ADVENTRX PHARMACEUTICALS INC
Form 10-K
March 27, 2009

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

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

For the fiscal year ended December 31, 2008

OR

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

For the transition period from _____ to _____

Commission File No. 001-32157

ADVENTRX Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

(858) 552-0866

(Registrant s telephone number, including area code)

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

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

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

None

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

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

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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Forward-Looking Statements

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

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

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

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Item 1. Business

Overview

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

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

Reducing the incidence and severity of adverse effects; and

Increasing their pharmacoeconomics and convenience to healthcare practitioners and patients.

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

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

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

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

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

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

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

Oncology Focus

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

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

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

Opportunities for New Formulations

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

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

Regulatory Strategy

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

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

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

Commercialization Strategy

HCPCS Product Codes and Reimbursement

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

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

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

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

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

Group Purchasing Organizations

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

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

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

ANX-530 (vinorelbine emulsion)

Background; Limitations of Current Formulations

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

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

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

Clinical and Regulatory Developments

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

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In January 2008, we announced safety results from the study. In post hoc analyses, relative to Navelbine, ANX-530 demonstrated a statistically significant reduction in injection site reactions. Notably, the incidence of injection site reactions attributed to Navelbine was consistent with its product label. Furthermore, ANX-530 was determined to be safe and well-tolerated with no significant differences observed in any other safety parameters.

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

Market and Opportunity

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

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

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

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

ANX-514 (docetaxel emulsion)

Background; Limitations of Taxotere

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

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

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

Preclinical Efficacy and Safety; Enrollment in Bioequivalence Study Complete

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

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

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

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

Market and Opportunity

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

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

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

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

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

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

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

Other Product Candidates and Potential Product Candidates

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

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

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

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

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

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

Competition

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

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

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

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

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

Manufacturing

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

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

Intellectual Property

ANX-530 (vinorelbine emulsion)

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

ANX-514 (docetaxel emulsion)

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

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

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

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

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

Research and Development

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

Licensing Agreements

SD Pharmaceuticals

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

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

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

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Government Regulations

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

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

FDA Approval Process

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

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

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

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

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

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

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Section 505(b)(2) New Drug Applications

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

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

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

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

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Other Regulatory Requirements

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

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

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

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

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

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

authorization vary widely from country to country.

Employees

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

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Available Information

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

Item 1A. Risk Factors

Not required.

Item 1B. Unresolved Staff Comments

Not required.

Item 2. Properties

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

Item 3. Legal Proceedings

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

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

Not applicable.

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PART II

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

Market Information

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

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

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

Dividend Policy

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

Recent Sales of Unregistered Securities

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

Item 6. Selected Financial Data

Not required.

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

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

OVERVIEW

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

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

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

Revenue Recognition. We recognize revenue in accordance with the SEC s Staff Accounting Bulletin Topic 13, Revenue Recognition, or Topic 13, and Emerging Issues Task Force Issue, or EITF, No. 00-21, Revenue Arrangements with Multiple 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, bioequivalence and 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 bioequivalence and clinical trials are often made under contracts with multiple CROs that conduct and manage these 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 milestones. Expenses related to bioequivalence and 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 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 bioequivalence or 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 bioequivalence and 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 bioequivalence and 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 SFAS 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 generating future economic benefits. We determine the future economic benefits from the purchased IPR&D to be uncertain until such technology is incorporated into products approved for marketing by the FDA or when other significant risk factors are abated.

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Stock-based Compensation Expenses. Effective January 1, 2006, we accounted for stock-based compensation awards granted to employees, including members of our board of directors, in accordance with the revised SFAS No. 123, Share-Based Payment, or SFAS 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. As of December 31, 2008, we had no awards with market or performance conditions. As stock-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 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 stock-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 stock-based compensation under the recognition and measurement principles of SFAS 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 stock-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 stock-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 stock-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.

Income Taxes. In July 2006, FASB issued Financial Interpretation No., or 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.

Costs Associated with Exit or Disposal Activities. In accordance with SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities, as part of a restructuring to reduce operating costs, on October 14, 2008, we completed a work force reduction of nine employees. As a result of the reduction in force, we recorded severance-related charges of $403,000, of which approximately $384,000 was recorded in research and development and the remainder in selling, general and administrative expenses. Severance payments and related employer taxes were $372,000 of the severance-related charges and $31,000 relates to health benefit allowance payments, which the eligible former employees may use, at their discretion, to pay the premiums required to continue their group health care coverage under COBRA or any other health care related expenses. Severance-related charges of $244,000 were recorded in the fourth quarter of 2008 and the remainder will be recorded in the first and second quarters of 2009. We may also incur other charges not currently contemplated due to events that may occur as a result of, or associated with, the restructuring.

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.

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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. In March 2009, we announced that we will discontinue substantially all of our development activities and fundamental business operations to provide additional time to consummate a strategic transaction or otherwise obtain financing.

If we are successful in consummating a strategic transaction, future expenditures on R&D programs are subject to many uncertainties, including whether our product candidates will be further developed with a partner or independently. At this time, due to such uncertainties and the risks inherent in drug development and the associated regulatory process, 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 revenues will be generated from the commercialization and sale of any of our product candidates. The duration and costs of our R&D programs, in particular those associated with bioequivalence trials and research-related manufacturing, can vary significantly among programs as a result of a variety of factors, including:

- the number and location of sites included in trials and the rate of site approval for the trial;
- the rates of patient recruitment and enrollment;
- the ratio of randomized to evaluable patients;
- the availability and cost of reference product in the jurisdiction of each site;
- the time and cost of process development activities related to our product candidates;
- the costs of manufacturing our product candidates; and
- the costs, requirements, timing of and the ability to secure regulatory approvals.

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We operate our business on the basis of a single reportable segment, which, fundamentally, is the business of in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. We evaluate our company as a single operating segment. The majority of our operating activities and work performed by our employees are currently conducted from a single location in the U.S. We recognized revenues of $0.5 million in each of 2008 and 2007, which revenues were derived solely from license fees under a license agreement with Theragenex, LLC, which we terminated in August 2007.

	Operating Expenses Years Ended December 31,	
	2008	**2007**
Research and development	64%	64%
In-process research and development	0%	0%
Selling, general and administrative	35%	35%
Depreciation and amortization	1%	1%
Total operating expenses	100%	100%

Comparison of 2008 and 2007

***Revenue*.** We recognized revenue of $0.5 million for each of the years ended December 31, 2008 and 2007. Revenue in 2007 represents nonrefundable licensing fees paid under our license agreement with Theragenex LLC, which we terminated in August 2007 as a result of Theragenex s breach of the agreement. Revenue in 2008 represents a portion of a settlement payment from Theragenex. In May 2008, we settled our dispute with Theragenex arising out of its breach of the license agreement and, in accordance with such settlement, Theragenex paid us $0.6 million. We recognized $0.5 million as revenue in 2008, which represents a portion of the $0.6 million settlement payment, because under the license agreement Theragenex was required to pay a total nonrefundable, up front licensing fee of $1.0 million ($0.5 million of which we received in January 2007 and $0.5 million of which was due in June 2007) and because we met the criteria for revenue recognition. The remainder of the settlement payment, $0.1 million, was recorded as other income.

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.

***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 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:

	Years Ended December 31,		January 1, 2005 through December 31,
	2008	2007	2008
External bioequivalence and clinical trial fees and expenses	$ 3,373,865	$ 7,535,923	$ 23,199,479
External non-clinical study fees and expenses (1)	10,585,695	4,346,397	18,945,474
Personnel costs	3,237,158	2,997,852	9,511,188
Stock-based compensation expense	725,465	1,054,237	2,884,161
Total	$ 17,922,183	$ 15,934,409	$ 54,540,302

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

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R&D expenses increased by $2.0 million, or 12%, to $17.9 million for the year ended December 31, 2008, compared to $15.9 million in 2007. The increase in R&D expenses was primarily due to a $6.2 million increase in expenses related to external research-related manufacturing and regulatory and quality assurance activities related to ANX-530 and ANX-514, a $1.3 million increase in external clinical trial expenses related to ANX-514 and a $0.2 million increase in personnel costs, offset by a $5.4 million decrease in external clinical trial expenses related to CoFactor and ANX-530 and a $0.3 million decrease in non-cash, stock-based compensation expenses.

Because of the uncertainty surrounding our ability to consummate a strategic transaction and the form, structure and terms of any potential strategic transaction, including whether we will continue as a going concern, as well as uncertainty surrounding our plans if we are unable to consummate a strategic transaction on a timeline that we believe is acceptable, we cannot predict our future R&D expenditures. However, in January 2009, we entered into retention and incentive agreements with seven employees, including our executive officers, pursuant to which, in certain circumstances, we may be obligated to make severance payments, though our obligation to make and the amount of such payments will be based on factors that are not yet known. In March 2009, we terminated two employees with whom we had entered into retention and incentive agreements. In addition, in the event we implement future workforce reductions or restructurings, we likely will incur charges. See also Management Outlook.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses increased by $1.0 million, or 12%, to $9.7 million for 2008, compared to $8.7 million in 2007. The increase was substantially due to a $0.7 million increase for severance expenses, a $0.4 million increase for consulting expenses related to market research, a $0.3 million increase in personnel expenses and a $0.1 million increase in professional services, offset by a decrease of $0.5 million in non-cash, stock-based compensation expenses. Because of the uncertainty surrounding our ability to consummate a strategic transaction and the form, structure and terms of any potential strategic transaction, including whether we will continue as a going concern, as well as uncertainty surrounding our plans if we are unable to consummate a strategic transaction on a timeline that we believe is acceptable, we cannot predict our future SG&A expenditures. However, in January 2009, we entered into retention and incentive agreements with seven employees, including our executive officers, pursuant to which, in certain circumstances, we may be obligated to make severance payments, though our obligation to make and the amount of such payments will be based on factors that are not yet known. In March 2009, we terminated two employees with whom we had entered into retention and incentive agreements. In addition, in the event we implement future workforce reductions or restructurings, we likely will incur charges. See also Management Outlook.

Interest Income and Other Income. Interest income and other income for 2008 decreased by $1.5 million, or 69%, to $0.7 million in 2008, compared to $2.2 million in 2007. The decrease was primarily attributable to lower interest income based on lower invested balances. The decrease was partially offset by $0.1 million received as part of the Theragenex settlement, which was recorded as other income. 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 $26.6 million or $0.30 per share in 2008, compared to a net loss of $22.1 million or $0.25 per share in 2007.

LIQUIDITY AND CAPITAL RESOURCES

We have a history of recurring losses from operations and we have funded our operations primarily through sales of our equity securities. We had a net loss of $26.6 million in 2008 and cash and cash equivalents of approximately $9.8 million and working capital of $5.7 million at December 31, 2008. We have an immediate need to raise additional capital to support our operations, though in the current financial and economic environment it is uncertain that we can obtain funding through our traditional sources of capital. These factors raise substantial doubt about our ability to continue as a going concern.

We are evaluating strategic options that may improve our liquidity and provide us with working capital to fund continuing business operations or that may result in the divestiture of future development and commercialization activities and related expenses, including the sale or exclusive license of one or more of our product candidate programs, a strategic business merger and other similar transactions. However, there can be no assurances that we will be successful in consummating a strategic transaction on a timely basis or at all. We likely will not be able to continue as a going concern, unless, as part of a strategic transaction or otherwise, we raise adequate capital. We announced

that we will eliminate all but a select, small number of personnel and will discontinue substantially all of our development activities and fundamental business operations and our ability to further curtail expenses to provide additional time to consummate a strategic transaction or otherwise obtain financing is limited.

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Explanations of cash flow from operating, investing and financing activities are provided below.

	December 31, 2008	Decrease During 2008	December 31, 2007
Cash and cash equivalents and investments in securities	$ 9,849,904	$ (23,613,252)	$ 33,463,156
Net working capital	$ 5,735,519	$ (24,922,542)	$ 30,658,061

	Year Ended December 31, 2008	Change Between Periods	Year Ended December 31, 2007
Net cash used in operating activities	$ (23,787,604)	$ (4,144,414)	$ (19,643,190)
Net cash provided by investing activities	18,856,769	10,848,497	8,008,272
Net cash provided by financing activities		(441,616)	441,616
Net (decrease) increase in cash and cash equivalents	$ (4,930,835)	$ 6,262,467	$ (11,193,302)

Operating activities. Net cash used in operating activities was $23.8 million in 2008, compared to $19.6 million in 2007. The increase in cash used in operating activities in 2008 was mainly due to the increase in our R&D and SG&A expenses.

Investing activities. Net cash provided by investing activities was $18.9 million in 2008, compared to net cash used in investing activities of $8.0 million in 2007. Net cash provided by investing activities in 2008 and 2007 was mainly net proceeds from sales of short-term investments.

Financing activities. There was no net cash provided by financing activities in 2008. In 2007, net cash provided by financing activities was $0.4 million, consisting of proceeds from option exercises.

Management Outlook

We have an immediate need to raise additional capital to support our operations. Our ability to raise capital has been materially and adversely affected by current credit conditions and the downturn in the financial markets and overall economy. In addition, our ability to timely raise capital on commercially reasonable terms may be limited by requirements, rules and regulations of the Securities and Exchange Commission and NYSE Amex (formerly the American Stock Exchange).

Currently, we are focused primarily on evaluating strategic options, including the sale or exclusive license of one or more of our product candidate programs, a strategic business merger and other similar transactions. We implemented restructuring and cost-cutting measures in October 2008, January 2009 and March 2009 and will eliminate all but a select, small number of personnel and discontinue substantially all of our development activities and fundamental business operations to provide additional time to consummate a strategic transaction or otherwise obtain financing. There can be no assurances that we will be able to consummate a strategic or other transaction on a timely basis or at all. Further, the restructuring and cost-cutting measures we have taken may not be successful. If we are unable to consummate a strategic transaction on a timeline that we believe is acceptable, we may divest our assets on best-available terms, entirely wind-down our operations and distribute any remaining cash to our stockholders. However, based on our current working capital and the estimated costs associated with seeking approval for and implementing a liquidation plan, we expect our remaining cash, if any, to be insignificant.

We are unable to predict when, if ever, we will consummate a strategic transaction or the form, structure or terms of any potential strategic transaction, including whether we will continue as a going concern, or whether we will entirely wind-down our operations. As a result, the duration that our existing cash and cash equivalents will sustain our current operations is uncertain.

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Recent Accounting Pronouncements

See Note 3, 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

Not required.

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(T). 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 principal executive officer and principal 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 principal executive officer and principal 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, 2008. Based on that evaluation, our principal executive officer and principal financial officer have concluded that these disclosure controls and procedures were effective as of December 31, 2008.

As discussed in Note 3, Summary of Significant Accounting Policies, under Change in Accounting Principle for Registration Payment Arrangements and Correction of Error, to the Notes to Consolidated Financial Statements contained herein, we have restated our financial statements for the year ended December 31, 2007 and for the quarters ended March 31, June 30 and September 30, 2007 and March 31, June 30 and September 30, 2008 to reflect an error in the application of Financial Accounting Standards Board Staff Position No. EITF 00-19-2, Accounting for Registration Payment Arrangements, (FSP EITF 00-19-2). In light of our determination that it was not correct in connection with our adoption on January 1, 2007 of FSP EITF 00-19-2 to retrospectively apply FSP EITF 00-19-2 to the years ended December 31, 2005 and December 31, 2006, we have reconsidered, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, the adequacy of our assertions concerning the effectiveness of our disclosure controls and procedures in our annual report on Form 10-K for the year ended December 31, 2007 and our quarterly reports on Form 10-Q for the periods ended March 31, June 30 and September 30, 2007 and March 31, June 30 and September 30, 2008.

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Following such reconsideration, we have concluded that we did not correctly apply generally accepted accounting principles as they related to accounting for warrant liability under FSP EITF 00-19-2 because our accounting staff did not have adequate training or expertise on the proper application of FSP EITF 00-19-2 at the time the financial statements contained in the 2007 10-K were prepared and filed. As a result of this inadequacy, we have further concluded that there was a material weakness in our internal control over financial reporting with respect to the application of generally accepted accounting principles as they related to accounting for warrant liability under FSP EITF 00-19-2 and, as a result, our disclosure controls and procedures and our internal control over financial reporting were not effective as of December 31, 2007. However, we have concluded that the lack of adequate training or expertise of our accounting staff was limited to the application of FSP EITF 00-19-2 and the material weakness in our internal control over financial reporting and related inadequacy of our disclosure controls and procedures did not otherwise affect the preparation of our financial statements in accordance with generally accepted accounting principles. In addition, because we did not identify the above-described material weakness until the fourth quarter of 2008, we have concluded that our disclosure controls and procedures were not effective in the periods covered by, and as asserted in, our quarterly reports on Form 10-Q for the periods ended March 31, June 30, and September 30, 2007 and March 31, June 30, and September 30, 2008.

During 2008, we made a number of improvements to our internal accounting resources and retained outside accounting experts in an effort to minimize financial reporting deficiencies in the future. Therefore, our management, including our principal executive officer and principal financial officer, have determined that the material weakness in our internal control over financial reporting and the related inadequacy in our disclosure controls and procedures were remedied as of December 31, 2008.

The misapplication of FSP EITF 00-19-2 to prior periods and our correction of this error have had no impact on our current assets (e.g., cash and cash equivalents and short-term investments) or our operating expenses and do not affect any loan covenants or other contractual requirements.

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, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, other than the changes described above under Disclosure Controls and Procedures.

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 principal executive officer and principal 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, 2008.

Pursuant to temporary rules of the Securities and Exchange Commission, our management s report on internal control over financial reporting is furnished with this annual report and shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933 or Securities Exchange Act of 1934.

This annual report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting. Management s report on internal control over financial reporting was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only our management s report on internal control over financial reporting in this annual report.

Item 9B. Other Information

Not applicable.

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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 2009 annual meeting of stockholders, 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 code of business conduct and ethics and available on our corporate website at 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 Accounting 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, 2008 and 2007

Consolidated Statements of Operations for the years ended December 31, 2008 and 2007 and from inception through December 31, 2008

Consolidated Statements of Stockholders Equity (Deficit) and Comprehensive Loss from inception through December 31, 2008

Consolidated Statements of Cash Flows for the years ended December 31, 2008 and 2007 and from inception through December 31, 2008

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)	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.

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Exhibit	Description
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(10)	Second Amendment to Rights Agreement, dated February 25, 2008, among the registrant and the Icahn purchasers (as defined therein)
4.22(8)	Form of $2.26 Common Stock Warrant issued on July 27, 2005 (including the original schedule of holders)
4.23(8)	Form of $2.26 Common Stock Warrant issued on July 27, 2005 (including the original schedule of holders)
4.24(12)	$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
4.25(11)	$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
4.26(11)	$2.50 Warrant to Purchase Common Stock issued on October 22, 2004 to Thomas J. DePetrillo
10.1#(12)	2005 Equity Incentive Plan

10.2#(13)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan
10.3#(14)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for director option grants beginning in 2008
10.4#(15)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for option grants to employees approved in March 2008)
10.5#(2)	Form of Restricted Share Award Agreement under the 2005 Equity Incentive Plan
10.6#(13)	2005 Employee Stock Purchase Plan
10.7#(13)	Form of Subscription Agreement under the 2005 Employee Stock Purchase Plan
10.8#(16)	2008 Omnibus Incentive Plan
10.9#(17)	Form of Non-Statutory Stock Option Grant Agreement (for directors) under the 2008 Omnibus Incentive Plan
10.10#(17)	Form of Non-Statutory/Incentive Stock Option Grant Agreement (for consultants / employees) under the 2008 Omnibus Incentive Plan

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Exhibit	Description
10.11#(15)	2008 Incentive Plan
10.12*(18)	Option and License Agreement, dated January 23, 1998, between the registrant and the University of Southern California
10.13(3)	First Amendment to License Agreement, dated August 16, 2000, between the registrant and the University of Southern California
10.14*(18)	Option and License Agreement, dated August 17, 2000, between the registrant and the University of Southern California
10.15*(19)	Amendment to Option and License Agreement, dated April 21, 2003, between the registrant and the University of Southern California
10.16*(20)	Second Amendment to Option and License Agreement, dated January 25, 2007, between the registrant and the University of Southern California
10.17*(2)	Agreement, effective as of May 1, 2005, between the registrant and Pharm-Olam International Ltd.
10.18(2)	Amendment dated July 19, 2005 to the Agreement between the registrant and Pharm-Olam International Ltd.
10.19(21)	License Agreement, dated October 20, 2006, between the registrant, through its wholly-owned subsidiary SD Pharmaceuticals, Inc., and Theragenex, LLC
10.20(14)	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
10.21(22)	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
10.22(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
10.23#(23)	Offer letter, dated March 5, 2003, to Joan M. Robbins
10.24#	Confidential Separation Agreement and General Release of All Claims, effective December 4, 2008, between the registrant and Joan M. Robbins
10.25#(24)	Offer letter, dated November 15, 2004, to Brian M. Culley
10.26#(25)	

	Severance Agreement and Release of All Claims, dated September 7, 2006, with Carrie Carlander
10.27#(25)	Consulting Agreement, dated September 7, 2006, with Carrie Carlander
10.28#(25)	Offer letter, dated September 7, 2006, to James A. Merritt
10.29#(14)	Letter agreement regarding terms of separation with James A. Merritt, effective as of February 12, 2008
10.30#(25)	Form of Stock Option Agreement between the registrant and James A. Merritt (included in Exhibit 10.28)
10.31#(26)	Offer letter, dated December 13, 2006, to Gregory P. Hanson
10.32#(26)	Stock Option Agreement, effective December 20, 2006, between the registrant and Gregory P. Hanson
10.33#(27)	Letter Agreement regarding terms of separation with Gregory P. Hanson, dated April 2, 2008
10.34#(27)	Consulting Agreement, dated April 2, 2008, with Gregory P. Hanson
10.35#(17)	Offer letter, dated April 1, 2008, to Mark N.K. Bagnall (including Exhibits A, B and C thereto)
10.36#	Confidential Separation Agreement and General Release of All Claims, effective December 31, 2008, between the registrant and Evan M. Levine, including letter, dated November 7, 2008, related thereto

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Exhibit	Description
10.37(21)	Form of Director and Officer Indemnification Agreement
10.38#(28)	Director compensation policy
10.39(29)	Placement Agency Agreement, dated November 2, 2006, among the registrant, ThinkEquity Partners LLC and Fortis Securities LLC
21.1	List of Subsidiaries
23.1	Consent of J.H. Cohn LLP, Independent Registered Public Accounting Firm
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a)
32.1±	Certification of principal executive officer and principal 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 Current Report on Form 8-K on December 15, 2008 (SEC file number 001-32157-081249921)

(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 Current Report on Form 8-K on February 25, 2008 (SEC file number 001-32157-08638638)

(11) Filed with the registrant s Registration Statement on Form S-3 on August 26, 2005 (SEC file number 333-127857-051050073)

(12) Filed with the registrant s Annual Report on Form 10-K on March 15, 2007 (SEC file number 001-32157-07697283)

(13) Filed with the registrant s Registration Statement on Form S-8 on July 13, 2005 (SEC file number 333-126551-05951362)

(14) Filed with registrant s Annual Report on Form 10-K on March 17, 2008 (SEC file number 001-32157-08690952)

(15) Filed with the registrant s Quarterly Report on Form 10-Q on May 12, 2008 (SEC file number 001-32157-08820541)

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(16) Filed with the registrant s Current Report on Form 8-K on June 7, 2008 (SEC file number 001-32157-08874724)

(17) Filed with the registrant s Quarterly Report on Form 10-Q on August 11, 2008 (SEC file number 001-32157-081005744)

(18) Filed with the registrant s Registration Statement on Form 10SB/A on January 14, 2002 (SEC file number 000-33219-2508012)

(19) Filed with the registrant s Quarterly Report on Form 10-QSB on August 14, 2003 (SEC file number 000-33219-03848890)

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

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

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

001-32157-04963741)

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

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

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

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

(27) Filed with the registrant s Current Report on Form 8-K on April 16, 2008 (SEC file number 001-32157-08760483)

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

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

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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/ Brian M. Culley
Brian M. Culley
Chief Business Officer & Senior Vice President

Date: March 27, 2009

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Brian M. Culley and Mark N.K. Bagnall, 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.

Signature	Title	Date
/s/ Brian M. Culley Brian M. Culley	Chief Business Officer and Sr. Vice President (Principal Executive Officer)	March 27, 2009
/s/ Mark N.K. Bagnall Mark N.K. Bagnall	Director (Principal Financial and Accounting Officer)	March 27, 2009
/s/ Jack Lief Jack Lief	Chair of the Board	March 27, 2009
Alexander J. Denner	Director	
/s/ Michael M. Goldberg Michael M. Goldberg	Director	March 27, 2009
/s/ Mark J. Pykett Mark J. Pykett	Director	March 27, 2009

/s/ Eric K. Rowinsky	Director	March 27, 2009
Eric K. Rowinsky		

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Index to Consolidated Financial Statements

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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, 2008 and 2007, and the related consolidated statements of operations, stockholders equity (deficit) and comprehensive loss and cash flows for the years then ended and for the period from January 1, 2002 through December 31, 2008. 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, 2008 and 2007, and the results of operations and their cash flows for years then ended and for the period from January 1, 2002 through December 31, 2008, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 3 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*.

As discussed in Note 3 to the consolidated financial statements, certain prior year amounts have been restated.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management s plans in regards to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ J.H. COHN LLP
San Diego, California
March 25, 2009

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

	December 31, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	$ 9,849,904	$ 14,780,739
Short-term investments		18,682,417
Interest and other receivables	121,736	72,029
Prepaid expenses	477,902	615,691
Total current assets	10,449,542	34,150,876
Property and equipment, net	199,052	332,444
Other assets	60,664	58,305
Total assets	$ 10,709,258	$ 34,541,625
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 1,721,376	$ 552,143
Accrued liabilities	2,077,188	2,317,910
Accrued compensation and payroll taxes	915,459	622,762
Total current liabilities	4,714,023	3,492,815
Long-term liabilities		14,270
Total liabilities	4,714,023	3,507,085
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized; 90,252,572 shares issued and outstanding at December 31, 2008 and 2007	90,254	90,254
Additional paid-in capital	131,751,439	130,140,549
Deficit accumulated during the development stage	(125,846,458)	(99,198,965)
Accumulated other comprehensive income		2,702
Total stockholders equity	5,995,235	31,034,540
Total liabilities and stockholders equity	$ 10,709,258	$ 34,541,625

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, 2008	2007	Inception (June 12, 1996) Through December 31, 2008 (as restated)
Licensing revenue	$ 500,000	$ 500,000	$ 1,000,000
Net sales			174,830
Grant revenue			129,733
Total net revenue	500,000	500,000	1,304,563
Cost of sales			51,094
Gross margin	500,000	500,000	1,253,469
Operating expenses:			
Research and development	17,922,183	15,934,409	62,014,556
Selling, general and administrative	9,719,613	8,678,853	42,969,202
Depreciation and amortization	168,039	197,783	10,798,071
In-process research and development			10,422,130
Impairment loss write-off of goodwill			5,702,130
Equity in loss of investee			178,936
Total operating expenses	27,809,835	24,811,045	132,085,025
Loss from operations	(27,309,835)	(24,311,045)	(130,831,556)
Loss on fair value of warrants			(12,239,688)
Interest income	549,964	2,169,005	4,582,028
Interest expense			(179,090)
Other income	112,378		112,378
Loss before income taxes	(26,647,493)	(22,142,040)	(138,555,928)
Provision for income taxes			
Loss before cumulative effect of change in accounting principle	(26,647,493)	(22,142,040)	(138,555,928)
Cumulative effect of change in accounting principle			(25,821)
Net loss	(26,647,493)	(22,142,040)	(138,581,749)

Preferred stock dividends			(621,240)
Net loss applicable to common stock	$ (26,647,493)	$ (22,142,040)	$ (139,202,989)
Loss per common share basic and diluted	$ (0.30)	$ (0.25)	
Weighted average shares outstanding basic and diluted	90,252,572	89,912,732	

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, 2008

	Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock		Additional paid-in capital	Deficit Accumulated other comprehensive income (loss)	Deficit Accumulated during the development stage	Treasury stock, at cost	Total stockholders equity (deficit)	Comprehensiv loss
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						
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 in acquisition							375,891	376	887,874				888,250	

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
Inception (June 12, 1996) Through December 31, 2008

Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Deficit accumulated during the development stage	Treasury stock, at cost	Total stockholders equity (deficit)	Comp
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						
								(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	
										(16,339,120)		(16,339,120)	$ (1

t											
31,											
	3,337	33				15,005,191	15,005	23,389,818	(24,043,342)	(638,486)	$ (1
								(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	
					70,109	701		700,392		701,093	
n of											
tock	(3,000)	(30)				1,800,000	1,800	(1,770)			
								335,440		335,440	
f											
o											
ing											
								163,109		163,109	
f											
tock											
						6,292	6	12,263		12,269	
f											
y											
	136	1						6,000		6,001	
								329,296		329,296	

									(2,105,727)	(2,105,727)	$
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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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, 2008

Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Deficit accumulated during the development stage	Treasury stock, at cost	Total stockholders equity (deficit)	C
Shares	Amount	Shares	Amount	Shares	Amount	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	

to										
								(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
nt										
k							72,800			72,800
k	(473)	(4)			236,500	236	(232)			
k			(200,000)	(2,000)	200,000	200	1,800			
					464,573	465	(465)			
					23,832	23	27,330			27,353
a							86,375			86,375
t										
					10,417,624	10,419	15,616,031			15,626,450
							(1,366,774)			(1,366,774)
to							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
Inception (June 12, 1996) Through December 31, 2008

Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Deficit accumulated during the development stage	Treasury stock, at cost	Total stockholders equity (deficit)	Compre
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						los
										(24,782,646)		(24,782,646)	$ (24,78
									(1,722)			(1,722)	
						10,810,809	10,811	(10,811)					
						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	52,105,329	(1,722)	(59,964,840)	(34,747)	(7,828,616)	$ (24,78
										(29,331,773)		(29,331,773)	$ (29,33

of change value of le- for- urities				(368)			(368)	
s exercise ants	420,161	420	(420)					
e of s, net of ng costs tion of	5,103,746	5,104	7,686,486				7,691,590	
ceuticals.	2,099,990	2,100	10,161,852				10,163,952	
common $2.75 per et of g costs	14,545,000	14,545	37,055,666				37,070,211	
e of stock erance ent	60,145	60	196,614				196,674	
e of stock	92,500	93	125,658				125,751	
e of ed stock to ployees	15,000	15	68,635				68,650	
e of stock to ees			1,697,452				1,697,452	
e of stock to ployee ation of y stock			104,225				104,225	
	(23,165)	(23)	(34,724)			34,747		
es at ber 31, s restated	89,676,739	89,678	109,166,773	(2,090)	(89,296,613)		19,957,748	$ (29,3
ative-effect ment of g FASB osition TF 00-19-2 te 3)			18,116,751		12,239,688		30,356,439	
s					(22,142,040)		(22,142,040)	$ (22,14
of change value of				4,792			4,792	

le- for curities										
e of stock			575,833	576	441,040			441,616		
e of stock to ees					2,414,077			2,414,077		
e of stock to ployee					1,908			1,908		
es at ber 31,			90,252,572	90,254	130,140,549	2,702	(99,198,965)	31,034,540	$	(22,1
s							(26,647,493)	(26,647,493)	$	(26,6
of change value of le-for -sale es						(2,702)		(2,702)		
e of stock										
e of stock to ees					1,605,908			1,605,908		
e of stock to ployee					4,982			4,982		
es at ber 31,	$	$	90,252,572	$ 90,254	131,751,439	$	$ (125,846,458)	$ 5,995,235	$	(26,6

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, 2008	2007	Inception (June 12, 1996) Through December 31, 2008 (as restated)
Cash flows from operating activities:			
Net loss	$ (26,647,493)	$ (22,142,040)	$ (138,581,749)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	168,039	197,783	10,348,071
Gain on disposal of fixed assets	(3,598)		(3,598)
Loss on fair value of warrants			12,239,688
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	1,605,907	2,414,077	7,852,562
Expenses related to options issued to non-employees	4,983	1,908	204,664
Expenses paid by issuance of common stock		78,333	1,341,372
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
Write-off of license agreement			152,866
Write-off assets available-for-sale			108,000
Cumulative effect of change in accounting principle			25,821
Accretion of discount	(208,103)	(1,041,750)	(1,249,853)
Accretion of discount on investments in securities			(354,641)
Changes in assets and liabilities, net of effect of acquisitions:			
Increase in prepaid and other assets	85,723	(174,388)	(907,671)
Increase in accounts payable and accrued liabilities	1,221,208	1,044,291	4,890,731
Decrease in long-term liabilities	(14,270)	(21,404)	
Net cash used in operating activities	(23,787,604)	(19,643,190)	(85,822,647)
Cash flows from investing activities:			
Proceeds from sales and maturities of short-term investments	33,243,602	59,240,000	112,788,378
Purchases of short-term investments	(14,355,784)	(51,104,469)	(111,183,884)
Purchases of property and equipment	(64,955)	(127,259)	(1,030,354)
Proceeds from sale of property and equipment	33,906		33,906

Purchase of certificate of deposit	(1,016,330)

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

	Years Ended December 31, 2008	2007	Inception (June 12, 1996) Through December 31, 2008 (as restated)
Maturity of certificate of deposit			1,016,330
Cash paid for acquisitions, net of cash acquired			32,395
Payment on obligation under license agreement			(106,250)
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
Net cash provided by investing activities	18,856,769	8,008,272	1,025,234
Cash flows from financing activities:			
Proceeds from sale of common stock			84,151,342
Proceeds from exercise of stock options		441,616	712,367
Proceeds from sale or exercise of warrants			11,382,894
Proceeds from sale of preferred stock			4,200,993
Repurchase of warrants			(55,279)
Payments for financing and offering costs			(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
Net cash provided by financing activities		441,616	94,647,317
Net (decrease) increase in cash and cash equivalents	(4,930,835)	(11,193,302)	9,849,904
Cash and cash equivalents at beginning of period	14,780,739	25,974,041	
Cash and cash equivalents at end of period	$ 9,849,904	$ 14,780,739	$ 9,849,904

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, 2008

(1) Description of Business

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation (ADVENTRX, we or the Company), is a development-stage biopharmaceutical company whose fundamental business is focused on in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. Through our acquisition of SD Pharmaceuticals, Inc. (SDP) in 2006 and our license agreements with the University of Southern California, we have rights to product candidates in varying stages of development. We have not yet marketed or sold any products or generated any significant revenue.

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.

Currently, we are focused primarily on evaluating strategic options, including the sale or exclusive license of one or more of our product candidate programs, a strategic business merger and other similar transactions. We implemented restructuring and cost-cutting measures in October 2008, January 2009 and March 2009 and will eliminate all but a select, small number of personnel and discontinue substantially all of our development activities and fundamental business operations to provide additional time to consummate a strategic transaction or otherwise obtain financing.

(2) Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. Going concern contemplates the realization of assets and the satisfaction of liabilities in the normal course of business over a reasonable length of time. However, as a result of the Company s continued losses and current cash and financing position, such realization of assets or satisfaction of liabilities, without substantial adjustments is uncertain. The future of the Company is dependent upon its ability to obtain additional funding. Management is evaluating various strategic options, including the sale or exclusive license of one or more of the Company s product candidate programs, a strategic business merger and other similar transactions, certain of which may result in a change of control of the Company. There can be no assurances that the Company will be successful in consummating a strategic transaction on a timely basis or at all. The Company likely will not be able to continue as a going concern, unless, as part of a strategic transaction or otherwise, it raises adequate capital. The Company will eliminate all but a select, small number of personnel and discontinue substantially all of its development activities and fundamental business operations and its ability to further curtail expenses to provide additional time to consummate a strategic transaction or otherwise obtain financing is limited. Given this uncertainty, there is significant doubt as to the Company s ability to continue as a going concern.

The Company s consolidated financial statements for the year ended December 31, 2008 do not include any adjustments related to the recovery and classification of recorded assets, or the amounts and classification of liabilities that might be necessary in the event the Company cannot continue as a going concern.

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ADVENTRX Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Enterprise)
Notes to Consolidated Financial Statements (continued)
December 31, 2008

(3) 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 and Correction of Error

On January 1, 2007, we adopted the provisions of the Financial Accounting Standards Board (FASB) Staff Position on No. EITF 00-19-2, Accounting for Registration Payment Arrangements"(FSP EITF 00-19-2). In December 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 was 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 the prior periods and as of December 31, 2006 were adjusted to apply the new method retrospectively.

The Company accounted for FSP EITF 00-19-2 appropriately by eliminating the warrant liability as of December 31, 2007, but upon further review in 2008, management determined that it was not correct to adjust the prior period comparative financial statements. Accordingly, the Company has made the appropriate adjustments to reinstate the warrant liability accounting as originally recorded.

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ADVENTRX Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Enterprise)
Notes to Consolidated Financial Statements
December 31, 2008

The following consolidated financial statement line items were affected by the correction of the error:

Consolidated Statement of Operations

Inception (June 12, 1996) through December 31, 2008

	As previously reported	As restated	Effect of change
	$	$ (12,239,688)	$ (12,239,688)

f Operations (Unaudited)

	March 31, 2007			Inception (June 12, 1996) through: June 30, 2007			As pre
	As previously reported	As restated	Effect of change	As previously reported	As restated	Effect of change	repo
	$	$ (12,239,688)	$ (12,239,688)	$	$ (12,239,688)	$ (12,239,688)	$
n accounting principle	(82,650,521)	(94,890,209)	(12,239,688)	(88,373,349)	(100,613,037)	(12,239,688)	(94,2
	(82,676,342)	(94,916,030)	(12,239,688)	(88,399,170)	(100,638,858)	(12,239,688)	(94,3
	(83,297,582)	(95,537,270)	(12,239,688)	(89,020,410)	(101,260,098)	(12,239,688)	(94,9

	March 31, 2008			Inception (June 12, 1996) through: June 30, 2008			As pre
	As previously reported	As restated	Effect of change	As previously reported	As restated	Effect of change	repo
	$	$ (12,239,688)	$ (12,239,688)	$	$ (12,239,688)	$ (12,239,688)	$
n accounting principle	(105,601,819)	(117,841,507)	(12,239,688)	(112,027,349)	(124,267,037)	(12,239,688)	(118,8
	(105,627,640)	(117,867,328)	(12,239,688)	(112,053,170)	(124,292,858)	(12,239,688)	(118,8
	(106,248,880)	(118,488,568)	(12,239,688)	(112,674,410)	(124,914,098)	(12,239,688)	(119,4

ers Equity (Deficit)

	As previously reported	As restated	Effect of change
	$ (13,202,986)	$ (24,782,646)	$ (11,579,660)
	70,222,080	52,105,329	(18,116,751)
ent stage	(48,385,180)	(59,964,840)	(11,579,660)
	21,867,795	(7,828,616)	(29,696,411)
	(28,671,745)	(29,331,773)	(660,028)
	127,283,254	109,166,773	(18,116,751)

ent stage	(77,056,925)	(89,296,613)	(12,239,688)
	50,314,187	19,957,748	(30,356,439)

ff Position No. EITF

		18,116,751	18,116,751
ent stage		12,239,688	12,239,688
		30,356,439	30,356,439

nber 31, 2008

	$	$ 12,239,688	$ 12,239,688

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ADVENTRX Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Enterprise)
Notes to Consolidated Financial Statements
December 31, 2008
Condensed Consolidated Statements of Cash Flow (Unaudited)

	Inception (June 12, 1996) through:								
	March 31, 2007			June 30, 2007			September 30, 2007		
As previously reported	As restated	Effect of change	As previously reported	As restated	Effect of change	As previously reported	As restated	E
(82,676,342)	$ (94,916,030)	$ (12,239,688)	$ (88,399,170)	$ (100,638,858)	$ (12,239,688)	$ (94,313,294)	$ (106,552,982)	$ (1
	12,239,688	12,239,688		12,239,688	12,239,688		12,239,688	1

	Inception (June 12, 1996) through:								
	March 31, 2008			June 30, 2008			September 30, 2008		
As previously reported	As restated	Effect of change	As previously reported	As restated	Effect of change	As previously reported	As restated	E
(105,627,640)	$ (117,867,328)	$ (12,239,688)	$ (112,053,170)	$ (124,292,858)	$ (12,239,688)	$ (118,830,033)	$ (131,069,721)	$ (1
	12,239,688	12,239,688		12,239,688	12,239,688		12,239,688	1

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ADVENTRX Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Enterprise)
Notes to Consolidated Financial Statements (continued)
December 31, 2008

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 SFAS 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 and cash equivalents and investment securities. We maintain our cash and cash equivalents in high-credit quality financial institutions. At times, such balances may exceed Federally insured limits. At December 31, 2008, our cash and cash equivalents were in excess of the Federal Deposit Insurance Corporation limit.

During 2008, approximately 12% or $2.3 million of our total vendor payments were made to a manufacturer that provided process development and scale-up manufacturing services. If we were to lose this vendor, our progress in completing a New Drug Application (NDA) would be severely impeded. During 2007, approximately 14% or $2.3 million of our total vendor payments were made to a contract research organization (CRO) that was assisting us in our clinical trial administration and data management.

Fair Value of Financial Instruments

At December 31, 2008, our financial instruments included cash and cash equivalents, accounts payable, accrued expenses and accrued compensation and payroll taxes. At December 31, 2007, our financial instruments also included short-term investments. 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.

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.

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ADVENTRX Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Enterprise)
Notes to Consolidated Financial Statements (continued)
December 31, 2008

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, 2008, 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, bioequivalence and 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 U.S. Food and Drug Administration (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
(A Development Stage Enterprise)
Notes to Consolidated Financial Statements (continued)
December 31, 2008

Payments in connection with our bioequivalence and clinical trials are often made under contracts with multiple CROs that conduct and manage these 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 milestones. Expenses related to bioequivalence and 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 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 bioequivalence or 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 bioequivalence and 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 bioequivalence or 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 SFAS 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 Stock-Based Compensation

Effective January 1, 2006, we adopted the provisions of revised SFAS No. 123, Share-Based Payment (SFAS 123(R)), including the provisions of Staff Accounting Bulletins No. 107 (SAB 107) and No. 110 (SAB 110). Under SFAS 123(R), stock-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 SFAS 123(R) 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. SFAS 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 SFAS 123(R). 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 stock-based compensation, which is available to absorb tax deficiencies recognized subsequent to the adoption of SFAS 123(R).

The valuation provisions of SFAS 123(R) 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 stock-based compensation under the recognition and measurement principles of SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 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 SFAS 123.

Stock-based compensation expense recognized in our consolidated statement of operations for the years ended December 31, 2008 and 2007 included compensation expense for stock-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 SFAS 123 and stock-based payment awards granted subsequent to December 31, 2005 based

on the grant date fair value estimated in accordance with SFAS 123(R). For share awards granted during the year ended December 31, 2008 and 2007, 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 SFAS 123. As stock-based compensation expense recognized in the consolidated statement of operations for the years ended December 31, 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) 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 SFAS 123.

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ADVENTRX Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Enterprise)
Notes to Consolidated Financial Statements (continued)
December 31, 2008

We account for stock-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 stock-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 Financial 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 income or 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.

Computation of Net Loss per Common Share

We calculate basic and diluted net loss per share in accordance with the SFAS 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.

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We have excluded the following options and warrants from the calculation of diluted net loss per common share for 2008 and 2007 because their effect is anti-dilutive:

	2008	2007
Warrants	13,373,549	13,373,549
Options	4,364,833	4,020,940
	17,738,382	17,394,489

Supplemental Cash Flow Information

	Years Ended December 31,		Inception (June 12, 1996) Through December 31,
	2008	2007	2008
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			1,482,781
Conversion of preferred stock			2,705
Acquisitions			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			34,737
Cancellation of treasury stock			(34,737)
Assumptions of liabilities in acquisitions			1,235,907
Acquisition of license agreement for long-term debt			161,180
Cashless exercise of warrants			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	2,702	(4,792)	

New Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141 (revised 2007) (SFAS 141(R)), Business Combinations, which replaces SFAS No. 141. SFAS 141(R) retains the purchase method of accounting for acquisitions, but requires a

number of changes, including changes in the way assets and liabilities are recognized in purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. SFAS 141(R) is effective for financial statements issued for fiscal year 2009 and will apply prospectively to business combinations completed on or after January 1, 2009. We do not expect the adoption of SFAS 141(R) to have a material effect on our consolidated financial statements.

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Effective January 1, 2008, we adopted SFAS No. 157, Fair Value Measurements (SFAS 157). In February 2008, the FASB issued FASB Staff Position (FSP) No. SFAS 157-2, Effective Date of FASB Statement No. 157, which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. As a result, we only partially adopted SFAS 157 as it relates to our financial assets and liabilities until we are required to apply this pronouncement to our non-financial assets and liabilities beginning with fiscal year 2009. The adoption of SFAS 157 did not have a material impact on our consolidated results of operations or financial condition.

In February 2008, the FASB issued FSP. No. 157-2, Effective Date of FASB Statement No. 157 (FSP 157-2). FSP 157-2 delays, for one year, the effective date of SFAS 157 for all nonfinancial assets and liabilities, except those that are recognized or disclosed in the consolidated financial statements on at least an annual basis.

In May 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles. SFAS No. 162 is intended to improve financial reporting by identifying a consistent hierarchy for selecting accounting principles to be used in preparing financial statements that are prepared in conformance with accounting principles generally accepted in the United States of America. Unlike Statement on Auditing Standards (SAS) No. 69, The Meaning of Present Fairly in Conformity With GAAP, SFAS No. 162 is directed to the entity rather than the auditor. SFAS No. 162 is effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board (PCAOB) amendments to AU Section 411, The Meaning of Present Fairly in Conformity with GAAP, and is not expected to have any impact on the Company s consolidated results of operations, financial condition or liquidity.

In October 2008, the FASB issued FSP No. SFAS 157-3 Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active (FSP SFAS 157-3). FSP SFAS 157-3 clarifies the application of SFAS No. 157, in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP SFAS 157-3 is effective upon issuance, including prior periods for which financial statements have not been issued. The adoption of FSP SFAS 157-3 had no impact on our consolidated results of operations, financial position or cash flows.

SFAS 157 was effective for the Company beginning January 1, 2008 for financial assets and liabilities recognized or disclosed in the Company s consolidated financial statements. SFAS 157 defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. SFAS 157 describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1	Quoted prices in active markets for identical assets or liabilities.
Level 2	Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
Level 3	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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The following table represents our fair value hierarchy for our financial assets (which consisted solely of cash equivalents) measured at fair value based on quoted market prices on a recurring basis as of December 31, 2008:

	Level 1	Level 2	Level 3	Total
Money market funds	$ 9,849,904	$	$	$ 9,849,904
Total	$ 9,849,904	$	$	$ 9,849,904

Effective January 1, 2008, we adopted SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS 159). SFAS 159 allows an entity the irrevocable option to elect to measure specified financial assets and liabilities in their entirety at fair value on a contract-by-contract basis. If an entity elects the fair value option for an eligible item, changes in the item s fair value must be reported as unrealized gains and losses in earnings at each subsequent reporting date. In adopting SFAS 159, we did not elect the fair value option for any of our financial assets or financial liabilities.

(4) Investments in Securities

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

	Cost	2008 Gross Unrealized Gains (Losses)	Fair Value
Cash and cash equivalents:			
Cash	$ 9,849,904	$	$ 9,849,904
Total cash and cash equivalents	$ 9,849,904	$	$ 9,849,904

	Cost	2007 Gross Unrealized Gains (Losses)	Fair Value
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

(5) Property and Equipment

Property and equipment at December 31, 2008 and 2007 were as follows:

	Useful Lives	2008	2007
Office furniture, computer and lab equipment	3 - 5 years	$ 720,257	$ 754,990
Computer software	3 years	103,306	122,162

	823,563	877,152
Less accumulated depreciation and amortization	(624,511)	(544,708)
Property and equipment, net	$ 199,052	$ 332,444

Depreciation and amortization expense was $168,039 and $197,783 for the years ended December 31, 2008 and 2007, respectively.

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(6) Accrued Liabilities

Accrued liabilities at December 31, 2008 and 2007 were as follows:

	2008	2007
Accrued contracts and study expenses	$ 1,620,988	$ 1,953,472
Other accrued liabilities	434,172	326,428
Deferred rent	22,028	38,010
Accrued liabilities	$ 2,077,188	$ 2,317,910

(7) Capital Stock and Warrants

Common Stock

During 2008, we issued no new additional common stock.

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.

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 11, *Registration Payment Arrangement*, for a detailed discussion.

At December 31, 2008, outstanding warrants to purchase shares of common stock are as follows:

Warrants	Exercise Price	Expiration Date
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.

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(8) Equity Incentive Plans

At December 31, 2008, we had the 2005 Equity Incentive Plan (the 2005 Plan), the 2005 Employee Stock Purchase Plan (the Purchase Plan), and the 2008 Omnibus Incentive Plan (the 2008 Plan) which are described below. The stock-based compensation expense from all stock-based awards that has been charged to our consolidated statements of operations in the years ended December 31, 2008 and 2007 was comprised of the following:

	Years Ended December 31.	
	2008	2007
Selling, general and administrative expense	$ 885,427	$ 1,440,081
Research and development expense	725,464	1,054,237
Stock-based compensation expense before taxes	1,610,891	2,494,318
Related income tax benefits		
Stock-based compensation expense	$ 1,610,891	$ 2,494,318
Net stock-based compensation expense per common share basic and diluted	$ 0.02	$ 0.03
Stock-based compensation expense from:		
Stock options	$ 1,610,890	$ 2,415,985
Share grant		78,333
Restricted stock awards		
	$ 1,610,890	$ 2,494,318

Since we accounted for employee stock-based awards using the recognition method under the provisions of SFAS 123 prior to 2006, the adoption of SFAS 123(R) did not have a material impact on our consolidated results of operations. Since we have net operating losses carry forward as of December 31, 2008, no excess tax benefits for the tax deductions related to stock-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, 2008 and 2007 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 and 2008 Omnibus Incentive Plan

The 2005 and the 2008 Plans, which are stockholder-approved, are 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 stock-based awards. Both plans provide 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 stock-based awards. Stock-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.

Since the 2008 Plan was approved by the Company s stockholders in May 2008, no awards have been or will be granted under the 2005 Plan. As of December 31, 2008, 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 2008 Plan is 13,097,500 shares. Any shares of common stock that are subject to options or stock appreciation rights granted under the 2008 Plan shall be counted against this limit as one (1) share of common stock for every one (1) share of common stock granted. Any shares of common stock that are subject to awards other than options or stock appreciation rights granted under the 2008 Plan shall be counted against this limit as 1.2 shares of common stock for every one (1) share of common stock granted. If any shares of common stock subject to an award under the 2008 Plan or the 2005 Plan are forfeited, expire or are settled for cash pursuant to the terms of an award, the shares subject to the award may be used again for awards under the 2008 Plan to the extent of the forfeiture, expiration or settlement. The shares of common stock will be added back as one (1) share for every share of common stock if the shares were subject to options or stock appreciation rights granted under the 2008 Plan or under the 2005 Plan, and as 1.2 shares for every share of common stock if the shares were subject to awards other than

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options or stock appreciation rights granted under the 2008 Plan or the 2005 Plan. The following shares of common stock will not be added to the shares issuable under the 2008 Plan: (i) shares tendered by the participant or withheld by the Company in payment of the purchase price of an option, (ii) shares tendered by the participant or withheld by the Company to satisfy tax withholding with respect to an award, and (iii) shares subject to a stock appreciation right that are not issued in connection with the stock settlement of the stock appreciation right on exercise. Shares of common stock under awards made in substitution or exchange for awards granted by a company acquired by the Company, or with which the Company combines, do not reduce the maximum number of shares that may be issued under the 2008 Plan. In addition, if a company acquired by the Company, or with which the Company combines, has shares remaining available under a plan approved by its stockholders, the available shares (adjusted to reflect the exchange or valuation ratio in the acquisition or combination) may be used for awards under the 2008 Plan and will not reduce the maximum number of shares of common stock that may be issued under the 2008 Plan; provided, however that awards using such available shares shall not be made after the date awards or grants could have been made under the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not our employees or directors prior to the acquisition or combination.

Under the 2008 Plan, the purchase price of shares of common stock covered by a stock option cannot be less than 100% of the fair market value of the common stock on the date the option is granted. Fair market value of the common stock is generally equal to the closing price for the common stock on the principal securities exchange on which the common stock is traded on the date the option is granted (or if there was no closing price on that date, on the last preceding date on which a closing price is reported). Option awards generally have ten-year contractual terms and vest over four years based on continuous service; however, the 2005 Plan and the 2008 Plan allow 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.

We cancelled 2,536,607 and 341,063 options in the years ended December 31, 2008 and 2007, respectively, related to terminated employees and board directors. The shares underlying such options were returned to and are available for re-issuance under the 2008 Plan pursuant to the terms described above.

The only types of awards granted under the 2005 Plan and the 2008 Plan in the years ended December 31, 2008 and 2007 were stock options. A summary of all of our option activity as of December 31, 2008 and 2007 and of changes in options outstanding under the plans during the years then ended are as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Years	Aggregate Intrinsic Value
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	
Granted	2,880,500	$ 0.49		

Exercised				
Cancelled/forfeited/expired	(2,536,607)	$	1.62	
Options outstanding at December 31, 2008	4,364,833	$	1.77	7.09
Options exercisable at December 31, 2008	2,126,952	$	2.67	5.82
Options exercisable at December 31, 2007	2,153,968	$	2.29	5.30

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The weighted-average grant-date fair value of options granted during the years ended December 31, 2008 and 2007 was $0.49 and $2.63, respectively. As of December 31, 2008, there was approximately $2.0 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 3.0 years.

There were no options exercised during the year ended December 31, 2008. The total intrinsic value of options exercised during the year ended December 31, 2007 was approximately $865,000, based on the difference in the market price on the dates of exercise and the applicable option exercise price. During the year ended December 31, 2007, we received $442,000 in cash from exercised options under all stock-based payment arrangements. No tax benefit was realized for the tax deductions from option exercises of the stock-based payment arrangements in the years ended December 31, 2008 and 2007.

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 option-valuation model for option grants during the years ended December 31, 2008 and 2007 are as follows:

	Years Ended December 31,	
	2008	**2007**
Risk-free interest rate	2.75 3.3%	4.6 4.8%
Dividend yield	0.0%	0.0%
Expected volatility	125 149%	137% 138%
Weighted-average volatility	146%	138%
Expected term (in years)	6.2 years	6.1 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 stock-based compensation was immaterial.

In 2007, we granted 15,000 options to consultants. No options were granted to consultants in 2008. 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, 2008 and 2007 are as follows:

	2008	**2007**
Risk-free interest rate	3.3 3.7%	4.0 4.8%
Dividend yield	0.0%	0.0%
Expected volatility	147%	125% 147%
Contractual term (in years)	6.5 7.3 years	2.5 8.3 years

We recognized approximately $5,000 and $2,000 in stock-based compensation expense associated with non-employee options in the years ended December 31, 2008 and 2007, respectively.

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The following table summarizes information concerning our outstanding and exercisable stock options as of December 31, 2008:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number Outstanding in 000 s	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable in 000 s	Weighted-Average Exercise Price
$0.19 to $0.54	2,196	8.63	0.46	338	0.44
$2.28 to $2.75	1,442	5.65	2.52	1,171	2.50
$2.86 to $4.89	727	5.29	4.20	618	4.23
	4,365	7.09	1.77	2,127	2.67

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 3,173,634 as of December 31, 2008. 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, 2008, no shares of common stock have been issued under the Purchase Plan. On January 1, 2009, 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.

(9) 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, 2008, the office lease requires a monthly payment of approximately $21,000, excluding common area maintenance charges. The lease expires in August 2009. We lease copiers and an automobile, which leases expire in 2010 and 2011, respectively.

Rent expense was approximately $258,000 and $246,000 during the years ended December 31, 2008 and 2007, respectively. Future rental commitments under all operating leases are as follows:

Year Ending December 31,	
2009	$ 192,731
2010	10,375
2011	2,452
Total	$ 205,558

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(10) Material License Agreements

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 ($0.5 million of which we received in January 2007 and $0.5 million of which was due in June 2007), milestone payments and royalties. In May 2007, we received a letter from TRx Pharma, a subsidiary of Theragenex, that we believed 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 $0.5 million payment and, in subsequent discussions, indicated that it did not intend to pay the remaining $0.5 million. On July 3, 2007, we notified Theragenex that, among other things, its failure to make the final $0.5 million 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. On October 11, 2007, we filed a demand for arbitration against 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 agreement. 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 $0.5 million payment, plus interest, rescission of the 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. In May 2008, we settled our dispute with Theragenex. In consideration of and conditioned upon Theragenex paying us $0.6 million, we and Theragenex agreed to jointly move to dismiss the underlying arbitration action, and in connection with dismissing the arbitration, we and Theragenex agreed to release each other from any and all claims related to our past relationship, including Theragenex s license rights to the product.

We recognized revenue of $0.5 million for each of the years ended December 31, 2008 and 2007. Revenue in 2007 represents nonrefundable licensing fees paid under the agreement with Theragenex. Revenue in 2008 represents a portion of a settlement payment from Theragenex. We recognized $0.5 million as revenue in 2008, which represents a portion of the $0.6 million settlement payment, because under the agreement Theragenex was required to pay a total nonrefundable, up front licensing fee of $1.0 million ($0.5 million of which we received in January 2007 and $0.5 million of which was due in June 2007) and because we met the criteria for revenue recognition. The remainder of the settlement payment, $0.1 million, was recorded as other income.

(11) 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. We have not incurred nor paid any Liquidated Damages in connection with the July 2005 Registration Payment Arrangement.

On January 1, 2007, we adopted the provisions of FSP EITF 00-19-2. In December 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 was 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 the prior periods and as of December 31, 2006 were adjusted to apply the new method retrospectively.

The Company accounted for FSP EITF 00-19-2 appropriately by eliminating the warrant liability as of December 31, 2007, but upon further review in 2008, management determined that it was not correct to adjust the prior period comparative financial statements. Accordingly, the Company has made the appropriate adjustments to reinstate the warrant liability accounting as originally recorded.

(12) Income Taxes

Due to our net loss for the years ended December 31, 2008 and 2007, 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, 2008 and 2007.

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(A Development Stage Enterprise)
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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:

	2008	2007
Income tax expense at federal statutory rate	$ 9,060,000	$ 7,503,000
State taxes	(2,000)	(2,000)
R & D Credit	310,000	628,000
Stock options	(542,000)	(432,000)
Net operating true-ups	1,600,000	
Other	49,000	(152,000)
Change in federal valuation allowance	(10,475,000)	(7,545,000)
Total Tax Expense/(Benefit) on Continuing Operations	$	$

On July 13, 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 de-recognition, 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 of December 31, 2008 we continue to have no unrecognized tax benefits. 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 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 balance sheets at December 31, 2008 and 2007, and has not recognized interest and/or penalties in the statement of operations for the year ended December 31, 2008.

We are subject to taxation in the United States and the state of California. All of our tax years are subject to examination by the United States and California tax authorities due to the carry forward 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, 2008, we had net deferred tax assets of approximately $39.6 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.

Subsequent to the filing of our 2007 Form 10K, we completed an Internal Revenue Code Section 382 study. As a result of this study, we determined that based upon ownership changes, only $158,000 of the $4.5 million net operating losses we had previously removed from the deferred tax assets in 2007 would expire unused. Accordingly, we have re-established approximately $1.6 million of the deferred tax assets related to these net operating losses with a corresponding increase to the valuation allowance.

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December 31, 2008

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, 2008 and 2007 are as follows:

	December 31, 2008	2007
Deferred tax assets:		
Accrued expenses	$ 248,776	$ 150,210
Stock options expense under SFAS No. 123	1,677,809	1,675,824
Net operating loss carryforwards	33,102,741	22,338,915
Income tax credit carryforwards	2,262,374	1,729,194
Property, plant and equipment	41,056	38,065
Intangibles	2,285,263	1,535,487
Other	6,553	577
Total deferred tax assets	39,624,572	27,468,272
Less: valuation allowance	(39,624,572)	(27,468,272)
Total deferred tax assets, net of valuation allowance	$	$

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 $39.6 million as of December 31, 2008 to reflect the estimated amount of deferred taxes that may not be realized. We increased the valuation allowance by approximately $12.1 million for the year ended December 31, 2008. The deferred tax asset for the net operating losses and the related valuation allowance includes approximately $47,000 related to stock option deductions, the benefit of which may eventually be credited to equity. As a result of our subsequent adoption of SFAS 123(R), we recognize windfall tax benefits associated with the exercise of stock options directly to 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 SFAS 123(R). At December 31, 2008, we do not have any windfall tax benefits under SFAS 123(R).

At December 31, 2008, we had Federal and California tax loss carryforwards of approximately $90.4 million and $41.4 million, respectively. The Federal and California net operating loss carryforwards begin to expire in 2020 and 2012 respectively, if unused. At December 31, 2008, we had Federal and state tax credit carryforwards of approximately $1.6 million and $973,000, respectively. The federal credits will begin to expire in 2024. The California research and experimentation credit does not expire.

(13) 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.

(14) 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 $218,150 and $118,000 in employer matching contributions in 2008 and 2007, respectively.

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December 31, 2008

(15) Segment Information

We operate our business on the basis of a single reportable segment, which, fundamentally, is the business of in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. We evaluate our company as a single operating segment. The majority of our operating activities and work performed by our employees are currently conducted from a single location in the U.S. We recognized revenues of $0.5 million in each of 2008 and 2007, which revenues were derived solely from license fees under a license agreement with Theragenex, LLC, which we terminated in August 2007.

(16) Summary of Quarterly Financial Data (unaudited)

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2008 and 2007:

Quarterly statement of operations data for 2008 (unaudited):	**Quarters Ended March 31**	**June 30**	**September 30**	**December 31**
Licensing revenue	$	$ 500,000	$	$
Gross margin		500,000		
Loss from operations	(6,232,280)	(6,691,199)	(6,856,013)	(7,530,343)
Net loss	(5,933,072)	(6,425,530)	(6,776,863)	(7,512,028)
Basic and diluted net loss per share	$ (0.07)	$ (0.07)	$ (0.08)	$ (0.08)
Basic and diluted weighted average number of shares of common stock outstanding	90,252,572	90,252,572	90,252,572	90,252,572

Quarterly statement of operations data for 2007 (unaudited):	**Quarters Ended March 31**	**June 30**	**September 30**	**December 31**
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 income (loss) per share	$ (0.06)	$ (0.06)	$ (0.07)	$ (0.06)
Basic and diluted weighted average number of shares of common stock outstanding	89,676,739	89,706,739	90,007,509	90,252,572

(17) Severance Related Expenses

In February 2008, a letter agreement regarding terms of separation of employment with James A. Merritt, our former president and chief medical officer, became effective. Dr. Merritt s employment relationship with us ended in January 2008. As a result of his separation, we recorded $185,916 in severance payments and related employer taxes and $16,038 for payments to cover the health, welfare and retirement benefits that we would have incurred had Dr. Merritt remained employed by us for 6 months after the end of our employment relationship. Severance-related charges were recorded in the first, second and third quarters of 2008.

In April 2008, a letter agreement regarding terms of separation of employment with Gregory P. Hanson, our former chief financial officer, treasurer and senior vice president, became effective. Mr. Hanson s employment relationship with us ended in April 2008. As a result of his separation, we recorded $128,157 in severance payments and related employer taxes and $20,997 for payments to cover the health, welfare and retirement benefits that we would have incurred had Mr. Hanson remained employed by us for 6 months after the end of our employment relationship. Total severance-related charges were recorded in the second, third and fourth quarters of 2008.

In October 2008, as part of a restructuring to reduce operating costs, we completed a work force reduction of nine employees in October 2008. As a result of the reduction in force, in accordance with FAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities, we recorded severance-related charges of $403,000, of which $384,000 was recorded as research and development expenses and the remainder as selling, general and administrative expenses. Of the severance-related charges, $372,000 relates to severance payments and related employer taxes, and $31,000 relates to health benefit allowance payments that eligible former employees may use, at their discretion, to pay the premiums required to continue their group health care coverage under COBRA or any other health care related expenses. Severance-related charges of $244,000 were recorded in the fourth quarter of 2008 and the remainder will be recorded in the first and second quarters of 2009.

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In December 2008, the Confidential Separation Agreement and General Release of All Claims governing the terms of separation of employment with Evan M. Levine, our former chief executive officer and president and member of our Board of Directors, became effective. Mr. Levine s employment relationship with us ended in October 2008 and he resigned from our Board of Directors in December 2008. As a result of his separation, we recorded $275,752 in severance payments and related employer taxes, $19,870 in health benefit allowance payments that Mr. Levine may use, at his discretion, to pay the premiums required to continue his group health care coverage under COBRA or any other health care related expenses and an additional payment of $110,650 in lieu of issuing shares of stock. Severance-related charges were recorded in the fourth quarter of 2008.

(18) Subsequent Events

In January 2009, the Confidential Separation Agreement and General Release of All Claims governing the terms of separation of employment with Mark N.K. Bagnall, our former executive vice president and chief financial officer, which was agreed to by Mr. Bagnall in December 2008, became effective. Mr. Bagnall s employment relationship with us ended in December 2008. As a result of his separation, we recorded $174,787 in severance payments and related employer taxes and $18,352 in health benefit allowance payments that Mr. Bagnall may use, at his discretion, to pay the premiums required to continue his group health care coverage under COBRA or any other health care related expenses. Severance-related charges were recorded in the fourth quarter of 2008.

In January 2009, in order to further reduce operating costs, we completed a work force reduction of six employees. As a result of the reduction in force, we estimate recording severance-related charges of approximately $192,000, of which we estimate approximately $95,000 will be recorded as research and development and the remainder as selling, general and administrative expenses. Of the severance-related charges, we estimate that approximately $173,000 will relate to severance payments and related employer taxes and approximately $19,000 will relate to health benefit allowance payments that eligible former employees may use, at their discretion, to pay the premiums required to continue their group health care coverage under COBRA or any other health care related expenses. We estimate that severance-related charges of approximately $132,000 will be recorded in the first quarter of 2009 and the remainder will be recorded in the second quarter of 2009. The severance-related charges that we expect to incur in connection with the reduction in force are subject to a number of assumptions and actual results may differ. We may also incur other charges not currently contemplated due to events that may occur as a result of, or associated with, the restructuring.

In January 2009, we entered into retention and incentive agreements with seven employees, including our executive officers, and granted under the 2008 Plan restricted stock units to these employees that represented the right to receive in the aggregate 3,700,000 shares of our common stock, including 1,200,000 units to our chief business officer and senior vice president, 850,000 units to our general counsel, 650,000 units to our senior vice president of operations and 450,000 units to our vice president of regulatory and quality. These units will vest immediately prior to a strategic transaction (as defined in the documentation evidencing the grant of the units). The retention and incentive agreements and associated restricted stock units awards are primarily intended to reinforce and encourage these employees continued employment with and dedication to our company without distraction from the possibility of involuntary termination or a change in control and related events and circumstances.

In February 2009, our Board of Directors appointed Brian M. Culley, our chief business officer and senior vice president, to additionally serve as our principal executive officer and appointed Mr. Bagnall to additionally serve as our principal financial officer and principal accounting officer.

In February 2009, we announced that we have received written indications of interest from numerous companies representing a range of strategic transactions and currently are evaluating all proposals and options. We also indicated that continued cost-containment measures may impact the timeline of our regulatory filings.

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In March 2009, we announced that, effective April 3, 2009, we will reduce our full-time workforce to five employees and will discontinue substantially all of our development activities and fundamental business operations to provide additional time to consummate a strategic transaction or otherwise obtain financing. Our remaining employees, which consist of our chief business officer and senior vice president, our general counsel, our senior vice president of operations, our vice president of regulatory affairs and quality and our manager of accounting, will focus their efforts primarily on continuing to evaluate and execute strategic options. We stated that, along with the reductions we implemented in October 2008 and January 2009, and our prior cost-containment measures, the reduction and other efforts will extend our cash cliff and increase the opportunity for us to close a strategic transaction with one of the parties with whom we currently are in discussions or another company that we identify in the future.

In March 2009, we announced that we and SDP had entered into a license agreement (the License Agreement) with Shin Poong Pharmaceutical Co., Ltd., a company organized under the laws of the Republic of Korea (Shin Poong), pursuant to which we granted to Shin Poong an exclusive license, including the right to sublicense, to research, develop, make, have made, use, offer for sale, sell and import licensed products, in each case solely for the treatment of cancer by intravenous administration of formulations of docetaxel as emulsified products and solely in South Korea. Under the terms of the License Agreement, we will receive an upfront licensing fee of $300,000, a regulatory milestone payment of either $200,000 or $400,000 (depending on whether Shin Poong is required by the Korea Food and Drug Administration to conduct a bioequivalence or clinical study in human subjects prior to receipt of regulatory approval) upon receipt of regulatory approval for marketing a licensed product in South Korea, one-time commercial milestone payments tied to annual net sales of licensed products in an aggregate amount of up to $1,500,000 and royalty payments on net sales of licensed products. Shin Poong is responsible for all development and commercial activities related to ANX-514 in South Korea. If Shin Poong is required by the Korea Food and Drug Administration to conduct a bioequivalence or clinical trial in human subjects prior to receipt of regulatory approval and we elect not to supply product to conduct such trial, which supply obligation is subject to limitations, we will pay Shin Poong $100,000.

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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)	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(10)	Second Amendment to Rights Agreement, dated February 25, 2008, among the registrant and the Icahn purchasers (as defined therein)
4.22(8)	Form of $2.26 Common Stock Warrant issued on July 27, 2005 (including the original schedule of holders)

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Exhibit	Description
4.23(8)	Form of $2.26 Common Stock Warrant issued on July 27, 2005 (including the original schedule of holders)
4.24(12)	$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
4.25(11)	$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
4.26(11)	$2.50 Warrant to Purchase Common Stock issued on October 22, 2004 to Thomas J. DePetrillo
10.1#(12)	2005 Equity Incentive Plan
10.2#(13)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan
10.3#(14)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for director option grants beginning in 2008
10.4#(15)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for option grants to employees approved in March 2008)
10.5#(2)	Form of Restricted Share Award Agreement under the 2005 Equity Incentive Plan
10.6#(13)	2005 Employee Stock Purchase Plan
10.7#(13)	Form of Subscription Agreement under the 2005 Employee Stock Purchase Plan
10.8#(16)	2008 Omnibus Incentive Plan
10.9#(17)	Form of Non-Statutory Stock Option Grant Agreement (for directors) under the 2008 Omnibus Incentive Plan
10.10#(17)	Form of Non-Statutory/Incentive Stock Option Grant Agreement (for consultants / employees) under the 2008 Omnibus Incentive Plan
10.11#(15)	2008 Incentive Plan
10.12*(18)	Option and License Agreement, dated January 23, 1998, between the registrant and the University of Southern California
10.13(3)	First Amendment to License Agreement, dated August 16, 2000, between the registrant and the University of Southern California
10.14*(18)	Option and License Agreement, dated August 17, 2000, between the registrant and the University of Southern California

10.15*(19)	Amendment to Option and License Agreement, dated April 21, 2003, between the registrant and the University of Southern California
10.16*(20)	Second Amendment to Option and License Agreement, dated January 25, 2007, between the registrant and the University of Southern California
10.17*(2)	Agreement, effective as of May 1, 2005, between the registrant and Pharm-Olam International Ltd.
10.18(2)	Amendment dated July 19, 2005 to the Agreement between the registrant and Pharm-Olam International Ltd.
10.19(21)	License Agreement, dated October 20, 2006, between the registrant, through its wholly-owned subsidiary SD Pharmaceuticals, Inc., and Theragenex, LLC
10.20(14)	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
10.21(22)	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
10.22(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

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Exhibit	Description
10.23#(23)	Offer letter, dated March 5, 2003, to Joan M. Robbins
10.24#	Confidential Separation Agreement and General Release of All Claims, effective December 4, 2008, between the registrant and Joan M. Robbins
10.25#(24)	Offer letter, dated November 15, 2004, to Brian M. Culley
10.26#(25)	Severance Agreement and Release of All Claims, dated September 7, 2006, with Carrie Carlander
10.27#(25)	Consulting Agreement, dated September 7, 2006, with Carrie Carlander
10.28#(25)	Offer letter, dated September 7, 2006, to James A. Merritt
10.29#(14)	Letter agreement regarding terms of separation with James A. Merritt, effective as of February 12, 2008
10.30#(25)	Form of Stock Option Agreement between the registrant and James A. Merritt (included in Exhibit 10.28)
10.31#(26)	Offer letter, dated December 13, 2006, to Gregory P. Hanson
10.32#(26)	Stock Option Agreement, effective December 20, 2006, between the registrant and Gregory P. Hanson
10.33#(27)	Letter Agreement regarding terms of separation with Gregory P. Hanson, dated April 2, 2008
10.34#(27)	Consulting Agreement, dated April 2, 2008, with Gregory P. Hanson
10.35#(17)	Offer letter, dated April 1, 2008, to Mark N.K. Bagnall (including Exhibits A, B and C thereto)
10.36#	Confidential Separation Agreement and General Release of All Claims, effective December 31, 2008, between the registrant and Evan M. Levine, including letter, dated November 7, 2008, related thereto
10.37(21)	Form of Director and Officer Indemnification Agreement
10.38#(28)	Director compensation policy
10.39(29)	Placement Agency Agreement, dated November 2, 2006, among the registrant, ThinkEquity Partners LLC and Fortis Securities LLC
21.1	List of Subsidiaries

23.1	Consent of J.H. Cohn LLP, Independent Registered Public Accounting Firm
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a)
32.1±	Certification of principal executive officer and principal 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 Current Report on Form 8-K on December 15, 2008 (SEC file number 001-32157-081249921)

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(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 Current Report on Form 8-K on February 25, 2008 (SEC file number 001-32157-08638638)

(11) Filed with the registrant s Registration Statement

on Form S-3 on August 26, 2005 (SEC file number 333-127857-051050073)

(12) Filed with the registrant s Annual Report on Form 10-K on March 15, 2007 (SEC file number 001-32157-07697283)

(13) Filed with the registrant s Registration Statement on Form S-8 on July 13, 2005 (SEC file number 333-126551-05951362)

(14) Filed with registrant s Annual Report on Form 10-K on March 17, 2008 (SEC file number 001-32157-08690952)

(15) Filed with the registrant s Quarterly Report on Form 10-Q on May 12, 2008 (SEC file number 001-32157-08820541)

(16) Filed with the registrant s Current Report on Form 8-K on June 7, 2008 (SEC file number 001-32157-08874724)

(17) Filed with the registrant s Quarterly Report on Form 10-Q on August 11, 2008 (SEC file number 001-32157-081005744)

(18) Filed with the registrant s Registration Statement on Form 10SB/A on January 14, 2002 (SEC file number 000-33219-2508012)

(19) Filed with the registrant s Quarterly Report on

Form 10-QSB on August 14, 2003 (SEC file number 000-33219-03848890)

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

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

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

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

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

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

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

(27) Filed with the registrant s Current Report on Form 8-K on April 16, 2008

(SEC file number 001-32157-08760483)

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

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