, is neutral or positive. Furthermore, for a variety of reasons, including anticipated frequent intravenous drug delivery and to avoid injection site reactions and loss of venous access, Navelbine often is administered through a central line, a more invasive procedure in which a catheter is inserted into and left for a period of time in a large vein in the neck, chest or groin. We believe ANX-530 may provide an alternative to placing a central line for those patients for whom central lines are used primarily to avoid injection site reactions.

ANX-514 (docetaxel emulsion)

Background; Limitations of Taxotere

ANX-514 is a novel emulsion formulation of the chemotherapy drug docetaxel. Taxotere, a branded formulation of docetaxel, is approved to treat breast, non-small cell lung, prostate, gastric and head and neck cancers. In the U.S., aspects of Taxotere are covered by patents through November 2013.

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According to Taxotere s label, patients should be observed closely for hypersensitivity, or allergic, reactions, which may occur within a few minutes following initiation of Taxotere administration. These reactions generally are believed to be associated with polysorbate 80, which is present in Taxotere, and range from mild, including flushing, rash, breathing difficulty and drop in blood pressure, to severe, including generalized rash/erythema, hypotension and, in rare cases, fatal anaphylaxis. Taxotere s label recommends that all patients should be premedicated with oral corticosteroids for three days starting one day prior to Taxotere administration to reduce the severity of hypersensitivity reactions, among other reasons. Even following premedication, hypersensitivity reactions have been observed, including, very rarely, fatal anaphylaxis.

ANX-514 is formulated without polysorbate 80 or other detergents and is designed to reduce the incidence and severity of hypersensitivity reactions.

Preclinical Efficacy and Safety; Enrollment in Bioequivalence Study Complete

In preclinical testing, we demonstrated that ANX-514 reduced hypersensitivity reactions without impacting pharmacokinetics or antitumor activity when compared to Taxotere. In an animal model, we observed anaphylactic reactions following Taxotere administration, including decreased respiration, swelling and tremors. Furthermore, decreases in blood pressure and increases in histamine levels were observed within 10-20 minutes of Taxotere administration. In contrast, we did not observe hypersensitivity reactions following administration of ANX-514. Specifically, we did not observe treatment-related changes in blood pressure or increases in histamine levels. On rechallenge at three weeks, hypersensitivity reactions were observed only in the Taxotere-treated animals.

In addition, in two separate studies in different animal species, ANX-514 showed equivalent pharmacokinetics to Taxotere. In animal models, ANX-514 demonstrated dose-dependent inhibition of tumor growth with equivalent antitumor activity when compared to Taxotere at equal dose levels.

In April 2008, we initiated enrollment in a registrational bioequivalence study of ANX-514 and, in February 2009, we announced that enrollment in the study was complete. The study will compare the blood levels of docetaxel following a single dose of ANX-514 or Taxotere in patients with advanced cancers. In addition, we will analyze the safety of ANX-514. The FDA has indicated that this single study, should it demonstrate bioequivalence between ANX-514 and Taxotere, may provide sufficient human data to support a Section 505(b)(2) NDA. We anticipate announcing preliminary pharmacokinetic results of this study in the second quarter of 2009.

In February 2009, we announced that our continued cost-containment measures could impact the timeline of our regulatory filings. Currently, because of the uncertainty surrounding our ability to consummate a strategic transaction and the form, structure and terms of any potential strategic transaction, including whether we will continue as a going concern, as well as uncertainty surrounding our plans if we are unable to consummate a strategic transaction on a timeline that we believe is acceptable, we cannot predict if or when an NDA for ANX-514 may be filed.

Market and Opportunity

Worldwide annual sales of Taxotere in 2007 were approximately $2.9 billion, making it one of the top-selling anti-cancer agents in the world. Based on its early success, substantial investment into researching the use of Taxotere in new indications, has led to numerous label expansions in the U.S. and abroad.

We believe ANX-514 is well-positioned as an alternative to Taxotere and any of its future generic equivalents. In established animal models, we demonstrated ANX-514 reduces hypersensitivity reactions relative to Taxotere. Our market research, conducted among practicing oncologists and oncology nurses, suggests a preference for a formulation of docetaxel that reduces hypersensitivity reactions, which are perceived as a significant issue. In addition, patients with a history of allergic reactions to Taxotere, but for whom docetaxel is the best or only therapeutic option, may benefit from ANX-514, particularly as Taxotere s label recommends against rechallenging patients with a history of severe hypersensitivity reactions.

If clinical studies validate our preclinical work, the need to premedicate patients, which is intended to reduce the severity of hypersensitivity reactions, may be reduced or eliminated. Many patients prefer to avoid premedication and the side effects often associated with steroids, which include agitation, altered mental state, sleeplessness and altered blood/sugar levels. In addition, ANX-514 may be well-suited for patients for whom steroid premedication causes other complications, such as diabetics.

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In addition to the improved safety and comparable efficacy observed in preclinical testing, ANX-514 may provide nonclinical benefits to patients and healthcare practitioners. ANX-514 is formulated without polysorbate 80, which can present practical problems during administration. Taxotere s label indicates foaming may occur when mixing Taxotere and the accompanying diluent due to the presence of polysorbate 80. Our market research suggests foaming is frequent, which can cause delays in administering the drug or disruption during administration if too much foam is present during administration. Practitioners have also expressed concern that foaming, as well as the physical process of extracting the initially diluted Taxotere mixture from the mixing vial, may result in patient underdosing.

Polysorbate 80 also is incompatible with plasticized polyvinyl chloride, or PVC, which is used in making the IV bags and tubing commonly used to infuse chemotherapy drugs. Polysorbate 80 can leach diethylhexyl phthalate, a potentially hepatotoxic and carcinogenic acid, from plasticized PVC bags and tubing, resulting in the addition of diethylhexyl phthalate into the infusion solution. Taxotere s label warns against contact between Taxotere and plasticized PVC equipment and recommends storing the fully-prepared Taxotere mixture in glass or polypropylene bottles or polypropylene or polyolefin plastic bags and administering through polyethylene-lined administration sets. As a result, healthcare providers must have available and remember to use more costly non-PVC supplies to prepare and administer Taxotere, the costs of which generally are not separately reimbursed.

Finally, infusion of the fully-prepared Taxotere mixture should begin within three hours of preparation. Our stability testing suggests fully-prepared ANX-514 is stable for up to 48 hours. In hospital settings, where a central pharmacy may prepare products for administration, the limited stability of the fully-prepared Taxotere mixture may result in expired doses. In addition to wasted product, patients must wait while additional Taxotere is prepared for administration and additional stress is placed on hospital resources, including room availability.

While in the U.S. aspects of Taxotere retain patent protection through November 2013, the active ingredient, docetaxel, loses its patent protection in May 2010; however, if an outstanding request for pediatric exclusivity is granted, this date would be extended by six months. This creates a significant opportunity to develop a formulation of docetaxel that does not infringe any of the remaining Taxotere patents. Without challenging the remaining Taxotere patents, a generic equivalent of Taxotere cannot be approved in the U.S. until November 2013, which could provide other formulations of docetaxel, including ANX-514, over three years (less any period of pediatric exclusivity that may be granted in the future) of marketing in the U.S. before the introduction of Taxotere generic equivalents. We believe this potential lead time over generic competition will be attractive to potential strategic partners as it provides an additional opportunity to establish ANX-514 as an alternative to Taxotere and to establish pricing for ANX-514 prior to the introduction of Taxotere generic equivalents.

Other Product Candidates and Potential Product Candidates

In addition to ANX-530 and ANX-514, we hold rights to a number of other compounds. These include:

- ANX-015, a novel formulation of clarithromycin. An intravenous formulation of clarithromycin is approved to treat mild to moderate bacterial infections (such as community-acquired pneumonia). ANX-015 is intended to reduce injection site reactions associated with intravenous delivery of clarithromycin;
- ANX-016, a novel formulation of vancomycin. An intravenous formulation of vancomycin is approved to treat Gram-positive bacterial infections. ANX-016 is intended to reduce injection site reactions associated with intravenous delivery of vancomycin;
- ANX-201, a member of a new class of reverse transcriptase inhibitor, that in preclinical studies has shown broad-spectrum antiviral activity against human immunodeficiency virus (HIV), human and avian influenza viruses and herpes simplex viruses (HSV);
- ANX-211, a broad spectrum antiviral agent that is a natural product formulated to provide antiviral activity against multiple strains of virus using excipients that are generally regarded as safe (GRAS);

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ANX-510 (CoFactor), a folate-based biomodulator designed to replace leucovorin as the preferred method to enhance the activity and reduce associated toxicity of the widely used cancer chemotherapeutic agent 5-fluorouracil, or 5-FU. CoFactor bypasses the metabolic pathway required by leucovorin to deliver the active form of folate, potentially allowing 5-FU to work more effectively;

ANX-513, a novel formulation of paclitaxel. Taxol, a branded formulation of paclitaxel, is approved to treat breast, ovarian, Kaposi s sarcoma and non-small cell lung cancers. ANX-513 is intended to be non-allergenic and to reduce the need for immunosuppressant premedication associated with administration of Taxol; and

ANX-575, a novel formulation of alpha-tocopheryl succinate, which has been shown in preclinical studies to selectively facilitate cell death in cancer cells.

In October 2008, we announced that we had discontinued active work on all product candidates other than ANX-530 and ANX-514. Prior to that time, we spent significant resources on the development of CoFactor, including a phase 2b and a discontinued phase 3 clinical trial of CoFactor in the first line treatment of metastatic colorectal cancer, and a phase 2 clinical trial of CoFactor in advanced breast cancer.

Competition

If regulatory authorities approve the marketing and selling of any of our product candidates, they will face significant and long-term competition from pharmaceutical companies, pharmaceutical divisions of companies and biotechnology, biopharmaceutical and specialty pharmaceuticals companies, among others. This competition likely will become more intense if any of our products or competitor products achieve commercial success. Most of our competitors, particularly large pharmaceutical companies, have greater clinical, regulatory, manufacturing, marketing, distribution, compliance and financial resources and experience than we have. Many of these companies have commercial arrangements with other companies to supplement their internal capabilities.

ANX-530 and ANX-514, if approved, may compete against Navelbine and Taxotere, respectively, as well as their generic equivalents and other formulations of vinorelbine and docetaxel. In addition to Navelbine, currently there are at least 6 generic versions of vinorelbine on the market. In the U.S., in May 2010 (but subject to any period of pediatric exclusivity that may be granted in the future), patent protection ends for docetaxel and, in November 2013, patent protection ends for Taxotere. We are aware of two leading generics companies that each have developed or acquired a formulation of docetaxel and have certified that, after May 2010, their respective formulations of docetaxel will not infringe any unexpired Taxotere patents.

Under our current regulatory strategy, because we anticipate submitting Section 505(b)(2) NDAs with only bioequivalence data, the ability to differentiate our products from competitor products will be limited. Even if we believe our products demonstrate clinical or pharmacoeconomic benefits, we may be unable to market our products based on these benefits. If our products fail to obtain separate HCPCS codes, we may be required to price our products at levels that do not cover our costs to manufacture, market and distribute the products or provide any profit, or to price our products at levels at which they are not competitive.

In addition, numerous companies are focused on reformulating currently marketed drugs. In particular, the taxanes, the class of drugs of which Taxotere is a member, have experienced substantial commercial success, in part as a result of their effectiveness in treating a wide variety of cancers. This commercial success has generated significant interest in reformulating Taxotere and other taxanes. In addition to our approach of emulsifying docetaxel, other companies are pursuing alternative delivery vehicles, including the use of albumin nanoparticles, prodrugs, polyglutamates, analogs, co-solvents, liposomes and microspheres. Many of these or similar approaches could be applied to vinorelbine. Relative to our formulations, formulations based on one or more of these other methods may result in greater efficacy or safety, provide better drug delivery to tumor sites or otherwise improve benefits to patients and healthcare providers. For instance, there is an oral formulation of vinorelbine approved for use in the EU against which we would compete if our emulsion formulation of vinorelbine were approved for use in the EU.

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Over the longer term, our ability, independently or with a strategic or other partner, to successfully manufacture, market, distribute and sell any of our or their approved products, expand their usage and bring new products to the marketplace will depend on many factors, including, but not limited to, the effectiveness and safety of those products, FDA and foreign regulatory agencies approvals of new products and indications, the degree of patent protection afforded to particular products and the rates at which those products are reimbursed.

Manufacturing

We do not have our own manufacturing facilities. We meet our preclinical and clinical trial manufacturing requirements (including manufacturing active pharmaceutical ingredient, or API, formulating and assembling final drug product, labeling, testing and release, packaging, storing API and finished drug product and similar activities) by establishing relationships with third-party manufacturers and other service providers to perform these services for us. In the past, we relied on individual proposals and purchase orders to meet our needs and typically relied on terms and conditions proposed by the third party or us to govern our rights and obligations under each order (including provisions with respect to intellectual property, if any). In 2008, we entered into a master services agreement with a new contract manufacturer, as well as individual work orders that are governed by the master services agreement, under which the manufacturer will provide process development and scale-up activities for ANX-530 and ANX-514. We do not have any long-term agreements or commitments for these services. Likewise, we do not have any long-term agreements or commitments with vendors to supply the underlying component materials of our product candidates, some of which are available from only a single supplier. In January 2009, we announced that, as part of on-going cost-containment measures, we had substantially reduced or delayed spending on third-party consulting and vendor services, including contract manufacturing.

Should any of our product candidates obtain marketing approval, relationships with third-party manufacturers and other service providers in connection with the commercial production of our products would need to be established. There is some flexibility in securing other manufacturers to produce our product candidates; however, our alternatives may be limited due to proprietary technologies or methods used in the manufacture of some of our product candidates. In addition, if we seek to make certain changes to an approved product, such as changing vendors who supply the underlying component materials of our product candidates, we may need FDA review and approval before the change can be implemented.

Intellectual Property

ANX-530 (vinorelbine emulsion)

We own world-wide rights (excluding China, Hong Kong, Macau and Taiwan) to patents and patent applications covering the composition and use of our vinorelbine emulsion product candidate, subject to the exclusive license we granted to Latitude Pharmaceuticals (described below under Licensing Agreements). Patent applications, entitled Compositions for Delivering Highly Water Soluble Drugs, currently are pending in the U.S., Canada and 20 additional countries, and regional patent applications are also pending in the European Patent Office and the Eurasian Patent Office. These applications have a priority date of July 12, 2004, and any patents granted thereon will expire in July 2025.

ANX-514 (docetaxel emulsion)

We own world-wide rights (excluding China, Hong Kong, Macau and Taiwan) to patent and patent applications covering the composition and use of our docetaxel emulsion product candidate for the treatment of cancer, subject to the exclusive license we granted to Latitude Pharmaceuticals (described below under Licensing Agreements). Patent applications, entitled Low Oil Emulsion Compositions for Delivering Taxoids and Other Insoluble Drugs, currently are pending in the U.S., Canada and 11 additional countries, and a regional patent application is also pending in the European Patent Office. These applications have a priority date of September 28, 2004, and any patents granted thereon will expire in September 2025. Patent applications, entitled Vitamin E Succinate Stabilized Pharmaceutical Compositions, Methods for the Preparation and Use Thereof, are also currently pending in the U.S., Canada and 10 additional countries, and regional patent applications are also pending in the European Patent Office and the Eurasion Patent Office. These applications have a priority date of February 1, 2006, and any patents granted on these applications will expire in February 2027.

We also hold rights to a number of other compounds, which compounds are described above under Other Product Candidates and Potential Product Candidates.

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We are aware of a substantial number of patents issued and patent applications filed in our technical areas or fields. There is a risk that third parties may allege that they have patent rights encompassing our product candidates or methods and no assurance can be given that patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering our product candidates or methods.

We cannot provide assurance that our pending patent applications will issue as patents, that any issued patents will provide us with significant competitive advantages, or that the validity or enforceability of any of our patents will not be challenged or, if instituted, that these challenges will not be successful. The cost of litigation to uphold the validity and prevent infringement of our patents could be substantial. Furthermore, we cannot provide assurance that others will not independently develop similar technologies or duplicate our technologies or design around the patented aspects of our technologies. We can provide no assurance that our proposed technologies will not infringe patents or rights owned by others, the licenses to which might not be available to us.

In addition, the approval process for patent applications in different countries may differ significantly. The patent authorities in each country administer that country s laws and regulations relating to patents independently of the laws and regulations of any other country and the patents must be sought and obtained separately, which can add substantial cost and expense. In addition, a favorable outcome or approval in one country does not necessarily indicate that a favorable outcome or approval can be obtained in other countries.

Research and Development

Our research and development expenses were $17.9 million in 2008 and $15.9 million in 2007. Our research and development expenses consist primarily of salaries and related employee benefits, costs associated with bioequivalence and clinical trials managed by contract research organizations, or CROs, and costs associated with non-clinical activities, such as research-related manufacturing, preclinical research studies, quality assurance and regulatory activities. In 2007, our most significant costs were for bioequivalence and clinical trials and, in 2008 our most significant costs were for research-related manufacturing, including the cost of API and other raw materials and components. Our bioequivalence and clinical trial expenses include payments to vendors such as CROs, investigators, clinical suppliers and related consulting. Our research-related manufacturing expenses include purchasing API, manufacturing materials for bioequivalence and clinical trials and stability testing to support regulatory filings and related labeling, testing and release, packaging and storing.

Licensing Agreements

SD Pharmaceuticals

In April 2006, we acquired SD Pharmaceuticals, Inc. in exchange for shares of our common stock. Under a prior license agreement between SD Pharmaceuticals, Latitude Pharmaceuticals, Inc. and Andrew X. Chen, the sole owner of Latitude Pharmaceuticals, Dr. Chen had assigned to SD Pharmaceuticals all rights and interests of Dr. Chen and Latitude Pharmaceuticals to certain patents throughout the world other than in China, Hong Kong, Macau and Taiwan. Under this agreement, SD Pharmaceuticals granted back to Latitude Pharmaceuticals a worldwide, exclusive, royalty-free and irrevocable license to use the assigned patents in all fields of use other than certain excluded fields as specified in the agreement. Our rights in ANX-530 (vinorelbine emulsion) and ANX-514 (docetaxel emulsion), as well as several other product candidates and potential product candidates to which we have rights, arise through our interest in SD Pharmaceuticals. Accordingly, we have no rights in these product candidates in China, Hong Kong, Macau and Taiwan, and our rights under the assigned patents in the rest of the world are limited to the following fields:

For ANX-530, vinca alkaloid intravenous emulsion formulation for cancer treatment and any other disease indication.

For ANX-514, docetaxel intravenous emulsion formulation for cancer treatment and any other disease indication.

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Government Regulations

Governmental authorities in the U.S. and other countries extensively regulate the testing, manufacturing, labeling, storage, recordkeeping, advertising, promotion, export, marketing and distribution, among other things, of pharmaceutical products. In the U.S., the FDA, under the Federal Food, Drug and Cosmetic Act, or FDCA, and other federal statutes and regulations, subjects pharmaceutical products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

We and our third-party manufacturers, distributors and CROs may also be subject to regulations under other federal, state, and local laws, including the Occupational Safety and Health Act, the Environmental Protection Act, the Clean Air Act, the Health Insurance Portability and Accountability Act, privacy laws and import, export and customs regulations as well as the laws and regulations of other countries.

FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

The process required by the FDA before a new drug may be marketed in the U.S. generally involves the following: completion of preclinical laboratory and animal testing in compliance with FDA regulations; submission of an investigational new drug application, or IND, which must become effective before human clinical trials may begin; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and submission and approval of an NDA by the FDA. The sponsor typically conducts human clinical trials in three sequential phases, but the phases may overlap. In phase 1 clinical trials, the product is tested in a small number of patients or healthy volunteers, primarily for safety at one or more doses. In phase 2, in addition to safety, the sponsor evaluates the efficacy of the product on targeted indications, and identifies possible adverse effects and safety risks, in a patient population somewhat larger than phase 1 clinical trials. Phase 3 clinical trials typically involve additional testing for safety and clinical efficacy in an expanded population at geographically-dispersed test sites.

As a product candidate moves through the clinical phases, manufacturing processes are further defined, refined, controlled and validated. The level of control and validation required by the FDA increases as clinical studies progress.

Clinical trials must be conducted in accordance with the FDA s good clinical practices requirements. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at each clinical site and may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions.

The applicant must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under PDUFA, the FDA ordinarily has 10 months in which to complete its initial review of the NDA and respond to the applicant. However, the PDUFA goal dates are not legal mandates and the FDA response often occurs several months beyond the original goal date. The review process and the target response date under PDUFA may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission. Following completion of the FDA s initial review of the NDA and the clinical and manufacturing procedures and facilities, the FDA will issue an action letter, which will either include an approval authorizing commercial marketing of the drug

for certain indications or contain the conditions that must be met in order to secure final approval of the NDA. If the FDA s evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA.

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Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for new or improved formulations of previously approved products, a company may file a Section 505(b)(2) NDA. Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely upon certain published preclinical or clinical studies conducted for an approved product or the FDA s conclusions from prior review of such studies. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. While references to preclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in a Section 505(b)(2) NDA.

To the extent that the Section 505(b)(2) applicant is relying on the FDA s conclusions regarding studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA s Orange Book publication. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product s listed patents or that such patents are invalid is called a paragraph IV certification. If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the NDA and patent holders for the referenced product once the applicant s NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant s NDA will not be subject to the 30-month stay. A paragraph IV certification would be required in connection with a Section 505(b)(2) NDA for ANX-514 that is filed before November 2013.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA s interpretation of Section 505(b)(2). Our regulatory strategy for both ANX-530 and ANX-514 involves submitting NDAs under Section 505(b)(2).

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Other Regulatory Requirements

Even if the FDA approves one or more of our product candidates, we will continue to be subject to a number of post-approval regulatory requirements. If we seek to make certain changes to an approved product, such as the addition of a new labeled indication or making certain manufacturing changes or product enhancements, we will need FDA review and approval before the change can be implemented. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications or product enhancements and, in some cases, for labeling claims or changes in manufacturing, is generally a time-consuming and expensive process that may require us to conduct clinical studies under the FDA s investigational new drug regulations. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. In addition, adverse experiences associated with use of the products must be reported to the FDA, and FDA rules govern how we can label, advertise or otherwise commercialize our products. The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we and the third-party manufacturers on which we rely for the manufacture of our products or their respective underlying components (including API) are subject to requirements that drugs be manufactured, packaged and labeled in conformity with current Good Manufacturing Practices promulgated by the FDA, or cGMP. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping and other requirements. The FDA periodically inspects drug manufacturing facilities to evaluate compliance with cGMP requirements.

Also, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning recordkeeping and control procedures.

Outside of the U.S., the ability to market our products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process includes all of the risks associated with the FDA approval described above. In addition, the requirements governing the conduct of clinical trials and marketing

authorization vary widely from country to country.

Employees

As of March 2, 2009 we employed 14 persons, all of whom are full-time employees, including 9 engaged in research and development activities, including preclinical research, clinical development, research-related manufacturing and regulatory affairs, and 5 in selling, general and administrative functions such as marketing, accounting, legal and investor relations. On March 20, 2009, we announced that, effective April 3, we will reduce our full-time workforce to five employees consisting of our chief business officer, our general counsel, our senior vice president of operations, our vice president of regulatory affairs and quality and our manager of accounting. None of our employees are unionized and we believe that our relationship with our employees is good.

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Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge on our corporate website (www.adventrx.com) as soon as reasonably practicable after they are filed with, or furnished to, the Securities and Exchange Commission, or SEC.

Item 1A. Risk Factors

Not required.

Item 1B. Unresolved Staff Comments

Not required.

Item 2. Properties

Our offices are located at 6725 Mesa Ridge Road, San Diego, California 92121. Our offices consist of 12,038 square feet of office and lab space, which we use pursuant to a lease which will expire on August 31, 2009. The base rent for this space is currently $258,000 annually, excluding incremental operating cost adjustments. We have not commenced negotiations to extend this lease nor begun considering alternative office space.

Item 3. Legal Proceedings

In the normal course of business, we may become subject to lawsuits and other claims and proceedings. Such matters are subject to uncertainty and outcomes are often not predictable with assurance.

Item 4. Submission of Matters to a Vote of Security Holders

Not applicable.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock trades under the symbol ANX on NYSE Amex (formerly, the American Stock Exchange). The following table sets forth the high and low closing prices for our common stock in each of the quarters over the past two years, as reported by NYSE Amex.

	Common Stock Price			
	2008		2007	
	High	Low	High	Low
First Quarter	$ 0.64	$ 0.36	$ 2.84	$ 1.98
Second Quarter	$ 0.54	$ 0.33	$ 2.90	$ 2.31
Third Quarter	$ 0.38	$ 0.18	$ 2.80	$ 2.07
Fourth Quarter	$ 0.21	$ 0.07	$ 0.88	$ 0.43

As of March 2, 2009, we had approximately 188 holders of record of our common stock. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in street name.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We expect to retain all available funds and future earnings, if any, to support operations and fund the development and growth of our business. Our board of directors will determine whether we pay and the amount of future dividends (including cash dividends), if any.

Recent Sales of Unregistered Securities

During the fiscal year ended December 31, 2008, we did not issue any securities that were not registered under the Securities Act of 1933, as amended.

Item 6. Selected Financial Data

Not required.

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Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes appearing elsewhere in this report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those identified under Forward-Looking Statements above in this report.

OVERVIEW

We are a development-stage biopharmaceutical company whose fundamental business is focused on in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. We seek to improve the performance and commercial potential of existing treatments by addressing limitations associated principally with their safety and use. We have devoted substantially all of our resources to R&D or to acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue.

We have an immediate need to raise additional capital to support our operations. We have incurred annual net losses since inception. We had a net loss of $26.6 million in 2008 and cash and cash equivalents of approximately $9.8 million and working capital of $5.7 million at December 31, 2008. These factors raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements for the year ended December 31, 2008 have been prepared assuming we will continue as a going concern. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Currently, we are focused primarily on evaluating strategic options, including the sale or exclusive license of one or more of our product candidate programs, a strategic business merger and other similar transactions. In March 2009, we announced that we will eliminate all but a select, small number of personnel and will discontinue substantially all of our development activities and fundamental business operations to provide additional time to consummate a strategic transaction or otherwise obtain financing. There can be no assurances that we will be able to consummate a strategic transaction on a timely basis or at all. Further, the restructuring and cost-cutting measures we have taken may not be successful. If we are unable to consummate a strategic transaction on a timeline that we believe is acceptable, we may divest our assets on best-available terms, entirely wind-down our operations and distribute any remaining cash to our stockholders. However, based on our current working capital and the estimated costs associated with seeking approval for and implementing a liquidation plan, we expect our remaining cash, if any, to be insignificant.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based upon consolidated financial statements that we have prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these consolidated financial statements requires management to make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our consolidated financial statements and accompanying notes. On an on-going basis, we evaluate these estimates and assumptions, including those related to recognition of expenses in service contracts, license agreements and stock-based compensation. Management bases its estimates on historical information and assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition. We recognize revenue in accordance with the SEC s Staff Accounting Bulletin Topic 13, Revenue Recognition, or Topic 13, and Emerging Issues Task Force Issue, or EITF, No. 00-21, Revenue Arrangements with Multiple Del