

ADVENTRX PHARMACEUTICALS INC

Form 10-K

March 17, 2008

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

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

**For the fiscal year ended December 31, 2007**

**OR**

**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**

*(State or other jurisdiction of incorporation or  
organization)*

**84-1318182**

*(I.R.S. Employer Identification No.)*

**6725 Mesa Ridge Road, Ste 100 San Diego CA**

*(Address of principal executive offices)*

**92121**

*(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:

Common Stock, par value \$0.001 per share

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

None

Name of each exchange on which registered:

The American Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

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  No

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  NO

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.

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  Accelerated filer  Non-accelerated filer  Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES  NO

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 29, 2007 was approximately \$201,267,000, based upon the closing price on 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 3, 2008.

**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 Annual Meeting of Stockholders to be held on May 28, 2008.

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*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, include 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 our future financial position. When used in this report, the words believe, may, could, will, estimate, continue, anticipate, intend, expect, indicate and similar expressions are intended to identify forward-looking statements.*

*We have based these forward-looking statements largely 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. 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, those discussed in this report, and in particular, the risks discussed in Item 1A Risk Factors, and those discussed in other 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, uncertainties and 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.*

**Item 1. Business**

**Overview**

We are a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates primarily for the treatment of cancer and infectious disease. We seek to improve the performance and commercial potential of existing treatments by addressing limitations associated with these treatment regimens.

Currently, we are focused primarily on advancing ANX-530 and ANX-514, which 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:

Improving their safety and reducing the incidence and severity of adverse effects; and

Increasing their pharmacoeconomics and convenience to healthcare practitioners and patients.

We are also developing ANX-510, or CoFactor, which 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 (5-fluorouracil). In October 2007, we announced results from our phase 2b clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. The CoFactor/5-FU arm did not demonstrate statistically significant improved safety in the trial's primary endpoint, a reduction in the proportion of patients reporting at least one hematological or gastrointestinal adverse event of grade 3 or greater. In November 2007, we announced that we discontinued enrolling patients in our phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. Despite the results of our phase 2b clinical trial of CoFactor, in which 5-FU was administered as an infusion, we continue to believe that CoFactor may improve 5-FU-based chemotherapy in which 5-FU is administered as a bolus and, using the right administration methods, that CoFactor remains a viable product candidate. We anticipate announcing three sets of CoFactor clinical data in mid-2008. Following our analysis of these data, we expect to have greater insight into the value of developing CoFactor independently in particular indications and cancer stages. We will assess development plans for our CoFactor program following this analysis.



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Our overall strategy is to continue developing and, as circumstances warrant, preparing to commercialize ANX-530, ANX-514 and CoFactor, either on our own or through license arrangements, co-marketing partnerships and similar transactions, and to develop other product candidates designed to enhance the commercial value of other currently approved products by improving their performance.

We intend to seek new and unique Healthcare Common Procedure Coding System, or HCPCS, product codes from the Centers for Medicare and Medicaid Services, or CMS, for both ANX-530 and ANX-514. CMS establishes the rates at which healthcare providers are reimbursed for treating beneficiaries covered under Medicare. In addition, nearly all United States, or U.S., private insurance plans use this coding system. Obtaining unique HCPCS codes may allow ANX-530 and ANX-514 to have reimbursement rates separate from Navelbine and Taxotere, respectively, and their generic equivalents, which share the same HCPCS product code and reimbursement rate as the original drug. In practice, this may provide us an opportunity to price our products at a premium to the reference product and its generic competition.

We are a developmental stage company and have not yet marketed any products or generated any significant revenue. We will need to obtain additional funding to support our planned level of operations and may do so through collaborations, licensing arrangements or other strategic transactions, public or private sales of our equity securities, or debt financings.

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. 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](http://www.adventrx.com).

Our trademark CoFactor<sup>®</sup> 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 Avastin<sup>®</sup>, Cremophor<sup>®</sup>, Navelbine<sup>®</sup>, Taxol<sup>®</sup>, Taxotere<sup>®</sup> and Xeloda<sup>®</sup> 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.

**Strategy**

Our goal is to be a leading biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates primarily for the treatment of cancer and infectious disease. Our near-term strategy is to obtain marketing approval of our existing product candidates and either partner or establish an infrastructure to support marketing, distributing and selling our products in the U.S. and abroad, should they be approved. Longer term, we intend to acquire additional product candidates that fit our areas of expertise in cancer and infectious disease. Specifically, we intend to:

*Seek marketing-approval for ANX-530 and ANX-514 in the U.S.* We are applying the expertise of our clinical, manufacturing and regulatory teams to complete and seek approval of new drug applications, or NDAs, that we intend to submit to the United States Food and Drug Administration, or FDA. In January 2008, we announced that we intend to submit a Section 505(b)(2) NDA for ANX-530 to the FDA in the fourth quarter of 2008. We believe the expertise and know-how that we gain from our experiences developing ANX-530 will prove beneficial in seeking regulatory approval of ANX-514.

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*Continue CoFactor development, independently or with a partner.* Despite the results of our phase 2b clinical trial of CoFactor, in which 5-FU was administered as an infusion, we continue to believe that CoFactor improves 5-FU-based chemotherapy in which 5-FU is administered as a bolus and, using the right administration methods, remains a viable product candidate. Following our analysis of the three sets of CoFactor clinical data we expect in mid-2008, we will assess the value of developing CoFactor independently in particular indications and cancer stages.

*Establish sales and marketing capabilities for ANX-530 and ANX-514 in the U.S.* We intend to gain access to a substantial portion of the U.S. markets for ANX-530 and ANX-514 through a focused, specialized sales force targeting distributors, provider networks and group purchasing organizations. In October 2007, we hired a vice president, commercialization, to establish the infrastructure and relationships necessary to access these concentrated markets and maximize their value to us. However, we also remain receptive to partnering these product candidates in the U.S. if presented with terms that are sufficiently attractive.

*Partner with leading organizations to develop and market ANX-530, ANX-514 and CoFactor outside the U.S. or globally.* We plan to draw on the development, regulatory and commercial expertise of other companies in instances where we believe our product candidates would benefit from such expertise. For example, for markets in which a large sales force is required to gain access, and for markets outside the U.S. and possibly within the U.S., we plan to commercialize products for which we obtain regulatory approval through a variety of licensing, collaboration and distribution arrangements with other pharmaceutical and biotechnology companies.

*Pursue additional indications and commercial opportunities for ANX-530, ANX-514, CoFactor and our other product candidates independently and through collaborations.* We plan to increase the value of our current and future product candidates by seeking approval for new indications and label changes and pursuing other commercial opportunities. For example, we or a future partner may conduct clinical and non-clinical studies that seek to differentiate ANX-530 and ANX-514 from Navelbine and Taxotere, respectively.

*Develop or acquire new and improved formulations of currently marketed products.* We may pursue other currently approved products that we believe can be improved, the markets for which in the U.S. are concentrated and to which we can apply our developmental, clinical, regulatory and commercial expertise.



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**Lead Product Candidates**

**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 Emulsion Formulations (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 practitioners that do not manifest themselves in traditional measures of safety or efficacy.

*Clinical and Regulatory Strategy*

Our strategy initially is to demonstrate the bioequivalence of each of our emulsion formulation product candidates to the currently marketed reference product. The bioequivalence of two drugs can be demonstrated in a single clinical 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 clinical data to support a Section 505(b)(2) NDA. Accordingly, we view these bioequivalence trials as registrational clinical 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 clinical 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 in the clinic the pharmacokinetic equivalence of each of our product candidates to the reference product in as little as 12 to 18 months, which information should provide the clinical data necessary to support a Section 505(b)(2) NDA. By securing in advance FDA agreement regarding our planned regulatory pathway, as we have done for ANX-530 and ANX-514, we mitigate aspects of the clinical and regulatory risk associated with drug development. Furthermore, if and after we obtain marketing approval, we can conduct additional clinical studies while marketing our products for use of these products in new indications or to expand product labels in ways that might increase their commercial value.

Furthermore, if any new 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**

Our commercial strategy in the U.S. for ANX-530 and ANX-514 includes seeking to obtain HCPCS product codes that are distinct from those for Navelbine and Taxotere, respectively. Additionally, we intend to price ANX-530 at a premium to competitive products.

In the U.S. and elsewhere, healthcare providers, including hospitals, nursing homes and physician offices, typically purchase the drugs they administer to patients and then seek reimbursement, primarily from third party payors such as Medicare, Medicaid and private insurance companies. As a result, sales of 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 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, CMS is responsible for reviewing and approving applications for new HCPCS codes for injectable oncology drugs. 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.

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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.

We intend to seek unique HCPCS codes for ANX-530 and ANX-514. If we obtain unique HCPCS codes for our products, 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 will provide us greater freedom to price our products at a premium to competitive products, enhancing their value to us.

**Group Purchasing Organizations**

Group purchasing organizations, or GPOs, including distributors and 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, once approved, to 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.

The concentrated nature of these markets in the U.S. may warrant retaining marketing rights to ANX-530 and ANX-514 in the U.S., which may provide us better value than we could obtain through a partnering relationship. By understanding the organization of our target markets and pursuing directly only those markets we believe are sufficiently concentrated, we seek to avoid the substantial direct and indirect expense associated with large sales and marketing organizations that pursue individual physicians. However, we also remain receptive to partnering these product candidates in the U.S. if presented with terms that are sufficiently attractive.

**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.

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*Positive Clinical Data*

In December 2006, we initiated a bioequivalence study of ANX-530. The study was an open-label crossover comparison of ANX-530 and Navelbine in 31 patients with a primary objective of demonstrating the pharmacokinetic equivalence of ANX-530 and Navelbine. Determining the safety of a single dose of ANX-530 was a secondary objective. In the first week, patients received either ANX-530 or Navelbine and, after a one-week period, received the other drug during the second week of treatment. The FDA indicated that this single clinical study, should it demonstrate bioequivalence between ANX-530 and Navelbine, may provide sufficient clinical data to support a Section 505(b)(2) NDA. Enrollment in the study was completed in October 2007.

In November 2007, we announced positive results from the study. 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 (C<sub>max</sub>).

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.

Based on this and other information, we are preparing and intend to submit to the FDA in the fourth quarter of 2008 a Section 505(b)(2) NDA for ANX-530. Based on a meeting with the FDA in December 2007, we reached agreement with the FDA regarding commercial manufacturing requirements for ANX-530, as well as requisites for the Chemistry Manufacturing and Controls, or CMC, section of the NDA.

*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 we successfully secure a separate HCPCS code for ANX-530 and are successful in selling ANX-530 at a price premium to Navelbine and its generic equivalents, the potential dollar value of this market to us could increase substantially.

Additionally, based 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 clinical 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.

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**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 July 2012.

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 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*

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 clinical 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.

Based on this and other information, we plan to initiate enrollment in a registrational bioequivalence clinical study before the end of April 2008. 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 clinical study, should it demonstrate bioequivalence between ANX-514 and Taxotere, may provide sufficient clinical data to support a Section 505(b)(2) NDA.

*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.

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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.

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 July 2012, 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. Generic equivalents of Taxotere cannot be approved in the U.S. until July 2012, which could provide other formulations of docetaxel, including ANX-514, over two 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. Our goal is to submit a Section 505(b)(2) NDA for ANX-514 on a schedule designed to enable us to begin marketing ANX-514 shortly after docetaxel loses its U.S. patent protection (which currently occurs in May 2010), should the FDA accept our application and approve it on the first cycle within the 10-month Prescription Drug User Fee Act, or PDUFA, review goal. This potential lead time over generic competition may provide us 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.

**ANX-510, or CoFactor***Background and Opportunity*

CoFactor is 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-FU. Compared to leucovorin, CoFactor creates more stable binding between the active form of 5-FU and the target enzyme, thymidylate synthase, or TS. CoFactor bypasses the metabolic pathway required by leucovorin to deliver the active form of folate, potentially allowing 5-FU to work more effectively.

Inhibiting TS is a well-established and effective method of killing rapidly dividing cells, such as tumor cells. Inhibition of TS is most frequently accomplished through use of 5-FU, the metabolite of which binds to TS and disrupts cell replication. Binding between TS and the metabolite of 5-FU requires the action of a specific folate: 5,10-methylenetetrahydrofolate, or MTHF.



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Currently, the source of MTHF in the clinical setting is leucovorin. Leucovorin effectiveness, however, may be limited because it undergoes as many as four metabolic conversions to become the active folate MTHF; that is, leucovorin is an indirect source of MTHF and often insufficient to achieve desired levels of TS inhibition in tumor cells. Even in high doses, leucovorin may not reach the desired concentration in the tumor tissue to be effective in helping 5-FU achieve its anti-tumor potential. We are developing CoFactor as a direct source of MTHF.

We believe that 5-FU/leucovorin will continue to form the backbone of chemotherapy in metastatic colorectal cancer. Although there are a number of drugs under development to treat colorectal cancer, most are additions to 5-FU/leucovorin-containing regimens. In 2005, global sales of leucovorin, including the single-isomer formulation of leucovorin, exceeded \$500 million.

*Clinical Development History*

Based on encouraging data from a phase 1/2 clinical trial completed in 1997 and our own preclinical work:

In July 2004, we initiated a 50-patient phase 2 clinical trial of CoFactor in first-line metastatic colorectal cancer, in which 5-FU was administered as a bolus;

In May 2005, we initiated a 300-patient phase 2b clinical trial of CoFactor in first-line metastatic colorectal cancer, in which 5-FU was administered as an infusion;

In June 2006, we initiated a 1,200-patient phase 3 clinical trial of CoFactor in first-line metastatic colorectal cancer, in which 5-FU was administered as a bolus; and

In December 2006, we initiated a 31-patient phase 2 clinical trial of CoFactor in advanced breast cancer, in which 5-FU is administered as a bolus.

Throughout 2005, we announced the results of the 50-patient phase 2 clinical trial. Blinded third-party radiologists determined that 35% of patients receiving 5-FU/CoFactor achieved an objective response, the primary endpoint for the clinical trial, defined as a complete (100% regression of tumors) or partial (at least 50% regression of tumors) response lasting at least four weeks. Based on historical comparator data, objective response for patients with first-line metastatic colorectal cancer receiving 5-FU/leucovorin was 21%. In addition, in June 2006, we announced that longer-term follow-up evaluations suggested that patients who initiated treatment with 5-FU/CoFactor had similar long-term survival to patients who initiated treatment with oxaliplatin- or irinotecan-containing regimens and that 5-FU/CoFactor was a viable first-line treatment in a sequential treatment strategy.

*Recent Developments and Future Plans*

In October 2007, we announced results from our phase 2b clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer, in which 5-FU was administered as an infusion. The 5-FU/CoFactor arm did not demonstrate statistically significant improved safety in the trial's primary endpoint, a reduction in the proportion of patients reporting at least one hematological or gastrointestinal adverse event of grade 3 or greater. Additionally, no statistically significant differences between the arms were observed across overall safety and efficacy variables.

In November 2007, we announced that we discontinued enrolling patients in our phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. This decision followed advice we received from our data safety monitoring board, or DSMB, and analysis of the phase 2b clinical trial results. While the DSMB did not identify safety concerns with CoFactor, it recommended closure of the phase 3 clinical trial, citing a slow accrual rate due, in part, to current and projected treatment preferences for colorectal cancer. In addition, further analysis of the phase 2b clinical trial, in which 5-FU was administered by infusion, uncovered no significant differences between the study arms with regard to either efficacy or safety. At the time we discontinued the phase 3 clinical trial, 89 patients had been enrolled.



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We anticipate announcing three sets of CoFactor clinical data in mid-2008:

Results relating to the primary endpoint in our phase 2 clinical trial of CoFactor in advanced breast cancer, in which 5-FU was administered as a bolus;

Results relating to overall survival in our phase 2b clinical trial of CoFactor in first-line metastatic colorectal cancer, in which 5-FU was administered by infusion; and

Available data from our discontinued phase 3 clinical trial of CoFactor in first-line metastatic colorectal cancer, in which 5-FU was administered as a bolus.

Following analysis of the three sets of CoFactor data we expect in mid-2008, we expect to have greater insight into the value of developing CoFactor independently in particular indications and cancer stages. We will assess development plans for our CoFactor program following this analysis. We continue to believe that CoFactor may improve 5-FU-based chemotherapy in which 5-FU is administered as a bolus and, using the right administration methods, that CoFactor remains a viable product candidate.

### **Other Product Candidates and Potential Product Candidates**

In addition to ANX-530, ANX-514 and CoFactor, we hold rights to a number of other compounds that from time to time we will evaluate for future preclinical and clinical development. 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-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.

Currently, our efforts and the majority of our resources are focused on advancing our lead emulsion formulation product candidates, ANX-530 and ANX-514, as well as CoFactor. Until we have successfully achieved particular milestones with respect to one or more of these product candidates (for example, partnering the product candidate outside the U.S. or globally, obtaining marketing approval in the U.S. or establishing a specialized sales force and related infrastructure), we do not anticipate allocating substantial resources toward other product candidates or development options.

### **Competition**

If we receive regulatory approval to market and sell any of our product candidates, we 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 will likely 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 and financial resources and experience than we have. Many of these companies have commercial arrangements with other companies to supplement their internal research capabilities.



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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 July 2012, patent protection ends for Taxotere. We are aware of a leading generic company that has developed a formulation of docetaxel and has certified that, after May 2010, its formulation of docetaxel will not infringe any Taxotere patents.

Under our Section 505(b)(2) strategy, because we anticipate submitting Section 505(b)(2) NDAs with only pharmacokinetic clinical data, our ability to differentiate our products from competitor products will be limited unless the FDA allows us to include certain data in our products' labels. Even if our products demonstrate clinical or pharmacoeconomic benefits, we may be unable to market our products based on these benefits. If we fail to obtain separate HCPCS codes for our products, 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. Likewise, with respect to CoFactor, Xeloda, an orally-delivered compound that converts to 5-FU and that may be used without leucovorin, could compete against CoFactor, if CoFactor is approved. In addition, orally-administered leucovorin, even if inferior to CoFactor in terms of safety and effectiveness, has a differentiating quality relative to CoFactor, which currently is being developed as an intravenous drug.

Over the longer term, our ability, independently or with our collaborators, 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 intend to continue to use our financial resources to accelerate development of our product candidates rather than diverting resources to establish 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. We rely on individual proposals and purchase orders to meet our needs and typically rely 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). 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.

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Should any of our product candidates obtain marketing approval, we anticipate establishing relationships with third-party manufacturers and other service providers in connection with the commercial production of our products. We have 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.

**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. A U.S. non-provisional patent application, and an international (PCT) patent application, entitled *Vitamin E Succinate Stabilized Pharmaceutical Compositions, Methods for the Preparation and Use Thereof*, are also pending, with a priority date of February 1, 2006. National and regional patent applications based upon the PCT application are expected to be filed later this year. Any patents granted on these applications will expire in February 2027.

*CoFactor*

We are the exclusive licensee of two issued U.S. patents and one issued Canadian patent assigned to the University of Southern California, or USC, that cover the composition and use for the treatment of cancer of a form of 5,10-methylenetetrahydrofolate. These patents will expire in 2011-2013. Based upon independent development, we filed and own the rights to an international (PCT) patent application and a Paris Convention patent application in Taiwan covering a novel formulation of CoFactor. National and regional patent applications based upon the PCT application are expected to be filed later this year. Any patents granted on these applications will expire in November 2026. In addition, based upon independent development, we filed and own the rights to national and regional patent applications in the U.S., the European Patent Office and seven additional countries covering the use of CoFactor in combination with an anti-VEGF antibody (e.g. Avastin) for the treatment of cancer.

We also hold rights to a number of other compounds that from time to time we will evaluate for future preclinical and clinical development.

We have not conducted an extensive search of patents issued to third parties, 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. Because of the number of patents issued and patent applications filed in our technical areas or fields, we believe there is a risk that third parties may allege that they have patent rights encompassing our product candidates or methods.

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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 foreign countries may differ significantly from the process in the U.S. 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. Therefore, approval in one country does not necessarily indicate that approval can be obtained in other countries.

*Trademarks*

Our trademark CoFactor is registered in the U.S. 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.

**Research and Development**

Our research and development expenses were \$15.9 million in 2007, \$12.0 million in 2006 and \$8.7 million in 2005. Our research and development expenses consist primarily of salaries and related employee benefits, costs associated with clinical trials managed by our contract research organizations, or CROs, and costs associated with non-clinical activities, such as research-related manufacturing, pre-clinical research studies and quality assurance and regulatory activities. Historically, our most significant costs were for clinical trials, though we expect costs associated with research-related manufacturing, including development activities associated with increasing the size and yield of individual batches of our product candidates and validating commercial manufacturers, to increase. Our 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 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. 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 right and interest 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.

*University of Southern California*

Under an option and license agreement with USC, entered into in January 1998 and amended in August 2000, we hold exclusive rights to a number of patents that have issued in the U.S. and Canada covering CoFactor and its use in connection with cancer chemotherapy.

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This agreement terminates on the last to expire of the licensed patents, which is expected to occur in July 2013. Upon breach or default under the agreement, which, with respect to our obligations, includes our failure to use reasonable efforts to commercialize the licensed technology, the non-breaching party may terminate the agreement by 45 days written notice. USC may terminate the agreement upon 20 days notice if we fail to obtain and maintain the insurance required by the agreement and may terminate the agreement immediately upon notice if we attempt to use, sublicense, transfer or assign our rights or obligations under the agreement in any manner contrary to its terms or in derogation of USC's proprietary rights and upon bankruptcy, reorganization, liquidation or receivership proceedings involving us. We may terminate the agreement at any time by providing USC 30 days written notice.

This agreement provides for the payment to USC of a 3% royalty on net sales by us or a sublicensee of licensed products, as well as a prepaid royalty of \$100,000 within 30 days of approval of an NDA by the FDA for any product covered by the claims of the licensed patents (which prepaid royalty is deductible from future royalty payments). In addition, we are required to reimburse all reasonable legal expenses incurred by USC in filing, prosecuting and maintaining the licensed patents. No royalties have been paid to date under this agreement.

Though the license granted to us under this agreement is ostensibly exclusive, because the technologies developed by USC were developed in part through funding provided by the U.S. government, our license is subject to a non-exclusive, non-transferable, royalty-free right of the U.S. government and USC to practice the licensed technologies for research purposes and, in the case of the U.S. government, other governmental purposes on behalf of the U.S. and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the U.S., but only to the extent the government funded the research. The government also reserves the right to require us to grant sublicenses to third parties when necessary to fulfill public health and safety needs or if we do not reasonably satisfy government requirements for public use of the technology. In addition, USC has the right to use all improvements to the licensed technology for research and educational purposes. In addition, licenses of technology developed through funding provided by the U.S. government, including the USC licenses, require that licensees in this case, us and our affiliates and sub-licensees, agree that products covered by the licenses will be manufactured substantially in the U.S. If we are unable to contract for manufacturing facilities in the U.S. or obtain an appropriate waiver, we risk losing our rights under this agreement.

**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 clinical research organizations 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.

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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. 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.

*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



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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.

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). We intend to submit an NDA under Section 505(b)(2) for ANX-530 and, if we observe pharmacokinetic equivalence between ANX-514 and Taxotere, ANX-514.

*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.

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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 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., our 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 3, 2008 we employed 32 persons, including 17 engaged in research and development activities, including preclinical research, clinical development, research-related manufacturing and regulatory affairs, and 15 in selling, general and administrative functions such as marketing, accounting, legal, purchasing and investor relations. Our staff includes 5 employees with Ph.D. or M.D. degrees. None of our employees are unionized and we believe that our relationship with our employees is good.

### **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](http://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.**

*An investment in our securities involves a high degree of risk. You should carefully consider the following risk factors together with all other information contained or incorporated by reference in this report before you decide to invest in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties we are not aware of or focused on or that we currently deem immaterial may also materially and adversely affect our business operations. This report is qualified in its entirety by these risk factors. If any of these risks or uncertainties actually occur, our business, financial condition and results of operations could be materially and adversely affected and the value of our securities could decline significantly, which could result in a loss of all or part of your investment.*

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**RISKS RELATED TO OUR BUSINESS**

**Risks Related to Our Financial Performance and Operations**

*We have incurred losses since our inception, we expect our operating expenses to continue to exceed our revenues for the foreseeable future and we may never generate revenues sufficient to achieve profitability.*

We are a development stage company and have not generated sustainable revenues from operations or been profitable since inception, and it is possible we will never achieve profitability. We have devoted our resources to developing a new generation of therapeutic products, but such products cannot be marketed until clinical testing is completed and governmental approvals have been obtained. Accordingly, there is no current source of revenues from operations, much less profits, to sustain our present activities, and no revenues from operations will likely be available until, and unless, our product candidates are clinically tested, approved by the FDA or other regulatory agencies and successfully marketed, either by us or a partner, an outcome which we are not able to guarantee.

*We will need to obtain additional funding to support our planned level of operations, and we may not be able to obtain such capital on a timely basis or under commercially reasonable terms, if at all.*

We have experienced significant operating losses in funding our research, development and clinical testing of product candidates, accumulating operating losses totaling over \$99.7 million as of December 31, 2007, and we expect to continue to incur substantial operating losses for the foreseeable future, even if we or a future partner of ours is successful in advancing our product candidates to market. As of December 31, 2007, we had approximately \$33.5 million in cash and cash equivalents and short-term investments in securities and we do not expect to generate positive net cash flows for the foreseeable future. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

the cost and timing of regulatory approvals;

the rate of progress and cost of our clinical trials, preclinical development activities and other research and development programs;

the cost related to establishing sales and marketing capabilities;

the timing and terms of any collaborative, licensing and other strategic arrangements that we may establish;

the scope, prioritization and number of development programs we pursue;

the extent to which we invest in or acquire new technologies, products or businesses;

the effect of competing technological and market developments; and

the cost involved in establishing, enforcing or defending patent claims and other intellectual property rights.

Based on our current loss rate and existing capital resources, we estimate that we have sufficient funds to sustain our operations at their current levels for at least the next twelve months. However, we may need or choose to seek additional funding within this time period. We may seek additional funding through collaborations, licensing arrangements or other strategic transactions, public or private sales of our equity securities, or debt financings. We may not be able to obtain sufficient additional funding on satisfactory terms, if at all.

In addition, our ability to timely raise capital on commercially reasonable terms may be impaired if we become ineligible to register our securities on registration statements on Form S-3. We will become ineligible if we fail to comply with all applicable requirements of Form S-3, including filing in a timely manner all reports required to be filed by us and having our common stock listed and registered on a national securities exchange. Additionally, if the aggregate market value of our common stock held by non-affiliates (which is referred to as "public float") is less than \$75 million (calculated as set forth in Form S-3 and SEC rules and regulations), we will not be able to sell more than the equivalent of one-third of our public float in primary offerings under a Form S-3 registration statement in any 12-month period. As of March 3, 2008, our public float was approximately \$48.0 million. Alternative means of raising

additional capital through sales of our securities, including through the use of a Form S-1 registration statement, may be more costly and time-consuming.

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Our ability to timely raise capital may be further limited by the rules and regulations and other requirements of the American Stock Exchange, or AMEX, which, as of March 3, 2008, is the exchange on which our common stock is listed. For instance, AMEX requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our presently outstanding common stock unless the transaction is deemed a public offering by the AMEX staff. Based on our outstanding common stock and closing price, as reported on AMEX, as of March 3, 2008, we could not raise more than approximately \$10.6 million without stockholder approval, unless the transaction is deemed a public offering or does not involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than market value.

Obtaining stockholder approval is a costly and time-consuming process. If we were required to obtain stockholder approval, we would expect to spend substantial additional money and resources and believe the process would distract management from our core business. In addition, obtaining stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our business, and there is no guarantee our stockholders would ultimately approve the transaction if proposed. A public offering typically requires broadly announcing the anticipated transaction, which often times depresses the issuer's stock price. Accordingly, the price at which we could sell our securities in a public offering may be less, and the dilution existing stockholders experience may in turn be greater, than if the offering were not public.

***Raising additional capital may cause dilution to our existing stockholders, require us to relinquish proprietary rights or restrict our operations.***

We may raise additional capital at any time and may do so through one or more financing alternatives, including public or private sales of our equity securities, collaboration or licensing arrangements or other strategic transactions, or debt financings. Each of these financing alternatives carries certain risks. Raising capital through the issuance of common stock may depress the market price of our stock and may substantially dilute our existing stockholders. If we instead seek to raise capital through strategic transactions, such as licensing arrangements or sales of one or more of our technologies or product candidates, we may be required to relinquish valuable rights. For example, any licensing arrangement would likely require us to share a significant portion of any revenues generated by our licensed technologies with our licensees. Additionally, the development of any product candidates licensed or sold to third parties will no longer be in our control and thus we may not realize the full value of any such product candidates. Debt financings could involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens or make investments and may, among other things, preclude us from making distributions to stockholders (either by paying dividends or redeeming stock) and taking other actions beneficial to our stockholders. In addition, investors could impose more one-sided investment terms and conditions on companies that have or are perceived to have limited remaining funds or limited ability to raise additional funds. As we continue our research and development and commercialization activities without raising additional funds, it may become more difficult to raise capital in the future on commercially reasonable terms, or at all.

In addition, in connection with past financings, we provided certain investors with warrants that contained price-based anti-dilution protection. Among other things, this protection lowers the exercise price of the warrants issued in connection with these financings in the event we issue common stock at a price per share that is less than the warrants then-effective exercise price, thereby allowing the warrant-holders to receive the same number of shares of our common stock for less consideration. If we raise additional capital by selling shares of our common stock at less than the then-effective exercise price of these warrants, their exercise price may be reduced. Existing stockholders could experience significant dilution in the future as a result of these or other provisions we provide in the future to investors. For example, if we were to sell approximately 18.0 million shares of common stock at \$0.59 per share, the closing price of a share of our common stock, as reported on AMEX, as of March 3, 2008 (for gross proceeds of approximately \$10.6 million), the currently outstanding warrants to purchase 2,445,740 shares of common stock at \$1.975 a share and currently outstanding warrants to purchase 117,000 shares of common stock at \$2.375 a share would be re-priced to \$1.745 (a 11.7% reduction in price) and \$2.078 a share (a 12.5% reduction in price),

respectively. The number of shares issuable upon exercise of these warrants would not change.

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***If we are unable to raise additional capital, we may be forced to reduce or abandon research and development programs, partner product candidates at inopportune times or pursue less-expensive but higher-risk development paths.***

If adequate funds are not available to fund our research and development programs and operations at current and anticipated levels, we may be required to delay or reduce the scope of our research and development programs, abandon them altogether or attempt to continue research and development by entering into arrangements with partners or others that, if available at all, may not be on favorable terms and may require us to relinquish some or all of our rights to our product candidates or the financial benefits thereof.

In addition, to conserve funds, we may pursue less expensive but higher-risk development paths. For instance, we may limit our process development activities to the minimum we feel is sufficient to support our development and commercialization goals, in particular, with respect to ANX-530. Process development helps define the various parameters and specifications for manufacturing products at commercial-scale. Without comprehensive process development activities, we may lack the information necessary to develop an accurate validation plan to support an NDA and may be unable to successfully manufacture at commercial scale. If we are unable to validate the manufacturing processes included in an NDA, we may be required to amend the NDA, which could result in substantial delays in commercializing the subject drug, as well as call into question our ability to ultimately obtain marketing approval for that drug. In addition, we would expect to spend significant funds undertaking the activities necessary to support an amendment to an NDA.

***If we are successful in our development efforts for our product candidates, we will need to increase the size of our organization, and we may experience difficulties in managing growth.***

As of March 3, 2008, we had 32 full-time employees. To the extent we are successful in our clinical trials, regulatory plans or other development efforts, we will need to continue to expand our managerial, financial, manufacturing, commercial, compliance and other resources in order to manage our operations and clinical trials, continue our research and development programs and commercialize our product candidates. Our management and personnel, systems and facilities currently in place will likely not be adequate to support this growth. To effectively manage our operations, growth and various projects we must:

- manage our clinical trials effectively, including our ANX-514 bioequivalence clinical trial and our phase 2 clinical trial of CoFactor for the treatment of advanced breast cancer;

- manage our internal research and development efforts effectively while carrying out our contractual obligations to collaborators and other third parties;

- continue to improve our operational, financial and management controls, reporting systems and procedures; and;

- attract and retain sufficient numbers of talented employees.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

***We may be unable to retain skilled personnel and maintain key relationships.***

The success of our business depends, in part, on our ability to attract and retain highly qualified management, scientific and other personnel, and on our ability to develop and maintain important relationships with leading research institutions and commercial organizations and consultants and advisors. Competition for these types of personnel and relationships is intense from numerous pharmaceutical and biotechnology companies, universities and other research institutions, particularly in the San Diego, California area. We are currently dependent upon our

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scientific staff, which has a deep background in our product candidates and our research and development programs, and our manufacturing and regulatory personnel, particularly with respect to ANX-530. Recruiting and retaining senior employees with relevant product development experience in cancer and infectious diseases and process development experience with emulsified cytotoxic drugs is costly and time-consuming. There can be no assurance that we will be able to attract and retain such individuals on an uninterrupted basis and on commercially acceptable terms, and the failure to do so could have a material and adverse effect on us by significantly delaying one or more of our research and development programs or commercialization of our products. The loss of any of our executive officers, including our chief executive officer and president, our chief scientific officer or our vice president, medical affairs, in particular, could have a material and adverse effect on us and the market for our common stock, particularly if such loss was abrupt or unexpected. None of our employees is obligated to provide services to us for any particular period of time. We do not have non-competition agreements with any of our employees. Furthermore, even if we successfully attract and retain qualified personnel, we may not select individuals with the appropriate skills for the jobs for which they are hired or that integrate well with our existing personnel. Underperforming employees and internal friction may divert the attention of our management and key personnel and negatively impact our product development efforts. In addition, we may incur costs and liabilities terminating our employment relationship with unsatisfactory employees.

***We may seek to merge with or be acquired by another company and the terms of that transaction may not be desirable.***

Because of our limited ability to raise funds, including for the reasons noted above, we may seek to merge with another company with a stronger cash position, complementary work force or product candidate portfolio or for other reasons. The market price for our common stock has been at a 4-year low following our announcement on October 1, 2007 of results of our phase 2b clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer and may not accurately reflect the value of our business. While we will continue to seek to maximize the value of our business to our stockholders, our short-term needs may require us to consummate a transaction involving an exchange of our common stock with that of another company, in which case our stockholders may not realize the full value of our business or their investment.

In addition, there are numerous risks associated with merging or being acquired. These risks include, among others, incorrectly assessing the quality of a prospective acquirer or merger-partner, encountering greater than anticipated costs in integrating businesses, facing resistance from employees and being unable to profitably deploy the assets of the new entity. The operations, financial condition, and prospects of the post-transaction entity depend in part on our and our acquirer/merger-partner's ability to successfully integrate the operations of our product candidates, business and technologies. We may be unable to integrate operations successfully or to achieve expected cost savings. Any cost savings which are realized may be offset by losses in revenues or other charges to operations.

***If we fail to maintain registration of the shares of common stock issued or issuable pursuant to the exercise of warrants we issued in our July 2005 private placement, we will be required to pay the holders of those securities liquidated damages, which could be material in amount.***

The terms of the securities purchase agreement that we entered into in connection with our July 2005 private placement require us to pay liquidated damages to the purchasers of those securities in the event any shares issued or issuable pursuant to the exercise of warrants we issued in the private placement cannot be resold pursuant to our registration statement on Form S-3 filed with and declared effective by the SEC on September 2, 2005. We refer to this as a maintenance failure. For each 30-day period or portion thereof during which a maintenance failure remains uncured, we are obligated to pay each purchaser an amount in cash equal to 1% of the purchaser's aggregate purchase price for any shares of common stock or shares of common stock issuable upon exercise of warrants then held by the purchaser (pro rated for any period less than a month), increasing by an additional 1% with regard to each additional 30-day period or portion thereof until the maintenance failure is cured. There is no cap with respect to the total amount of these liquidated damages. The aggregate gross proceeds from our July 2005 private placement were approximately \$20 million. We are required to maintain the registration statement until the earlier of the date (i) all of the securities issued in our July 2005 private placement have been resold and (ii) each purchaser can resell the securities pursuant to Rule 144 under the Securities Act of 1933, as amended, without regard to the adequate current public information,



volume, manner of sale or notice filing restrictions. The amount of these liquidated damages could be substantial and could have a material adverse effect on our financial condition. See Note 12 of the Notes to Consolidated Financial Statements, Registration Payment Arrangement, for further discussion.

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***Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.***

Our corporate headquarters are located at a single business park in San Diego, California. Important documents and records, including copies of our laboratory books and records for our product candidates, are located at our facilities and we depend on our facilities for the continued operation of our business. Natural disasters and other catastrophic events, such as wildfires and other fires, earthquakes and extended power interruptions, which have impacted San Diego businesses in the past, and terrorist attacks, drought or flood, could significantly disrupt our operations and result in additional, unplanned expense. As a small company, we have limited capability to establish and maintain a comprehensive disaster recovery program and, accordingly, we do not have a formal business continuity or disaster recovery plan, and any natural disaster or catastrophic event could delay our research and development programs. Even though we believe we carry commercially reasonable insurance, we might suffer losses that exceed the coverage available under these insurance policies. In addition, we are not insured against terrorist attacks or earthquakes.

**Risks Related to Drug Development and Commercialization**

***Further testing of our product candidates is required and regulatory approval may be delayed or denied, which would limit or prevent us from marketing our product candidates and significantly impair our ability to generate revenues.***

Human pharmaceutical products are subject to rigorous preclinical testing and clinical trials and other approval procedures mandated by the FDA and foreign regulatory authorities. Various federal and foreign statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U.S. and foreign statutes and regulations is time-consuming and requires the expenditure of substantial resources. In addition, these requirements and processes vary widely from country to country.

To varying degrees based on the regulatory plan for each product candidate, the effect of government regulation and the need for FDA and other regulatory agency approval will delay commercialization of our product candidates, impose costly procedures upon our activities, and put us at a disadvantage relative to larger companies with which we compete. There can be no assurance that FDA or other regulatory approval for any products developed by us will be granted on a timely basis, or at all. Even though the FDA has confirmed the appropriateness of a Section 505(b)(2) regulatory path for ANX-530 and ANX-514, the FDA's views may change. If the FDA requires the longer-term regulatory approval pathway associated with traditional drug development for ANX-530 and ANX-514, we may determine that the associated time and cost is not financially justifiable and, as a result, discontinue those development programs. If we discontinue the development of one or both of these product candidates, our business and stock price may suffer.

***We may not achieve our projected development goals in the time frames we announce. Delays in the commencement or completion of preclinical testing, clinical trials or regulatory activities could result in increased costs to us and delay or limit our ability to generate revenues.***

We set goals for and make public statements regarding our estimates of the timing of the accomplishment of objectives material to our success. The actual timing of these events can vary dramatically due to any number of factors, including delays or failures in our preclinical testing and clinical trials and the uncertainties inherent in the regulatory approval process.

We use our preclinical program to assess the merits of potential product candidates and future research and development activities. Delays in our preclinical program could occur for a number of reasons, including:

delays in reaching agreement on acceptable terms with prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs;

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failures on the part of our CROs in developing study procedures or otherwise conducting the studies on timeframes requested by us;

changes in regulatory requirements or other standards or guidance relating to preclinical testing, including testing of pharmaceutical products in animals;

a lack of availability of animals that are suitable for the types of studies we plan to conduct; and

unforeseen results of preclinical testing that require us to amend study designs or delay future preclinical testing, clinical trials and related regulatory filings.

In addition, we do not know whether planned clinical trials will commence on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a variety of reasons, including delays related to:

obtaining regulatory approval to commence a clinical trial;

identifying appropriate trial sites and reaching agreement on acceptable terms with prospective CROs, trial sites and clinical investigators, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and clinical investigators;

manufacturing sufficient quantities of a product candidate;

obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;

recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the same indication as our product candidates and the perception that the design of a clinical trial or the proposed treatment regimen is less beneficial to patients than available alternatives; and

retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unforeseen safety issues;

lack of adequate funding to continue the clinical trial; or

the impact that results of one clinical trial of a product candidate may have on other clinical trials for the product candidate, even if the trials involve different indications, administration methods or dosing regimens.

For example, in October 2007, we announced results of our phase 2b clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer, which demonstrated that the CoFactor/5-FU arm did not demonstrate statistically significant improved safety in the trial's primary endpoint. In November 2007, we announced that we would discontinue enrolling patients in our phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer.

Additionally, changes in regulatory requirements and guidance relating to clinical trials may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical

trial protocols to IRBs for reexamination or renegotiate terms with CROs, trial sites and clinical investigators, all of which may impact the costs, timing or successful completion of a clinical trial.

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There can be no assurance that our preclinical testing and clinical trials will commence or be completed, that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our current schedule for the launch of any of our products. If we experience delays in completion of, or if we terminate, our clinical trials or preclinical testing, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials or preclinical testing may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same indications may have been introduced to the market and established a competitive advantage.

***Positive results in our preclinical testing and clinical trials do not ensure that future clinical trials will be successful or that our product candidates will receive the regulatory approvals necessary for their commercialization.***

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through preclinical testing and clinical trials that each product is safe and effective for use in each target indication. Success in preclinical testing and clinical trials does not ensure that subsequent or large-scale clinical trials will be successful. Additionally, throughout clinical development, we must provide adequate assurance to the FDA and other regulatory authorities that we can consistently produce our product candidates in conformance with cGMP and other regulatory standards. For instance, CoFactor plus 5-FU failed to show improved safety in our phase 2b clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer despite generating positive safety data in our phase 2 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. Clinical trial results are frequently susceptible to varying interpretations and regulatory authorities may disagree on what are appropriate methods for analyzing data, any of which may delay, limit or prevent regulatory approvals. For instance, with respect to our bioequivalence clinical trial of ANX-530, the FDA may perform its pharmacokinetic equivalence analysis based a patient population other than the population on which we based our analysis, which may result in the FDA determining that ANX-530 and Navelbine are not bioequivalent, requiring that we evaluate additional patients or take other remedial action. In addition, the ANX-530 bioequivalence clinical trial was open-label, meaning physician-investigators, as well as patients, may have been aware of which drug was being administered. There is a risk of investigator bias in reporting adverse events as a result of the study's open-label nature, 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.

The length of time necessary to complete clinical trials and manufacturing development work and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict. In addition, delays or rejections may be encountered based upon changes in FDA policy for drug approval during the period of product development and FDA regulatory review of each submitted NDA. There is a significant risk that any of our product candidates could fail to show satisfactory results in clinical trials or manufacturing development, and would not justify further development. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope requested will delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

***If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance (including as a result of failing to differentiate our products from competitor products or as a result of failing to obtain reimbursement rates for our products that are competitive from the healthcare provider's perspective), the revenues we generate from their sales will be limited and our business may not be profitable.***

Our success will depend in substantial part on the extent to which our products for which we obtain marketing approval from the FDA and comparable foreign regulatory authorities are accepted by the medical community and reimbursed by third-party payors, including government payors. The degree of market acceptance will depend upon a number of factors, including, among other things:

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limitations or warnings in a product's approved labeling;

the establishment and demonstration in the medical community of the safety and efficacy of our products and our ability to provide acceptable evidence of safety and efficacy;

availability of alternative treatments;

the product's perceived advantages over existing treatment methods (including relative convenience and ease of administration and prevalence and severity of any adverse side effects);

pricing and cost-effectiveness;

reimbursement and coverage policies of government and third-party payors;

the prevalence of off-label substitution of chemically equivalent products; and

in the U.S., the ability of GPOs (including distributors and other network providers) to sell our products to their constituencies.

We cannot predict whether physicians, patients, healthcare insurers or maintenance organizations, or the medical community in general, will accept or utilize any of our products. If our products are approved but do not achieve an adequate level of acceptance by these parties, we may not generate sufficient revenues from these products to become or remain profitable. In addition, our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

Under our Section 505(b)(2) regulatory strategy for ANX-530 and ANX-514, because we anticipate submitting Section 505(b)(2) NDAs with only pharmacokinetic clinical data, our ability to differentiate our products from competitor products will be limited unless the FDA allows us to include certain data in our products' labels. Even if our products demonstrate clinical or pharmacoeconomic benefits, we may be unable to market our products based on these benefits.

If we fail to obtain separate HCPCS codes for ANX-530, it is unlikely we will be able to sell that product at a price that exceeds its manufacturing, marketing and distribution costs. Even if we obtain separate HCPCS codes for our products, if our products are perceived to provide little or no advantage relative to competitive products or for other reasons, 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.

***We do not have manufacturing capabilities and are dependent on single source manufacturers and suppliers for certain of our product candidates and their component materials, and the loss of any of these manufacturers or suppliers, or their failure to provide us with an adequate supply of products or component materials on commercially acceptable terms, or at all, could harm our business.***

We do not have any manufacturing capability. We rely on third-party manufacturers and component materials suppliers for the manufacture of our product candidates for clinical trial purposes and we anticipate establishing relationships with third-party manufacturers and component materials suppliers for the commercial production of our products. Currently we do not have any long-term agreements or commitments with our third-party manufacturers or component suppliers, and we cannot ensure that we will be able to establish relationships with these parties on commercially acceptable terms, or at all. If we fail to establish and maintain such relationships, we expect it would have a material and adverse effect on our operations. Even if we successfully establish relationships with third-party manufacturers and component suppliers on commercially acceptable terms, our manufacturers and suppliers may not perform as agreed or may terminate their agreements with us. Because many of our single source suppliers provide manufacturing services to a number of other pharmaceutical companies, our suppliers may experience capacity constraints or choose to prioritize one or more of their other customers over us. Any significant problem that our single source manufacturers or suppliers experience could delay or interrupt the supply to us of clinical trial materials

or products until the manufacturer or supplier cures the problem or until we locate an alternative source of supply, if an alternative source is available, and, as a result, any such delay or interruption could materially and adversely affect our development activities and operations.

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For instance, ANX-530 is an emulsified cytotoxic product that must be aseptically-filled. There are a limited number of contract manufacturers capable and willing to manufacture this type of product at the commercial scale at which we anticipate requiring in accordance with our marketing plans for ANX-530, which will make identifying and establishing short- or long-term relationships with willing manufacturers more difficult and provide them with substantial leverage over us in any negotiations. Furthermore, certain of the underlying component materials of ANX-530 are available only from a particular supplier, and currently we do not have any short- or long-term agreements for the supply of those materials.

Even if we successfully establish a long-term relationship with our current contract manufacturer for ANX-530 on commercially acceptable terms, our contract manufacturer may be unable to successfully and consistently manufacture ANX-530 at commercial scale. We and this manufacturer have limited experience manufacturing ANX-530, and the experience we and this manufacturer do have is limited to manufacturing at non-commercial scales. Because data from a single clinical trial of ANX-530 may be sufficient clinical data to support a Section 505(b)(2) NDA, our and our current contract manufacturer's ability to gain experience manufacturing ANX-530, in particular at various scales, has been limited. If our current contract manufacturer is unable to manufacture ANX-530 successfully and consistently at commercial scale and within established parameters, we may be unable to validate our manufacturing process, even if the FDA approves our NDA, and therefore unable to sell ANX-530.

All manufacturers of our products and product candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program, as well as applicable requirements of foreign regulatory authorities. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products and product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. While we monitor and audit our manufacturer's systems, we have little control over our manufacturers' ongoing compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval.

Furthermore, the manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing and shortages of qualified personnel.

If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their contractual obligations, our ability to provide product candidates to patients in our clinical trials may be jeopardized. Any delay or interruption in the supply of clinical supplies could delay the completion of our clinical trials, increase the costs associated with maintaining our research and development programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely. We cannot ensure that manufacturing or quality control problems will not arise in connection with the manufacture of our products or product candidates, or that third-party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such products or product candidates. Any of the above factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, entail higher costs or result in our being unable to effectively commercialize our products. Our dependence upon third parties for the manufacture of our products and product candidates may adversely affect our future costs and our ability to develop and commercialize our products and product candidates on a timely and competitive basis.

If any of our product candidates should be approved, any problems or delays experienced in their manufacturing processes may impair our ability to provide commercial quantities of the products, which would limit our ability to sell the products and would adversely affect our business. It could take significant time to redesign our manufacturing processes or identify alternative suppliers in response to problems we may encounter as we manufacture our products, if such alternative processes and suppliers are available at all. Even if we are able to identify alternative suppliers, they may be unwilling to manufacture our products on commercially reasonable terms.



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Any new supplier of products or API would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such products or ingredients. The FDA may require us to conduct additional clinical trials, collect stability data and provide additional information concerning any new supplier before we could distribute products from that supplier. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new supplier to bear significant additional costs which may be passed on to us.

***We rely in part on third parties to conduct our clinical trials and other aspects of our research and development programs and if those third parties do not satisfactorily perform their contractual obligations or meet anticipated deadlines, the clinical development of our product candidates could be adversely affected.***

We do not possess research and development facilities necessary to conduct all of the activities associated with our research and development programs. We engage consultants, advisors and CROs to design and conduct preclinical and clinical trials in connection with the research and development of our product candidates. As a result, many important aspects of our product candidates' development are outside our direct control. In addition, there can be no assurance that such third parties will perform all of their obligations under arrangements with us or will perform those obligations satisfactorily.

The CROs with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and subsequent collection and analysis of data, and we will likely depend on these and other CROs and clinical investigators to conduct our future clinical trials or assist with our on-going clinical trials. Individuals working at the CROs with which we contract, as well as clinical investigators at the sites at which our clinical trials are conducted, are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If these CROs fail to devote sufficient time and resources to our clinical trials, or if their performance is substandard, it will delay the approval of our applications to regulatory agencies and the introduction of our products. Failure of these CROs to meet their obligations could adversely affect clinical development of our product candidates. Moreover, these CROs may have relationships with other commercial entities, some of which may compete with us. If they assist our competitors at our expense, it could harm our competitive position.

***We currently have no sales capability and only limited marketing capability and our failure to develop these capabilities internally or contract with third parties to perform these activities successfully could delay and/or limit our ability to generate revenues in the event one or more of our product candidates obtains regulatory approval.***

We currently do not have sales personnel. We have limited marketing and business development personnel and only recently hired a vice president, commercialization. To commercialize our products, including ANX-530, we will have to acquire or develop sales, marketing and distribution capabilities, or rely on marketing partners or other arrangements with third parties for the marketing, distribution and sale of our products. There is no guarantee that we will be able to establish marketing, distribution or sales capabilities or make arrangements with third parties to perform those activities on terms satisfactory to us, or that any internal capabilities or third party arrangements will be cost-effective. The acquisition or development of a sales and distribution and associated regulatory compliance infrastructure will require substantial resources, which may divert the attention of our management and key personnel and negatively impact our product development efforts.

In addition, any third parties with which we establish marketing, distribution or sales arrangements may have significant control over important aspects of the commercialization of our products, including market identification, marketing methods, pricing, composition of sales force and promotional activities. There can be no assurance that we will be able to control the amount and timing of resources that any third party may devote to our products or prevent any third party from pursuing alternative technologies or products that could result in the development of products that compete with, or the withdrawal of support for, our products.

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***Even if we receive regulatory approval for our product candidates, we may face competition from generic products, which could put downward pressure on pricing and market share and limit our ability to generate revenues.***

Many of the currently marketed and anticipated products against which our product candidates may compete are, or we anticipate will be, available as generics. For instance, ANX-530 will compete against Navelbine, for which generic equivalents are also available. ANX-514 will compete against Taxotere. We anticipate that ANX-514 will also compete against other formulations of docetaxel and that generic Taxotere will enter the market in July 2012. CoFactor will compete against leucovorin, a well-established generic product. Even if we obtain unique HCPCS codes for our products, the existence of generic products could make it more difficult for our branded products, including ANX-530 and ANX-514, to gain or maintain market share and could cause prices for our products to drop, each of which could adversely affect our business.

We may also face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. Proposed federal legislative changes may expand consumers' ability to import lower priced versions of our and competing products from Canada. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own products could negatively impact our business and prospects.

***Even if we receive regulatory approval for any of our product candidates, we may rely on third parties to perform many essential services for our commercial products, including services related to the distribution, storage and transportation of our products.***

If we received regulatory approval for any of our product candidates, we may retain third-party service providers to perform a variety of functions related to the sale and distribution of our products, key aspects of which would be out of our direct control, such as warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management. In this event, we would place substantial reliance on third-party providers to perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter natural or other disasters at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we may use third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms.

***If we receive regulatory approval in the United States for ANX-530 and/or ANX-514, we will likely depend on a limited number of group purchasing organizations for retail distribution of these products, and if we subsequently lose any significant GPO customer, our business could be harmed.***

Our U.S. commercialization strategy for our lead emulsion formulations involves marketing and selling these products to approximately eight to ten GPOs. Even if we are successful in securing relationships and sales with these entities, the subsequent loss of any one or more of these GPO customers' accounts or a material reduction in their purchases could harm our business, financial condition or results of operations. In addition, we may face pricing pressure from these GPO customers.

***Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties that could materially and adversely affect our business, financial condition and results of operations and cause our stock price to decline.***

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Even if initial regulatory approval is obtained, the FDA or a foreign regulatory agency may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or marketing surveillance programs. Our product candidates will also be subject to ongoing FDA requirements related to the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the product. For instance, in September 2007, amendments to the FDCA were signed into law. These amendments significantly strengthen the FDA's regulatory authority over drugs, including new controls over the post-approval monitoring of drugs. The FDA may now require changes to approved drug labels, require post-approval clinical trials and impose distribution and use restrictions on certain drugs. In addition, approved products, manufacturers and manufacturers' facilities are subject to continuing regulatory review and periodic inspections. If previously unknown problems with a product are discovered, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, the FDA may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we or a contract manufacturer of ours fail to comply with applicable regulatory requirements, a regulatory agency may:

issue warning letters or untitled letters;

impose civil or criminal penalties;

suspend or withdraw regulatory approval;

suspend or terminate any ongoing clinical trials;

refuse to approve pending applications or supplements to approved applications;

impose restrictions or affirmative obligations on our or our contract manufacturer's operations, including costly new manufacturing requirements;

close the facilities of a contract manufacturer; or

seize or detain products or require a product recall.

***Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States, which would limit our ability to realize the full market potential of our product candidates.***

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S., as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on potential royalties and product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or commercialization.***

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all indications, and in

turn prevent us from commercializing our product candidates and generating revenues from their sale.

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In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;

regulatory authorities may withdraw their approval of the product;

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from its sale.

**Risks Related to Our Intellectual Property**

*Our success will depend on patents and other protection we and our licensors obtain on our product candidates and proprietary technology.*

Our success will depend in part on our ability and, in certain cases, our licensors' ability to:

obtain and maintain patent protection with respect to our products;

maintain our licenses;

prevent third parties from infringing upon our proprietary rights;

maintain trade secrets;

operate without infringing upon the patents and proprietary rights of others; and

obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, both in the U.S. and in foreign countries.

The patent and intellectual property positions of biopharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we or our licensors have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims allowed will be sufficient to protect the technology we develop or have developed or that is licensed to or by us. In addition, we cannot be certain that patents issued or licensed to us will not be challenged, invalidated, infringed or circumvented, including by our competitors, or that the rights granted thereunder will provide competitive advantages to us.

Furthermore, patent applications in the U.S. are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months. As a result, we cannot be certain that the inventors listed in any patent or patent application owned by or licensed to us were the first to conceive of the inventions covered by such patents and patent applications or that such inventors were the first to file patent applications for such inventions.

We may also rely on unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants, collaborators and others. We also have invention or patent assignment agreements with our employees and certain consultants. There can be no assurance, however, that binding agreements will not be breached, that we will have adequate remedies for any breach, or that trade secrets will not otherwise become known or be independently discovered by competitors. In addition, there can be no assurance that inventions relevant to us will not be developed by a person not bound by an invention assignment agreement with us.



**Table of Contents*****Exclusivity for our emulsion-formulation product candidates and CoFactor may be limited because of the nature of patent protection available for these candidates.***

While the patent applications covering our emulsion-formulation product candidates, including ANX-530 and ANX-514, and CoFactor include product claims, they cover only specific formulations of the underlying chemical entity, or API, and not the API itself. Such product claims are not as strong as claims covering new APIs, which are widely viewed as the strongest form of intellectual property protection for pharmaceutical products, as they apply without regard to how the API is formulated or the method in which the API is used. A competitor may modify our formulations and obtain regulatory approval for products with the same API as our products. Such competitive products may not infringe the patents we hold covering our specific formulations of the API.

In addition, the basic patents pertaining to CoFactor that we licensed from the USC issued only in the U.S. and Canada. Additional patents pertaining to CoFactor are pending outside the U.S. and Canada, but they include only method claims; that is, methods of using CoFactor for the treatment of cancer in combination with other cancer therapies. This type of patent protection is limited, since it cannot be used to prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, physicians may prescribe a competitive product that is identical to ours for off-label indications that are covered by our patents. Although such off-label prescriptions may infringe or contribute to the infringement of method claims, the practice is common and such infringement is difficult to prevent or prosecute.

***We have licensed several of our product candidates from third parties and, if we default on any of our obligations, we could lose rights to our product candidates.***

We have licensed rights to our product candidates that are important to our business, and we expect to enter into similar licenses in the future. For instance, the license agreement pursuant to which we license CoFactor permit the licensor, USC, to terminate the agreement under certain circumstances, such as our failure to use our reasonable efforts to commercialize the licensed technology or the occurrence of any other uncured breach by us. These license agreements also provide that the licensor is primarily responsible for obtaining patent protection for the technology licensed, and we are required to reimburse the licensor for the costs it incurs in performing these activities. These license agreements also require the payment of specified royalties. Any inability or failure to observe these terms or pay these costs or royalties could result in the termination of the applicable license agreement in certain cases. The termination of any license agreement could have a material and adverse effect on us.

In October 2007, we announced results of our phase 2b clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer, which demonstrated that the CoFactor/5-FU arm did not demonstrate statistically significant improved safety in the trial's primary endpoint. In November 2007, we announced that we would discontinue enrolling patients in our phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. In light of these events, there is no guarantee that we will be viewed by USC to be using reasonable efforts to commercialize the technology licensed from USC, which could lead USC to seek to terminate the related license agreement.

***The United States government and USC retain certain rights in the technologies we have licensed from USC.***

The technologies developed by USC were developed in part through funding provided by the U.S. government. Therefore, in addition to USC's termination rights described above, our licenses are subject to a non-exclusive, non-transferable, royalty-free right of the U.S. government and USC to practice the licensed technologies for research purposes and, in the case of the U.S. government, other governmental purposes on behalf of the U.S. and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the U.S., but only to the extent that the government funded the research. The government also reserves the right to require us to grant sublicenses to third parties when necessary to fulfill public health and safety needs or if we do not reasonably satisfy government requirements for public use of the technology. In addition, USC has the right to use all improvements to the licensed technology for research and educational purposes. Although we are currently the only parties licensed to actively develop the technology, we cannot assure you that the government will not in the future require us to sublicense the technology. Any action by the government to force us to issue such sublicenses or development activities pursuant to its reserved rights in the technology would erode our ability to exclusively develop our products and product candidates based on the technology and could materially harm our financial condition and

operating results.



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Licenses of technology developed through funding provided by the U.S. government, including the USC licenses, require that licensees-in this case, us-and our affiliates and sub-licensees agree that products covered by the licenses will be manufactured substantially in the U.S. We cannot assure you that we will be able to contract for manufacturing facilities in the U.S. on favorable terms or obtain waivers of such requirement, or that such requirement will not impede our ability to license our products or product candidates to others. If we are unable to contract for manufacturing facilities in the U.S. or obtain an appropriate waiver, we risk losing our rights under the USC licenses, which could materially harm our financial condition and operating results.

***If we are sued for infringing the proprietary rights of third parties, it will be costly and time consuming, and an unfavorable outcome would have an adverse effect on our business.***

Our commercial success depends on our ability and the ability of our future collaborators to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our future collaborators are or may be developing products. As the biotechnology and pharmaceutical industry expands and more patents are issued, the risk increases that our products and product candidates may give rise to claims that our products or product candidates infringe the rights of others. Because patent applications can take many years to publish and issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our products, product candidates or technologies infringe.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our products, product candidates and/or technologies infringe their intellectual property rights. If one of these patents was found to cover our products, product candidates, technologies or their uses, we or our future collaborators could be required to pay damages and could be unable to commercialize our products or use our technologies or methods unless we or they are able to obtain a license to the patent or intellectual property right. A license may not be available to us or our future collaborators on acceptable terms, if at all. In addition, during litigation, a patent holder could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using or selling our products, technologies or methods.

In connection with any NDA that we file under Section 505(b)(2) of the FDCA, we may be required to notify third parties that we have certified to the FDA that any patents listed for the approved drug in the FDA's Orange Book publication are invalid or will not be infringed by the manufacture, use or sale of our drug. If the third-party files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our Section 505(b)(2) NDA until, subject to certain adjustments, the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to us. Accordingly, we may invest significant time and expense in the development of our product candidates, including ANX-530 and ANX-514, only to be subject to significant delay and patent litigation before our products may be commercialized.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert our management's attention from our core business;

substantial damages for infringement, including treble damages and attorneys' fees, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights;

a court prohibiting us from selling or licensing the product unless the third party licenses its product rights to us, which it is not required to do;

if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross-licenses to our products; and

redesigning our products or processes so they do not infringe, which may not be possible or may require substantial funds and time.

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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 products, technology or methods. Because of the number of patents issued and patent applications filed in our field, we believe there is a risk that third parties may allege they have patent rights encompassing our products, technology or methods.

In addition, it may be necessary for us to enforce patents under which we have rights, or to determine the scope, validity and unenforceability of other parties' proprietary rights, which may affect our rights. There can be no assurance that our owned or licensed patents would be held valid by a court or administrative body or that an alleged infringer would be found to be infringing. The uncertainty resulting from the mere institution and continuation of any technology-related litigation or interference proceeding could have a material and adverse effect on us.

### **RISKS RELATED TO OUR INDUSTRY**

#### ***We expect intense competition in the marketplace for all of our product candidates.***

The industry in which we operate is highly competitive and rapidly changing. If successfully developed and approved, all of our products will likely compete with existing and new products and therapies and our competitors may succeed in commercializing products more rapidly or effectively than us, which would have a material and adverse effect on our results of operations and financial condition. In addition, there are numerous companies with a focus in oncology and/or anti-viral therapeutics that are pursuing the development of pharmaceuticals that target the same diseases as are targeted by the products being developed by us. We anticipate that we will face intense and increasing competition in the future as new products enter the market and advanced technologies become available. There is no assurance that existing products or new products developed by competitors will not be more effective, or more effectively marketed and sold, than those we may market and sell. Competitive products may render our products and product candidates obsolete or noncompetitive.

For instance, 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, which 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 increase benefits to patients and healthcare providers. In addition, 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. Likewise, Xeloda, an orally-delivered compound marketed by Roche that converts to 5-FU and may be used without leucovorin, could compete against CoFactor, if CoFactor is approved. In addition, orally-administered leucovorin, even if inferior to CoFactor in terms of safety and effectiveness, has a differentiating quality relative to CoFactor, which currently is being developed as an intravenous drug.

Companies likely to have products that will compete with our product candidates have significantly greater financial, technical and human resources and are better equipped to develop, manufacture, market and distribute products. Many of these companies have extensive experience in preclinical testing and clinical trials, obtaining FDA and other regulatory approvals and manufacturing and marketing products and have products that have been approved or are in late-stage development and operate large, well-funded research and development programs.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, academic institutions, government agencies and other public and private research organizations are becoming increasingly aware of the commercial value of their inventions and are actively seeking to commercialize the technology they have developed.

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***We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent our products' commercial success.***

Our ability to commercialize our products successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly approved medical products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely effect:

our ability to set a price we believe is fair for our products;

our ability to generate revenues or achieve or maintain profitability;

the future revenues and profitability of our potential customers, suppliers and collaborators; and

the availability to us of capital.

If we are successful in getting FDA approval for ANX-530, we will compete with Navelbine and several generic versions of Navelbine. Our ability to commercialize ANX-530 will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate coverage and reimbursement levels for the cost of our products and related treatments. These payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement, particularly for new therapeutic products. Accordingly, even if coverage and reimbursement are provided, market acceptance of our products would be adversely affected if the amount of coverage and/or reimbursement available for the use of our products proved to be unprofitable for healthcare providers.

There have been federal and state proposals to subject the pricing of healthcare goods and services, including prescription drugs, to government control and to make other changes to the U.S. healthcare system. For example, the Medicare Prescription Drug Improvement Act of 2003 provides a new Medicare prescription drug benefit, which became effective January 1, 2006, and mandates other reforms. While we cannot predict the full outcome of the implementation of this legislation, it is possible that the new Medicare prescription drug benefit, which will be managed by private health insurers and other managed care organizations, will result in additional government reimbursement for prescription drugs, which may make some prescription drugs more affordable but may further exacerbate industry-wide pressure to reduce prescription drug prices. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain if future legislative proposals, whether domestic or abroad, will be adopted that might affect the product candidates in our programs or what actions federal, state, or private payors for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Any such healthcare reforms could have a material and adverse effect on the marketability of any products for which we ultimately receive FDA or other regulatory agency approval.

***We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization. In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage and it is uncertain that such increased or additional insurance coverage can be obtained on commercially reasonable terms.***

Our business (in particular, the use of our product candidates in clinical trials and the sale of our products for which we obtain marketing approval) will expose us to product liability risks. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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decreased demand for our products or product candidates;

impairment of our business reputation;

withdrawal of clinical trial participants;

costs of related litigation;

substantial monetary awards to patients or other claimants;

loss of revenues; and

the inability to commercialize our products and product candidates.

We maintain limited product liability insurance for our clinical trials, but our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval of any of our product candidates, but we may be unable to obtain product liability insurance on commercially acceptable terms or may not be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect us against potential losses. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

***Changes in laws and regulations that affect the governance of public companies have increased our operating expenses and may continue to do so.***

Recently enacted changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and AMEX listing requirements, as well as disclosure requirements related to executive and director compensation, have imposed increased duties on us and on our executives, directors, attorneys and independent accountants. In order to comply with these extensive rules, we hired additional personnel and engaged outside legal, accounting and advisory services, which in the past increased our operating expenses. We expect to continue to incur administrative expenses as we continue to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, which requires management to extensively evaluate and report on, and our independent registered public accounting firm to attest to, our internal controls. We have incurred significant expenses, and expect to continue to incur expenses, in connection with the evaluation, implementation, documentation and testing of our internal control systems. Management time associated with these compliance efforts necessarily reduces time available for other operating activities, which could adversely affect operating results. If we are unable to achieve full and timely compliance with these regulatory requirements, we could be required to incur additional costs and expend additional money and management time on additional remedial efforts, all of which could adversely affect our results of operations.

**RISKS RELATED TO OUR COMMON STOCK**

***Our common stock may be delisted from AMEX if we fail to maintain compliance with continued listing criteria.***

AMEX will normally consider suspending dealings in, or removing from the list, securities selling for a substantial period of time at a low price per share if the issuer fails to effect a reverse split of such stock within a reasonable time after being notified that AMEX deems such action to be appropriate under the circumstances. While AMEX does not provide bright line minimum share price standards for continued listing, we believe that a price less than \$1.00 per share for a substantial period of time will be investigated. On October 1, 2007, the closing price of a share of our common stock, as reported on AMEX, was \$0.55 and, through March 3, 2008, it has closed at less than \$1.00.



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If we are unable to comply with AMEX's continued listing requirements, including its trading price requirements, our common stock may be suspended from trading on and/or delisted from AMEX. The delisting of our common stock from AMEX may materially impair our stockholders' ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. In addition, the delisting of our common stock could significantly impair our ability to raise capital.

***The market price of our common stock has been and is likely to continue to be highly volatile.***

On October 1, 2007, the market price for our common stock dropped almost 80% following our announcement of the results of our phase 2b clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. In addition, the market price for our common stock has historically been highly volatile, and the market for our common stock has from time to time experienced significant price and volume fluctuations that are unrelated to our operating performance. The market price of our common stock may fluctuate significantly in response to a number of factors, including:

changes in the regulatory status of our product candidates, including results of our clinical trials and other research and development programs;

FDA or international regulatory actions and regulatory developments in the U.S. and foreign countries;

announcements of new products or technologies, commercial relationships or other events (including clinical trial results and regulatory events and actions) by us or our competitors;

market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors;

developments concerning intellectual property rights generally or those of us or our competitors;

litigation or public concern about the safety of our products or product candidates;

changes in securities analysts' estimates of our financial performance or deviations in our business and the trading price of our common stock from the estimates of securities analysts;

events affecting our existing in-license agreements and any future collaborations, commercial agreements and grants;

fluctuations in stock market prices and trading volumes of similar companies;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders or pursuant to effective shelf registration statements that register shares of our common stock that may be sold by certain of our current stockholders;

discussion of us or our stock price by the financial and scientific press and in online investor communities;

additions or departures of key personnel; and

changes in third party reimbursement policies.

As evidenced by the October 1, 2007 decline, the realization of any of the foregoing could have a dramatic and adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Moreover, regulatory entities often undertake investigations of investor transactions in securities that experience volatility following an announcement of a significant event or condition. Any such litigation brought against us or investigation involving our investors could result in substantial costs and a diversion of management's attention and resources, which could hurt

our business, operating results and financial condition.



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***Sales of substantial amounts of our common stock or the perception that such sales may occur could cause the market price of our common stock to drop significantly, even if our business is performing well.***

The market price of our common stock could decline as a result of sales by, or the perceived possibility of sales by, us or our existing stockholders of shares of our common stock. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate. In addition, we have filed shelf and resale registration statements to register shares of our common stock that may be sold by us or certain of our stockholders, which may increase the likelihood of sales by, or the perception of an increased likelihood of sales by, us or our existing stockholders of shares of our common stock.

***Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult, which could depress our stock price. Alternatively, prohibitions on anti-takeover provisions in our charter documents may restrict us from acting in the best interests of our stockholders.***

We are incorporated in Delaware. Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change in control would be beneficial to our stockholders. Our bylaws limit who may call a special meeting of stockholders and establish advance notice requirements for nomination for election to our board of directors or for proposing matters that can be acted upon at stockholders' meetings. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors may use these provisions to prevent changes in the management and control of our company. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future. In addition, provisions of certain contracts, such as stock option agreements under our 2005 Equity Incentive Plan and employment agreements with our executive officers, may have an anti-takeover effect. In particular, we agreed with our chief financial officer that, among other things, in the event of our acquisition, 50% of any unvested portion of an option we granted to him would vest upon such acquisition, with the remaining unvested portion vesting monthly over the 12 months following such acquisition. As a result, if an acquirer desired to retain the services of our chief financial officer following an acquisition, it may be required to provide additional incentives to him with additional options or other securities, which may deter or affect the terms of an acquisition or potential acquisition.

In connection with a July 2005 private placement, we agreed with the investors in that transaction that we would not implement certain additional measures that would have an anti-takeover effect. As a result, under our amended and restated certificate of incorporation, we are prohibited from dividing our board of directors into classes and adopting or approving any rights plan, poison pill or other similar plan or device. A classified board of directors could serve to protect our stockholders against unfair treatment in takeover situations, by making it more difficult and time-consuming for a potential acquirer to take control of our board of directors. A company may also adopt a classified board of directors to ensure stability in the board of directors and thereby improve long-term planning, which may benefit stockholders. A poison pill or similar plan or device may encourage potential acquirers to discuss their intentions with the board of directors of a company and avoid the time, expense and distraction of a hostile take-over. Any benefit to us and our stockholders from instituting a classified board or adopting or approving a poison pill or similar plan or device in these and other circumstances would be unavailable unless and until we amend our amended and restated certificate of incorporation.

***Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.***

Our executive officers and directors and the beneficial owners of 5% or more of our common stock and their affiliates, in aggregate, beneficially own approximately 15.6% of our outstanding common stock as of March 3, 2008. These persons, if acting together, will be able to exercise significant influence over all matters requiring stockholders approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control our management and affairs. Further, the interests of significant stockholders may be different than yours and they may support transactions that you feel are not in your best interest. This concentration of ownership may harm the market price of our common

stock by delaying or preventing a change in control of our company at a premium price even if beneficial to our other stockholders.

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***Because we do not expect to pay dividends in the foreseeable future, you must rely on stock appreciation for any return on your investment.***

We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we are subject to various laws and regulations that may restrict our ability to pay dividends and we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our capital stock will likely depend entirely upon any future appreciation and there is no guarantee that our capital stock will appreciate in value.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**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 \$257,595 annually, excluding incremental operating cost adjustments. If we commercialize ANX-530 or ANX-514 in the U.S. without a partner, we may lease additional office and/or lab space to accommodate our anticipated growth associated with commercial activities.

**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.

On October 11, 2007, we filed a demand for arbitration against Theragenex, LLC, or Theragenex, (doing business as TRx Pharma, LLC and/or TRx Pharmaceuticals, LLC) and David M. Preston, founder, Chairman, President and Chief Executive Officer of Theragenex in his individual capacity as the alter ego of Theragenex, seeking damages of up to \$10 million with respect to breach of the license agreement, dated October 20, 2006, between us and Theragenex. We terminated the license agreement in August 2007 as a result of Theragenex's breach. In accordance with the terms of the license agreement, we filed our demand with the American Arbitration Association and requested that the hearing take place in San Diego, California. On November 8, 2007, Theragenex responded to our demand, asserting numerous affirmative defenses counterclaiming intentional misrepresentation, negligent misrepresentation and rescission and seeking a refund of its \$500,000 payment, plus interest, rescission of the license agreement and that we pay its reasonable attorneys fees and costs associated with the action. Also on November 8, 2007, Mr. Preston objected to his participation and being named as a respondent in the arbitration. We believe the likelihood of an unfavorable outcome as a result of Theragenex's counterclaims is remote. Unless we earlier settle or otherwise determine not to pursue the matter, we expect an arbitration hearing date in the fourth quarter of 2008. We are unable to predict the outcome of our claim against Theragenex and the amount that we could receive, if any, from the arbitration proceedings.

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

Not applicable.

**Table of Contents****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 the American Stock Exchange, or AMEX. 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 AMEX.

|                | <b>Common Stock Price</b> |            |             |            |
|----------------|---------------------------|------------|-------------|------------|
|                | <b>2007</b>               |            | <b>2006</b> |            |
|                | <b>High</b>               | <b>Low</b> | <b>High</b> | <b>Low</b> |
| First Quarter  | \$2.84                    | \$1.98     | \$5.00      | \$3.30     |
| Second Quarter | \$2.90                    | \$2.31     | \$5.28      | \$3.05     |
| Third Quarter  | \$2.80                    | \$2.07     | \$3.65      | \$2.40     |
| Fourth Quarter | \$0.88                    | \$0.43     | \$3.37      | \$2.33     |

As of March 3, 2008, we had approximately 209 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.

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## Cumulative Total Return to Stockholders

The following graph compares the cumulative 5-year total return to stockholders on our common stock relative to the cumulative total returns of the Russell 2000 index, the AMEX Composite index and the AMEX Biotechnology index. The graph assumes that the value of the investment in our common stock and in each index (including reinvestment of dividends) was \$100 on December 31, 2002 and tracks it through December 31, 2007.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***

Among ADVENTRX Pharmaceuticals, Inc. The Russell 2000 Index,  
The AMEX Composite Index And The AMEX Biotechnology Index

| <b>Years ending December 31,</b>  | <b>2002</b> | <b>2003</b> | <b>2004</b> | <b>2005</b> | <b>2006</b> | <b>2007</b> |
|-----------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| ADVENTRX Pharmaceuticals,<br>Inc. | 100.00      | 220.51      | 287.18      | 841.03      | 756.41      | 115.38      |
| Russell 2000                      | 100.00      | 147.25      | 174.24      | 182.18      | 215.64      | 212.26      |
| AMEX Composite                    | 100.00      | 143.18      | 175.20      | 215.26      | 257.04      | 299.37      |
| AMEX Biotechnology                | 100.00      | 159.74      | 181.93      | 237.92      | 227.81      | 208.94      |

\* \$100 invested on December 31, 2002 in stock or index-including reinvestment of dividends. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

**Recent Sales of Unregistered Securities**

During the fiscal year ended December 31, 2007, we did not issue any securities that were not registered under the Securities Act of 1933, as amended.

**Table of Contents****Item 6. Selected Financial Data**

The selected consolidated financial data set forth below at December 31, 2007 and 2006, and for the years ended December 31, 2007, 2006 and 2005, are derived from our audited consolidated financial statements included elsewhere in this report. This information should be read in conjunction with those consolidated financial statements, the notes thereto, and the report of independent registered public accounting firm thereon, and with Management's Discussion and Analysis of Financial Condition and Results of Operations. The selected consolidated financial data set forth below at December 31, 2005, 2004 and 2003, and for the years ended December 31, 2004 and 2003, are derived from our audited consolidated financial statements that are contained in reports previously filed with the SEC.

**Summary Financial Information**

| <b>Statement of operations data:</b>  | <b>Years Ended December 31,</b> |                 |                 |                |                |
|---|---------------------------------|-----------------|-----------------|----------------|----------------|
|   | <b>2007</b>                     | <b>2006 (2)</b> | <b>2005 (2)</b> | <b>2004</b>    | <b>2003</b>    |
| Loss from operations  | \$ (24,311,045)                 | \$ (29,836,467) | \$ (13,699,045) | \$ (6,804,090) | \$ (2,339,960) |
| Net loss  | \$ (22,142,040)                 | \$ (28,671,745) | \$ (13,202,986) | \$ (6,701,048) | \$ (2,332,077) |
| Net loss applicable to common stock   | \$ (22,142,040)                 | \$ (28,671,745) | \$ (13,202,986) | \$ (6,701,048) | \$ (2,369,917) |
| Basic and diluted net loss per common share (1)                                     | \$ (0.25)                       | \$ (0.39)       | \$ (0.22)       | \$ (0.13)      | \$ (0.07)      |
| Basic and diluted weighted average number of shares of common stock outstanding (1) | 89,912,732                      | 73,988,206      | 59,828,357      | 50,720,180     | 31,797,986     |
| Cash dividends declared per share   | \$                              | \$              | \$              | \$             | \$             |

| <b>Balance sheet data:</b>                              | <b>December 31,</b> |                 |                 |               |              |
|---|---------------------|-----------------|-----------------|---------------|--------------|
|   | <b>2007</b>         | <b>2006 (2)</b> | <b>2005 (2)</b> | <b>2004</b>   | <b>2003</b>  |
| Cash and cash equivalents                               | \$ 14,780,739       | \$ 25,974,041   | \$ 14,634,618   | \$ 13,032,263 | \$ 4,226,397 |
| Short-term investments                                  | 18,682,417          | 25,771,406      | 7,958,458       |               |              |
| Total cash, cash equivalents and short-term investments | 33,463,156          | 51,745,447      | 22,593,076      | 13,032,263    | 4,226,397    |
| Working capital (2)                                     | 30,658,061          | 49,888,588      | 21,162,192      | 12,047,819    | 4,091,730    |
| Total assets  | 34,541,625          | 52,798,385      | 23,621,773      | 13,608,787    | 4,283,356    |
| Long-term obligations                                   | 14,270              | 35,674          | 57,078          |               |              |
| Total liabilities (2)                                   | 3,507,085           | 2,484,198       | 1,753,978       | 1,218,396     | 163,043      |
| Stockholders' equity (2)                                | 31,034,540          | 50,314,187      | 21,867,795      | 12,390,391    | 4,120,313    |

(1) See Note 2 of the Notes to Consolidated Financial Statements, Summary of Significant Accounting Policies Computation of Net Loss per Common Share, for an explanation of the method used to calculate the net loss per common share and the number of shares used to compute the per share amount.

(2) On January 1, 2007, we adopted the provisions of the Financial Accounting Standards Board, or FASB, Staff Position on No. EITF 00-19-2, Accounting for Registration Payment Arrangements, or FSP EITF 00-19-2. Accordingly, the consolidated financial statements at December 31, 2006 and 2005 and for the years then ended were adjusted retrospectively. See Note 2 of the Notes to Consolidated Financial Statements, Summary of Significant Accounting Policies Change in Accounting Principle for Registration Payment Arrangements, for a detailed discussion.

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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 set forth under Item 1A of Part I, Risk Factors, in this report.*

**OVERVIEW**

We are a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates primarily for the treatment of cancer and infectious disease. We seek to improve the performance and commercial potential of existing treatments by addressing limitations associated with these treatment regimens.

Our recent research and development and other highlights include:

*ANX-530*

In November 2007, we announced that pharmacokinetic equivalence, the primary endpoint in our registrational bioequivalence clinical study, was observed between ANX-530 and Navelbine. In addition, in post hoc analyses, relative to Navelbine, ANX-530 demonstrated a statistically significant reduction in injection site reactions. 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. Based on a meeting with the FDA in December 2007, we reached agreement with the FDA regarding commercial manufacturing requirements for ANX-530, as well as requisites for the CMC section of our anticipated Section 505(b)(2) NDA submission.

*ANX-514*

In September 2007, we obtained FDA agreement regarding our planned Section 505(b)(2) NDA regulatory path for ANX-514. The FDA has indicated that data from a single study of approximately 28 patients that demonstrates the bioequivalence of ANX-514 and Taxotere may provide sufficient clinical data to support a Section 505(b)(2) NDA. In preclinical testing, ANX-514 demonstrated reduced hypersensitivity reactions without impacting pharmacokinetics or antitumor activity when compared to Taxotere.

*ANX-510, or CoFactor*

In November 2007, we announced that we discontinued enrolling patients in our phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. This decision followed advice we received from our DSMB and analysis of our phase 2b clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer that was completed in October 2007. While the DSMB did not identify safety concerns with CoFactor, it recommended closure of the phase 3 clinical trial, citing a slow accrual rate due, in part, to current and projected treatment preferences for colorectal cancer. Analysis of the phase 2b clinical trial, in which 5-FU was administered by infusion, uncovered no significant differences between the study arms with regard to either efficacy or safety.

*Regulatory and Commercial Capabilities*

In 2007, we strengthened our management team's regulatory and commercial development capabilities with the appointment of a vice president of regulatory affairs, a vice president of commercialization, and other staff additions that support the development of third party manufacturing resources.

*New Board Member*

In February 2008, Eric K. Rowinsky, M.D., chief medical officer and executive vice president of ImClone Systems Incorporated, joined our board of directors.



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We are a development stage company and have incurred annual net losses since inception. We have devoted substantially all of our resources to R&D or to acquisition of our product candidates. We have not yet marketed any products or generated any significant revenue from licensing our products or technology. As of December 31, 2007, our accumulated net losses amounted to \$99.7 million. We expect that our R&D, selling, general and administrative and other operating costs will continue to exceed revenues for the foreseeable future. We believe that cash, cash equivalents and short-term investments of approximately \$33.5 million at December 31, 2007 should be sufficient to sustain our planned level of operations for at least the next 12 months. However, in order to maintain sufficient cash and investments to fund future operations longer term, and to continue developing our existing product candidates, we may need or choose to seek additional capital in 2008 through collaborations, licensing arrangements or other strategic transactions, public or private sales of our equity securities, and/or debt financings.

We may seek to commercialize ANX-530 and ANX-514 ourselves. In that event, we will likely incur substantial costs undertaking the activities associated with preparing for commercial launch of a product, including hiring sales personnel and creating and maintaining a sales and distribution organization and associated regulatory compliance infrastructure. Substantial costs may be incurred in advance of the FDA's decisions regarding marketing approvals of ANX-530 and ANX-514. We may also incur significant additional costs continuing clinical development of CoFactor, depending on our assessment of the value of developing CoFactor independently in particular indications and cancer stages following our analysis of the three sets of CoFactor clinical data we expect in mid-2008.

**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, share-based compensation and registration payment arrangements. 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.

***Change in Accounting Principle for Registration Payment Arrangements.*** In December 2006, the FASB issued FSP EITF 00-19-2, *Accounting for Registration Payment Arrangements*, which provides that a contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement is separately recognized and measured in accordance with Statement of Financial Accounting Standards ( FAS ) No. 5, *Accounting for Contingencies*, which provides that loss contingencies should be recognized as liabilities if they are probable and reasonably estimable. On January 1, 2007, the first day of our fiscal year ended December 31, 2007, we adopted the provisions of FSP EITF 00-19-2 to account for an outstanding registration payment arrangement. The comparative consolidated financial statements of prior periods have been adjusted to apply the new method retrospectively. See Note 2 of the Notes to Consolidated Financial Statements, *Summary of Significant Accounting Policies - Change in Accounting Principle for Registration Payment Arrangements*, for a detailed discussion.

***Income Taxes.*** In July 2006, FASB issued FIN 48, *Accounting for Uncertainty in Income Taxes-an Interpretation of FASB Statement 109*, which clarifies the accounting for uncertainty in tax positions. FIN 48 provides that the tax effects from an uncertain tax position can be recognized in our consolidated financial statements only if the position is more likely than not of being sustained upon an examination by tax authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The provisions of FIN 48 were effective for us as of January 1, 2007, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings in the year of adoption. We adopted FIN 48 on January 1, 2007, which did not have a material impact on our consolidated results of operations or financial position.

**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 Deliverables, or EITF 00-21. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured.

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Revenue from licensing agreements is recognized based on the performance requirements of the agreement. Revenue is deferred for fees received before earned. Nonrefundable upfront fees that are not contingent on any future performance by us are recognized as revenue when revenue recognition criteria under Topic 13 and EITF 00-21 are met and the license term commences. Nonrefundable upfront fees, where we have ongoing involvement or performance obligations, are recorded as deferred revenue and recognized as revenue over the life of the contract, the period of the performance obligation or the development period, whichever is appropriate in light of the circumstances.

Payments related to substantive, performance-based milestones in an agreement are recognized as revenue upon the achievement of the milestones as specified in the underlying agreement when they represent the culmination of the earnings process. Royalty revenue from licensed products will be recognized when earned in accordance with the terms of the applicable license agreements.

**R&D Expenses.** R&D expenses consist of expenses incurred in performing R&D activities, including salaries and benefits, facilities and other overhead expenses, clinical trials, research-related manufacturing services, contract services and other outside expenses. R&D expenses are charged to operations as they are incurred. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future R&D activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

Milestone payments that we make in connection with in-licensed technology or product candidates are expensed as incurred when there is uncertainty in receiving future economic benefits from the licensed technology or product candidates. We consider the future economic benefits from the licensed technology or product candidates to be uncertain until such licensed technology or product candidates are approved for marketing by the FDA or when other significant risk factors are abated. For expense accounting purposes, management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain.

Payments in connection with our clinical trials are often made under contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price or on a time-and-material basis. Payments under these contracts depend on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones. Expenses related to clinical trials are accrued based on our estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies, and clinical trials progress. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we modify our accruals accordingly on a prospective basis. Revisions in scope of contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. Because of the uncertainty of possible future changes to the scope of work in clinical trials contracts, we are unable to quantify an estimate of the reasonably likely effect of any such changes on our consolidated results of operations or financial position. Historically, we have had no material changes in our clinical trial expense accruals that would have had a material impact on our consolidated results of operations or financial position.

**Purchased In-Process Research and Development.** In accordance with FAS No. 141, Business Combinations, we immediately charge the costs associated with purchased in-process research and development, or IPR&D, to statement of operations upon acquisition. These amounts represent an estimate of the fair value of purchased IPR&D for projects that, as of the acquisition date, had not yet reached technological feasibility, had no alternative future use, and had uncertainty in receiving future economic benefits from the purchased IPR&D. We determine the future economic benefits from the purchased IPR&D to be uncertain until such technology is approved by the FDA or when other significant risk factors are abated. In the year ended December 31, 2006, we incurred approximately \$10.4 million IPR&D expense related to our acquisition of SD Pharmaceuticals, Inc. in April 2006.

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**Share-based Compensation Expenses.** Effective January 1, 2006, we accounted for share-based compensation awards granted to employees in accordance with the revised FAS No. 123, *Share-Based Payment*, or FAS 123R, including the provisions of Staff Accounting Bulletins No. 107 and No. 110. Share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period. We have no awards with market or performance conditions. As share-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. Although estimates of share-based compensation expenses are significant to our consolidated financial statements, they are not related to the payment of any cash by us. Prior to January 1, 2006, we accounted for share-based compensation under the recognition and measurement principles of FAS 123, *Accounting for Stock-Based Compensation*.

We estimate the fair value of stock option awards on the date of grant using the Black-Scholes option-pricing model, or Black-Scholes model. The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, a risk-free interest rate and expected dividends. We may elect to use different assumptions under the Black-Scholes model in the future, which could materially affect our net income or loss and net income or loss per share.

We account for share-based compensation awards granted to non-employees in accordance with EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or EITF 96-18. Under EITF 96-18, we determine the fair value of the share-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured using the stock price and other measurement assumptions as of the earlier of either (1) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached or (2) the date at which the counterparty's performance is complete.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In most cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the U.S.

**RESULTS OF OPERATIONS**

A general understanding of the drug development process is critical to understanding our results of operations. Drug development in the U.S. and most countries throughout the world is a process that includes several steps defined by the FDA and similar regulatory authorities in foreign countries. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit an NDA, which includes complete reports of pre-clinical, clinical and laboratory studies and extensive manufacturing information to prove such product's safety and effectiveness. The NDA process generally requires, before the submission of the NDA, filing of an IND, pursuant to which permission is sought to begin clinical testing of the new drug product. An NDA based on published safety and effectiveness studies conducted by others, or previous findings of safety and effectiveness by the FDA, may be submitted under Section 505(b)(2) of the FDCA. Development of new formulations of pharmaceutical products under Section 505(b)(2) of the FDCA may have shorter timelines than those associated with developing new chemical entities.

Generally, with respect to any drug product with active ingredients not previously approved by the FDA, an NDA must be supported by data from at least phase 1, phase 2 and phase 3 clinical trials. Phase 1 clinical trials can be expected to last from 6 to 18 months, phase 2 clinical trials can be expected to last from 12 to 24 months and phase 3 clinical trials can be expected to last from 18 to 36 months. However, clinical development timelines vary widely, as do the total costs of clinical trials and the likelihood of success. We anticipate that we will make determinations as to which R&D programs to pursue and how much funding to direct to each program on an ongoing basis in response to

the scientific and clinical success of each product candidate, our ongoing assessment of its market potential and our available resources.

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Our expenditures on R&D programs are subject to many uncertainties, including whether we develop our product candidates with a partner or independently. At this time, due to such uncertainties and the risks inherent in the clinical trial process and given the early stage of development of many of our product candidates, we cannot estimate with reasonable certainty the duration of or costs to complete our R&D programs or whether or when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of our R&D programs, in particular those associated with clinical trials, vary significantly among programs or within a particular program as a result of a variety of factors, including:

the number of trials necessary to demonstrate the safety and efficacy of a product candidate;

the number of patients who participate in the trials;

the number of sites included in the trials and rate of site approval for the trial;

the rates of patient recruitment and enrollment;

the duration of patient treatment and follow-up;

the costs of manufacturing our product candidates; and

the costs, requirements, timing of, and the ability to secure regulatory approvals.

The difficult process of seeking regulatory approvals for our product candidates, in particular those containing new chemical entities, and compliance with applicable regulations, requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our R&D expenditures to increase and, in turn, have a material and unfavorable effect on our results of operations. We cannot be certain when, if ever, we will generate revenues from sales of any of our products.

We operate our business on the basis of a single reportable segment, which is the business of in-licensing, developing and commercializing proprietary product candidates primarily for the treatment of cancer and infectious disease. Our chief operating decision-maker is our chief executive officer and president, who evaluates our company as a single operating segment. All of our operating activities and work performed by our employees are currently conducted from a single location in the U.S. Revenues of \$500,000 in 2007 were derived solely from fees earned from a license agreement with Theragenex, LLC., which we terminated in August 2007. We did not generate any revenues in either 2006 or 2005.

|                                     | <b>Operating Expenses</b>       |             |             |
|-------------------------------------|---------------------------------|-------------|-------------|
|                                     | <b>Years Ended December 31,</b> |             |             |
|                                     | <b>2007</b>                     | <b>2006</b> | <b>2005</b> |
| Research and development            | 64%                             | 40%         | 63%         |
| In-process research and development | 0%                              | 35%         | 0%          |
| Selling, general and administrative | 35%                             | 24%         | 36%         |
| Depreciation and amortization       | 1%                              | 1%          | 1%          |
| Total operating expenses            | 100%                            | 100%        | 100%        |

**Comparison of 2007 and 2006**

**Revenue.** Revenue for the year ended December 31, 2007 amounted to \$500,000, compared to no revenue for the year ended December 31, 2006. Revenue in 2007 represents a \$500,000 nonrefundable license fee paid under our license agreement with Theragenex, which we terminated in August 2007 as a result of Theragenex's breach of the agreement. We recognized the license fee as revenue in the period our performance obligations were complete, collectibility was reasonably assured and there were no continuing obligations for us to perform under the agreement.

We have not generated any revenue from product sales to date, and we do not expect to generate revenue from product sales until such time that we have obtained approval from a regulatory agency to sell one of our product candidates, which we cannot predict will occur.

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**R&D Expenses.** We maintain and evaluate our R&D expenses by the type of cost incurred rather than by project. We maintain and evaluate R&D expenses by type primarily because of the uncertainties described above, as well as because we out-source a substantial portion of our work and our R&D personnel work across multiple programs rather than dedicating their time to one particular program. We began maintaining such expenses by type on January 1, 2005. The following table summarizes our consolidated R&D expenses by type for each of the periods listed and since January 1, 2005:

|   | Years Ended December 31, |               |              | January 1,<br>2005<br>through<br>December 31,<br>2007 |
|---|--------------------------|---------------|--------------|---|
|   | 2007                     | 2006          | 2005         |   |
| External clinical trial fees and expenses         | \$ 7,535,923             | \$ 7,312,691  | \$ 4,977,000 | \$ 19,825,614   |
| External non-clinical study fees and expenses (1) | 4,346,397                | 2,089,413     | 1,923,969    | 8,359,779   |
| Personnel costs                                   | 2,997,852                | 2,089,142     | 1,187,036    | 6,274,030   |
| Share-based compensation expense                  | 1,054,237                | 509,966       | 594,493      | 2,158,696   |
| Total   | \$ 15,934,409            | \$ 12,001,212 | \$ 8,682,498 | \$ 36,618,119   |

(1) External non-clinical study fees and expenses include preclinical, research-related manufacturing, quality assurance and regulatory expenses.

R&D expenses increased by \$3.9 million, or 33%, to \$15.9 million for the year ended December 31, 2007, compared to \$12.0 million in 2006. The increase in R&D expenses was primarily due to a \$2.3 million increase in expenses related to external preclinical, research-related manufacturing, quality assurance and regulatory activities, a \$1.5 million increase in personnel and related costs and \$223,000 increase in external clinical trial expenses.

If we continue to develop our product candidates without a partner, we expect that our R&D expenses in 2008 will increase by up to approximately \$5.0 million over what we incurred in 2007, primarily as a result of our plans to devote increased resources to manufacturing and related validation activities for ANX-530 and ANX-514. Plans for 2008 include expenditures related to CoFactor to complete the treatment phase of the phase 2 advanced breast cancer clinical trial and analyze the data, as well as to compile and analyze data from and close the phase 2b and phase 3 clinical trials for the first-line treatment of metastatic colorectal cancer. We have not allocated funds to continuing development of CoFactor other than in connection with our phase 2, phase 2b and phase 3 clinical trials. We could incur significant additional costs to continue clinical development of CoFactor in the second half of 2008, depending on our assessment of the value of developing the drug independently in particular indications and cancer stages following our analysis of the three sets of CoFactor clinical data we expect in mid-2008. See also Management Outlook.



**IPR&D.** In 2006, we recorded a charge of \$10.4 million in connection with purchased IPR&D related to the acquisition of SD Pharmaceuticals, Inc. in April 2006.

**Selling, General and Administrative Expenses.** Selling, general and administrative, or SG&A, expenses increased by \$1.4 million, or 20%, to \$8.7 million for 2007, compared to \$7.2 million in 2006. The increase was substantially due to a \$1.0 million increase in personnel and related costs and a \$321,000 increase in legal fees, of which \$204,000 was related to the enforcement of our rights under the Theragenex license agreement, which we terminated in August 2007. If we continue our plans to commercialize ANX-530 in the U.S. on our own, we expect that SG&A expenses in 2008 will increase by up to approximately \$2.5 million over what we incurred in 2007. If we commercialize ANX-530 or ANX-514 in the U.S. without a partner, we may lease additional office and/or lab space to accommodate our anticipated growth associated with commercial activities.

**Interest Income.** Interest income for 2007 increased by \$1.0 million, or 86%, to \$2.2 million in 2007, compared to \$1.2 million in 2006. The increase was primarily attributable to higher invested balances resulting from the receipt of \$37.1 million in net proceeds from the sale of our common stock to institutional investors in November 2006. We expect that interest income will decline in future quarters as forecasted interest rates decline along with lower invested balances.

**Net Loss.** Net loss was \$22.1 million or \$0.25 per share in 2007, compared to a net loss of \$28.7 million or \$0.39 per share in 2006.

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We expect to continue the development of ANX-530 and ANX-514, as well as CoFactor if the data from the three data sets we expect in mid-2008 are favorable. To help fund and develop our product development efforts, we may license certain of our technologies and product candidates to third parties. These potential license arrangements could materially change our outlook for future revenues and costs. However, the timing of such potential arrangements is unpredictable.

**Comparison of 2006 and 2005**

**R&D Expenses.** R&D expenses increased by approximately \$3.3 million, or 38%, to \$12.0 million in 2006, compared to \$8.7 million in 2005. The increase was due to a \$2.0 million increase in spending for launching a phase 3 clinical trial of CoFactor and continuing a phase 2b CoFactor clinical trial for the first-line treatment of metastatic colorectal cancer, a \$902,000 increase in personnel and related costs, a \$330,000 increase in outside services expense related to clinical support efforts and a \$144,000 increase in preclinical expenditures related to CoFactor, ANX-530 and ANX-201.

**IPR&D.** In 2006, we recorded a charge of \$10.4 million in connection with purchased IPR&D related to the acquisition of SD Pharmaceuticals, Inc. in April 2006.

**SG&A Expenses.** SG&A expenses increased by \$2.3 million, or 47%, to \$7.2 million in 2006, compared to \$4.9 million in 2005. The increase was primarily due to a \$1.3 million increase in personnel and related costs, a \$579,000 increase in professional and consulting fees and a \$226,000 increase in insurance costs related to an increase in liability coverage.

**Interest Income.** Interest income increased by \$669,000, or 135%, to \$1.2 million in 2006, compared to \$496,000 in 2005. The increase was primarily due to higher invested balances resulting from the receipt of \$37.1 million in net proceeds from the sale of our common stock to institutional investors in November 2006, and from higher interest rate yields on these balances in 2006 compared to 2005.

**Net Loss.** Net loss was \$28.7 million or \$0.39 per share in 2006, compared to a net loss of \$13.2 million or \$0.22 per share in 2005.

**LIQUIDITY AND CAPITAL RESOURCES**

Historically, we have funded our operations primarily through sales of our equity securities. As of December 31, 2007, we had cash, cash equivalents and short-term investments in securities totaling \$33.5 million, with cash and cash equivalents of \$14.8 million and short-term investments of \$18.7 million. Our net working capital balance as of December 31, 2007 was \$30.7 million. As of December 31, 2006, we had cash, cash equivalents and short-term investments totaling \$51.7 million and a net working capital balance of \$49.9 million. Explanations of net cash provided by or used in operating, investing and financing activities are provided below.

|  | <b>December 31,<br/>2007</b>                | <b>Decrease<br/>During 2007</b>       | <b>December 31,<br/>2006</b>                |
|--|---|---------------------------------------|---|
| Cash, cash equivalents and investments in securities | \$33,463,156                                | \$(18,282,291)                        | \$51,745,447                                |
| Net working capital (1)                              | \$30,658,061                                | \$(19,230,527)                        | \$49,888,588                                |
|  | <b>Year Ended<br/>December 31,<br/>2007</b> | <b>Change<br/>Between<br/>Periods</b> | <b>Year Ended<br/>December 31,<br/>2006</b> |
| Net cash used in operating activities                | \$ (19,643,190)                             | \$ (3,869,646)                        | \$ (15,773,544)                             |
| Net cash provided by (used in) investing activities  | 8,008,272                                   | 25,782,857                            | (17,774,585)                                |
| Net cash provided by financing activities            | 441,616                                     | (44,445,936)                          | 44,887,552                                  |
| Net (decrease) increase in cash and cash equivalents | \$ (11,193,302)                             | \$ (22,532,725)                       | \$ 11,339,423                               |

1. On January 1,  
2007, we

*adopted the provisions of FSP EITF 00-19-2. Accordingly, the consolidated financial statements at December 31, 2006 and 2005 and for the years then ended were adjusted retrospectively. See Note 2 of the Notes to Consolidated Financial Statements, Summary of Significant Accounting Policies Change in Accounting Principle for Registration Payment Arrangements, for a detailed discussion.*

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**Operating activities.** Net cash used in operating activities was \$19.6 million in 2007, compared to \$15.8 million in 2006 and \$11.6 million in 2005. The increase in cash used in operating activities in 2007 and 2006 was mainly due to the increase in our R&D and SG&A expenses.

**Investing activities.** Net cash provided by investing activities was \$8.0 million in 2007, compared to net cash used in investing activities of \$17.8 million in 2006 and \$8.1 million in 2005. Net cash provided by investing activities in 2007 was mainly net proceeds from sales of short-term investments of \$8.1 million. The net cash used in investing activities in 2006 as compared to 2005 was mainly due to net purchases of short-term investments of \$17.6 million.

**Financing activities.** Net cash provided by financing activities was \$442,000 in 2007, consisting of proceeds from option exercises. Net cash provided by financing activities in 2006 was \$44.9 million, consisting primarily of \$37.1 million in net proceeds from the sale of our common stock to institutional investors in November 2006 and \$7.7 million in net proceeds from exercises of warrants to purchase our common stock. Net cash provided by financing activities in 2005 was \$21.3 million, consisting primarily of \$18.1 million in net proceeds from sales of our common stock and warrants to purchase our common stock through private placements and \$3.1 million from exercises of warrants to purchase our common stock.

**Contractual Obligations.** As of December 31, 2007, we have contractual obligations for operating leases and purchase obligations, as summarized in the table that follows. We anticipate being able to satisfy the obligations described below out of cash, cash equivalents and investments in securities held by us as of December 31, 2007. We do not have any off-balance sheet arrangements and no commitments for any significant additional capital expenditures.

|                             | Total        | Payments Due by Period |              |           | More Than 5 Years |
|-----------------------------|--------------|------------------------|--------------|-----------|-------------------|
|                             |              | Less Than 1 Year       | 1-3 Years    | 3-5 Years |                   |
| Purchase obligations        | \$ 8,856,192 | \$ 7,811,485           | \$ 1,021,878 | \$ 22,829 | \$                |
| Operating lease obligations | 463,383      | 270,087                | 193,296      |           |                   |
| Total                       | \$ 9,319,575 | \$ 8,081,572           | \$ 1,215,174 | \$ 22,829 | \$                |

Purchase obligations presented above represent contractual commitments entered into for goods and services in the normal course of our business. The amount includes all known contracts and open purchase orders related to our clinical and preclinical activities. In many cases, amounts related to service contracts may be cancelled based on contract provisions prior to completion. The allocation of the obligations by year is based on our best estimate of the timing of the expenditures.

The following contingent payments are excluded from the contractual obligations presented above:

Royalties (including prepaid royalties), milestone payments, payments resulting from sublicensing activities and reimbursement of legal expenses due to certain licensors.

Milestone payments (payable in cash and stock) to a consultant based on the regulatory success of CoFactor and our ability to partner CoFactor.

Annual fees conditioned on non-termination of an agreement that we have the right to terminate prior to our payment obligation becoming due.

Also, excluded from the contractual obligations presented above are payments expected to be made in 2008 to our former president and chief medical officer in connection with the termination of his employment with us in January 2008. See Note 18 of the Notes to Consolidated Financial Statements, Subsequent Event, for a detailed discussion.



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**Management Outlook**

We believe that cash, cash equivalents, and short-term investments of approximately \$33.5 million at December 31, 2007 should be sufficient to sustain our planned level of operations for at least the next 12 months. However, in order to maintain sufficient cash and investments to fund future operations longer term, and to continue developing our existing product candidates, we may need or choose to seek additional capital in 2008 through collaborations, licensing arrangements or other strategic transactions, public or private sales of our equity securities, and/or debt financings. The balance of securities available for sale under our existing shelf registration was approximately \$60.0 million as of December 31, 2007, but we may be subject to limitations with respect to the number of securities we can sell under this shelf registration. If we are unable to raise capital as needed to fund future operations, then we may defer or abandon one or more of our R&D programs and may need to take additional cost-cutting measures. Our ability to timely raise capital on commercially reasonable terms may be limited by requirements, rules and regulations of the SEC and the AMEX.

We have held discussions with, and intend to continue to seek, potential partners regarding certain of our product candidates, though some of our product candidates could take several more years of development before they reach the stage of being partnerable with other companies on terms that we believe are appropriate. If we successfully consummate a partnering deal, we may be entitled to upfront or license fees and milestone payments; however, any such fees and payments will depend on successfully consummating a deal and achieving milestones under such arrangements.

For information regarding the risks associated with our need to raise capital to fund our ongoing and planned operations and limitations on our ability to do so, see Item 1A of Part I, Risk Factors, in this report.

**Recent Accounting Pronouncements**

See Note 2, Summary of Significant Accounting Policies Recent Accounting Pronouncements, of the Notes to Consolidated Financial Statements for a discussion of recent accounting pronouncements and their effect, if any, on us.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

We are not subject to any meaningful market risk related to foreign currency exchange rates, commodity prices or similar market risks. Because substantially all of our expenses and capital purchasing activities are transacted in U.S. dollars, our exposure to foreign currency exchange rates is immaterial. However, as described below, we are sensitive to interest rate fluctuations.

The primary objective of our investing activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing the risk of loss. Some of the investable securities permitted under our cash management policy may be subject to market risk for changes in interest rates. To mitigate this risk, we maintain a portfolio of cash equivalent and short-term investments in a variety of securities which may include investment grade commercial paper, money market funds, government debt issued by the United States of America, state debt, certificates of deposit and investment grade corporate debt. Presently, we are exposed to minimal market risks associated with interest rate changes because of the relatively short maturities of our investments and we do not expect interest rate fluctuations to materially affect the aggregate value of our financial instruments. We manage our sensitivity to these risks by maintaining investment grade short-term investments. Our cash management policy does

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not allow us to purchase or hold derivative or commodity instruments or other financial instruments for trading purposes. Additionally, our policy stipulates that we periodically monitor our investments for adverse material holdings related to the underlying financial solvency of the issuer. As of December 31, 2007, our investments consisted mostly of cash, commercial paper and U.S. government debt. Our results of operations and financial condition would not be significantly impacted by either a 10% increase or decrease in interest rates due mainly to the short-term nature of our investment portfolio. We have not used derivative financial instruments in our investment portfolio. Additionally, we do not invest in foreign currencies or other foreign investments.

**Item 8. Financial Statements and Supplementary Data**

The consolidated financial statements and supplementary financial information required by this item are filed with this report as described under Item 15.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures**

***Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of December 31, 2007. Based on that evaluation, our chief executive officer and chief financial officer have concluded that these disclosure controls and procedures were effective as of December 31, 2007.

***Changes in Internal Control over Financial Reporting***

There was no change in our internal control over financial reporting that occurred during the fiscal quarter ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

***Management's Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control - Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2007.

Our internal control over financial reporting as of December 31, 2007 has been attested to by J.H. Cohn, LLP, our independent registered public accounting firm, as stated in their report, which is set forth below in this Item 9A.

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***Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting***

To the Board of Directors and Stockholders

ADVENTRX Pharmaceuticals, Inc.

We have audited ADVENTRX Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. ADVENTRX Pharmaceuticals, Inc. and Subsidiaries' management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, ADVENTRX Pharmaceuticals, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007 based on the criteria established in Internal Control - Integrated Framework issued by the Committee of the Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of ADVENTRX Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity (deficit) and comprehensive loss and cash flows for each of the three years in the period ended December 31, 2007 and our report dated March 14, 2008 expressed an unqualified opinion, and includes an explanatory paragraph related to the adoption of Financial Accounting Standards Board Staff Position on No. EITF 00-19-2, *Accounting for Registration Payment Arrangements*, as discussed in Note 2 to the consolidated financial statements.

/s/ J. H. Cohn LLP  
San Diego, California  
March 14, 2008



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**Item 9B. Other Information**

On February 4, 2008, we entered into a letter agreement regarding terms of separation with James A. Merritt, M.D., our former president and chief medical officer, whose employment relationship with us ended on January 29, 2008. The letter agreement became effective on February 12, 2008. The terms of Dr. Merritt's employment separation, as provided in the letter agreement, are substantially identical to those set forth in his offer letter, dated September 7, 2006, and in the stock option agreement relating to the stock option granted to him in September 2007 in connection with the commencement of his employment, both of which have been previously filed with the SEC, except that we agreed to extend the exercise period of that option from June 29, 2008 to December 31, 2008.

**PART III**

Certain information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our fiscal year pursuant to Regulation 14A, or the Proxy Statement, for our annual meeting of stockholders to be held on May 28, 2008, and such information included in the Proxy Statement is incorporated herein by reference.

**Item 10. Directors, Executive Officers and Corporate Governance**

**Code of Ethics**

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or persons performing similar functions, as well as all of our other officers, directors and employees. This code of ethics is a part of our conduct of business conduct and ethics and available on our corporate website at [www.adventrx.com](http://www.adventrx.com). We intend to disclose future amendments to, or waivers of, certain provisions of our code of ethics that apply to our principal executive officer, principal financial officer, principal accounting officer or persons performing similar functions on the above website within four business days following such amendment or waiver.

The other information required by this item will be set forth in the Proxy Statement and is incorporated into this report by reference.

**Item 11. Executive Compensation**

The information required by this item will be set forth in the Proxy Statement and is incorporated into this report by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this item will be set forth in the Proxy Statement and is incorporated into this report by reference.

**Item 13. Certain Relationships and Related Transactions and Director Independence**

The information required by this item will be set forth in the Proxy Statement and is incorporated into this report by reference.

**Item 14. Principal Accountant Fees and Services**

The information required by this item will be set forth in the Proxy Statement and is incorporated into this report by reference.

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**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

(a) Documents Filed. The following documents are filed as part of this report:

(1) Financial Statements. The following report of J.H. Cohn LLP and financial statements:  
Report of J.H. Cohn LLP, Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2007 and 2006

Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005 and from inception through December 31, 2007

Consolidated Statements of Stockholders' Equity (Deficit) and Comprehensive Loss from inception through December 31, 2007

Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005 and from inception through December 31, 2007

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules. See subsection (c) below.

(3) Exhibits. See subsection (b) below.

(b) Exhibits.

| Exhibit | Description   |
|---------|---|
| 2.1 (1) | Agreement and Plan of Merger, dated April 7, 2006, among the registrant, Speed Acquisition, Inc., SD Pharmaceuticals, Inc. and certain individuals named therein (including exhibits thereto) |
| 3.1 (2) | Amended and Restated Certificate of Incorporation of the registrant   |
| 3.2 (3) | Amended and Restated Bylaws of the registrant (formerly known as Biokeys Pharmaceuticals, Inc.)   |
| 4.1 (4) | Form of Registration Rights Agreement entered into in October and November 2001 (including the original schedule of holders)  |
| 4.2 (5) | \$2.50 Warrant to Purchase Common Stock issued on April 12, 2002 to Emisphere Technologies, Inc.  |
| 4.3 (4) | Form of \$0.60 Warrant to Purchase Common Stock issued May 28, 2003 (including the original schedule of holders)  |
| 4.4 (4) | Form of \$1.25 Warrant to Purchase Common Stock issued between October 15, 2003 and December 29, 2003 (including the original schedule of holders)  |
| 4.5 (4) | Common Stock and Warrant Purchase Agreement, dated as of April 5, 2004, among the registrant and the Investors (as defined therein)   |
| 4.6 (4) | Registration Rights Agreement, dated April 5, 2004, among the registrant and the Investors (as defined therein)   |
| 4.7 (4) |   |



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| Exhibit   | Description  |
|-----------|--|
| 4.8 (4)   | Form of \$2.50 A-2 Warrant to Purchase Common Stock issued April 8, 2004 (including the original schedule of holders)  |
| 4.9 (6)   | Common Stock and Warrant Purchase Agreement, dated April 8, 2004, between the registrant and CD Investment Partners, Ltd.  |
| 4.10 (6)  | Registration Rights Agreement, dated April 8, 2004, between the registrant and CD Investment Partners, Ltd.  |
| 4.11 (6)  | \$2.00 A-1 Warrant to Purchase Common Stock issued on April 8, 2004 to CD Investment Partners, Ltd.  |
| 4.12 (6)  | \$2.00 A-1 Warrant to Purchase Common Stock issued on April 8, 2004 to Burnham Hill Partners   |
| 4.13 (6)  | \$2.00 A-1 Warrant to Purchase Common Stock issued on April 8, 2004 to Ernest Pernet   |
| 4.14 (6)  | \$2.00 A-1 Warrant to Purchase Common Stock issued on April 8, 2004 to W.R. Hambrecht + Co., LLC   |
| 4.15 (7)  | Common Stock and Warrant Purchase Agreement, dated April 19, 2004, between the registrant and Franklin M. Berger   |
| 4.16 (7)  | Registration Rights Agreement, dated April 19, 2004, between the registrant and Franklin M. Berger   |
| 4.17 (7)  | \$2.00 A-1 Warrant to Purchase Common Stock issued on April 19, 2004 to Franklin M. Berger   |
| 4.18 (8)  | Securities Purchase Agreement, dated July 21, 2005, among the registrant and the Purchasers (as defined therein)   |
| 4.19 (8)  | Rights Agreement, dated July 27, 2005, among the registrant, the Icahn Purchasers and Viking (each as defined therein)   |
| 4.20 (9)  | First Amendment to Rights Agreement, dated September 22, 2006, among the registrant and the Icahn Purchasers (as defined therein)                                |
| 4.21 (8)  | Form of \$2.26 Common Stock Warrant issued on July 27, 2005 (including the original schedule of holders)   |
| 4.22 (8)  | Form of \$2.26 Common Stock Warrant issued on July 27, 2005 (including the original schedule of holders)   |
| 4.23 (11) | \$0.50 Warrant (WC-291) to Purchase Common Stock transferred on June 15, 2005 to S. Neborsky and R Neborsky TTEE Robert J. Neborsky MD Inc Comb Retirement Trust |
| 4.24 (10) | \$0.50 Warrant (WC-292) to Purchase Common Stock transferred on June 15, 2005 to S. Neborsky and R Neborsky TTEE Robert J. Neborsky MD Inc Comb Retirement Trust |
| 4.25 (10) | \$2.50 Warrant to Purchase Common Stock issued on October 22, 2004 to Thomas J. DePetrillo   |

|               |  |
|---------------|--|
| 10.1#<br>(11) | 2005 Equity Incentive Plan   |
| 10.2#<br>(12) | Form of Stock Option Agreement under the 2005 Equity Incentive Plan  |
| 10.3#         | Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for director option grants beginning in 2008)     |
| 10.4# (2)     | Form of Restricted Share Award Agreement under the 2005 Equity Incentive Plan  |
| 10.5#<br>(12) | 2005 Employee Stock Purchase Plan  |
| 10.6#<br>(12) | Form of Subscription Agreement under the 2005 Employee Stock Purchase Plan   |
| 10.7*<br>(13) | Option and License Agreement, dated January 23, 1998, between the registrant and the University of Southern California |

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| Exhibit     | Description  |
|-------------|--|
| 10.8 (3)    | First Amendment to License Agreement, dated August 16, 2000, between the registrant and the University of Southern California  |
| 10.9* (13)  | Option and License Agreement, dated August 17, 2000, between the registrant and the University of Southern California  |
| 10.10* (14) | Amendment to Option and License Agreement, dated April 21, 2003, between the registrant and the University of Southern California  |
| 10.11* (15) | Second Amendment to Option and License Agreement, dated January 25, 2007, between the registrant and the University of Southern California   |
| 10.12* (2)  | Agreement, effective as of May 1, 2005, between the registrant and Pharm-Olam International Ltd.   |
| 10.13 (2)   | Amendment dated July 19, 2005 to the Agreement between the registrant and Pharm-Olam International Ltd.  |
| 10.14 (16)  | License Agreement, dated October 20, 2006, between the registrant, through its wholly-owned subsidiary SD Pharmaceuticals, Inc., and Theragenex, LLC   |
| 10.15       | License Agreement, dated December 10, 2005, between SD Pharmaceuticals, Latitude Pharmaceuticals and Andrew Chen, including a certain letter, dated November 20, 2007, clarifying the scope of rights thereunder |
| 10.16 (17)  | Standard Multi-Tenant Office Lease Gross, dated June 3, 2004, between the registrant and George V. Casey & Ellen M. Casey, Trustees of the Casey Family Trust dated June 22, 1998                                |
| 10.17 (2)   | First Amendment to the Standard Multi-Tenant Office Lease Gross, dated June 3, 2004 between the registrant and George V. & Ellen M. Casey, Trustees of the Casey Family Trust dated June 22, 1998                |
| 10.18# (18) | Offer letter, dated March 5, 2003, to Joan M. Robbins  |
| 10.19# (19) | Offer letter, dated November 15, 2004, to Brian M. Culley  |
| 10.20# (20) | Severance Agreement and Release of All Claims, dated September 7, 2006, with Carrie Carlander  |
| 10.21# (20) | Consulting Agreement, dated September 7, 2006, with Carrie Carlander   |
| 10.22# (20) | Offer letter, dated September 7, 2006, to James A. Merritt   |
| 10.23#      | Letter agreement regarding terms of separation with James A. Merritt, effective as of February 12, 2008  |
| 10.24# (20) | Form of Stock Option Agreement between the registrant and James A. Merritt (included in Exhibit 10.22)   |
| 10.25# (21) | Offer letter, dated December 13, 2006, to Gregory P. Hanson  |

|             |  |
|-------------|--|
| 10.26# (21) | Stock Option Agreement, effective December 20, 2006, between the registrant and Gregory P. Hanson                            |
| 10.27 (16)  | Form of Director and Officer Indemnification Agreement   |
| 10.28# (22) | Director compensation policy   |
| 10.29 (23)  | Placement Agency Agreement, dated November 2, 2006, among the registrant, ThinkEquity Partners LLC and Fortis Securities LLC |
| 14.1 (24)   | Code of Business Conduct and Ethics  |
| 21.1        | List of Subsidiaries   |
| 23.1        | Consent of J.H. Cohn LLP, Independent Registered Public Accounting Firm  |
| 31.1        | Certification of chief executive officer pursuant to Rule 13a-14(a)/15d-14(a)  |
| 31.2        | Certification of chief financial officer pursuant to Rule 13a-14(a)/15d-14(a)  |

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| Exhibit | Description  |
|---------|--|
| 32.1 ±  | Certification of chief executive officer and chief financial officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002  |
| *       | Indicates that confidential treatment has been requested or granted to certain portions, which portions have been omitted and filed separately with the SEC  |
| #       | Indicates management contract or compensatory plan   |
| ±       | These certifications are being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing. |
| (1)     | Filed with the registrant's Amendment No. 1 to Current Report on Form 8-K/A on May 1, 2006 (SEC file number 001-32157-06796248)  |
| (2)     | Filed with the registrant's Annual Report on Form 10-K on March 16, 2006 (SEC file number 001-32157-06693266)  |



- (3) Filed with the registrant's Registration Statement on Form 8-K on December 19, 2007 (SEC file number 001-32157-071315801)
- (4) Filed with the registrant's Registration Statement on Form S-3 on June 30, 2004 (SEC file number 333-117022-03848890)
- (5) Filed with the registrant's Amendment No. 1 to Quarterly Report on Form 10-Q/A on October 30, 2006 (SEC file number 001-32157-061170484)
- (6) Filed with the registrant's Current Report on Form 8-K/A on April 13, 2004 (SEC file number 000-33219-04730584)
- (7) Filed with the registrant's Quarterly Report on Form 10-QSB on May 12, 2004 (SEC file number 001-32157-04797806)
- (8) Filed with the registrant's Quarterly Report on Form 10-Q on August 12, 2005 (SEC file number 001-32157-051022046)
- (9) Filed with the registrant's Current Report on Form 8-K on September 22, 2006 (SEC file number 001-32157-061103268)
- (10) Filed with the registrant's Registration Statement on Form S-3 on August 26, 2005 (SEC

file number  
333-127857-051050073)

- (11) Filed with the registrant's Annual Report on Form 10-K on March 15, 2007 (SEC file number 001-32157-07697283)
- (12) Filed with the registrant's Registration Statement on Form S-8 on July 13, 2005 (SEC file number 333-126551-05951362)
- (13) Filed with the registrant's Registration Statement on Form 10SB/A on January 14, 2002 (SEC file number 000-33219-2508012)
- (14) Filed with the registrant's Quarterly Report on Form 10-QSB on August 14, 2003 (SEC file number 000-33219-03848890)
- (15) Filed with the registrant's Quarterly Report on Form 10-Q on May 8, 2007 (SEC file number 001-32157-07829156)
- (16) Filed with the registrant's Current Report on Form 8-K on October 23, 2006 (SEC file number 001-32157-061156993)
- (17) Filed with the registrant's Quarterly Report on Form 10-QSB on August 10, 2004 (SEC file number 001-32157-04963741)

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(18) Filed with the registrant's Annual Report on Form 10-KSB on April 16, 2003 (SEC file number 000-33219-03651464)

(19) Filed with the registrant's Annual Report on Form 10-KSB on March 31, 2005 (SEC file number 001-32157-05719975)

(20) Filed with the registrant's Current Report on Form 8-K on September 8, 2006 (SEC file number 001-32157-061082484)

(21) Filed with the registrant's Current Report on Form 8-K on December 20, 2006 (SEC file number 001-32157-061290689)

(22) Filed with the registrant's Current Report on Form 8-K on June 23, 2006 (SEC file number 001-32157-06922676)

(23) Filed with the registrant's Current Report on Form 8-K on November 3, 2006 (SEC file number 001-32157-061184445)

(24) Filed with the registrant's Current Report on Form 8-K on January 23, 2007 (SEC file number 001-32157-07545489)

(c)

Financial Statement Schedules. All schedules are omitted because they are not applicable, the amounts involved are not significant or the required information is shown in the financial statements or notes thereto.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ADVENTRX Pharmaceuticals, Inc.

By: /s/ Evan M. Levine

Evan M. Levine  
Chief Executive Officer and President

Date: March 14, 2008

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Evan M. Levine and Gregory P. Hanson, jointly and severally, as his true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| <b>Signature</b>        | <b>Title</b>   | <b>Date</b>    |
|-------------------------|--|----------------|
| /s/ Evan M. Levine      | Chief Executive Officer and President<br>(Principal Executive Officer)   | March 14, 2008 |
| Evan M. Levine          |  |                |
| /s/ Gregory P. Hanson   | Chief Financial Officer, Senior Vice<br>President and Treasurer<br>(Principal Financial and Accounting<br>Officer) | March 14, 2008 |
| Gregory P. Hanson       |  |                |
| /s/ Jackie Lief         | Chair of the Board   | March 14, 2008 |
| Jack Lief               |  |                |
| /s/ Mark N.K. Bagnall   | Director   | March 14, 2008 |
| Mark N.K. Bagnall       |  |                |
|                         | Director   |                |
| Alexander J. Denner     |  |                |
| /s/ Michael M. Goldberg | Director   | March 14, 2008 |
| Michael M. Goldberg     |  |                |

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/s/ Mark J. Pykett

Director

March 14, 2008

Mark J. Pykett

/s/ Eric K. Rowinsky

Director

March 14, 2008

Eric K. Rowinsky

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Financial Statement Schedules:

Financial statement schedules have been omitted for the reason that the required information is presented in financial statements or notes thereto, the amounts involved are not significant or the schedules are not applicable.

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

ADVENTRX Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of ADVENTRX Pharmaceuticals, Inc. and Subsidiaries (a development stage enterprise) as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity (deficit) and comprehensive loss and cash flows for each of the three years in the period ended December 31, 2007 and for the period from January 1, 2002 to December 31, 2007. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of ADVENTRX Pharmaceuticals, Inc. and Subsidiaries (a development stage enterprise) as of December 31, 2007 and 2006, and the results of operations and their cash flows for each of the years in the three-year period ended December 31, 2007 and for the period from January 1, 2002 to December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2007, ADVENTRX Pharmaceuticals, Inc. and Subsidiaries adopted the Financial Accounting Standards Board Staff Position on No. EITF 00-19-2, *Accounting for Registration Payment Arrangements*.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of ADVENTRX Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2008 expressed an unqualified opinion thereon.

/s/ J.H. Cohn LLP

San Diego, California

March 14, 2008

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
(A Development Stage Enterprise)  
**Consolidated Balance Sheets**

|   | <b>December 31,</b>  |                      |
|---|----------------------|----------------------|
|   | <b>2007</b>          | <b>2006</b>          |
|   |                      | (Note 2)             |
| <i>Assets</i>   |                      |                      |
| Current assets:   |                      |                      |
| Cash and cash equivalents   | \$ 14,780,739        | \$ 25,974,041        |
| Short-term investments  | 18,682,417           | 25,771,406           |
| Interest and other receivables  | 72,029               | 80,338               |
| Prepaid expenses  | 615,691              | 511,327              |
| <b>Total current assets</b>   | <b>34,150,876</b>    | <b>52,337,112</b>    |
| Property and equipment, net   | 332,444              | 402,968              |
| Other assets  | 58,305               | 58,305               |
| <b>Total assets</b>   | <b>\$ 34,541,625</b> | <b>\$ 52,798,385</b> |
| <i>Liabilities and Stockholders Equity</i>  |                      |                      |
| Current liabilities:  |                      |                      |
| Accounts payable  | \$ 552,143           | \$ 480,402           |
| Accrued liabilities   | 2,317,910            | 1,675,226            |
| Accrued compensation and payroll taxes  | 622,762              | 292,896              |
| <b>Total current liabilities</b>  | <b>3,492,815</b>     | <b>2,448,524</b>     |
| Long-term liabilities   | 14,270               | 35,674               |
| <b>Total liabilities</b>  | <b>3,507,085</b>     | <b>2,484,198</b>     |
| Commitments and contingencies   |                      |                      |
| Stockholders' equity:   |                      |                      |
| Common stock, \$0.001 par value; 200,000,000 shares authorized; 90,252,572 and 89,676,739 shares issued and outstanding at December 31, 2007 and 2006, respectively | 90,254               | 89,678               |
| Additional paid-in capital  | 130,140,549          | 127,283,524          |
| Deficit accumulated during the development stage  | (99,198,965)         | (77,056,925)         |
| Accumulated other comprehensive income (loss)   | 2,702                | (2,090)              |
| <b>Total stockholders' equity</b>   | <b>31,034,540</b>    | <b>50,314,187</b>    |
| <b>Total liabilities and stockholders' equity</b>   | <b>\$ 34,541,625</b> | <b>\$ 52,798,385</b> |

See accompanying notes to consolidated financial statements.



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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
(A Development Stage Enterprise)  
**Consolidated Statements of Operations**

|  | Years Ended December 31, |                  |                  | Inception<br>(June 12,<br>1996)<br>Through<br>December 31,<br>2007 |
|--|--------------------------|------------------|------------------|--|
|  | 2007                     | 2006<br>(Note 2) | 2005<br>(Note 2) | (Note 2)   |
| Licensing revenue  | \$ 500,000               | \$               | \$               | \$ 500,000   |
| Net sales  |                          |                  |                  | 174,830  |
| Grant revenue  |                          |                  |                  | 129,733  |
| Total net revenue  | 500,000                  |                  |                  | 804,563  |
| Cost of net sales  |                          |                  |                  | 51,094   |
| Gross margin   | 500,000                  |                  |                  | 753,469  |
| Operating expenses:  |                          |                  |                  |  |
| Research and development   | 15,934,409               | 12,001,212       | 8,682,498        | 44,092,373   |
| Selling, general and administrative                                | 8,678,853                | 7,236,437        | 4,901,002        | 33,249,589   |
| Depreciation and amortization                                      | 197,783                  | 176,688          | 115,545          | 10,630,032   |
| In-process research and development                                |                          | 10,422,130       |                  | 10,422,130   |
| Impairment loss write-off of goodwill                              |                          |                  |                  | 5,702,130  |
| Equity in loss of investee   |                          |                  |                  | 178,936  |
| Total operating expenses   | 24,811,045               | 29,836,467       | 13,699,045       | 104,275,190  |
| Loss from operations   | (24,311,045)             | (29,836,467)     | (13,699,045)     | (103,521,721)  |
| Interest income  | 2,169,005                | 1,164,722        | 496,059          | 4,032,064  |
| Interest expense   |                          |                  |                  | (179,090)  |
| Loss before income taxes   | (22,142,040)             | (28,671,745)     | (13,202,986)     | (99,668,747)   |
| Provision for income taxes   |                          |                  |                  |  |
| Loss before cumulative effect of change<br>in accounting principle | (22,142,040)             | (28,671,745)     | (13,202,986)     | (99,668,747)   |
| Cumulative effect of change in<br>accounting principle             |                          |                  |                  | (25,821)   |
| Net loss   | (22,142,040)             | (28,671,745)     | (13,202,986)     | (99,694,568)   |

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|  |                 |                 |                 |                  |
|--|-----------------|-----------------|-----------------|------------------|
| Preferred stock dividends                                |                 |                 |                 | (621,240)        |
| Net loss applicable to common stock                      | \$ (22,142,040) | \$ (28,671,745) | \$ (13,202,986) | \$ (100,315,808) |
| Loss per common share basic and diluted                  | \$ (0.25)       | \$ (0.39)       | \$ (0.22)       |                  |
| Weighted average shares outstanding<br>basic and diluted | 89,912,732      | 73,988,206      | 59,828,357      |                  |

See accompanying notes to consolidated financial statements.

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
(A Development Stage Enterprise)  
**Consolidated Statements of Stockholders Equity (Deficit) and Comprehensive Loss**  
Inception (June 12, 1996) Through December 31, 2007

|   | Cumulative convertible preferred stock, series A |        |        | Cumulative convertible preferred stock, series B |           | Cumulative convertible preferred stock, series C |        | Common stock |                 | Deficit Accumulated         |                   | Total                   |                  |                        |
|---|--|--------|--------|--|-----------|--|--------|--------------|-----------------|-----------------------------|-------------------|-------------------------|------------------|------------------------|
|   | Shares   | Amount | Shares | Amount   | Shares    | Amount   | Shares | Amount       | paid-in capital | comprehensive income (loss) | development stage | Treasury stock, at cost | equity (deficit) | Comprehensive loss     |
| Balances at June 12, 1996 (date of incorporation)                   |  | \$     |        | \$   |           | \$   |        | \$           | \$              |                             |                   | \$                      | \$               |                        |
| Sale of common stock without par value                              |  |        |        |  | 503       | 5  |        |              | 5               |                             |                   |                         |                  | 10                     |
| Change in par value of common stock                                 |  |        |        |  |           | (4)  |        |              | 4               |                             |                   |                         |                  |                        |
| Issuance of common stock and net liabilities assumed in acquisition |  |        |        |  | 1,716,132 | 1,716  |        |              | 3,224           |                             | (18,094)          |                         |                  | (13,154)               |
| Issuance of common stock  |  |        |        |  | 2,010,111 | 2,010  |        |              | 456             |                             | (2,466)           |                         |                  |                        |
| Net loss  |  |        |        |  |           |  |        |              |                 |                             | (259,476)         |                         |                  | (259,476) \$ (259,476) |
| Balances at December 31, 1996                                       |  |        |        |  | 3,726,746 | 3,727  |        |              | 3,689           |                             | (280,036)         |                         |                  | (272,620) \$ (259,476) |
| Sale of common stock, net of offering costs of \$9,976              |  |        |        |  | 1,004,554 | 1,004  |        |              | 1,789,975       |                             |                   |                         |                  | 1,790,979              |
| Issuance of common stock  |  |        |        |  | 375,891   | 376  |        |              | 887,874         |                             |                   |                         |                  | 888,250                |

|  |       |           |       |             |             |                           |
|--|-------|-----------|-------|-------------|-------------|---------------------------|
| in acquisition   |       |           |       |             |             |                           |
| Minority interest  |       |           |       |             |             |                           |
| deficiency at acquisition                                  |       |           |       |             |             |                           |
| charged to the Company                                     |       |           |       | (45,003)    | (45,003)    |                           |
| Net loss   |       |           |       | (1,979,400) | (1,979,400) | \$(1,979,400)             |
| Balances at December 31, 1997                              |       | 5,107,191 | 5,107 | 2,681,538   | (2,304,439) | 382,206 \$(1,979,400)     |
| Rescission of acquisition                                  |       | (375,891) | (376) | (887,874)   | 561,166     | (327,084)                 |
| Issuance of common stock at conversion of notes payable    |       | 450,264   | 451   | 363,549     |             | 364,000                   |
| Expense related to stock warrants issued                   |       |           |       | 260,000     |             | 260,000                   |
| Net loss   |       |           |       | (1,204,380) | (1,204,380) | \$(1,204,380)             |
| Balances at December 31, 1998                              |       | 5,181,564 | 5,182 | 2,417,213   | (2,947,653) | (525,258) \$(1,204,380)   |
| Sale of common stock                                       |       | 678,412   | 678   | 134,322     |             | 135,000                   |
| Expense related to stock warrants issued                   |       |           |       | 212,000     |             | 212,000                   |
| Net loss   |       |           |       | (1,055,485) | (1,055,485) | \$(1,055,485)             |
| Balances at December 31, 1999                              |       | 5,859,976 | 5,860 | 2,763,535   | (4,003,138) | (1,233,743) \$(1,055,485) |
| Sale of preferred stock, net of offering costs of \$76,500 | 3,200 | 32        |       | 3,123,468   |             | 3,123,500                 |
|  |       | 412,487   | 412   | 492,085     |             | 492,497                   |

|  |       |    |            |        |            |             |  |             |               |
|--|-------|----|------------|--------|------------|-------------|--|-------------|---------------|
| Issuance of common stock at conversion of notes and interest payable |       |    |            |        |            |             |  |             |               |
| Issuance of common stock at conversion of notes payable              |       |    | 70,354     | 70     | 83,930     |             |  | 84,000      |               |
| Issuance of common stock to settle obligations                       |       |    | 495,111    | 496    | 1,201,664  |             |  | 1,202,160   |               |
| Issuance of common stock for acquisition                             |       |    | 6,999,990  | 7,000  | 9,325,769  |             |  | 9,332,769   |               |
| Issuance of warrants for acquisition                                 |       |    |            |        | 4,767,664  |             |  | 4,767,664   |               |
| Stock issued for acquisition costs                                   |       |    | 150,000    | 150    | 487,350    |             |  | 487,500     |               |
| Expense related to stock warrants issued                             |       |    |            |        | 140,000    |             |  | 140,000     |               |
| Dividends payable on preferred stock                                 |       |    |            |        | (85,000)   |             |  | (85,000)    |               |
| Cashless exercise of warrants  |       |    | 599,066    | 599    | (599)      |             |  |             |               |
| Net loss   |       |    |            |        |            | (3,701,084) |  | (3,701,084) | \$(3,701,084) |
| Balances at December 31, 2000  | 3,200 | 32 | 14,586,984 | 14,587 | 22,299,866 | (7,704,222) |  | 14,610,263  | \$(3,701,084) |

See accompanying notes to consolidated financial statements.

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
 (A Development Stage Enterprise)  
**Consolidated Statements of Stockholders' Equity (Deficit) and Comprehensive Loss (continued)**  
 Inception (June 12, 1996) Through December 31, 2007

| Cumulative convertible preferred stock, series A |        | Cumulative convertible preferred stock, series B |        | Cumulative convertible preferred stock, series C |         | Common stock    |                             | Deficit           |                  | Total     |
|--|--------|--|--------|--|---------|-----------------|-----------------------------|-------------------|------------------|-----------|
|  |        |  |        |  |         |                 |                             | Accumulated       | Accumulated      |           |
| Shares   | Amount | Shares   | Amount | Shares   | Amount  | paid-in capital | comprehensive income (loss) | development stage | equity (deficit) |           |
|  |        |  |        |  |         |                 |                             | (256,000)         |                  | (256,000) |
|  |        |  |        |  |         |                 |                             | (55,279)          |                  | (55,279)  |
|  |        |  |        |  |         |                 |                             | 47,741            |                  | 47,741    |
|  |        |  |        |  | 218,493 | 219             | (219)                       |                   |                  |           |
|  |        |  |        |  | 93,421  | 93              | 212,907                     |                   |                  | 213,000   |
|  |        |  |        |  |         |                 | 450,000                     |                   |                  | 450,000   |
|  |        |  |        |  |         |                 | 167,138                     |                   |                  | 167,138   |
|  |        |  |        |  | 106,293 | 106             | 387,165                     |                   |                  | 387,271   |
| 137  | 1      |  |        |  |         |                 | 136,499                     |                   |                  | 136,500   |



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|               |                   |         |        |            |        |              |              |                           |
|---------------|-------------------|---------|--------|------------|--------|--------------|--------------|---------------------------|
|               |                   |         |        |            |        | (16,339,120) | (16,339,120) | \$ (10,000,000)           |
| at<br>31,     | 3,337             | 33      |        | 15,005,191 | 15,005 | 23,389,818   | (24,043,342) | (638,486) \$ (10,000,000) |
|               |                   |         |        |            |        | (242,400)    | (242,400)    |                           |
| e of          |                   |         |        | 240,000    | 240    | 117,613      |              | 117,853                   |
|               |                   |         |        | 100,201    | 100    | (100)        |              |                           |
| f             |                   |         |        | 344,573    | 345    | 168,477      |              | 168,822                   |
| .50           |                   | 200,000 | 2,000  |            |        | 298,000      |              | 300,000                   |
| n of          |                   |         | 70,109 | 701        |        | 700,392      |              | 701,093                   |
| stock         | (3,000)           | (30)    |        | 1,800,000  | 1,800  | (1,770)      |              |                           |
|               |                   |         |        |            |        | 335,440      |              | 335,440                   |
| f<br>o<br>ing |                   |         |        |            |        | 163,109      |              | 163,109                   |
| f<br>stock    |                   |         |        | 6,292      | 6      | 12,263       |              | 12,269                    |
| y             | 136               | 1       |        |            |        | 6,000        |              | 6,001                     |
|               | Table of Contents |         |        |            |        |              |              | 105                       |

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473 4 200,000 2,000 70,109 701 17,496,257 17,496 25,276,138 (26,149,069) (852,730) \$ (

See accompanying notes to consolidated financial statements.

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**Table of Contents****ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**

(A Development Stage Enterprise)

**Consolidated Statements of Stockholders' Equity (Deficit) and Comprehensive Loss (continued)**

Inception (June 12, 1996) Through December 31, 2007

| Cumulative convertible preferred stock, series A | Cumulative convertible preferred stock, series B | Cumulative convertible preferred stock, series C | Common stock |            | Additional paid-in capital | Comprehensive income (loss) | Development stage | Treasury stock, at cost | Total equity (deficit) |
|--|--|--|--------------|------------|----------------------------|-----------------------------|-------------------|-------------------------|------------------------|
|  |  |  | Shares       | Amount     |                            |                             |                   |                         |                        |
|  |  |  |              |            |                            |                             |                   |                         |                        |
|  |  |  |              |            |                            | (37,840)                    |                   |                         | (37,840)               |
|  |  | (70,109)   | (701)        | 14,021,860 | 14,022                     | (13,321)                    |                   |                         |                        |
|  |  |  |              | 165,830    | 165                        | 53,326                      |                   |                         | 53,491                 |
|  |  |  |              | 6,640,737  | 6,676                      | 2,590,656                   |                   |                         | 2,597,332              |
|  |  |  |              | 3,701,733  | 3,668                      | 3,989,181                   |                   |                         | 3,992,849              |
|  |  |  |              | 235,291    | 235                        | 49,486                      |                   |                         | 49,721                 |
|  |  |  |              | 230,000    | 230                        | 206,569                     |                   |                         | 206,799                |
|  |  |  |              |            |                            | 156,735                     |                   |                         | 156,735                |

|       |     |           |         |            |        |            |             |              |             |
|-------|-----|-----------|---------|------------|--------|------------|-------------|--------------|-------------|
|       |     |           |         |            |        |            | 286,033     |              | 286,033     |
|       |     |           |         |            |        |            |             | (2,332,077)  | (2,332,077) |
| 473   | 4   | 200,000   | 2,000   | 42,491,708 | 42,492 | 32,556,963 |             | (28,481,146) | 4,120,313   |
|       |     |           |         |            |        |            | 72,800      |              | 72,800      |
| (473) | (4) |           |         | 236,500    | 236    | (232)      |             |              |             |
|       |     | (200,000) | (2,000) | 200,000    | 200    | 1,800      |             |              |             |
|       |     |           |         | 464,573    | 465    | (465)      |             |              |             |
|       |     |           |         | 23,832     | 23     | 27,330     |             |              | 27,353      |
|       |     |           |         |            |        |            | 86,375      |              | 86,375      |
|       |     |           |         | 10,417,624 | 10,419 | 15,616,031 |             |              | 15,626,450  |
|       |     |           |         |            |        |            | (1,366,774) |              | (1,366,774) |
|       |     |           |         |            |        |            | 524,922     |              | 524,922     |
|       |     |           |         |            |        |            | 34,747      | (34,747)     |             |
|       |     |           |         |            |        |            |             | (6,701,048)  | (6,701,048) |
|       |     |           |         | 53,834,237 | 53,835 | 47,553,497 |             | (35,182,194) | (34,747)    |
|       |     |           |         |            |        |            |             |              | 12,390,391  |

See accompanying notes to consolidated financial statements.

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
(A Development Stage Enterprise)  
**Consolidated Statements of Stockholders' Equity (Deficit) and Comprehensive Loss (continued)**  
Inception (June 12, 1996) Through December 31, 2007

| Cumulative convertible preferred stock, series A | Cumulative convertible preferred stock, series B | Cumulative convertible preferred stock, series C | Common stock |        | Additional paid-in capital (Note 2) | Deficit Accumulated               |                            | Treasury stock, at cost | Total stockholders' equity (deficit) (Note 2) | Comprehensive loss (Note 2) |
|--|--|--|--------------|--------|-------------------------------------|-----------------------------------|----------------------------|-------------------------|---|-----------------------------|
|  |  |  | Shares       | Amount |                                     | other comprehensive income (loss) | development stage (Note 2) |                         |   |                             |
|  |  |  |              |        |                                     |                                   |                            |                         |   |                             |
|  |  |  | 10,810,809   | 10,811 | 18,105,940                          |                                   |                            |                         | 18,116,751                                    |                             |
|  |  |  | 149,613      | 149    | (149)                               |                                   |                            |                         |   |                             |
|  |  |  | 2,258,703    | 2,259  | 3,071,179                           |                                   |                            |                         | 3,073,438                                     |                             |
|  |  |  | 185,000      | 185    | 144,815                             |                                   |                            |                         | 145,000                                       |                             |
|  |  |  |              |        | 994,874                             |                                   |                            |                         | 994,874                                       |                             |
|  |  |  |              |        | 93,549                              |                                   |                            |                         | 93,549  |                             |
|  |  |  | 125,000      | 125    | 258,375                             |                                   |                            |                         | 258,500                                       |                             |
|  |  |  | 67,363,362   | 67,364 | 70,222,080                          | (1,722)                           | (48,385,180)               | (34,747)                | 21,867,795                                    | \$(13,202,986)              |

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|   |            |        |                |              |                |               |                |
|---|------------|--------|----------------|--------------|----------------|---------------|----------------|
| Change in fair value of equity securities                                 |            |        |                | (28,671,745) |                | (28,671,745)  | \$(28,671,745) |
| Change in fair value of debt securities                                   |            |        |                | (368)        |                | (368)         |                |
| Change in fair value of equity investments                                | 420,161    | 420    | (420)          |              |                |               |                |
| Change in fair value of debt investments                                  | 5,103,746  | 5,104  | 7,686,486      |              |                | 7,691,590     |                |
| Change in fair value of other investments                                 | 2,099,990  | 2,100  | 10,161,852     |              |                | 10,163,952    |                |
| Change in fair value of common stock                                      | 14,545,000 | 14,545 | 37,055,666     |              |                | 37,070,211    |                |
| Change in fair value of preferred stock                                   | 60,145     | 60     | 196,614        |              |                | 196,674       |                |
| Change in fair value of restricted stock                                  | 92,500     | 93     | 125,658        |              |                | 125,751       |                |
| Change in fair value of restricted stock to employees                     | 15,000     | 15     | 68,635         |              |                | 68,650        |                |
| Change in fair value of restricted stock to directors                     |            |        | 1,697,452      |              |                | 1,697,452     |                |
| Change in fair value of restricted stock to employee stock ownership plan |            |        | 104,225        |              |                | 104,225       |                |
| Change in fair value of other equity investments                          | (23,165)   | (23)   | (34,724)       |              | 34,747         |               |                |
| Fair value at December 31, 2018   | 89,676,739 | 89,678 | \$ 127,283,524 | \$(2,090)    | \$(77,056,925) | \$ 50,314,187 | \$(28,671,745) |
| Change in fair value of equity securities                                 |            |        |                | (22,142,040) |                | (22,142,040)  | \$(22,142,040) |
| Change in fair value of debt securities                                   |            |        |                | 4,792        |                | 4,792         |                |
| Change in fair value of equity investments                                | 575,833    | 576    | 441,040        |              |                | 441,616       |                |

|                             |  |                            |
|-----------------------------|--|----------------------------|
| e of stock<br>to<br>rees    | 2,414,077  | 2,414,077                  |
| e of stock<br>to<br>mployee | 1,908  | 1,908                      |
| es at<br>ber 31,            | \$      \$      \$      90,252,572    \$ 90,254    \$ 130,140,549    \$ 2,702    \$ (99,198,965)    \$ | \$ 31,034,540    \$ (22,13 |

See accompanying notes to consolidated financial statements.

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
(A Development Stage Enterprise)  
**Consolidated Statements of Cash Flows**

|   | Years Ended December 31, |                  |                  | Inception<br>(June 12,<br>1996)<br>Through<br>December 31,<br>2007 |
|---|--------------------------|------------------|------------------|--|
|   | 2007                     | 2006<br>(Note 2) | 2005<br>(Note 2) | (Note 2)   |
| <b>Cash flows from operating activities:</b>                                |                          |                  |                  |  |
| Net loss  | \$ (22,142,040)          | \$ (28,671,745)  | \$ (13,202,986)  | \$ (99,694,568)  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                          |                  |                  |  |
| Depreciation and amortization   | 197,783                  | 176,688          | 115,545          | 10,180,032   |
| Amortization of debt discount   |                          |                  |                  | 450,000  |
| Forgiveness of employee receivable  |                          |                  |                  | 30,036   |
| Impairment loss write-off of goodwill                                       |                          |                  |                  | 5,702,130  |
| Expenses related to employee stock options and restricted stock issued      | 2,414,077                | 1,894,127        | 994,874          | 6,443,329  |
| Expenses related to options issued to non-employees                         | 1,908                    | 104,225          | 93,549           | 199,682  |
| Expenses paid by issuance of common stock                                   | 78,333                   | 146,983          | 101,833          | 1,144,697  |
| Expenses paid by issuance of warrants                                       |                          |                  |                  | 573,357  |
| Expenses paid by issuance of preferred stock                                |                          |                  |                  | 142,501  |
| Expenses related to stock warrants issued                                   |                          |                  |                  | 612,000  |
| Equity in loss of investee  |                          |                  |                  | 178,936  |
| In-process research and development   |                          | 10,422,130       |                  | 10,422,130   |
| Write-off of license agreement  |                          |                  |                  | 152,866  |
| Write-off assets available for sale   |                          |                  | 108,000          | 108,000  |
| Cumulative effect of change in accounting principle                         |                          |                  |                  | 25,821   |
| Accretion of discount on investments in securities                          | (1,041,750)              | (242,681)        | (111,960)        | (1,396,391)  |
| Changes in assets and liabilities, net of effect of acquisitions:           |                          |                  |                  |  |
| Increase in prepaid and other assets  | (174,388)                | (107,151)        | (281,266)        | (993,394)  |
| Increase in accounts payable and accrued liabilities                        | 1,044,291                | 525,284          | 478,504          | 3,669,522  |
| Increase (decrease) in long-term liabilities                                | (21,404)                 | (21,404)         | 57,078           | 14,270   |
| Net cash used in operating activities                                       | (19,643,190)             | (15,773,544)     | (11,646,829)     | (62,035,044)   |

**Cash flows from investing activities:**



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|  |              |              |              |              |
|--|--------------|--------------|--------------|--------------|
| Proceeds from sales and maturities of short-term investments | 59,240,000   | 15,029,776   | 5,275,000    | 79,544,776   |
| Purchases of short-term investments                          | (51,104,469) | (32,600,411) | (13,123,220) | (96,828,100) |
| Purchases of property and equipment                          | (127,259)    | (172,112)    | (237,785)    | (965,398)    |
| Purchase of certificate of deposit                           |              |              |              | (1,016,330)  |
| Maturity of certificate of deposit                           |              |              |              | 1,016,330    |
| Cash paid for acquisitions, net of cash acquired             |              | (31,838)     |              | 32,395       |
| Payment on obligation under license agreement                |              |              |              | (106,250)    |
| See accompanying notes to consolidated financial statements. |              |              |              |              |

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
(A Development Stage Enterprise)  
**Consolidated Statements of Cash Flows (continued)**

|   | <b>Years Ended December 31,</b> |                   |                   | <b>Inception<br/>(June 12,<br/>1996)<br/>Through<br/>December 31,<br/>2007</b> |
|---|---------------------------------|-------------------|-------------------|--|
|   | <b>2007</b>                     | <b>2006</b>       | <b>2005</b>       | <b>(Note 2)</b>  |
|   |                                 | (Note 2)          | (Note 2)          |  |
| Issuance of note receivable related party                       |                                 |                   |                   | (35,000)   |
| Payments on note receivable                                     |                                 |                   |                   | 405,993  |
| Advance to investee   |                                 |                   |                   | (90,475)   |
| Cash transferred in rescission of acquisition                   |                                 |                   |                   | (19,475)   |
| Cash received in rescission of acquisition                      |                                 |                   |                   | 230,000  |
| <br>Net cash provided by (used in) investing activities         | <br>8,008,272                   | <br>(17,774,585)  | <br>(8,086,005)   | <br>(17,831,534)   |
| <b>Cash flows from financing activities:</b>                    |                                 |                   |                   |  |
| Proceeds from sale of common stock                              |                                 | 39,998,749        | 19,999,997        | 84,151,342   |
| Proceeds from exercise of stock options                         | 441,616                         | 125,751           | 145,000           | 712,367  |
| Proceeds from sale or exercise of warrants                      |                                 | 7,897,866         | 3,073,438         | 11,382,894   |
| Proceeds from sale of preferred stock                           |                                 |                   |                   | 4,200,993  |
| Repurchase of warrants  |                                 |                   |                   | (55,279)   |
| Payments for financing and offering costs                       |                                 | (3,134,814)       | (1,883,246)       | (6,483,809)  |
| Payments on notes payable and long -term debt                   |                                 |                   |                   | (605,909)  |
| Proceeds from issuance of notes payable and detachable warrants |                                 |                   |                   | 1,344,718  |
| <br>Net cash provided by financing activities                   | <br>441,616                     | <br>44,887,552    | <br>21,335,189    | <br>94,647,317   |
| <br>Net (decrease) increase in cash and cash equivalents        | <br>(11,193,302)                | <br>11,339,423    | <br>1,602,355     | <br>14,780,739   |
| Cash and cash equivalents at beginning of period                | 25,974,041                      | 14,634,618        | 13,032,263        |  |
| <br>Cash and cash equivalents at end of period                  | <br>\$ 14,780,739               | <br>\$ 25,974,041 | <br>\$ 14,634,618 | <br>\$ 14,780,739  |

See accompanying notes to consolidated financial statements.

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
(A Development Stage Enterprise)  
**Notes to Consolidated Financial Statements**  
**December 31, 2007**

**(1) Description of Business**

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation ( ADVENTRX, we or the Company ), is a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates primarily for the treatment of cancer and infectious disease. Our business is in the development stage; we have not yet marketed any products or generated any significant revenue. Through our license agreements with the University of Southern California ( USC ) and our acquisition of SD Pharmaceuticals, Inc. ( SDP ), we have rights to product candidates in varying stages of development.

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. The merger had no effect on our financial statements. 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. In April 2006, we acquired all of the outstanding capital stock of SDP through a merger with our newly created wholly-owned subsidiary, Speed Acquisition, Inc. (the Merger Sub ) and changed the name of the Merger Sub to SD Pharmaceuticals, Inc.

**(2) Summary of Significant Accounting Policies**

***Basis of Presentation***

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, SDP and ADVENTRX (Europe) Ltd. All intercompany accounts and transactions have been eliminated in consolidation.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ( U.S. ) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

***Change in Accounting Principle for Registration Payment Arrangements***

In December 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Staff Position on No. EITF 00-19-2, *Accounting for Registration Payment Arrangements* ( FSP EITF 00-19-2 ). FSP EITF 00-19-2 provides that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement should be separately recognized and measured in accordance with Statement of Financial Accounting Standards ( FAS ) No. 5, *Accounting for Contingencies*, which provides that loss contingencies should be recognized as liabilities if they are probable and reasonably estimable. Subsequent to the adoption of FSP EITF 00-19-2, any changes in the carrying amount of the contingent liability will result in a gain or loss that will be recognized in the consolidated statement of operations in the period the changes occur. The guidance in FSP EITF 00-19-2 was effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of FSP EITF 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of FSP EITF 00-19-2, this guidance was effective for our consolidated financial statements issued for the year beginning January 1, 2007, and interim periods within that year.

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
(A Development Stage Enterprise)  
**Notes to Consolidated Financial Statements(continued)**  
**December 31, 2007**

On January 1, 2007, we adopted the provisions of FSP EITF 00-19-2 to account for the registration payment arrangement associated with our July 2005 financing (the July 2005 Registration Payment Arrangement). As of January 1, 2007 and December 31, 2007, management determined that it was not probable that we would have any payment obligation under the July 2005 Registration Payment Arrangement; therefore, no accrual for contingent obligation is required under the provisions of FSP EITF 00-19-2. Accordingly, the warrant liability account was eliminated and the comparative condensed consolidated financial statements of prior periods and as of December 31, 2006 have been adjusted to apply the new method retrospectively. The following consolidated financial statement line items for the years ended December 31, 2007, 2006 and 2005 were affected by the change in accounting principle:

**Consolidated Statements of Operations**

|   | <b>As Reported<br/>under FSP<br/>EITF 00-19-2</b> | <b>As Computed<br/>under<br/>EITF 00-19</b> | <b>Effect of<br/>Change</b> |
|---|---|---|-----------------------------|
| <b><i>Year Ended December 31, 2007</i></b>                        |   |   |                             |
| Loss from operations  | \$ (24,311,045)                                   | \$ (24,311,045)                             | \$                          |
| Gain on fair value of warrants                                    |   | 27,653,737                                  | (27,653,737)                |
| Net income (loss)   | (22,142,040)                                      | 5,511,697                                   | (27,653,737)                |
| Net income (loss) per share                                       | \$ (0.25)   | \$ 0.06                                     | \$ (0.31)                   |
| <b><i>Inception (June 12, 1996) Through December 31, 2007</i></b> |   |   |                             |
| Loss from operations  | \$(103,521,721)                                   | \$(103,521,721)                             | \$                          |
| Gain (loss) on fair value of warrants                             |   | 15,414,049                                  | (15,414,049)                |
| Net loss  | (99,694,568)                                      | (84,280,519)                                | (15,414,049)                |
| Net loss applicable to common stock                               | (100,315,808)                                     | (84,901,759)                                | (15,414,049)                |
| <b><i>Year Ended December 31, 2006</i></b>                        |   |   |                             |
| Loss from operations  | \$ (29,836,467)                                   | \$ (29,836,467)                             | \$                          |
| Loss on fair value of warrants                                    |   | (660,028)                                   | 660,028                     |
| Net loss  | (28,671,745)                                      | (29,331,773)                                | 660,028                     |
| Net loss per share  | \$ (0.39)   | \$ (0.40)                                   | \$ 0.01                     |
| <b><i>Inception (June 12, 1996) Through December 31, 2006</i></b> |   |   |                             |
| Loss from operations  | \$ (79,210,676)                                   | \$ (79,210,676)                             | \$                          |
| Loss on fair value of warrants                                    |   | (12,239,688)                                | 12,239,688                  |
| Net loss  | (77,552,528)                                      | (89,792,216)                                | 12,239,688                  |
| Net loss applicable to common stock                               | (78,173,768)                                      | (90,413,456)                                | 12,239,688                  |
| <b><i>Year Ended December 31, 2005</i></b>                        |   |   |                             |
| Loss from operations  | \$ (13,699,045)                                   | \$ (13,699,045)                             | \$                          |
| Loss on fair value of warrants                                    |   | (11,579,660)                                | 11,579,660                  |
| Net loss  | (13,202,986)                                      | (24,782,646)                                | 11,579,660                  |
| Net loss per share  | \$ (0.22)   | \$ (0.41)                                   | \$ 0.19                     |
| <b><i>Inception (June 12, 1996) Through December 31, 2005</i></b> |   |   |                             |
| Loss from operations  | \$ (49,374,209)                                   | \$ (49,374,209)                             | \$                          |

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|                                     |              |              |            |
|-------------------------------------|--------------|--------------|------------|
| Loss on fair value of warrants      |              | (11,579,660) | 11,579,660 |
| Net loss                            | (48,880,783) | (60,460,443) | 11,579,660 |
| Net loss applicable to common stock | (49,502,023) | (61,081,683) | 11,579,660 |

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
(A Development Stage Enterprise)  
**Notes to Consolidated Financial Statements (continued)**  
**December 31, 2007**

**Consolidated Balance Sheet**

|  | <b>As Reported<br/>under FSP<br/>EITF 00-19-2</b> | <b>As Computed<br/>under<br/>EITF 00-19</b> | <b>Effect of<br/>Change</b> |
|--|---|---|-----------------------------|
| <b><i>December 31, 2007</i></b>                  |   |   |                             |
| Warrant liability                                | \$  | \$ 2,702,702                                | \$ (2,702,702)              |
| Total liabilities                                | 3,507,085   | 6,209,787                                   | (2,702,702)                 |
| Additional paid-in capital                       | 130,140,549                                       | 112,023,798                                 | 18,116,751                  |
| Deficit accumulated during the development stage | (99,198,965)                                      | (83,784,916)                                | (15,414,049)                |
| Total stockholders' equity                       | 31,034,540  | 28,331,838                                  | 2,702,702                   |
| <b><i>December 31, 2006</i></b>                  |   |   |                             |
| Warrant liability                                | \$  | \$ 30,356,439                               | \$(30,356,439)              |
| Total liabilities                                | 2,484,198   | 32,840,637                                  | (30,356,439)                |
| Additional paid-in capital                       | 127,283,524                                       | 109,166,773                                 | 18,116,751                  |
| Deficit accumulated during the development stage | (77,056,925)                                      | (89,296,613)                                | 12,239,688                  |
| Total stockholders' equity                       | 50,314,187  | 19,957,748                                  | 30,356,439                  |
| <b><i>December 31, 2005</i></b>                  |   |   |                             |
| Warrant liability                                | \$  | \$ 29,696,411                               | \$(29,696,411)              |
| Total liabilities                                | 1,753,978   | 31,450,389                                  | (29,696,411)                |
| Additional paid-in capital                       | 70,222,080  | 52,105,329                                  | 18,116,751                  |
| Deficit accumulated during the development stage | (48,385,180)                                      | (59,964,840)                                | 11,579,660                  |
| Total stockholders' equity                       | 21,867,795  | (7,828,616)                                 | 29,696,411                  |

**Consolidated Statements of Cash Flows**

|   | <b>As Reported<br/>under FSP<br/>EITF<br/>00-19-2</b> | <b>As Computed<br/>under<br/>EITF 00-19</b> | <b>Effect of<br/>Change</b> |
|---|---|---|-----------------------------|
| <b><i>December 31, 2007</i></b>                                   |   |   |                             |
| Net income (loss)   | \$(22,142,040)  | \$ 5,511,697                                | \$(27,653,737)              |
| Gain on fair value of warrants                                    |   | (27,653,737)                                | 27,653,737                  |
| <b><i>Inception (June 12, 1996) through December 31, 2007</i></b> |   |   |                             |
| Net loss  | \$(99,694,568)  | \$(84,280,519)                              | \$(15,414,049)              |
| Gain on fair value of warrants                                    |   | (15,414,049)                                | 15,414,049                  |
| <b><i>December 31, 2006</i></b>                                   |   |   |                             |
| Net loss  | \$(28,671,745)  | \$(29,331,773)                              | \$ 660,028                  |
| Loss on fair value of warrants                                    |   | 660,028                                     | (660,028)                   |

***Inception (June 12, 1996) through December 31, 2006***

|                                |                |                |               |
|--------------------------------|----------------|----------------|---------------|
| Net loss                       | \$(77,552,528) | \$(89,792,216) | \$ 12,239,688 |
| Loss on fair value of warrants |                | 12,239,688     | (12,239,688)  |

***December 31, 2005***

|                                |                |                |               |
|--------------------------------|----------------|----------------|---------------|
| Net loss                       | \$(13,202,986) | \$(24,782,646) | \$ 11,579,660 |
| Loss on fair value of warrants |                | 11,579,660     | (11,579,660)  |

***Inception (June 12, 1996) through December 31, 2005***

|                                |                |                |               |
|--------------------------------|----------------|----------------|---------------|
| Net loss                       | \$(48,880,783) | \$(60,460,443) | \$ 11,579,660 |
| Loss on fair value of warrants |                | 11,579,660     | (11,579,660)  |

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
(A Development Stage Enterprise)  
**Notes to Consolidated Financial Statements (continued)**  
**December 31, 2007**

***Purchase Price Allocation***

The allocation of purchase price for an acquisition requires extensive use of accounting estimates and judgments in allocating the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development ( IPR&D ), and liabilities assumed based on their respective fair values. In 2006, we completed the acquisition of SDP. See Note 3, *Acquisition of SDP*, for a detailed discussion.

***Cash Equivalents***

Cash equivalents consist of highly liquid investments with original maturities of three months or less at the date of purchase.

***Short-term Investments***

We account for and report our investments in accordance with FAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Investments are comprised of marketable securities consisting primarily of certificates of deposit, federal, state and municipal government obligations and corporate bonds. Short-term investments are marketable securities with maturities of less than one year from the balance sheet date. All marketable securities are held in our name and primarily under the custodianship of two major financial institutions. Our policy is to protect the principal value of our investment portfolio and minimize principal risk.

Our marketable securities are classified as available-for-sale and stated at fair value, with net unrealized gains or losses recorded as a component of accumulated other comprehensive income (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity with all amortization and accretion included in interest income. Realized gains and losses on available-for-sale securities are included in other income (loss). The cost of securities sold is based on the specific identification method. Interest on securities classified as available-for-sale is included in interest income. Marketable securities are evaluated periodically for impairment. If it is determined that a decline of any investment is other than temporary, then the investment basis would be written down to fair value and the write-down would be included in earnings as a loss.

***Concentrations***

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash, cash equivalents and investment securities. Our cash and cash equivalents are in excess of the Federal Deposit Insurance Corporation limit at year end. We invest our excess cash primarily in marketable debt securities of corporations, financial institutions and government agencies with strong credit ratings. We have adopted an investment policy that includes guidelines related to diversification and maturities to maintain safety and liquidity.

During 2007 and 2006, approximately 14%, or \$2.3 million, and 16%, or \$2.8 million, respectively, of our total vendor payments were made to a contract research organization ( CRO ) that is assisting us in our clinical trial administration and data management. If we were to lose this vendor, we could experience delays in continuing our clinical trial efforts which would result in increased costs as well as delays in seeking U.S. Food and Drug Administration ( FDA ) approvals.

***Fair Value of Financial Instruments***

At December 31, 2007 and 2006, our financial instruments included cash and cash equivalents, short-term investments, accounts payable, accrued expenses and accrued compensation and payroll taxes. The carrying amounts of cash and cash equivalents, accounts payable, accrued expenses and accrued compensation and payroll taxes approximate fair value due to the short-term maturities of these instruments. Our short-term investments in securities are carried at fair value based on quoted market prices.



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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
(A Development Stage Enterprise)  
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**December 31, 2007**

***Property and Equipment***

Property and equipment are stated at cost. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets. The costs of improvements that extend the lives of the assets are capitalized. Repairs and maintenance are expensed as incurred.

***Impairment of Long-Lived Assets***

Long-lived assets with finite lives are evaluated for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the evaluation indicates that intangibles or long-lived assets are not recoverable (i.e., carrying amount is less than the future projected undiscounted cash flows), their carrying amount would be reduced to fair value. Since inception through December 31, 2007, we recognized an impairment loss of the value of goodwill in the amount of \$5.7 million, which was recorded in the year ended December 31, 2001.

***Revenue Recognition***

We recognize revenue in accordance with the Securities and Exchange Commission's (SEC) Staff Accounting Bulletin Topic 13, *Revenue Recognition* (Topic 13), and Emerging Issues Task Force Issue (EITF) No. 00-21, *Revenue Arrangements with Multiple Deliverables*, or EITF 00-21. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured.

Revenue from licensing agreements is recognized based on the performance requirements of the agreement. Revenue is deferred for fees received before earned. Nonrefundable upfront fees that are not contingent on any future performance by us are recognized as revenue when revenue recognition criteria under Topic 13 and EITF 00-21 are met and the license term commences. Nonrefundable upfront fees, where we have ongoing involvement or performance obligations, are recorded as deferred revenue and recognized as revenue over the life of the contract, the period of the performance obligation or the development period, whichever is appropriate in light of the circumstances.

Payments related to substantive, performance-based milestones in an agreement are recognized as revenue upon the achievement of the milestones as specified in the underlying agreement when they represent the culmination of the earnings process. Royalty revenue from licensed products will be recognized when earned in accordance with the terms of the applicable license agreements.

***Research and Development Expenses***

Research and development (R&D) expenses consist of expenses incurred in performing R&D activities, including salaries and benefits, facilities and other overhead expenses, clinical trials, research-related manufacturing services, contract services and other outside expenses. R&D expenses are charged to operations as they are incurred. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future R&D activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

Milestone payments that we make in connection with in-licensed technology or product candidates are expensed as incurred when there is uncertainty in receiving future economic benefits from the licensed technology or product candidates. We consider the future economic benefits from the licensed technology or product candidates to be uncertain until such licensed technology or product candidates are approved for marketing by the FDA or when other significant risk factors are abated. For expense accounting purposes, management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain.

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
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Payments in connection with our clinical trials are often made under contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price or on a time-and-material basis. Payments under these contracts depend on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones. Expenses related to clinical trials are accrued based on our estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies, and clinical trials progress. Other incidental costs related to patient enrollment and treatment are accrued when reasonably certain. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we modify our accruals accordingly on a prospective basis. Revisions in scope of contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. Because of the uncertainty of possible future changes to the scope of work in clinical trials contracts, we are unable to quantify an estimate of the reasonably likely effect of any such changes on our consolidated results of operations or financial position. Historically, we have had no material changes in our clinical trial expense accruals that would have had a material impact on our consolidated results of operations or financial position.

***Purchased In-Process Research and Development***

In accordance with FAS No. 141, *Business Combinations*, we immediately charge the costs associated with purchased IPR&D to statement of operations upon acquisition. These amounts represent an estimate of the fair value of purchased IPR&D for projects that, as of the acquisition date, had not yet reached technological feasibility, had no alternative future use, and had uncertainty in receiving future economic benefits from the purchased IPR&D. We determine the future economic benefits from the purchased IPR&D to be uncertain until such technology is approved by the FDA or when other significant risk factors are abated. In the year ended December 31, 2006, we recorded approximately \$10.4 million of IPR&D expense related to our acquisition of SD Pharmaceuticals, Inc. in April 2006.

***Accounting for Share-Based Compensation***

Effective January 1, 2006, we adopted the provisions of revised FAS No. 123, *Share-Based Payment* ( FAS 123R ), including the provisions of Staff Accounting Bulletins No. 107 ( SAB 107 ) and No. 110 ( SAB 110 ). Under FAS 123R, share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period. We have no awards with market or performance conditions. We adopted the provisions of FAS 123R using the modified prospective transition method. Accordingly, prior periods were not revised for comparative purposes.

On November 10, 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards*. We elected to adopt the alternative transition method provided in FAS 123R. The alternative transition method included a simplified method to establish the beginning balance of the additional paid-in capital pool ( APIC pool ) related to the tax effects of employee share-based compensation, which is available to absorb tax deficiencies recognized subsequent to the adoption of FAS 123R. The valuation provisions of FAS 123R apply to new awards and to awards that are outstanding on the effective date, January 1, 2006, which are subsequently modified or cancelled. Prior to 2006, we accounted for share-based compensation under the recognition and measurement principles of FAS No. 123, *Accounting for Stock-Based Compensation* ( FAS 123 ). Estimated compensation expense for awards outstanding at January 1, 2006 is recognized over the remaining service period using the compensation cost calculated for recognition purposes under FAS 123.

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
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Share-based compensation expense recognized in our consolidated statement of operations for the years ended December 31, 2007 and 2006 included compensation expense for share-based payment awards granted prior to, but not yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the recognition provisions of FAS 123 and share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with FAS 123R. For share awards granted during the year ended December 31, 2007 and 2006, expenses are amortized under the straight-line method. For share awards granted prior to 2006, expenses are amortized under the straight-line method prescribed by FAS 123. As share-based compensation expense recognized in the consolidated statement of operations for the years ended December 31, 2007 and 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In the year ended December 31, 2005, we accounted for forfeitures as they occurred in accordance with the recognition provisions of FAS 123.

We account for share-based compensation awards granted to non-employees in accordance with EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* ( EITF 96-18 ). Under EITF 96-18, we determine the fair value of the share-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured using the stock price and other measurement assumptions as of the earlier of either of (1) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached or (2) the date at which the counterparty's performance is complete.

**Patent Costs**

Legal costs in connection with approved patents and patent applications are expensed as incurred and classified as selling, general and administrative expense in our consolidated statement of operations.

**Income Taxes**

We account for income taxes and the related accounts under the liability method. Deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts and the income tax bases of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. In July 2006, FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an Interpretation of FASB Statement 109* ( FIN 48 ), which clarifies the accounting for uncertainty in tax positions. FIN 48 provides that the tax effects from an uncertain tax position can be recognized in our consolidated financial statements only if the position is more likely than not of being sustained upon an examination by tax authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The provisions of FIN 48 were effective for us as of January 1, 2007, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings in the year of adoption. We adopted FIN 48 on January 1, 2007, which did not have a material impact on our consolidated results of operations or financial position. See Note 13, *Income Taxes*.

**Comprehensive Loss**

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, including foreign currency translation adjustments and unrealized gains and losses on marketable securities. We present comprehensive loss in our consolidated statements of stockholders' equity (deficit) and comprehensive loss.

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
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**Computation of Net Loss per Common Share**

We calculate basic and diluted net loss per share in accordance with the FAS No. 128, *Earnings Per Share*. Basic net loss per share was calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share was calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding during the period. For purposes of this calculation, options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

We have excluded the following options and warrants from the calculation of diluted net loss per common share for 2007, 2006 and 2005 because their effect is anti-dilutive:

|          | <b>2007</b> | <b>2006</b> | <b>2005</b> |
|----------|-------------|-------------|-------------|
| Warrants | 13,373,549  | 13,458,549  | 19,629,933  |
| Options  | 4,020,940   | 3,767,103   | 2,457,000   |
|          | 17,394,489  | 17,225,652  | 22,086,933  |

**Supplemental Cash Flow Information**

|  | <b>Years Ended December 31,</b> |             |             | <b>Inception<br/>(June 12, 1996)<br/>Through<br/>December 31,<br/>2007</b> |
|--|---------------------------------|-------------|-------------|--|
|  | <b>2007</b>                     | <b>2006</b> | <b>2005</b> |  |
| Supplemental disclosures of cash flow information:                       |                                 |             |             |  |
| Interest paid  | \$                              | \$          | \$          | \$ 179,090   |
| Income taxes paid  |                                 |             |             |  |
| Supplemental disclosures of non-cash investing and financing activities: |                                 |             |             |  |
| Issuance of warrants, common stock and preferred stock for:              |                                 |             |             |  |
| Conversion of notes payable and accrued interest                         | \$                              | \$          | \$          | \$ 1,213,988   |
| Prepaid services to consultants  |                                 |             | 258,500     | 1,482,781  |
| Conversion of preferred stock  |                                 |             |             | 2,705  |
| Acquisitions   |                                 | 10,163,952  |             | 24,781,555   |
| Payment of dividends   |                                 |             |             | 213,000  |
| Financial advisor services in conjunction with private placement         |                                 |             |             | 1,137,456  |
| Acquisition of treasury stock in settlement of a claim                   |                                 |             |             | 34,747   |
| Cancellation of treasury stock   |                                 | (34,747)    |             | (34,747)   |
| Assumptions of liabilities in acquisitions                               |                                 | 226,340     |             | 1,235,907  |
| Acquisition of license agreement for long-term debt                      |                                 |             |             | 161,180  |

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|   |         |       |       |         |
|---|---------|-------|-------|---------|
| Cashless exercise of warrants                     |         | 420   | 150   | 4,312   |
| Dividends accrued                                 |         |       |       | 621,040 |
| Trade asset converted to available for sale asset |         |       |       | 108,000 |
| Dividends extinguished                            |         |       |       | 408,240 |
| Trade payable converted to note payable           |         |       |       | 83,948  |
| Issuance of warrants for return of common stock   |         |       |       | 50,852  |
| Detachable warrants issued with notes payable     |         |       |       | 450,000 |
| Unrealized (gain) loss on short-term investments  | (4,792) | 368   | 1,722 | (2,702) |
|   |         | F -18 |       |         |

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
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***New Accounting Pronouncements***

In September 2006, the FASB issued FAS No. 157, *Fair Value Measurements* ( FAS 157 ), which defines fair value, establishes a framework for measuring fair value under GAAP and expands disclosures about fair value measurements. In February 2008, the FASB issued FASB Staff Position FAS 157-2, *Effective Date of FASB Statement No. 157* ( FSP 157-2 ). FSP 157-2 delayed, for one year, the effective date of FAS 157 for all nonfinancial assets and liabilities, except those that are recognized or disclosed in the financial statements on at least an annual basis. Consequently, FAS 157 will be effective for us beginning January 1, 2008 for financial assets and liabilities recognized or disclosed in our consolidated financial statements. The deferred provisions of FAS 157 will be effective for us beginning January 1, 2009. We do not expect the adoption of FAS 157 will have a material impact on our consolidated results of operations or financial position.

In February 2007, the FASB issued FAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ( FAS 159 ), which provides companies the irrevocable option to measure many financial assets and liabilities at fair value with the changes in fair value recognized in earnings resulting in an opportunity to mitigate volatility in earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. FAS 159 will be effective for us beginning on January 1, 2008. We do not expect the adoption of FAS 159 will have a material impact on our consolidated results of operations or financial position.

In June 2007, the FASB ratified the EITF consensus on EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 provides that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be capitalized and deferred. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed or such time when an entity does not expect the goods to be delivered or services to be performed. EITF 07-3 is effective for fiscal periods beginning after December 15, 2007. We do not expect the adoption of EITF 07-3 will have a material impact on our consolidated results of operations or financial position.

In November 2007, the EITF issued EITF No. 07-01, *Accounting for Collaborative Arrangements* (EITF 07-01). EITF No. 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-01 clarified that transactions within a collaborative arrangement that are part of a vendor-customer (or analogous) relationship are subject to Issue 01-9, *Accounting for Consideration Given by a Vendor to a Customer*. EITF 07-01 is effective for fiscal years beginning December 15, 2008. We do not expect the adoption of EITF 07-01 will have a material impact on our consolidated results of operations or financial position.

In December 2007, the FASB issued FAS No. 141(R), *Business Combinations* ( FAS 141(R) ). FAS 141(R) will significantly change the accounting for and reporting of business combination transactions in consolidated financial statements. FAS 141(R) is effective for the first annual reporting period beginning on or after December 15, 2008. Thus, we are required to adopt this standard on January 1, 2009. Earlier adoption is prohibited. We do not expect the adoption of FAS 141(R) will have a material impact on our consolidated results of operations or financial position.

In December 2007, the FASB issued FAS No. 160, *Accounting and Reporting of Noncontrolling Interest in Consolidated Financial Statements, an amendment of ARB No. 51* ( FAS 160 ). FAS 160 will significantly change the accounting for and reporting of noncontrolling (minority) interests in consolidated financial statements. FAS 160 is effective for the first annual reporting period beginning on or after December 15, 2008. Earlier adoption is prohibited. We do not expect the adoption of FAS 160 will have a material impact on our consolidated results of operations or financial position.



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**(3) Acquisition of SDP**

On April 26, 2006, we completed the acquisition of all of the outstanding capital stock of SDP, a Delaware corporation, a privately-held drug development company, for a total purchase price of \$10,195,790. We accounted for the acquisition as a purchase of net assets and not as a business combination primarily because our acquisition did not include revenue-producing operations, an employee base or self-sustaining operations, among other things, at the acquisition date. We acquired SDP's rights to certain oncology and infectious disease product candidates (the SDP Product Candidates), including rights to a product candidate that we licensed from SDP in October 2005. The results of operations of SDP have been included in the consolidated financial statements since the date of acquisition. The aggregate purchase price of \$10,195,790 consisted of 2,099,990 shares of common stock valued at \$10,163,952 and transaction costs of \$31,838. The value of the common shares issued was determined based on the average market price of our common shares over the two-day period before and after the terms of the acquisition were agreed to and announced.

We determined that the assets acquired consisted principally of incomplete IPR&D assets and that these assets had no alternative future uses in their current state. The estimated fair values of assets acquired and liabilities assumed are as follows:

|  |                      |
|--|----------------------|
| Intangible assets - IPR&D              | \$ 10,422,130        |
| Accounts payable, net of cash acquired | (226,340)            |
|  | <b>\$ 10,195,790</b> |

Acquired IPR&D represents the cost of acquired SDP Product Candidates for which (a) technological feasibility had not been established at the acquisition date, (b) the Product Candidate had not been approved by the FDA for marketing at the acquisition date, (c) there was no alternative future use, and (d) the fair value was estimable based on reasonable assumptions. The estimated fair value of the IPR&D was determined based on the use of a discounted cash flow model using an income approach for the acquired SDP Product Candidates. Estimated revenues were adjusted to take into account the stage of completion and the risks surrounding the successful development and commercialization. The acquired IPR&D was valued at approximately \$10.4 million and expensed on the acquisition date, and included in the accompanying consolidated statements of operations for the year ended December 31, 2006.

Information regarding the SDP Product Candidates we acquired follows:

1. SDP-012 (now ANX-530 (vinorelbine emulsion)) was assigned a value of approximately \$3.2 million. ANX-530, a novel emulsion formulation of the chemotherapy drug vinorelbine, a formulation of which is currently approved and available as a generic for the treatment of non-small cell lung cancer and metastatic breast cancer, is designed to reduce the incidence and severity of vein irritation from intravenous delivery of vinorelbine. The acquired formulation emulsifies vinorelbine into a homogeneous suspension of nanoparticles that may protect the venous endothelium during administration into a peripheral vein, thereby reducing irritation associated with administration of the drug. We continue to pursue development of this product candidate and expect to submit a new drug application (NDA) under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (FDCA) in the fourth quarter of 2008.
2. SDP-014 (now ANX-514 (docetaxel emulsion)) was assigned a value of approximately \$4.1 million. SDP-014, a novel emulsion formulation of docetaxel, a formulation of which is currently approved for the treatment of various cancers, is designed to eliminate the need for multi-day immunosuppressant premedication. The acquired formulation of docetaxel is formulated without polysorbate 80 or other detergents and is designed to reduce the severity and/or incidence of hypersensitivity reactions. As a result,



the need for multi-day immunosuppressant premedication could be eliminated. We continue to pursue development of this product candidate and plan to initiate a registrational bioequivalence clinical study in 2008, pending appropriate regulatory clearances.

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3. SDP-013 (now ANX-513 (paclitaxel emulsion)) was assigned a value of approximately \$2.7 million. ANX-513, a novel formulation of paclitaxel, a formulation of which is currently approved, is intended to be non-allergenic and to reduce the need for immunosuppressant premedication. The acquired emulsion formulation of paclitaxel is formulated without Cremophor or detergents and is designed to reduce the severity and/or incidence of hypersensitivity reactions. As a result, the need for multi-day immunosuppressant premedication could be eliminated. Subsequent to the acquisition of SDP, we have conducted various preclinical studies for these product candidates.

4. Five secondary product candidates were assigned a combined value of approximately \$400,000. Subsequent to the acquisition of SDP, we have conducted various preclinical studies for these product candidates.

We plan to continue development of the acquired product candidates, which are emulsion formulations of currently marketed products, with particular emphasis on ANX-530 and ANX-514 in 2008. Solely for the purpose of estimating the fair value of SDP Product Candidates at the time of the acquisition, we assumed that:

We would incur future research and development costs of approximately \$7.75 million for ANX-530, ANX-514 and ANX-513 from the date of acquisition through and including the year when commercialization was expected to occur;

We would seek marketing approval under Section 505(b)(2) of the FDCA, which typically has shorter timelines than those associated with developing new chemical entities; and

The commercialization dates for ANX-530, ANX-514 and ANX-513 ranged from 2009-2016 based on the anticipated timeline for Section 502(b)(2) approvals.

The estimated fair value of the IPR&D was determined based on the use of a discounted cash flow model using an income approach for the acquired SDP Product Candidates. Estimated revenues and cash flows were adjusted to take into account:

The stage of completion of each of the SDP Product Candidates;

The risks surrounding the successful development and commercialization;

The assumption of out-licensing the product candidate to a pharmaceutical manufacturer after NDA approval for each product candidate;

Future milestone and royalty revenues;

Growth rates of each product candidate; and

Future operating expenses.

The estimated after-tax cash flows were then discounted to a present value using a discount rate of 14%.

The major risks and uncertainties associated with the timely and successful completion of the acquired in-process projects consist of the ability to confirm the safety and efficacy of the product candidates based on the data from clinical trials and obtaining necessary regulatory approvals. No assurance can be given that the underlying assumptions used to forecast the cash flows or the timely and successful completion of the product candidates will materialize, as estimated. For these reasons, among others, actual results may vary significantly from the estimated results.

The following unaudited financial information presents the pro forma results of operations and gives effect to the SDP acquisition as if the acquisition was consummated at the beginning of 2005. This information is presented for

informational purposes only, and is not intended to be indicative of any expected results of operations for future periods, or the results of operations that actually would have been realized if the acquisition had in fact occurred as of the beginning of 2005.

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|   | <b>2006 (1)(2)</b> | <b>2005 (2)</b> |
|---|--------------------|-----------------|
| Pro forma net revenues  | \$                 | \$              |
| Pro forma net loss before cumulative effect of change in accounting principle (3) | \$(28,730,545)     | \$(23,801,516)  |
| Pro forma net loss (3)  | \$(28,730,545)     | \$(23,801,516)  |
| Pro forma loss per basic and diluted share:                                       |                    |                 |
| Loss before cumulative effect of change in accounting principle                   | \$ (0.38)          | \$ (0.38)       |
| Net loss  | \$ (0.38)          | \$ (0.38)       |
| Shares used for basic and diluted computation (4)                                 | 76,088,196         | 61,928,347      |

(1) SDP's results of operations for the period from January 1, 2006 through acquisition date were not available; therefore, the amounts were estimated using 2005 actual results on a pro rata basis.

(2) On January 1, 2007, we adopted the provisions of FSP EITF 00-19-2. Accordingly, the consolidated financial statements at December 31, 2006 and 2005 and for the years then ended were adjusted retrospectively. See Note 2, *Summary of Significant*

*Accounting Policies Change in Accounting Principle for Registration Payment Arrangements,*  
for a detailed discussion.

- (3) Includes a non-recurring charge of \$10,422,130 in each year for purchased in-process research and development costs as if the transaction occurred on the first day of each year presented.
- (4) Includes 2,099,990 shares of our common stock issued as part of consideration for the acquisition.

**(4) Investments in Securities**

The following table summarizes our investments in securities, all of which are classified as available for sale:

|                              | <b>Cost</b>  | <b>2007<br/>Gross<br/>Unrealized<br/>Gains (Losses)</b> | <b>Fair Value</b> |
|------------------------------|--------------|---|-------------------|
| Short-term investments:      |              |   |                   |
| Commercial paper             | \$ 9,494,050 | \$ 2,420  | \$ 9,496,470      |
| Government debt securities   | 7,438,669    | (1,617)   | 7,437,052         |
| Corporate bonds              | 1,748,504    | 391   | 1,748,895         |
| Total short-term investments | 18,681,223   | 1,194   | 18,682,417        |
| Cash equivalents:            |              |   |                   |
| Commercial paper             | 5,880,410    | 1,658   | 5,882,068         |

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|                                 |               |          |               |
|---------------------------------|---------------|----------|---------------|
| Government debt securities      | 2,489,812     | (150)    | 2,489,662     |
| Total cash equivalents          | 8,370,222     | 1,508    | 8,371,730     |
| Total investments in securities | \$ 27,051,445 | \$ 2,702 | \$ 27,054,147 |

|                                 | <b>Cost</b>   | <b>2006<br/>Gross<br/>Unrealized<br/>Gains (Losses)</b> | <b>Fair Value</b> |
|---------------------------------|---------------|---|-------------------|
| Short-term investments:         |               |   |                   |
| Commercial paper                | \$ 16,800,966 | \$ (1,906)  | \$ 16,799,060     |
| Government debt securities      | 4,079,400     | 1,104   | 4,080,504         |
| Corporate bonds                 | 4,893,130     | (1,288)   | 4,891,842         |
| Total investments in securities | \$ 25,773,496 | \$ (2,090)  | \$ 25,771,406     |

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**(5) Property and Equipment**

Property and equipment at December 31, 2007 and 2006 were as follows:

|  | <b>Useful<br/>Lives</b> | <b>2007</b> | <b>2006</b> |
|--|-------------------------|-------------|-------------|
| Office furniture, computer and lab equipment   | 3 - 5 years             | \$ 754,990  | \$ 651,012  |
| Computer software                              | 3 years                 | 122,162     | 98,881      |
|  |                         | 877,152     | 749,893     |
| Less accumulated depreciation and amortization |                         | (544,708)   | (346,925)   |
| Property and equipment, net                    |                         | \$ 332,444  | \$ 402,968  |

Depreciation and amortization expense was approximately \$198,000, \$177,000 and \$116,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

**(6) Accrued Liabilities**

Accrued liabilities at December 31, 2007 and 2006 were as follows:

|                                      | <b>2007</b>  | <b>2006</b>  |
|--------------------------------------|--------------|--------------|
| Accrued contracts and study expenses | \$ 1,953,472 | \$ 1,479,505 |
| Other accrued liabilities            | 326,428      | 157,389      |
| Deferred rent                        | 38,010       | 38,332       |
| Accrued liabilities                  | \$ 2,317,910 | \$ 1,675,226 |

**(7) Capital Stock****Common Stock**

2007. During 2007, we issued an aggregate of 575,833 shares of our common stock in connection with the exercises of employee stock options at a weighted average price of \$0.77 per share for cash in the aggregate amount of approximately \$442,000.

2006. In April 2006, we issued 2,099,990 shares of common stock at \$4.84 per share for a fair value of \$10,163,952 to acquire SDP. See Note 3, *Acquisition of SDP*, for a detailed discussion.

In September 2006, we ended an employment relationship with our former chief financial officer who also served as treasurer, vice president, finance and secretary. In connection with the separation from us, a severance agreement was entered into wherein the former chief financial officer's outstanding vested and unvested options were cancelled upon the separation and we issued 60,145 shares of common stock with a fair value of \$196,674 and paid employment taxes totaling \$109,434. The entire severance amount of \$306,108 was charged to selling, general and administrative expense for the year ended December 31, 2006.

In November 2006, we issued and sold to certain accredited institutional investors 14,545,000 shares of common stock in a registered direct offering at a price of \$2.75 per share, for aggregate offering proceeds of approximately \$40.0 million and net offering proceeds of approximately \$37.1 million, after deducting commissions and offering fees and expenses. The offering was made pursuant to our shelf registration statement on Form S-3, filed with the SEC on May 1, 2006.

During 2006, we issued an aggregate of 420,161 shares of our common stock upon the cashless exercises of warrants to purchase an aggregate of 527,528 shares of common stock at the weighted average exercise price of \$0.57 per

share.

Also during 2006, we issued an aggregate of 5,196,246 shares of our common stock in connection with the exercises of stock purchase warrants (5,103,746 shares at a weighted average price of \$1.55 per share for cash in the aggregate amount of \$7,691,590, net of \$206,274 in commissions) and employee stock options (92,500 shares at a weighted average price of \$1.36 per share for cash in the aggregate amount of approximately \$125,751). We also issued 15,000 shares of restricted stock to our consultants for services performed with a fair value of \$68,650.

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2005. In April 2005, we issued 25,000 shares of common stock as partial payment for services rendered by a consulting firm. Those shares were recognized at fair market value as of the date of obligation and resulted in compensation expense of \$23,500 in the year ended December 31, 2005, when the services were performed. In July 2005, we issued 100,000 shares of common stock, with a fair market value at the date of issuance of \$235,000, pursuant to a consulting agreement entered into in January 2005. The compensation cost related to those shares is recognized over the three-year service period at an annual amortization of \$78,333.

In July 2005, we issued and sold to certain accredited institutional investors 10,810,809 shares of common stock at \$1.85 per share, for aggregate gross proceeds of \$19,999,997 and net proceeds of \$18,116,751, after deducting commissions and offering costs. In connection with this transaction, we issued warrants to purchase 10,810,809 shares of common stock at an exercise price of \$2.26 per share. See Note 12, *Registration Payment Arrangement*, for a detailed discussion.

During 2005, we issued an aggregate of 149,613 shares of our common stock upon the cashless exercises of warrants to purchase an aggregate of 252,049 shares of common stock at the weighted average exercise price of \$1.18 per share.

Also during 2005, we issued an aggregate of 2,443,703 shares of our common stock in connection with the exercises of stock purchase warrants (2,258,703 shares at a weighted average price of \$1.37 per share for cash in the aggregate amount of \$3,073,439) and employee stock options (185,000 shares at a weighted average price of \$0.78 per share for cash in the aggregate amount of \$145,000).

**(8) Warrants**

In July 2005, we issued warrants to purchase 10,810,809 shares of common stock at an exercise price of \$2.26 per share in connection with the sale of 10,810,809 shares of common stock in July 2005. See Note 12, *Registration Payment Arrangement*, for a detailed discussion.

At December 31, 2007, outstanding warrants to purchase shares of common stock are as follows:

| <b>Warrants</b> | <b>Exercise<br/>Price</b> | <b>Expiration<br/>Date</b> |
|-----------------|---------------------------|----------------------------|
| 1,872,693*      | \$ 1.98                   | Apr-09                     |
| 117,000*        | \$ 2.38                   | Apr-09                     |
| 573,047*        | \$ 1.98                   | Jun-09                     |
| 10,810,809      | \$ 2.26                   | Jul-12                     |
| 13,373,549      |                           |                            |

- \* These warrants contain price-based anti-dilution protection. Among other things, this protection lowers the exercise price of these warrants

in the event we  
issue common  
stock at a price  
per share that is  
less than the  
warrants  
then-effective  
exercise price,  
thereby  
allowing the  
warrant holders  
to receive the  
same number of  
shares of our  
common stock  
for less  
consideration.

**(9) Equity Incentive Plans**

At December 31, 2007, we had the 2005 Equity Incentive Plan (the 2005 Plan ) and the 2005 Employee Stock Purchase Plan (the Purchase Plan ), which are described below. The share-based compensation expense from all share-based awards that has been charged to our consolidated statements of operations in the years ended December 31, 2007, 2006 and 2005 was comprised of the following:

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|   | <b>Years Ended December 31,</b> |              |              |
|---|---------------------------------|--------------|--------------|
|   | <b>2007</b>                     | <b>2006</b>  | <b>2005</b>  |
| Selling, general and administrative expense                             | \$ 1,440,081                    | \$ 1,635,369 | \$ 572,263   |
| Research and development expense  | 1,054,237                       | 509,966      | 594,493      |
| Share-based compensation expense before taxes                           | 2,494,318                       | 2,145,335    | 1,166,756    |
| Related income tax benefits   |                                 |              |              |
| Share-based compensation expense  | \$ 2,494,318                    | \$ 2,145,335 | \$ 1,166,756 |
| Net share-based compensation expense per common share basic and diluted | \$ 0.03                         | \$ 0.03      | \$ 0.02      |
| Share-based compensation expense from:                                  |                                 |              |              |
| Stock options   | \$ 2,415,985                    | \$ 1,801,677 | \$ 1,088,423 |
| Share grant   | 78,333                          | 275,008      | 78,333       |
| Restricted stock awards   |                                 | 68,650       |              |
|   | \$ 2,494,318                    | \$ 2,145,335 | \$ 1,166,756 |

Since we accounted for employee share-based awards using the recognition method under the provisions of FAS 123 prior to 2006, the adoption of FAS 123R did not have a material impact on our consolidated results of operations. Since we have net operating losses carry-forward as of December 31, 2007, no excess tax benefits for the tax deductions related to share-based awards were recognized in the consolidated statement of operations. Additionally, no incremental tax benefits were recognized from stock options exercised in the years ended December 31, 2007 and 2006 that would have resulted in a reclassification to reduce net cash provided by operating activities with an offsetting increase in net cash provided by financing activities.

**2005 Equity Incentive Plan**

The 2005 Plan, which is stockholder-approved, is intended to encourage ownership of shares of common stock by our directors, officers, employees, consultants and advisors and to provide additional incentive for them to promote the success of our business through the grant of share-based awards. The 2005 Plan provides for the grant of incentive and non-statutory stock options as well as share appreciation rights, restricted shares, restricted share units, performance units, shares and other share-based awards. Share-based awards are subject to terms and conditions established by the Board of Directors or the Compensation Committee of our Board of Directors. Our policy is to issue new common shares upon the exercise of stock options, conversion of share units or issuance of shares or restricted stock.

The maximum aggregate number of shares of common stock which may be issued pursuant to or subject to the foregoing types of awards granted under the 2005 Plan is 7,423,634 as of December 31, 2007. This maximum number is subject to an annual automatic increase beginning on January 1, 2006 equal to the lesser of (i) 1% of the number of outstanding shares of common stock on such day, (ii) 750,000 or (iii) such other amount as our board of directors may specify. The 2005 Plan is intended to comply with applicable securities law requirements, permit performance-based awards that qualify for deductibility under Section 162(m) of the Internal Revenue Code ( IRC ) and allow for the issuance of incentive stock options. As of December 31, 2007 and 2006, 2,374,216 and 2,453,886 shares of common

stock, respectively, remained available for issuance under the 2005 Plan. On January 1, 2008, the number of shares of common stock available for issuance under the 2005 Plan increased by 750,000 shares in accordance with the provisions for annual increases under the 2005 Plan.

Stock options are typically granted with an exercise price equal to the current market price of our common stock at the grant date and have ten-year contractual terms. Option awards generally vest over four years based on continuous service; however, our equity compensation plan allows for other vesting periods and we have granted employees options where the requisite service period is three years and we grant our directors options where the requisite service period is one year. During the years ended December 31, 2007, 2006 and 2005, we granted stock options and issued stock under the 2005 Plan.

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During January through April 2004, which was prior to the adoption of the 2005 Plan and prior to listing our common stock on American Stock Exchange ( AMEX ), we granted employees options to purchase an aggregate of 310,000 shares of common stock at a purchase price of \$1.50 per share. The total value of all the options on the dates of grant was \$395,403.

Subsequent to listing our common stock on AMEX, in the period of May 2004 through August 2004 we granted employees options to purchase an aggregate of 66,000 shares of common stock at purchase prices of \$1.20 to \$1.80 per share. AMEX listing requirements prohibit granting equity without a stockholder vote or an approved stock option plan; therefore, the options were rescinded in February 2005. Accordingly, the financial statement effect of the options granted was reversed in 2004.

In July 2005, we granted 1,625,000 options to employees under the 2005 Plan to replace pre-existing options that were not issued under the 2005 Plan or any other incentive plan approved by our stockholders. In addition in July 2005, we granted 1,103,000 new options to employees and board members under the 2005 Plan.

In December 2005, the exercise prices on 743,000 of the 1,103,000 options were increased to equal the fair market value of common stock on the date of grant in July 2005. In addition, the exercise prices on 730,000 of the pre-existing options were increased to equal the fair market value of common stock on the original grant dates. There was no material impact to the compensation expense as a result of this change. There were 14 employees affected by this change.

We cancelled 341,063, 413,397 and 200,000 options in the years ended December 31, 2007, 2006 and 2005, respectively, related to terminated employees and board directors, and the shares underlying such options were returned to and are available for re-issuance under the 2005 Plan.

A summary of all of our option activity as of December 31, 2007, 2006 and 2005 and of changes in options outstanding under the plans during the years then ended are as follows:

|  | Shares    | Weighted-Average<br>Exercise<br>Price | Weighted-Average<br>Remaining<br>Contractual<br>Term | Aggregate<br>Intrinsic<br>Value |
|--|-----------|---------------------------------------|--|---------------------------------|
| Outstanding at January 1, 2005           | 1,625,000 | \$ 0.75                               |  |                                 |
| Granted                                  | 1,217,000 | \$ 2.34                               |  |                                 |
| Exercised                                | (185,000) | \$ 0.78                               |  |                                 |
| Canceled/forfeited/expired               | (200,000) | \$ 1.41                               |  |                                 |
| Options outstanding at December 31, 2005 | 2,457,000 | \$ 1.45                               |  |                                 |
| Granted                                  | 1,816,000 | \$ 3.84                               |  |                                 |
| Exercised                                | (92,500)  | \$ 1.36                               |  |                                 |
| Canceled/forfeited/expired               | (413,397) | \$ 3.37                               |  |                                 |
| Options outstanding at December 31, 2006 | 3,767,103 | \$ 2.39                               |  |                                 |
| Granted                                  | 1,170,733 | \$ 2.63                               |  |                                 |
| Exercised                                | (575,833) | \$ 0.77                               |  |                                 |
| Canceled/forfeited/expired               | (341,063) | \$ 3.52                               |  |                                 |

|   |           |         |      |    |
|---|-----------|---------|------|----|
| Options outstanding at December 31, 2007                                | 4,020,940 | \$ 2.60 | 6.90 | \$ |
| Options vested and expected to vest in the future,<br>December 31, 2007 | 3,633,051 | \$ 2.55 | 6.71 | \$ |
| Options exercisable at December 31, 2007                                | 2,153,968 | \$ 2.29 | 5.30 | \$ |
| Options exercisable at December 31, 2006                                | 1,996,460 | \$ 1.46 |      |    |
| Options exercisable at December 31, 2005                                | 1,557,503 | \$ 1.03 |      |    |
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The weighted-average grant-date fair value of options granted during the years ended December 31, 2007, 2006 and 2005 was \$2.40, \$2.97 and \$2.14, respectively. As of December 31, 2007, there was approximately \$4.2 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a weighted-average remaining period of approximately 2.6 years.

The total intrinsic value of options exercised during the years ended December 31, 2007, 2006 and 2005 was approximately \$865,000, \$154,000 and \$395,000, respectively, based on the differences in the market prices on the dates of exercise and the option exercise prices. During the years ended December 31, 2007, 2006 and 2005, we received a total of approximately \$442,000, \$126,000 and \$145,000, respectively, in cash from exercised options under all share-based payment arrangements. No tax benefit was realized for the tax deductions from option exercises of the share-based payment arrangements in the years ended December 31, 2007, 2006 or 2005.

Our determination of fair value is affected by our stock price as well as a number of assumptions that require judgment. The fair value of each option award is estimated on the date of grant using the Black-Scholes option-valuation model. The assumptions used in the Black-Scholes model for option grants during the years ended December 31, 2007, 2006 and 2005 are as follows:

|                             | <b>Years Ended December 31,</b> |             |             |
|-----------------------------|---------------------------------|-------------|-------------|
|                             | <b>2007</b>                     | <b>2006</b> | <b>2005</b> |
| Risk-free interest rate     | 4.6 - 4.8%                      | 4.1 - 5.2%  | 3.7 - 4.3%  |
| Dividend yield              | 0.0%                            | 0.0%        | 0.0%        |
| Expected volatility         | 137%-138%                       | 85-142%     | 90%         |
| Weighted-average volatility | 138%                            | 111%        | 90%         |
| Expected term (in years)    | 6.1 years                       | 5-6.1 years | 5 years     |

The risk-free interest rate assumption is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have not paid any dividends on common stock since our inception and do not anticipate paying dividends on our common stock in the foreseeable future. The expected option term is computed using the simplified method as permitted under the provisions of SAB 107 and SAB 110. The expected volatility is based on the historical volatility of our common stock and other factors. In 2006, we began using an alternative historical volatility based on the daily close price of our common stock, which we determined was a better indicator of volatility than the method used in the prior years. The effect of this change on share-based compensation was immaterial.

In 2007 and 2005, we granted 15,000 and 114,000 options, respectively, to consultants. No options were granted to consultants in 2006. These option grants were valued as of the date at which the consultants' performance is complete using the Black-Scholes pricing model. The assumptions used in the Black-Scholes model for non-employee option grants for the years ended December 31, 2007, 2006 and 2005 are as follows:

|                             | <b>2007</b>     | <b>2006</b>     | <b>2005</b>     |
|-----------------------------|-----------------|-----------------|-----------------|
| Risk-free interest rate     | 4.0 - 4.8%      | 4.7%            | 4.4%            |
| Dividend yield              | 0.0%            | 0.0%            | 0.0%            |
| Expected volatility         | 125% - 147%     | 139%            | 90%             |
| Contractual term (in years) | 2.5 - 8.3 years | 3.5 - 6.1 years | 3.5 - 6.1 years |

We recognized approximately \$2,000, \$104,000 and \$94,000 in share-based compensation expense associated with non-employee options in the years ended December 31, 2007, 2006 and 2005, respectively.

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The following table summarizes information concerning our outstanding and exercisable stock options as of December 31, 2007:

| Range of Exercise Price | Options Outstanding            |   |                                 | Options Exercisable            |                                 |
|-------------------------|--------------------------------|---|---------------------------------|--------------------------------|---------------------------------|
|                         | Number Outstanding<br>in 000 s | Weighted-Average Remaining Contractual Life | Weighted-Average Exercise Price | Number Exercisable<br>in 000 s | Weighted-Average Exercise Price |
| \$0.50 to \$2.42        | 1,402                          | 3.89  | \$1.48                          | 1,249                          | \$1.38                          |
| \$2.45 to \$2.75        | 1,416                          | 8.68  | \$2.62                          | 302                            | \$2.56                          |
| \$2.86 to \$4.89        | 1,203                          | 8.32  | \$3.86                          | 603                            | \$4.05                          |
|                         | 4,021                          | 6.90  | \$2.60                          | 2,154                          | \$2.29                          |

**Restricted Stock Awards.** During the year ended December 31, 2006, we granted 15,000 shares of restricted stock awards to consultants for services performed. These restricted stock awards vested monthly over twelve months of service. No restricted stock awards were granted in the years ended December 31, 2007 or 2005. The shares underlying our restricted stock awards cannot be sold, pledged or otherwise disposed of until the award vests and any unvested shares may be transferred back to us following the awardee's termination of service.

A summary of our unvested restricted share awards as of December 31, 2007, 2006 and 2005 and changes during the years then ended are presented below:

|                             | Number of shares | Weighted Average Grant Date Fair Value |
|-----------------------------|------------------|--|
| Unvested, January 1, 2005   |                  | \$                                     |
| Granted                     |                  | \$                                     |
| Vested                      |                  | \$                                     |
| Forfeited                   |                  | \$                                     |
| Unvested, December 31, 2005 |                  | \$                                     |
| Granted                     | 15,000           | \$ 4.58                                |
| Vested                      | (15,000)         | \$ 4.58                                |
| Forfeited                   |                  | \$                                     |
| Unvested, December 31, 2006 |                  | \$                                     |
| Granted                     |                  | \$                                     |
| Vested                      |                  | \$                                     |
| Forfeited                   |                  | \$                                     |
| Unvested, December 31, 2007 |                  | \$                                     |

The fair value of restricted stock awards granted in the year ended December 31, 2006 was approximately \$69,000. As of December 31, 2007, there are no unrecognized compensation costs related to restricted stock awards.



**Stock Grants.** Stock grants are grants of shares of our common stock not subject to restrictions or other forfeiture conditions. During the year ended December 31, 2006, we granted an employee 60,145 shares of common stock with a grant-date fair value of \$196,674. During the year ended December 31, 2005, we granted a consultant 100,000 shares of common stock with a fair value of \$235,000. No stock grants were granted under the 2005 Plan in the year ended December 31, 2007. As of December 31, 2007, there was no unrecognized compensation cost related to stock grants.

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
 (A Development Stage Enterprise)  
**Notes to Consolidated Financial Statements (continued)**  
**December 31, 2007**

**Employee Stock Purchase Plan**

The Purchase Plan was approved by our stockholders in 2005; however, we have not implemented the Purchase Plan. The Purchase Plan allows all eligible employees to purchase shares of common stock at 85% of the lower of the fair market value on the first or the last day of each offering period. Employees may authorize us to withhold up to 15% of their compensation during any offering period, subject to certain limitations. The maximum aggregate number of shares of common stock which may be issued under the Purchase Plan is 2,423,634 as of December 31, 2007. This maximum number is subject to an annual automatic increase beginning on January 1, 2006 equal to the lesser of (i) 1% of the number of outstanding shares of common stock on such day, (ii) 750,000 or (iii) such other amount as our board of directors may specify. At December 31, 2007, no shares of common stock have been issued under the Purchase Plan. On January 1, 2008, the number of shares of common stock available for issuance under the Purchase Plan increased by 750,000 in accordance with the provisions for annual increases under the Purchase Plan.

**(10) Commitments****Operating Leases**

We are obligated under operating leases for office space and equipment. In July 2004, we entered into a lease for our current office space in San Diego, California. In June 2005, we leased additional space in the same facility. At December 31, 2007, the office lease requires a monthly payment of approximately \$21,000, excluding common area maintenance charges. The lease expires in August 2009.

Rent expense was approximately \$246,000, \$246,000 and \$221,000 during the years ended December 31, 2007, 2006 and 2005, respectively. Future rental commitments under all operating leases are as follows:

**Year Ending December 31,**

|       |            |
|-------|------------|
| 2008  | \$ 270,087 |
| 2009  | 187,826    |
| 2010  | 5,470      |
| Total | \$ 463,383 |

**(11) Material License Agreements****USC Agreement**

Under an option and license agreement with USC entered into in January 1998 and amended in August 2000, we hold exclusive rights to a number of patents that have issued in the U.S. and Canada covering CoFactor and its use in connection with cancer chemotherapy. An additional patent included in the agreement relates to compounds in our organoselenones program that we are currently evaluating for future preclinical and clinical development.

This agreement terminates on the last to expire of the licensed patents, which is expected to occur in March 2014.

Upon breach or default under the agreement, the non-breaching party may terminate the agreement by 45 days' written notice. USC may terminate the agreement upon 20 days' notice if we fail to obtain and maintain the insurance required by the agreement and may terminate the agreement immediately upon notice if we attempt to use, sublicense, transfer or assign our rights or obligations under the agreement in any manner contrary to its terms or in derogation of USC's proprietary rights and upon bankruptcy, reorganization, liquidation or receivership proceedings involving us. We may terminate the agreement at any time by providing USC 30 days' written notice.

This agreement provides for the payment to USC of a 3% royalty on net sales by us or a sublicensee of licensed products, as well as a prepaid royalty of \$100,000 within 30 days of approval of an NDA by the FDA for any product covered by the claims of the licensed patents (which prepaid royalty is deductible from future royalty payments). In addition, we are required to reimburse all reasonable legal expenses incurred by USC in filing, prosecuting and maintaining the licensed patents. No royalties have been paid to date under this agreement.



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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
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**December 31, 2007**

***Theragenex Agreement***

In October 2006, we entered into a license agreement with Theragenex, LLC. Under the agreement, we granted Theragenex exclusive rights to develop and commercialize ANX-211 in the U.S. in exchange for a licensing fee of \$1.0 million (\$500,000 of which we received in January 2007 and \$500,000 of which was due in June 2007 but remains unpaid), milestone payments and royalties. In May 2007, we received a letter from TRx Pharma, a subsidiary of Theragenex, that we believe was intended to constitute notice of termination of the agreement with Theragenex, though the letter did not explicitly state that it constituted notice of termination. In its letter, TRx Pharma requested a refund of the initial \$500,000 payment and, in subsequent discussions, has indicated that it does not intend to pay the remaining \$500,000. On July 3, 2007, we notified Theragenex that, among other things, its failure to make the final \$500,000 payment constituted a material breach of the agreement. On August 9, 2007, we delivered a letter to Theragenex confirming our termination of the agreement as a result of Theragenex's breach, pursuant to the terms of the agreement. See Note 14, *Litigation*, for further discussion.

For the year ended December 31, 2007, we recognized \$500,000 in license fee revenue, which we received in January 2007, because our performance obligations were complete, collectibility was reasonably assured and we had no continuing obligations for performance under the agreement. No license revenue was recognized in the year ended December 31, 2006. We do not intend to refund the initial \$500,000 payment from Theragenex and we intend to pursue appropriate action to collect payment of the final \$500,000 payment due in June 2007; however, in accordance with the provisions of Topic 13, we will not recognize revenue with respect to the uncollected amount until collectibility is reasonably assured.

**(12) Registration Payment Arrangement**

On July 21, 2005, we entered into a securities purchase agreement (the *Agreement*) with certain accredited institutional investors (the *Purchasers*) for the sale of 10,810,809 shares of our common stock (the *Shares*) at a purchase price of \$1.85 per share for aggregate gross proceeds of \$19,999,997. In connection with this financing, we issued the Purchasers seven-year warrants to purchase 10,810,809 shares of our common stock (the *Warrant Shares*) at an exercise price of \$2.26 per share. We received net proceeds of \$18,116,751, after deducting commissions and offering fees and expenses, which included cash payments of \$1,403,000 to placement agents and \$283,246 in legal and accounting fees.

Pursuant to the terms of the Agreement, if (i) a registration statement covering (A) all of the Shares and the Warrant Shares and (B) any other shares of common stock issued or issuable in respect to the Shares and the Warrant Shares because of stock splits, stock dividends, reclassifications, recapitalizations or similar events (together, the *Registrable Shares*) required to be covered thereby and required to be filed by us is (A) not filed with the SEC on or before 45 days after the closing of such financing (a *Filing Failure*) or (B) if such registration statement is not declared effective by the SEC on or before 90 days after the closing of such financing (an *Effectiveness Failure*) or (ii) on any day after the effective date of the registration statement sales of all the Registrable Shares required to be included on such registration statement cannot be made (other than as permitted during a suspension pursuant to the Agreement) pursuant to such registration statement (including, without limitation, because of a failure to keep the registration statement effective, to disclose such information as is necessary for sales to be made pursuant to such registration statement or to register sufficient number of Shares) (a *Maintenance Failure*), then, we will be obligated, without limiting any other remedies of any Purchaser, to pay as liquidated damages (the *Liquidated Damages*) for such failure and not as a penalty to any Purchaser an amount in cash determined in accordance with the formula set forth below:

For each 30-day period that a Filing Failure, Effectiveness Failure or Maintenance Failure remains uncured, we will pay an amount equal to the purchase price paid to us for all Shares then held by such Purchaser multiplied by 1% for the first 30-day period or any portion thereof and increasing by an additional 1% with regard to each additional 30-day period until such Filing Failure, Effectiveness Failure or Maintenance Failure is cured.



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For any partial 30-day period in which a Filing Failure, Effectiveness Failure or Maintenance Failure exists but is cured prior to the end of the 30-day period, we will pay the Purchasers a pro rata portion of the amount which would be due if the failure continued for the entire 30-day period. For example, if the purchase price paid for all Shares then held by a Purchaser is \$5,000,000, then, (a) at the end of the 30th day, the Liquidated Damages would be 1% or \$50,000, (b) at the end of the 60th day, the Liquidated Damages for the first 30-day period would have been 1% or \$50,000 and for the second 30-day period would be 2% or \$100,000, and (c) at the end of the 105th day, the Liquidated Damages for the first 30-day period would have been 1% or \$50,000, for the second 30-day period 2% or \$100,000, for the third 30-day period 3% or \$150,000, and for the final 15-day period, 4% applied pro rata to such 15 days, or \$100,000.

There is no cap to the amount of Liquidated Damages that we may be obligated to pay. Payments to be made pursuant to the July 2005 Registration Payment Arrangement will be due and payable to the Purchasers at the end of each calendar month during which Liquidated Damages will have accrued. No Liquidated Damages will be due or payable to a Purchaser in any event if as of the date of the Filing Failure, Effectiveness Failure or Maintenance Failure such Purchaser could sell all of the Registrable Shares such Purchaser then holds without registration by reason of subsection (k) of Rule 144 under the Securities Act of 1933, as amended. Recent changes to Rule 144 eliminated subsection (k) of Rule 144. These changes liberalized the rules governing the resale of securities issued in private transactions; however, resales of securities held by affiliates are still subject to the current public information, volume, manner of sale and notice requirements contained in Rule 144 and, as a result, we do not expect such changes to Rule 144 to necessarily reduce the potential length of our payment obligations in the event of a Maintenance Failure. The registration statement was filed and declared effective by the SEC on September 2, 2005, which was within the allowed time. As of February 28, 2008, we have not incurred nor paid any Liquidated Damages in connection with the July 2005 Registration Payment Arrangement.

Effective January 1, 2007, we accounted for the July 2005 Registration Payment Arrangement under the provisions of FSP EITF 00-19-2. See Note 2, *Summary of Significant Accounting Policies – Change in Accounting Principle for Registration Payment Arrangements*, for a detailed discussion. As of March 3, 2008, management determined that it is not probable that we will be obligated to pay any Liquidated Damages in connection with the July 2005 Registration Payment Arrangement. Accordingly, no accrual for contingent obligation is required at December 31, 2007.

**(13) Income Taxes**

Due to our net loss for the years ended December 31, 2007, 2006, and 2005, and as we have recorded a full valuation allowance against deferred tax assets, there was no provision or benefit for income taxes recorded. There were no components of current or deferred federal, state or foreign tax provisions for the years ended December 31, 2007, 2006, or 2005.

The income tax provision is different from that which would be obtained by applying the statutory Federal income tax rate (34%) to income before income tax expense. The items causing this difference for the periods are as follows:

|  | <b>2007</b>  | <b>2006</b>  | <b>2005</b>  |
|--|--------------|--------------|--------------|
| Income tax benefit at federal statutory rate       | \$ 7,503,000 | \$ 9,973,000 | \$ 4,489,000 |
| State tax on continuing operations                 | (2,000)      | (2,000)      | (1,000)      |
| IPR&D (SDP acquisition)                            |              | (3,544,000)  |              |
| Federal effect of state valuation allowance change | (710,000)    | (119,000)    |              |
| R & D Credit                                       | 628,000      | 143,000      | 478,000      |
| Stock options                                      | (432,000)    |              |              |
| Other  | (152,000)    | (617,000)    | (105,000)    |
| Change in federal valuation allowance (1)          | (6,835,000)  | (5,834,000)  | (4,861,000)  |

\$

\$

\$

- (1) The removal of the valuation allowance related to the net operating loss carryforwards is not included in the change in the valuation allowance, as explained below.

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
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In July 2006, the FASB issued FIN 48. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We adopted the provisions of FIN 48 on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption. As a result of the implementation of FIN 48, we did not recognize an increase in the liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the consolidated balance sheet that would, if recognized, affect the effective tax rate.

Our policy is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrual for interest or penalties on our consolidated balance sheets at December 31, 2007 or 2006, and have not recognized interest and/or penalties in the consolidated statement of operations for the year ended December 31, 2007. We are subject to taxation in the U.S. and the state of California. All of our tax years are subject to examination by the U.S. and California tax authorities due to the carryforward of unutilized net operating losses and R&D credits.

The adoption of FIN 48 did not impact our consolidated financial condition, results of operations or cash flows. At December 31, 2007, we had net deferred tax assets of approximately \$27.5 million. Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation has been established to offset the net deferred tax asset. Additionally, the future utilization of our net operating loss and R&D credit carryforwards to offset future taxable income may be subject to an annual limitation, pursuant to IRC Sections 382 and 383, as a result of ownership changes that may have occurred previously or that could occur in the future.

We are currently analyzing our net operating losses, but are still in the process of collecting data from stockholders regarding indirect holdings. We believe we may have had an ownership change on October 10, 2000, limiting our use of the net operating losses. Until this analysis is completed, we have removed the deferred tax assets for our net operating losses of approximately \$4.5 million generated through October 10, 2000 from our deferred tax asset schedule and have recorded a corresponding decrease to our valuation allowance. When this analysis is finalized, we plan to update our unrecognized tax benefits under FIN 48. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of deferred tax assets and liabilities at December 31, 2007 and 2006 are as follows:

|                                      | <b>December 31,</b> |             |
|--------------------------------------|---------------------|-------------|
|                                      | <b>2007</b>         | <b>2006</b> |
| Deferred tax assets:                 |                     |             |
| Accrued expenses                     | \$ 150,210          | \$ 115,453  |
| Stock options expense under FAS 123R | 1,675,824           | 1,636,685   |
| Net operating loss carryforwards     | 22,338,915          | 16,693,749  |
| Income tax credit carryforwards      | 1,729,194           | 720,067     |
| Property, plant and equipment        | 38,065              | 20,295      |
| Intangibles                          | 1,535,487           | 811,597     |
| Other                                | 577                 | 577         |
| <br>                                 |                     |             |
| Total deferred tax assets            | 27,468,272          | 19,998,423  |



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|   |              |              |
|---|--------------|--------------|
| Less: valuation allowance                             | (27,468,272) | (19,998,423) |
| Total deferred tax assets, net of valuation allowance | \$           | \$           |

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**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**  
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We have established a valuation allowance against our deferred tax asset due to the uncertainty surrounding the realization of such assets. Management periodically evaluates the recoverability of the deferred tax asset. At such time as it is determined that it is more likely than not that the deferred tax assets are realizable, the valuation allowance will be reduced. We have recorded a valuation allowance of approximately \$27.5 million as of December 31, 2007 to reflect the estimated amount of deferred taxes that may not be realized. We increased the valuation allowance by approximately \$7.5 million for the year ended December 31, 2007. The deferred tax asset for the net operating losses and the related valuation allowance includes approximately \$50,000 related to stock option deductions, the benefit of which may eventually be credited to equity. As a result of our subsequent adoption of FAS 123R, we recognize windfall tax benefits associated with the exercise of stock options directly to consolidated stockholders' equity only when realized. Accordingly, as we are in a cumulative loss position, deferred tax assets have not been recognized for net operating loss carryforwards resulting from windfall tax benefits generated under FAS 123R. At December 31, 2007, we do not have any windfall tax benefits under FAS 123R.

At December 31, 2007, we had federal and California tax loss carryforwards of approximately \$60.7 million and \$29.8 million, respectively. The federal and California net operating loss carryforwards begin to expire in 2020 and 2012 respectively, if unused. At December 31, 2007, we had federal and state tax credit carryforwards of approximately \$1.3 million and \$640,000, respectively. The federal credits will begin to expire in 2024.

**(14) Litigation**

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.

On October 11, 2007, we filed a demand for arbitration against Theragenex, LLC (doing business as TRx Pharma, LLC and/or TRx Pharmaceuticals, LLC) and David M. Preston, founder, Chairman, President and Chief Executive Officer of Theragenex in his individual capacity as the alter ego of Theragenex, seeking damages of up to \$10 million with respect to breach of the license agreement, dated October 20, 2006, between us and Theragenex. We terminated the license agreement in August 2007 as a result of Theragenex's breach. In accordance with the terms of the license agreement, we filed our demand with the American Arbitration Association and requested that the hearing take place in San Diego, California. On November 8, 2007, Theragenex responded to our demand, asserting numerous affirmative defenses counterclaiming intentional misrepresentation, negligent misrepresentation and rescission and seeking a refund of its \$500,000 payment, plus interest, rescission of the license agreement and that we pay its reasonable attorneys fees and costs associated with the action. Also on November 8, 2007, Mr. Preston objected to his participation and being named as a respondent in the arbitration. We believe the likelihood of an unfavorable outcome as a result of Theragenex's counterclaims is remote. Unless we earlier settle or otherwise determine not to pursue the matter, we expect an arbitration hearing date in the fourth quarter of 2008. We are unable to predict the outcome of our claim against Theragenex and the amount that we could receive, if any, from the arbitration proceedings.

**(15) 401(k) Plan**

We have a defined contribution savings plan pursuant to Section 401(k) of the IRC. The plan is for the benefit of all qualifying employees and permits voluntary contributions by employees up to 100% of eligible compensation, subject to the Internal Revenue Service (IRS)-imposed maximum limits. Up until January 1, 2008, we were required to make matching contributions in the amount of 100% of employee contributions to 3% of eligible compensation and 50% of employee contributions between 3% and 5% of eligible compensation. Effective January 1, 2008, our 401(k) Plan was amended, which required us to make matching contributions equal to 100% of employee contributions up to 6% of eligible compensation, limited by the IRS-imposed maximum. We incurred total expenses of approximately \$118,000, \$80,000 and \$61,000 in employer matching contributions in 2007, 2006 and 2005, respectively.

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**(16) Segment Information**

We operate our business on the basis of a single reportable segment, which is the business of in-licensing, developing and commercializing proprietary product candidates primarily for the treatment of cancer and infectious disease. Our chief operating decision-maker is the chief executive officer and president, who evaluates our company as a single operating segment. All of our operating activities and work performed by our employees are currently conducted from a single location in the U.S. Revenues of \$500,000 in 2007 were derived solely from fees earned from a license agreement with Theragenex, LLC. We did not generate any revenues in either 2006 or 2005.

**(17) Summary of Quarterly Financial Data (unaudited)**

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2007 and 2006:

| <b>Quarterly statement of operations data<br/>for 2007 (unaudited):</b>            | <b>Quarters Ended</b> |                |                     |                    |
|--|-----------------------|----------------|---------------------|--------------------|
|  | <b>March 31</b>       | <b>June 30</b> | <b>September 30</b> | <b>December 31</b> |
| Licensing revenue  | \$ 500,000            | \$             | \$                  | \$                 |
| Gross margin   | \$ 500,000            | \$             | \$                  | \$                 |
| Loss from operations   | \$ (5,745,998)        | \$ (6,299,042) | \$ (6,446,415)      | \$ (5,819,590)     |
| Net loss   | \$ (5,123,814)        | \$ (5,722,828) | \$ (5,914,124)      | \$ (5,381,274)     |
| Basic and diluted net loss per share   | \$ (0.06)             | \$ (0.06)      | \$ (0.07)           | \$ (0.06)          |
| Basic and diluted weighted average number of<br>shares of common stock outstanding | 89,676,739            | 89,706,739     | 90,007,509          | 90,252,572         |

| <b>Quarterly statement of operations data<br/>for 2006 (unaudited) (1):</b>        | <b>Quarters Ended</b> |                   |                     |                    |
|--|-----------------------|-------------------|---------------------|--------------------|
|  | <b>March 31</b>       | <b>June 30(2)</b> | <b>September 30</b> | <b>December 31</b> |
| Licensing revenue  | \$                    | \$                | \$                  | \$                 |
| Gross margin   | \$                    | \$                | \$                  | \$                 |
| Loss from operations   | \$ (4,256,143)        | \$ (15,451,711)   | \$ (5,328,321)      | \$ (4,800,292)     |
| Net income (loss)  | \$ (4,019,616)        | \$ (15,199,597)   | \$ (5,107,050)      | \$ (4,345,482)     |
| Basic and diluted net income (loss) per share                                      | \$ (0.06)             | \$ (0.21)         | \$ (0.07)           | \$ (0.05)          |
| Basic and diluted weighted average number of<br>shares of common stock outstanding | 67,976,352            | 71,214,523        | 73,435,715          | 83,092,233         |

(1) On January 1, 2007, we adopted the provisions of FSP EITF 00-19-2. Accordingly, the consolidated financial statements at December 31, 2006 and for the year then ended were adjusted

retrospectively.  
See Note 2,  
*Summary of  
Significant  
Accounting  
Policies  
Change in  
Accounting  
Principle for  
Registration  
Payment  
Arrangements,*  
for a detailed  
discussion.

- (2) Includes a charge of \$10,442,130 for purchased IPR&D in connection with our acquisition of SDP in the quarter ended June 30, 2006.

**(18) Subsequent Event**

In January 2008, Evan M. Levine, our chief executive officer, resumed his position as chief executive officer and president, a position he held from September 2004 through September 2006. At the same time, our employment relationship with James A. Merritt, M.D., ended effective January 29, 2008. Dr. Merritt previously served as our president and chief medical officer. In connection with these events, the underlying responsibilities of the chief medical officer and president positions were consolidated. Joachim P.H. Schupp, M.D., who has served as our vice president, medical affairs since August 2006, began to lead our clinical group and assumed Dr. Merritt's clinical responsibilities, and Mr. Levine resumed the corporate responsibilities of president.

Pursuant to a letter agreement describing the terms of Dr. Merritt's separation, we agreed to the terms set forth in Dr. Merritt's offer letter, dated September 7, 2006, and a stock option agreement, dated September 27, 2006 (the Option Agreement), except that we extended the exercise period of the option governed by the Option Agreement from June 29, 2008 to December 31, 2008.

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**Exhibit Index**

| Exhibit  | Description   |
|----------|---|
| 2.1 (1)  | Agreement and Plan of Merger, dated April 7, 2006, among the registrant, Speed Acquisition, Inc., SD Pharmaceuticals, Inc. and certain individuals named therein (including exhibits thereto) |
| 3.1 (2)  | Amended and Restated Certificate of Incorporation of the registrant   |
| 3.2 (3)  | Amended and Restated Bylaws of the registrant (formerly known as Biokeys Pharmaceuticals, Inc.)   |
| 4.1(4)   | Form of Registration Rights Agreement entered into in October and November 2001 (including the original schedule of holders)  |
| 4.2 (5)  | \$2.50 Warrant to Purchase Common Stock issued on April 12, 2002 to Emisphere Technologies, Inc.  |
| 4.3 (4)  | Form of \$0.60 Warrant to Purchase Common Stock issued May 28, 2003 (including the original schedule of holders)  |
| 4.4 (4)  | Form of \$1.25 Warrant to Purchase Common Stock issued between October 15, 2003 and December 29, 2003 (including the original schedule of holders)  |
| 4.5 (4)  | Common Stock and Warrant Purchase Agreement, dated as of April 5, 2004, among the registrant and the Investors (as defined therein)   |
| 4.6 (4)  | Registration Rights Agreement, dated April 5, 2004, among the registrant and the Investors (as defined therein)   |
| 4.7 (4)  | Form of \$2.00 A-1 Warrant to Purchase Common Stock issued April 8, 2004 (including the original schedule of holders)   |
| 4.8 (4)  | Form of \$2.50 A-2 Warrant to Purchase Common Stock issued April 8, 2004 (including the original schedule of holders)   |
| 4.9 (6)  | Common Stock and Warrant Purchase Agreement, dated April 8, 2004, between the registrant and CD Investment Partners, Ltd.   |
| 4.10 (6) | Registration Rights Agreement, dated April 8, 2004, between the registrant and CD Investment Partners, Ltd.   |
| 4.11 (6) | \$2.00 A-1 Warrant to Purchase Common Stock issued on April 8, 2004 to CD Investment Partners, Ltd.   |
| 4.12 (6) | \$2.00 A-1 Warrant to Purchase Common Stock issued on April 8, 2004 to Burnham Hill Partners  |
| 4.13 (6) | \$2.00 A-1 Warrant to Purchase Common Stock issued on April 8, 2004 to Ernest Pernet  |
| 4.14 (6) | \$2.00 A-1 Warrant to Purchase Common Stock issued on April 8, 2004 to W.R. Hambrecht + Co., LLC  |
| 4.15 (7) |   |

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Common Stock and Warrant Purchase Agreement, dated April 19, 2004, between the registrant and Franklin M. Berger

- 4.16 (7) Registration Rights Agreement, dated April 19, 2004, between the registrant and Franklin M. Berger
  - 4.17 (7) \$2.00 A-1 Warrant to Purchase Common Stock issued on April 19, 2004 to Franklin M. Berger
  - 4.18 (8) Securities Purchase Agreement, dated July 21, 2005, among the registrant and the Purchasers (as defined therein)
  - 4.19 (8) Rights Agreement, dated July 27, 2005, among the registrant, the Icahn Purchasers and Viking (each as defined therein)
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| Exhibit     | Description  |
|-------------|--|
| 4.20 (9)    | First Amendment to Rights Agreement, dated September 22, 2006, among the registrant and the Icahn Purchasers (as defined therein)                                |
| 4.21 (8)    | Form of \$2.26 Common Stock Warrant issued on July 27, 2005 (including the original schedule of holders)   |
| 4.22 (8)    | Form of \$2.26 Common Stock Warrant issued on July 27, 2005 (including the original schedule of holders)   |
| 4.23 (11)   | \$0.50 Warrant (WC-291) to Purchase Common Stock transferred on June 15, 2005 to S. Neborsky and R Neborsky TTEE Robert J. Neborsky MD Inc Comb Retirement Trust |
| 4.24 (10)   | \$0.50 Warrant (WC-292) to Purchase Common Stock transferred on June 15, 2005 to S. Neborsky and R Neborsky TTEE Robert J. Neborsky MD Inc Comb Retirement Trust |
| 4.25 (10)   | \$2.50 Warrant to Purchase Common Stock issued on October 22, 2004 to Thomas J. DePetrillo   |
| 10.1# (11)  | 2005 Equity Incentive Plan   |
| 10.2# (12)  | Form of Stock Option Agreement under the 2005 Equity Incentive Plan  |
| 10.3#       | Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for director option grants beginning in 2008)   |
| 10.4# (2)   | Form of Restricted Share Award Agreement under the 2005 Equity Incentive Plan  |
| 10.5# (12)  | 2005 Employee Stock Purchase Plan  |
| 10.6# (12)  | Form of Subscription Agreement under the 2005 Employee Stock Purchase Plan   |
| 10.7* (13)  | Option and License Agreement, dated January 23, 1998, between the registrant and the University of Southern California   |
| 10.8 (3)    | First Amendment to License Agreement, dated August 16, 2000, between the registrant and the University of Southern California                                    |
| 10.9* (13)  | Option and License Agreement, dated August 17, 2000, between the registrant and the University of Southern California  |
| 10.10* (14) | Amendment to Option and License Agreement, dated April 21, 2003, between the registrant and the University of Southern California                                |
| 10.11* (15) | Second Amendment to Option and License Agreement, dated January 25, 2007, between the registrant and the University of Southern California                       |
| 10.12* (2)  | Agreement, effective as of May 1, 2005, between the registrant and Pharm-Olam International Ltd.   |

- 10.13 (2) Amendment dated July 19, 2005 to the Agreement between the registrant and Pharm-Olam International Ltd.
  - 10.14 (16) License Agreement, dated October 20, 2006, between the registrant, through its wholly-owned subsidiary SD Pharmaceuticals, Inc., and Theragenex, LLC
  - 10.15 License Agreement, dated December 10, 2005, between SD Pharmaceuticals, Latitude Pharmaceuticals and Andrew Chen, including a certain letter, dated November 20, 2007, clarifying the scope of rights thereunder
  - 10.16 (17) Standard Multi-Tenant Office Lease Gross, dated June 3, 2004, between the registrant and George V. Casey & Ellen M. Casey, Trustees of the Casey Family Trust dated June 22, 1998
  - 10.17 (2) First Amendment to the Standard Multi-Tenant Office Lease Gross, dated June 3, 2004 between the registrant and George V. & Ellen M. Casey, Trustees of the Casey Family Trust dated June 22, 1998
  - 10.18# (18) Offer letter, dated March 5, 2003, to Joan M. Robbins
  - 10.19# (19) Offer letter, dated November 15, 2004, to Brian M. Culley
-



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| Exhibit     | Description   |
|-------------|---|
| 10.20# (20) | Severance Agreement and Release of All Claims, dated September 7, 2006, with Carrie Carlander   |
| 10.21# (20) | Consulting Agreement, dated September 7, 2006, with Carrie Carlander  |
| 10.22# (20) | Offer letter, dated September 7, 2006, to James A. Merritt  |
| 10.23#      | Letter agreement regarding terms of separation with James A. Merritt, effective as of February 12, 2008   |
| 10.24# (20) | Form of Stock Option Agreement between the registrant and James A. Merritt (included in Exhibit 10.22)  |
| 10.25# (21) | Offer letter, dated December 13, 2006, to Gregory P. Hanson   |
| 10.26# (21) | Stock Option Agreement, effective December 20, 2006, between the registrant and Gregory P. Hanson   |
| 10.27 (16)  | Form of Director and Officer Indemnification Agreement  |
| 10.28# (22) | Director compensation policy  |
| 10.29 (23)  | Placement Agency Agreement, dated November 2, 2006, among the registrant, ThinkEquity Partners LLC and Fortis Securities LLC  |
| 14.1 (24)   | Code of Business Conduct and Ethics   |
| 21.1        | List of Subsidiaries  |
| 23.1        | Consent of J.H. Cohn LLP, Independent Registered Public Accounting Firm   |
| 31.1        | Certification of chief executive officer pursuant to Rule 13a-14(a)/15d-14(a)   |
| 31.2        | Certification of chief financial officer pursuant to Rule 13a-14(a)/15d-14(a)   |
| 32.1 ±      | Certification of chief executive officer and chief financial officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

\* Indicates that confidential treatment has been requested or granted to certain portions, which portions have been omitted and filed separately with the SEC

# Indicates management contract or

compensatory plan

- ± These certifications are being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
- (1) Filed with the registrant's Amendment No. 1 to Current Report on Form 8-K/A on May 1, 2006 (SEC file number 001-32157-06796248)
  - (2) Filed with the registrant's Annual Report on Form 10-K on March 16, 2006 (SEC file number 001-32157-06693266)
  - (3) Filed with the registrant's Registration Statement on Form 8-K on December 19, 2007 (SEC file number 001-32157-071315801)
  - (4) Filed with the registrant's Registration Statement on Form S-3 on June 30, 2004 (SEC file number 333-117022-03848890)
  - (5)

Filed with the  
registrant's Amendment  
No. 1 to Quarterly  
Report on Form 10-Q/A  
on October 30, 2006  
(SEC file number  
001-32157-061170484)

- (6) Filed with the  
registrant's Current  
Report on Form 8-K/A  
on April 13, 2004 (SEC  
file number  
000-33219-04730584)
-

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- (7) Filed with the registrant s  
Quarterly Report on  
Form 10-QSB on  
May 12, 2004 (SEC file  
number  
001-32157-04797806)
- (8) Filed with the registrant s  
Quarterly Report on  
Form 10-Q on  
August 12, 2005 (SEC  
file number  
001-32157-051022046)
- (9) Filed with the registrant s  
Current Report on Form  
8-K on September 22,  
2006 (SEC file number  
001-32157-061103268)
- (10) Filed with the registrant s  
Registration Statement  
on Form S-3 on  
August 26, 2005 (SEC  
file number  
333-127857-051050073)
- (11) Filed with the registrant s  
Annual Report on Form  
10-K on March 15, 2007  
(SEC file number  
001-32157-07697283)
- (12) Filed with the registrant s  
Registration Statement  
on Form S-8 on July 13,  
2005 (SEC file number  
333-126551-05951362)
- (13) Filed with the registrant s  
Registration Statement  
on Form 10SB/A on  
January 14, 2002 (SEC  
file number  
000-33219-2508012)
- (14) Filed with the registrant s  
Quarterly Report on  
Form 10-QSB on

August 14, 2003 (SEC  
file number  
000-33219-03848890)

(15) Filed with the registrant s  
Quarterly Report on  
Form 10-Q on May 8,  
2007 (SEC file number  
001-32157-07829156)

(16) Filed with the registrant s  
Current Report on Form  
8-K on October 23, 2006  
(SEC file number  
001-32157-061156993)

(17) Filed with the registrant s  
Quarterly Report on  
Form 10-QSB on  
August 10, 2004 (SEC  
file number  
001-32157-04963741)

(18) Filed with the registrant s  
Annual Report on Form  
10-KSB on April 16,  
2003 (SEC file number  
000-33219-03651464)

(19) Filed with the registrant s  
Annual Report on Form  
10-KSB on March 31,  
2005 (SEC file number  
001-32157-05719975)

(20) Filed with the registrant s  
Current Report on Form  
8-K on September 8,  
2006 (SEC file number  
001-32157-061082484)

(21) Filed with the registrant s  
Current Report on Form  
8-K on December 20,  
2006 (SEC file number  
001-32157-061290689)

(22) Filed with the registrant s  
Current Report on Form  
8-K on June 23, 2006  
(SEC file number

001-32157-06922676)

- (23) Filed with the registrant's  
Current Report on Form  
8-K on November 3,  
2006 (SEC file number  
001-32157-061184445)
- (24) Filed with the registrant's  
Current Report on Form  
8-K on January 23, 2007  
(SEC file number  
001-32157-07545489)
- (c) Financial Statement Schedules. All schedules are omitted because they are not applicable, the amounts involved are not significant or the required information is shown in the financial statements or notes thereto.