ADVENTRX PHARMACEUTICALS INC
Form 10-K
March 18, 2010

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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, 2009

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES o 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. þ

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, 2009 was approximately $14,689,567 based upon the closing price of the registrant s common stock on the NYSE Amex reported for such date. Shares of the registrant s common stock held by each officer and director of the registrant 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 for purposes of the foregoing calculation on the basis 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.

As of March 1, 2010, the registrant had 257,237,572 shares of its common stock issued and outstanding.

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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 acquisition, and our future financial position. When used in this report, the words believe, may, could, will, estimate, continue, anticipate, intend, expect, indicate and similar expressions are inte 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. These forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from those reflected in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to those described in Item 1A Risk Factors of this report. Except as required by law, we do not intend to update the forward-looking statements discussed in this report 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 specialty pharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. We seek to improve the performance of existing drugs 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 (vinorelbine injectable emulsion) and ANX-514 (docetaxel injectable emulsion), 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® (vinorelbine tartrate) Injection and Taxotere® (docetaxel) Injection Concentrate, respectively, by:

- reducing the incidence and severity of adverse effects; and
- improving their pharmacoeconomics and convenience to healthcare practitioners and patients.

In December 2009, we submitted a new drug application, or NDA, for ANX-530 to the U.S. Food and Drug Administration, or FDA. In March 2010, we announced that we had received a refusal-to-file letter from the FDA regarding our ANX-530 NDA submission. In the letter, the FDA indicated that the data included in our December 2009 NDA submission from the intended commercial manufacturing site was insufficient to support a commercially-viable expiration dating period. The FDA identified only this one chemistry, manufacturing and controls, or CMC, reason for the refusal to file. We have requested a face-to-face meeting with the FDA to understand its requirements and define the path to a successful filing of the ANX-530 NDA at the earliest possible time. In addition, we expect to meet with the FDA in the summer of 2010 to discuss the results of our bioequivalence study of ANX-514, following which we will provide an update on planned activities with respect to, or a potential NDA submission timeline for, ANX-514.

Business Strategy

Our goal is to be a leading specialty pharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates that improve the performance of currently approved products. Our near-term strategy is to obtain marketing approval of our lead product candidates and establish capability to support marketing, distributing and selling these products in the U.S., should they be approved. Longer term, we intend to acquire additional product candidates that fit our areas of expertise. Specifically, we intend to:

Seek regulatory approval for ANX-530 in the U.S. In December 2009, we submitted an NDA for ANX-530 to the FDA. In March 2010, we announced that we had received a refusal-to-file letter from the FDA. We have requested a face-to-face meeting with the FDA to understand its requirements and define the path to a successful filing of the ANX-530 NDA at the earliest possible time.

Seek regulatory approval for ANX-514 in the U.S. We have assembled an expert team of individuals and contract organizations with highly specific and relevant backgrounds to assist us in evaluating the data from our bioequivalence study of ANX-514. We expect to meet with the FDA in the summer of 2010 to discuss our analyses of the bioequivalence study data.

Establish highly leverageable sales and marketing capabilities in the U.S. The nature of the oncology marketplace in general, and the anticipated target audience for our product candidates in particular, are relatively concentrated. Accordingly, we believe a meaningful portion of the U.S. markets for our product candidates can be accessed through an experienced sales force that targets key constituents of the treatment/product-selection decision-making process. In addition, we will evaluate opportunities to leverage an existing sales force by adding complementary products with a similar target audience. However, we remain receptive to partnering our product candidates in the U.S. if presented with terms that are sufficiently attractive.

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Partner with leading organizations to develop and market ANX-530 and ANX-514 outside the U.S. We plan to draw on the development, regulatory and commercial expertise of other companies in instances where we believe our product candidates would benefit from such expertise. In addition, if we determine that the commercial potential of our product candidates is best realized through an established sales organization, whether within or outside the U.S., we may, and for markets outside the U.S., we plan to, commercialize products for which we obtain regulatory approval through a variety of licensing, collaboration and distribution arrangements with other pharmaceutical and biotechnology companies. For example, in March 2009, we entered into a license agreement with Shin Poong Pharmaceutical Co., Ltd. pursuant to which we granted Shin Poong an exclusive license to make use and sell ANX-514 in South Korea.

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

Acquire and develop new and improved formulations of currently marketed products. We may pursue development of novel formulations of other currently approved products, whether for the treatment of cancer or other diseases or conditions, that we believe can be improved, the U.S. markets for which are relatively concentrated and to which we can apply our operational capabilities.

Oncology Focus

Despite recent advances in the treatment of tumor types, cancer remains a serious disease. The Centers for Disease Control and Prevention consistently ranks cancer as the second most common cause of death in the U.S. The American Cancer Society estimates that, in the U.S. in 2009, almost 1.5 million people were diagnosed with and over 550,000 people died from cancer.

Our lead product candidates are designed to improve treatments for cancer patients. Treatment selection for cancer patients depends on the histology, stage and progression of the disease, 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. Cancer treatments, including chemotherapy, typically are associated with side effects, some of which can be severe and, in rare cases, fatal. Not all side effects are the result of an active ingredient. Many side effects are associated with the manner in which a particular drug s active ingredient is formulated that is, side effects can be associated with the non-active components required to administer a drug. We believe formulating drugs with less toxic components can reduce undesirable side effects and provide other advantages. Without compromising the efficacy of a particular drug s active ingredient, novel formulations may provide patients with superior treatment options.

Our Lead Product Candidates ANX-530 (vinorelbine injectable emulsion) and ANX-514 (docetaxel injectable emulsion)

Opportunities for New Formulations

Reformulating existing pharmaceutical products is an increasingly common product lifecycle-management strategy. A 2004 report on the U.S. drug market from BCC, Inc. projected that reformulations would grow from 62% of the market in 2003 to 79% in 2008. Finding new markets for and ways to modify and enhance existing products is often an essential element of pharmaceutical companies efforts to innovate and improve treatment outcomes in the context 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, such as phlebitis, erythema, hypersensitivity reactions and fluid retention, that present opportunities for improvement. We are developing novel ways to formulate the active ingredient underlying each of these drugs that we believe will improve their safety profiles without adversely affecting efficacy. In addition, we believe our formulations may provide benefits to patients and practitioners that do not manifest themselves in traditional measures of safety or efficacy.

Regulatory Strategy

The regulatory strategy for our lead product candidates is to demonstrate the bioequivalence of each to a 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 is sufficient to support an 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 generally will be the same as for the reference product, but may reflect differences between our product candidate and the reference product (such as, for ANX-514, the absence of detergent in our formulation) or data generated during the bioequivalence trials, including comparative adverse event information. Ultimately, because the label for our product candidates, if approved, will be based on discussions with the FDA, we cannot predict with accuracy the final label of a product candidate, should any be approved.

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 modest financial investment relative to traditional development of new chemical entities, 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 as we intend to reconfirm for 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 an NDA submitted under Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, or FDCA, during the exclusivity period based on the conditions of approval of our product.

Commercialization Strategy

Currently, we intend to build a commercial capability in the U.S. focused on ANX-530, as well as other products that we may develop, license or acquire, including ANX-514, should it be approved. We believe we can achieve our strategic goals by deploying an experienced sales force supported by an internal commercial infrastructure that targets community oncology practices and other organizations with defined characteristics, such as high vinorelbine use or an expected willingness to switch vinorelbine formulations. Following our submission of the ANX-530 NDA in December 2009, we began to refine our commercialization strategy for ANX-530 and to undertake certain activities related to its commercialization. Despite our announcement in March 2010 that we had received a refusal-to-file letter regarding our ANX-530 NDA submission, we intend to continue these activities, though we will re-evaluate our commercialization timelines following our planned meeting with the FDA. For the near-term, unless following our meeting with the FDA we believe that the refusal-to-file letter will not delay our prior timelines and we are able to raise substantial additional capital to support the commercial launch of ANX-530 and development activities primarily related to ANX-514, we expect to maintain our current cost-effective and flexible infrastructure by limiting the number of our full-time employees, though we expect to hire certain individuals to help develop and execute our commercial strategies. As we near expected regulatory approval, or if we are successful in raising substantial

additional capital, we plan to invest in the infrastructure necessary for the commercial launch of those product candidates nearing approval or those product candidates with the highest near-term market potential. In addition, we remain receptive to partnering our product candidates in the U.S. if presented with sufficiently attractive terms.

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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. Healthcare providers 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 product code as the original drug. Virtually all U.S. payors, including Medicare and private insurance plans, use the HCPCS, 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 product 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.

A key component to our commercial strategy in the U.S. for ANX-530 and ANX-514 is to obtain unique HCPCS product codes that are distinct from those for Navelbine and Taxotere, respectively. If our products are provided unique HCPCS product 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 will provide greater freedom to price our products appropriately relative to competitive products, which may enhance their commercial value to us.

ANX-530 (vinorelbine injectable 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. As reported in the Navelbine label, injection site reactions occurred in approximately one-third of 365 patients treated in three clinical studies with Navelbine as a single agent, 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 to protect the venous endothelium during administration into a peripheral vein, thereby reducing irritation associated with administration of the drug.

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ANX-530 NDA Submission and FDA Refusal-to-File Letter

In December 2009, we submitted an NDA for ANX-530 to the FDA. Our ANX-530 NDA included data from one clinical bioequivalence study designed to assess the pharmacokinetic equivalence of ANX 530 and Navelbine, the reference drug for ANX-530. We submitted the ANX-530 NDA under Section 505(b)(2) of the FDCA. As such, in seeking approval of ANX-530, we are relying in part on the FDA s findings of safety and effectiveness with respect to Navelbine. We are seeking approval of ANX-530 for the same indications as Navelbine, including non-small cell lung cancer.

Our decision to develop ANX-530 is based in part on positive results from a bioequivalence study of ANX-530 that we conducted. 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). In addition, in post hoc analyses, relative to Navelbine, ANX-530 demonstrated a statistically significant reduction in injection site reactions. Notably, in our study, 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.

In March 2010, we announced that we had received a refusal-to-file letter from the FDA. In the letter, the FDA indicated that the data included in our ANX-530 NDA submission from the intended commercial manufacturing site was insufficient to support a commercially-viable expiration dating period. The FDA identified only this one CMC reason for the refusal to file. To support a commercially-viable expiration dating period, we included in our NDA submission data that met the filing requirements for a new drug promulgated by the International Conference of Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, or ICH. In addition, site-specific stability data from lots manufactured at the intended commercial manufacturing site also were included in our NDA submission.

We have requested a face-to-face meeting with the FDA to understand its requirements and define the path to a successful filing of the ANX-530 NDA at the earliest possible time. Following our meeting with the FDA, we will provide guidance on the timeline for resubmission of the ANX-530 NDA.

Market and Opportunity

The use of vinorelbine in the U.S. generally has been steady since 2003, when generic equivalents first became available in the U.S. While total vinorelbine volume (measured in milligrams to treat lung and breast cancer) generally has been consistent, the dollar value of the U.S. vinorelbine market varies, in part due to competition among manufacturers of Navelbine and its generic equivalents. For instance, in September 2009, a new manufacturer of generic Navelbine entered the U.S. market. According to industry data, the current price for this new entrant s product is lower than alternatives, which will induce a lower average sales price for all products in the same HCPCS product code. To remain price-competitive and, since practitioners are reimbursed by CMS based on a percentage of average sales price, to prevent practitioners from being reimbursed at a level that is less than the acquisition cost of their product, other manufacturers may further reduce the prices for their products. As a result, each new entrant s pricing strategy may erode the total dollar value of the entire U.S. vinorelbine market. We estimate the current total dollar value of the U.S. vinorelbine market is between $15 million and $20 million.

As more fully described above under HCPCS Product Codes and Reimbursement, we intend to apply to CMS for a HCPCS product code for ANX-530 that is distinct from the HCPCS product code for Navelbine and its generic equivalents. If granted, ANX-530 would not be directly impacted by pricing competition in the way that products sharing the same HCPCS product code may be impacted. This should provide us the flexibility to establish an appropriate price for ANX-530. While we have not determined a price for ANX-530 if it were approved, we expect decision makers to value its unique formulation as compared to Navelbine and its generic equivalents. If ANX-530 is approved, granted a unique HCPCS product code and is priced to reflect its potential benefits, the potential dollar value of the U.S. ANX-530 market likely will be greater than the dollar value of the existing U.S. vinorelbine market, assuming the same volume of vinorelbine demand.

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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.

FDA Acceptance of Brand Name Exelbine

In March 2010, we announced that the FDA has accepted our proposed proprietary name, Exelbine, for ANX-530. The FDA s acceptance of our Exelbine brand name is conditioned upon its review of an ANX-530 NDA and its confirmation of the information in the NDA regarding the safety of interchanging ANX-530 with other vinorelbine injectable products.

ANX-514 (docetaxel injectable 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.

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, in rare cases, fatal anaphylaxis.

ANX-514 is formulated without polysorbate 80 or other detergents and is designed to reduce the incidence and severity of side effects associated with detergents, such as hypersensitivity reactions.

Nonclinical Efficacy and Safety

In nonclinical 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 to 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 re-challenge at three weeks, hypersensitivity reactions were observed only in the Taxotere-treated animals.

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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.

Bioequivalence Study

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. In May 2009, we announced that ANX-514 was determined to have comparable overall safety as Taxotere, with no differences between treatment groups in severe toxicities. However, pharmacokinetic equivalence, the primary endpoint of the study, was not demonstrated based on benchmark regulatory standards.

The study data revealed higher blood-levels of total (bound and unbound) docetaxel during and immediately following infusion of the study drug (i.e., during the first hour of treatment) in patients receiving ANX-514 relative to those receiving Taxotere, but, at 10 minutes after the completion of infusion, total docetaxel blood-levels were comparable and remained so through the end of the observation period. We are analyzing these short-term increased levels, which were the reason ANX-514 was outside benchmarks standards established by the FDA for determining bioequivalence. Interestingly, the data also revealed lower blood-levels of unbound, or free, docetaxel in patients receiving ANX-514 relative to those receiving Taxotere. It is unclear how the FDA will view the different levels of total versus free docetaxel.

Following discussions with clinicians and experts in taxane pharmacokinetics, we believe that the differences between study drugs observed in the bioequivalence study are not clinically relevant and do not affect adversely the safety or efficacy of ANX-514 relative to Taxotere. We have assembled an expert team of individuals and contract organizations with highly specific and relevant backgrounds to assist us in evaluating the data from our bioequivalence study of ANX-514. We expect to meet with the FDA in the summer of 2010 to discuss with the FDA our analyses of the bioequivalence study data.

Market and Opportunity

According to Sanofi-aventis, sales of Taxotere in 2008 were 737 million in the U.S. and 2.0 billion worldwide (or approximately U.S.$999 million and U.S.$2.8 billion, respectively, based on the New York closing exchange rate on March 1, 2010), 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.

Assuming we are able to demonstrate that the differences between study drugs observed in the bioequivalence study of ANX-514 are not clinically relevant and do not affect adversely the safety or efficacy of ANX-514 relative to Taxotere, we believe ANX-514 is well-positioned as an alternative to Taxotere, alternative formulations of docetaxel and generic equivalents of Taxotere. We are not aware of any detergent-free formulation of docetaxel that has near-term market potential, other than ANX-514.

We believe the need to premedicate patients prior to administering a detergent-free formulation of docetaxel 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.

Further, 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 or polysorbate 80, but for whom docetaxel is the best or only therapeutic option, may benefit from ANX-514, particularly as Taxotere s label recommends against re-challenging patients with a history of severe hypersensitivity reactions.

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In addition to the improved safety and comparable efficacy observed in nonclinical testing, ANX-514 may provide other 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 preliminary 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, placing additional stress on hospital resources, including room availability.

Prior Cost-Containment and Fundraising Activities

In the past, we spent significant resources on the development of ANX-510, or CoFactor®, including a phase 2b clinical trial and a discontinued phase 3 clinical trial in the first line treatment of metastatic colorectal cancer, and a phase 2 clinical trial in the treatment of advanced breast cancer. Following our announcement in October 2007 that the CoFactor/5-FU arm of our phase 2b clinical trial of CoFactor did not demonstrate statistically significant improved safety in the trial s primary endpoint, we discontinued enrolling patients in our phase 3 clinical trial of CoFactor.

Beginning in October 2008 and through June 2009, we implemented numerous restructuring, cost-cutting and re-prioritization initiatives to reduce operating costs and to focus on those of our options that we believed maximized the overall value of our company. For instance, in October 2008, we discontinued active work on all compounds, other than ANX-530 and ANX-514, to which we have or had rights and on which we may have previously spent resources developing, including our CoFactor program. In addition, during that period, we effected three reductions in our full-time employee workforce.

Since June 2009, we have completed five financing transactions, raising an aggregate of approximately $25 million in adjusted gross proceeds, after deducting our aggregate dividend and related payment obligations, but before deducting the fees and expenses of our placement agent in those financings and our other estimated offering expenses. In addition, in December 2009 and January 2010, we raised an aggregate of approximately $3.3 million in net proceeds in connection with the exercise of warrants issued in connection with certain of these financings. Though we are in the process of rebuilding our organizational infrastructure, currently, we outsource substantially all of our development and commercialization activities, including research-related manufacturing and regulatory affairs, and our general and administrative activities, such as finance, accounting, human resources, marketing and investor relations.

Competition

If regulatory authorities approve the marketing and selling of any of our product candidates, our product candidates will face significant and long-term competition from pharmaceutical companies, pharmaceutical divisions of companies and biotechnology, biopharmaceutical and specialty pharmaceutical 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 do. Many of these companies have commercial arrangements with other companies to supplement their internal capabilities.

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ANX-530 and ANX-514, if approved, may compete against Navelbine and Taxotere, respectively, as well as their generic equivalents and other formulations of vinorelbine and docetaxel. In addition to Navelbine, in the U.S., currently there are seven approved generic equivalents of vinorelbine. In the U.S., in May 2010 (but subject to any period of pediatric exclusivity that may be granted in the future and excluding exclusivity for certain approved indications extending into September 2010), patent protection ends for docetaxel and, in November 2013, patent protection ends for Taxotere. We are aware of three 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 or that such unexpired patents are invalid or unenforceable. In addition, a fourth company has submitted an application seeking approval of a generic equivalent of Taxotere and has certified that, after May 2010, its product will not infringe any unexpired Taxotere patents or that such unexpired patents are invalid or unenforceable.

Under our current regulatory strategy (but before discussing with the FDA the results of our bioequivalence study of ANX-514), because we have submitted and anticipate submitting and resubmitting 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 relative to competing products, we may be unable to market our products based on these benefits. If our products fail to obtain unique HCPCS product 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.

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 nonclinical 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.

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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 will need FDA review and approval before the change can be implemented. For example, if we change the manufacturer of a product or of the API component of a product, the FDA may require stability or other data from the new manufacturer, which data will take time and is costly to generate, and the delay associated with generating this data may cause interruptions in our ability to meet commercial demand, if any.

Intellectual Property

ANX-530 (vinorelbine injectable emulsion)

We own world-wide rights (excluding China, Hong Kong, Macau and Taiwan) to patent applications covering the composition and use of our vinorelbine injectable emulsion product candidate, subject to the exclusive license we granted to Latitude Pharmaceuticals (described below under Licensing Agreement). Patent applications, entitled Compositions for Delivering Highly Water Soluble Drugs, currently are pending in the U.S., Canada, and seven additional countries, and regional patent applications are pending in the European Patent Office and Eurasian Patent Office. These applications have a priority date of July 12, 2004, and any patents granted thereon will have an expected expiration date of July 2024 in the U.S. and July 2025 in the other countries.

ANX-514 (docetaxel injectable emulsion)

We own world-wide rights (excluding China, Hong Kong, Macau and Taiwan) to patent applications covering the composition and use of our docetaxel injectable emulsion product candidate, subject to the exclusive license we granted to Latitude Pharmaceuticals (described below under Licensing Agreement). Patent applications, entitled Low Oil Emulsion Compositions for Delivering Taxoids and Other Insoluble Drugs, currently are pending in the U.S., Canada and seven additional countries, and a regional patent application is pending in the European Patent Office. These applications have a priority date of September 28, 2004, and any patents granted thereon will have an expected expiration date of September 2024 in the U.S. and September 2025 in the other countries.

Patent applications, entitled Vitamin E Succinate Stabilized Pharmaceutical Compositions, Methods for the Preparation and Use Thereof, currently are pending in the U.S., Canada and eight additional countries, and regional patent applications are pending in the European Patent Office and the Eurasian Patent Office. These applications have a priority date of February 1, 2006, and any patents granted thereon will have an expected expiration date of February 2027 in the U.S. and in the other countries.

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, that 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, licenses to which might not be available to us.

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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 $6.5 million in 2009 and $17.9 million in 2008. 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 nonclinical activities, such as research-related manufacturing, nonclinical research studies, quality assurance and regulatory activities. In 2009 our most significant costs were for manufacturing, analytical and stability testing for ANX-530 and consulting services related to our ANX-530 NDA, 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 Agreement

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 and ANX-514 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.

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 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.

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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: (i) completion of nonclinical laboratory and animal testing in compliance with FDA regulations; (ii) submission of an investigational new drug application, which must become effective before human clinical trials may begin; (iii) performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and (iv) 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 nonclinical studies 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, unless waived. 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 the Prescription Drug User Fee Act, or 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 PDUFA 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 NDA submission. Following completion of the FDA s initial review of the NDA and the clinical and manufacturing procedures and facilities, the FDA will issue a complete response or 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 formulations of previously approved products, a company may file an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) 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 nonclinical 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 any changes 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 nonclinical 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 an NDA submitted under Section 505(b)(2). We submitted and intend to resubmit our NDA for ANX-530 under Section 505(b)(2), and, subject to the outcome of the meeting we expect to hold with the FDA in the summer of 2010, we also intend to submit an NDA under Section 505(b)(2) for ANX-514.

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) application 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 Section 505(b)(2) application will not be subject to the 30-month stay. A paragraph IV certification would be required in connection with a Section 505(b)(2) application for ANX-514 that is accepted for filing by the FDA before November 2013.

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. For example, if we change the manufacturer of a product or of the API component of a product, FDA may require stability or other data from the new manufacturer, which data will take time and is costly to generate, and the delay associated with generating this data may cause interruptions in our ability to meet commercial demand, if any. 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.

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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, and the time may be longer or shorter than that required for FDA approval. In addition, regulatory approval of prices is required in most countries other than the U.S. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or any collaborator of ours.

Employees

As of March 1, 2010, we have four employees, three of whom are full-time. Our employees are not unionized and we believe that our relationship with our employees is good.

We have started the process of rebuilding our organizational infrastructure following the restructuring, cost-cutting and re-prioritization initiatives we began in October 2008, and the five financing transactions we ve completed since June 2009. However, currently, we outsource substantially all of our development and commercialization activities, including research-related manufacturing and regulatory affairs, and our general and administrative activities, such as finance, accounting, human resources, marketing and investor relations.

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Formation and Subsidiaries

Our company 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 EU, which we dissolved in December 2009. In April 2006, we acquired SD Pharmaceuticals, Inc., a Delaware corporation, as a wholly-owned subsidiary.

Item 1A. Risk Factors

Our financial position, results of operations and cash flows are subject to various risks, many of which are not exclusively within our control, that may cause actual performance to differ materially from historical or projected future performance. We urge investors to carefully consider the risk factors described below in evaluating the information contained in this report.

RISKS RELATED TO OUR BUSINESS

Risks Related to Our Capital Requirements, Finances and Operations

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

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

The success of our business currently is dependent primarily on the success of ANX-530 and ANX-514 and we cannot be certain these product candidates will receive regulatory approval or be successfully commercialized.

We currently have no products for sale and only two product candidates, ANX-530 and ANX-514, for which we are pursuing regulatory approval and commercialization. We discontinued active development on other development programs in late 2008. As a result, the success of our business currently depends primarily on our ability to obtain regulatory approval for and successfully market and sell ANX-530 and ANX-514, efforts that may prove unsuccessful. In December 2009, we submitted an NDA to the FDA for ANX-530. However, in March 2010, we announced that we had received a refusal-to-file letter from the FDA regarding our ANX-530 NDA submission. In addition, we have not yet submitted an NDA, or any foreign regulatory equivalent, for ANX-514. If ANX-530 and/or ANX-514 is approved by the FDA or any foreign regulatory agency, our ability to generate revenues from these products will depend in substantial part on the extent to which they are accepted by the medical community and reimbursed by third-party payors and our ability to ensure that our third-party manufacturer or manufacturers produce sufficient quantities of the products to meet commercial demand.

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Our financial resources are limited, we will need to obtain additional funding to pursue our business strategy and we may not be able to obtain such funding on a timely basis or on commercially reasonable terms, if at all.

We have experienced significant operating losses in acquiring and funding the development of our product candidates, accumulating net losses totaling approximately $149.9 million as of December 31, 2009, and we expect to continue to incur substantial operating losses for the foreseeable future, even if we or a future partner of ours is successful in advancing our product candidates to market. We do not expect to generate cash flows from sales of our products unless and until our products are approved for marketing, the timing of which we cannot predict accurately. As of December 31, 2009, our working capital was approximately $6.6 million.

Our future expenditures on our programs are subject to many uncertainties, including whether our product candidates will be developed with a partner or independently. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the costs of seeking regulatory approval for ANX-530 and ANX-514, including any bioequivalence or clinical studies, process development, scale-up and other manufacturing and stability activities, or other work required to achieve such approval, as well as the timing of such activities and approval;
- the timing and terms of any collaborative, licensing and other strategic arrangements that we may establish;
- the costs related to developing, acquiring and/or contracting for sales, marketing and distribution capabilities and regulatory compliance capabilities, most immediately with respect to ANX-530;
- the extent to which we invest in or acquire new technologies, product candidates, products or businesses;
- the scope, prioritization and number of development and/or commercialization programs we pursue and the rate of progress and costs with respect to such programs;
- the extent to which we will need to rebuild our workforce, which currently consists of three full-time employees and one part-time employee, and the cost involved in recruiting, training and incentivizing new employees;
- the effect of competing technological and market developments; and
- the cost involved in establishing, enforcing or defending patent claims and other intellectual property rights.

We anticipate that our cash as of December 31, 2009, which was approximately $8.7 million, together with the net proceeds from the equity financing we completed in January 2010, will be sufficient to fund our operations at their current levels for at least the next 12 months. However, we may determine to grow our organization or product candidate pipeline or pursue development and/or commercialization activities at levels or on timelines that shorten the period through which our current operating funds will sustain us. As a result, we may need or choose to seek additional funding within the next 12 months. We may seek additional funding through public or private sales of our equity securities, debt financings, collaborations, licensing arrangements or other strategic or partnering transactions. However, we may not be able to obtain sufficient additional funding on satisfactory terms, if at all. We believe global economic conditions, including the heightened volatility of U.S. and international equity markets and the recent credit crisis, may adversely impact our ability to raise additional capital.

We may incur substantial costs in connection with evaluating and negotiating future capital-raising and/or strategic or partnering transactions, the effect of which may be to shorten the period through which our current operating funds will sustain us. Even if we incur costs in pursuing, evaluating and negotiating particular capital-raising and/or strategic or partnering transactions, our efforts may not prove successful.

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Our ability to raise capital may be limited by applicable laws and regulations.

Historically, we have raised capital through the sale and issuance of our equity securities. Our ability to raise additional capital through the sale and issuance of our equity securities may be limited by, among other things, current Securities and Exchange Commission, or SEC, and NYSE Amex rules and regulations. During 2009 and in January 2010, we completed four equity financings under a shelf registration statement on Form S-3. Use of a shelf registration statement for primary offerings typically enables an issuer to raise additional capital on a more timely and cost effective basis than through other means, such as registration of a securities offering under a Form S-1 registration statement. Under current SEC rules and regulations, to be eligible to use a Form S-3 registration statement for primary offerings without restriction as to the amount of securities to be sold and issued, an issuer must, among other requirements, have outstanding common equity with a market value of at least $75.0 million held by non-affiliates. If we file a shelf Form S-3 registration statement at a time when the aggregate market value of our common stock held by non-affiliates, or public float, is less than $75.0 million (calculated as set forth in Form S-3 and SEC rules and regulations), the amount we could raise through primary offerings of our securities in any 12-month period using the Form S-3 registration statement may be limited to an aggregate of one-third of our public float. Moreover, the market value of all securities sold by us under a Form S-3 registration statement during the prior 12 months will be subtracted from that amount to determine the amount we can then raise under the Form S-3 registration statement. Even if we file a shelf Form S-3 registration statement at a time when our public float is $75.0 million or more (calculated as set forth in Form S-3 and SEC rules and regulations), we may become subject to the one-third of public float limitation described above in the future. The SEC s rules and regulations require that we periodically re-evaluate the value of our public float. If, at a re-evaluation date, our public float is less than $75.0 million (calculated as set forth in Form S-3 and SEC rules and regulations), the amount we could raise through primary offerings of our securities in any 12-month period using a Form S-3 registration statement would be subject to the one-third of public float limitation described above.

In addition under current SEC rules and regulations, if our public float is less than $75.0 million or if we seek to register a secondary offering (i.e., an offering of securities of ours by persons other than us), we must, among other requirements, maintain our listing with the NYSE Amex or have our common stock listed and registered on another national securities exchange in order to be eligible to use a Form S-3 registration statement for any primary or secondary offering. Alternative means of raising capital through sales of our securities, including through the use of a Form S-1 registration statement, may be more costly and time-consuming.

Currently, we do not meet certain of the NYSE Amex s continued listing standards and are at risk of being delisted from the NYSE Amex equities market. The NYSE Amex will review the appropriateness of continued listing of any issuer that falls below the exchange s continued listing standards and may, in its discretion, at any time and without notice, suspend dealings in, or may remove any security from, listing privileges. For additional information regarding this risk, see the risk factor below titled We currently are not in compliance with NYSE Amex continued listing standards and are at risk of being delisted from the NYSE Amex equities market. If our common stock were delisted from the NYSE Amex, our ability to raise capital on terms and conditions we deem acceptable, if at all, may be materially impaired. Currently, we do not anticipate being eligible to register and list our common stock on any other national securities exchange.

Our ability to timely raise sufficient additional capital also may be limited by the NYSE Amex s requirements relating to stockholder approval for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, the NYSE Amex requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our presently outstanding common stock, unless the transaction is considered a public offering by the NYSE Amex staff. Based on our outstanding common stock as of March 1, 2010 and a closing price of $0.238, which was the closing price of our common stock on March 12, 2010, we could not raise more than approximately $12.2 million without stockholder approval, unless the transaction is deemed a public offering or does not involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. However,

certain prior sales by us may be aggregated with any offering we may propose in the near-term, further limiting the amount we could raise in any future offering that is not considered a public offering by the NYSE Amex staff and would involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. The NYSE Amex will also require stockholder approval if the issuance or potential issuance of additional shares will be considered by the exchange staff to result in a change of control of us.

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Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our business strategy, and there is no guarantee our stockholders would ultimately approve a proposed transaction. A public offering under the NYSE Amex rules typically involves broadly announcing the proposed transaction, which often times has the effect of depressing the issuer s stock price. Accordingly, the price at which we could sell our securities in a public offering may be less and the dilution existing stockholders experience may in turn be greater than if we were able to raise capital through other means.

Our ability to raise capital may be limited by contractual restrictions.

In the past, in connection with raising capital through the sale and issuance of our equity securities, we have agreed to certain restrictions on our ability to raise additional capital through additional equity financing transactions. For example, in connection with an equity financing we completed in July 2005, we entered into a rights agreement with certain of the purchasers of our securities, including the entities affiliated with Carl C. Icahn. Pursuant to the Rights Agreement, dated July 27, 2005, as amended, or the Rights Agreement, we agreed to, among other things, grant the investors that were party to the Rights Agreement, or the Rights Investors, the right to participate in sales of our securities for up to seven years (with certain enumerated exceptions as set forth in the Rights Agreement) including the right to purchase (i) up to 50% of securities we propose to sell in a public offering if the offering price is equal to or below $8.00 per share, (ii) up to 20% of the securities we propose to sell in a public offering if the offering price is above $8.00 per share, and (iii) up to 50% of the securities we propose to sell in a private offering. Pursuant to the Rights Agreement, we must notify the Rights Investors of a proposed transaction in which they have participation rights at least 15 days but not later than 30 days prior to the sale of our securities and the Rights Investors have 10 days after receipt of such notice to notify us of their intention to participate. Historically, we have requested and received waivers from the Rights Investors with respect to their participation rights, but if we are unable to obtain such waivers with respect to any future financing transactions in a timely manner, or at all, we may be unable to consummate a financing opportunity that otherwise may be available to us and in the best interest of our company and stockholders.

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

We may raise additional capital at any time and may do so through one or more financing alternatives, including public or private sales of our equity securities, debt financings, collaborations, licensing arrangements or other strategic transactions. Each of these financing alternatives carries certain risks. Raising capital through the issuance of common stock may depress the market price of our stock and may substantially dilute our existing stockholders. If we instead seek to raise capital through strategic transactions, such as licensing arrangements or sales of one or more of our technologies or product candidates, we may be required to relinquish valuable rights. For example, any licensing arrangement would likely require us to share a significant portion of any revenues generated by our licensed technologies with our licensees. Additionally, our control over the development of any products or product candidates licensed or sold to third parties may be reduced and thus we may not realize the full value of any such products or product candidates. Debt financings could involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens or make investments and may, among other things, preclude us from making distributions to stockholders (either by paying dividends or redeeming stock) and taking other actions beneficial to our stockholders. In addition, investors could impose more one-sided investment terms and conditions on companies that have or are perceived to have limited remaining funds or limited ability to raise additional funds. The lower our cash balance, the more difficult it is likely to be for us to raise additional capital on commercially reasonable terms, or at all.

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We will need to increase the size of our organization, and we may experience difficulties in attracting and retaining qualified personnel and managing growth.

Currently, we have three full-time employees and one part-time employee and we rely on third parties to perform many essential services for us. We will need to substantially expand our financial, regulatory, research and development, manufacturing, commercial, quality, compliance and other resources in order to manage our operations, submit applications to and respond to inquiries from the FDA, commercialize ANX-530, should it be approved, and continue the development of ANX-514. We do not expect that our current management, personnel, systems and facilities will be adequate to support these activities.

The success of our business will depend, in part, on our ability to attract and retain highly qualified management, commercialization, scientific and other personnel, and on our ability to develop and maintain important relationships with respected service providers and industry-leading consultants and advisors. Competition for these types of personnel and relationships is intense from numerous pharmaceutical and biotechnology companies, universities and other research institutions, particularly in the San Diego, California area. In connection with the cost-cutting measures we implemented in October 2008, January 2009 and March 2009, we eliminated, among others, our scientific staff and our manufacturing and regulatory personnel, who had a deep background in our product candidates and our research and development programs. Recruiting and retaining employees, including senior-level personnel, with relevant product development and commercialization experience in cancer and process development experience with emulsified cytotoxic drugs may be costly and time-consuming. Our ability to provide competitive compensation to our management and other employees may also be adversely affected by our current capital resources and anticipated need to raise additional capital to pursue our business strategy. If we cannot attract and retain additional skilled personnel, we may not achieve our development and commercialization goals. For additional information regarding our need to develop our sales and marketing capabilities, see the risk factor below titled, We currently have no sales or marketing capability and our failure to develop these and related capabilities internally or contract with third parties to perform these activities successfully could delay and/or limit our ability to generate revenues in the event one or more of our product candidates obtains regulatory approval.

We may not be able to manage our business effectively if we are unable to retain key personnel.

We are highly dependent on the expertise and deep background in our product candidates of our chief executive officer and our president and chief operating officer, who currently are the only members of our management team. If we lose one or both of these key employees, our ability to successfully implement our business strategy could be seriously harmed. Replacing these key employees may be difficult and take an extended period of time, particularly due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California area. Our chief executive officer and our president and chief operating officer may terminate their employment with us at any time with or without notice.

If we are unable to raise sufficient additional capital, we may be forced to reduce our current and/or planned development and commercialization activities, partner our product candidates or products at inopportune times or pursue less expensive but higher-risk development and commercialization paths, which we have done in the past.

We expect to need to raise additional capital in order to execute our business plans. If we are not able to raise sufficient additional capital, we may be required to reduce our development and commercialization activities or attempt to continue them by entering into arrangements with partners or others that may not be available on favorable terms, or at all, and may require us to relinquish some or all of our rights to our product candidates or products or the financial benefits thereof. For example, in late 2008, due to an immediate need for additional capital, we discontinued all of our development programs other than with respect to ANX-530 and ANX-514 and limited our activities with respect to ANX-530 and ANX-514 to those we believed necessary to preparing and submitting NDAs for ANX-530 and ANX-514. Going forward, if we do not have sufficient capital, we may determine, for example, not to conduct post-approval clinical studies to support uses of our products in new indications or other label changes intended to expand the scale and scope of market potential for our products.

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The use of our net operating loss carry forwards and research and development tax credits may be limited.

Net operating loss carry forwards and research and development tax credits may expire and not be used. As of December 31, 2009, we had generated federal and state net operating loss carry forwards of approximately $101.4 million and $51.1 million, respectively, and federal and state research and development tax credit carry forwards of approximately $1.8 million and $1.1 million, respectively. Federal net operating loss carry forwards and research and development tax credits have a 20-year carry forward period and California net operating losses have a carry forward period that varies depending on the year such net operating losses are generated. California research and development tax credits carry forward indefinitely. Our federal net operating loss carry forwards will begin to expire in 2020 and our California net operating loss carry forwards will begin to expire in 2012 if we have not used them prior to that time. Our federal research and development tax credits will begin to expire in 2024.

Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, our ability to use any net operating loss carry forwards and research and development credits to offset taxable income in the future may be limited if we have a cumulative change in ownership of more than 50% within a three-year period. We have not completed an analysis to determine whether such a change in ownership has occurred since January 1, 2008, but we believe a change in ownership may have occurred as a result of our equity securities financings in 2009 and/or in January 2010. If such a change in ownership has occurred or were to occur in the future, the amount of our net operating loss carry forwards and research and development tax credits we could utilize annually in the future to offset taxable income could be significantly restricted or eliminated. Inability to fully utilize our net operating loss carry forwards and research and development tax credits could have an adverse impact on our financial position and results of operations.

If we fail to maintain an effective system of internal control over financial reporting and disclosure controls and procedures, we may not be able to accurately report our financial results. As a result, current and potential investors could lose confidence in our financial reporting, which could harm our business and have an adverse effect on our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to annually furnish a report by our management on our internal control over financial reporting. Such report must contain, among other matters, an assessment by our principal executive officer and our principal financial officer on the effectiveness of our internal control over financial reporting, including a statement as to whether or not our internal control over financial reporting is effective as of the end of our fiscal year. This assessment must include disclosure of any material weakness in our internal control over financial reporting identified by management. Performing the system and process documentation and evaluation needed to comply with Section 404 is both costly and challenging. In addition, under current SEC rules, we will be required to obtain an attestation report from our independent registered public accounting firm as to our assessment of the effectiveness of our internal control over financial reporting for our annual report on Form 10-K for the fiscal year ending December 31, 2010, which may require commitment of significant additional financial and managerial resources.

We have in the past discovered, and may in the future discover, areas of internal controls that need improvement. For example, during the fourth quarter of 2008, we discovered that we did not correctly apply generally accepted accounting principles relating to accounting for warrant liability because our accounting staff did not have adequate training or expertise, and determined that we had a material weakness in our internal control over financial reporting as of December 31, 2007. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. For a detailed description of this material weakness and our remediation of this material weakness, see Part II Item 9A(T) Controls and Procedures of our annual report on Form 10-K for the year ended December 31, 2008. If we identify a material weakness in our internal control over financial reporting and/or disclosure controls and procedures in the future, we may not be able to conclude that our internal control over financial reporting and/or our disclosure controls and procedures, as applicable, are effective, and we may need to implement expensive and time-consuming remedial measures. As a result of reductions in our workforce and other personnel departures that occurred in 2008 and 2009, we have experienced substantial turnover in our personnel responsible for performing activities related to our internal control over financial

reporting and disclosure controls and procedures. Since July 2009, our president and chief operating officer, who has no formal education in finance or accounting, has additionally served as our principal financial and principal accounting officer. We have used third-party contractors in an effort to maintain effective internal control over financial reporting and disclosure controls and procedures during this turn-over. However, we cannot be certain that a material weakness will not be identified in the future and if we fail to maintain effective internal control over financial reporting and/or disclosure controls and procedures we could lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on our stock price.

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Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations, including the possibility of human error and circumvention by collusion or overriding of controls. Accordingly, even an effective internal control system may not prevent or detect material misstatements on a timely basis. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

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

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

Risks Related to Drug Development and Commercialization

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

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

To varying degrees based on the regulatory plan for each product candidate, the effect of government regulation and the need for FDA and other regulatory agency approval will delay commercialization of our product candidates, impose costly procedures upon our activities, and put us at a disadvantage relative to larger companies with which we compete. There can be no assurance that FDA or other regulatory approval for any product candidates developed by us will be granted on a timely basis, or at all. For example, despite our including in the December 2009 submission of our ANX-530 NDA data that we believe met the filing requirements for a new drug promulgated by ICH, as well as site-specific stability data from lots manufactured at the intended commercial manufacturing site, we received a refusal-to-file letter from the FDA indicating that the data included in the December 2009 submission was insufficient to support a commercially-viable expiration dating period. Likewise, even though the FDA has confirmed the appropriateness of a Section 505(b)(2) regulatory path for ANX-530 and ANX-514, the FDA s views may change. If the FDA requires the longer-term regulatory approval pathway associated with traditional drug development for ANX-530 and ANX-514, we may determine that the associated time and cost is not financially justifiable and, as a result, discontinue these programs. If we discontinue the development of one or both of these product candidates, our business and stock price may suffer.

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

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

We set goals for and make public statements regarding our estimates of the timing of the accomplishment of objectives material to successful development and commercialization of our product candidates. The actual timing of these events can vary dramatically due to any number of factors, including delays or failures in our nonclinical testing, bioequivalence and clinical trials and manufacturing, regulatory and commercial launch activities and the uncertainties inherent in the regulatory approval process. While our regulatory strategy for ANX-530 and ANX-514 has been to demonstrate the bioequivalence of each to the currently approved reference product in small, bioequivalence trials in humans, we may determine to conduct clinical studies to support uses in new indications or other label changes or for other reasons.

We conduct nonclinical activities in the course of our development programs, including in connection with the manufacture of our product candidates, and in response to requests by regulatory authorities, as well as for other reasons. Delays in our nonclinical activities could occur for a number of reasons, including:

- delays in reaching agreement on acceptable terms with prospective CROs and contract manufacturing organizations, or CMOs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and CMOs;
- failures on the part of our CROs and CMOs in developing procedures and protocols or otherwise conducting activities on timeframes requested by us;
- changes in regulatory requirements or other standards or guidance relating to nonclinical testing, including testing of pharmaceutical products in animals;
- a lack of availability of capacity at our CMOs, or of the component materials, including the API or related materials, including vials and stoppers, necessary to manufacture our product candidates or products; and
- unforeseen results of nonclinical testing that require us to amend study or test designs or delay future testing or bioequivalence or clinical trials and related regulatory filings.

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

- obtaining regulatory approval to commence a trial;
- identifying appropriate trial sites and reaching agreement on acceptable terms with prospective CROs, trial sites and investigators, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and investigators;
- manufacturing sufficient quantities of a product candidate;

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obtaining IRB approval to conduct a trial at a prospective site;

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

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

Even if we complete a planned bioequivalence or clinical trial, we may not achieve our projected development and commercialization goals in the time frames we initially anticipate or announce. For example, although we completed our bioequivalence study of ANX-514 in 2009, the study did not demonstrate bioequivalence between ANX-514 and the reference product based on the FDA s benchmark regulatory standards, resulting in additional uncertainty around the cost and timeline to obtaining FDA approval for ANX-514.

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

failure to conduct the trial in accordance with regulatory requirements or the trial s protocol;

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

unforeseen safety issues; or

lack of adequate funding to continue the trial.

Additionally, changes in regulatory requirements and guidance relating to bioequivalence or clinical trials may occur and we may need to amend trial protocols to reflect these changes. Amendments may require us to resubmit protocols to IRBs for reexamination or renegotiate terms with CROs, trial sites and trial investigators, all of which may impact the costs, timing or successful completion of a trial. Changes may also occur in regulatory requirements relating to the data required to be included in applications at the time of initial submission to the FDA or other regulatory agencies. For example, while we have not yet met with the FDA to discuss the refusal-to-file letter we announced in March 2010 that we had received regarding our December 2009 ANX-530 NDA submission, we believe a change in regulatory policy, which may not have been formalized or publicly disseminated, may have been a factor underlying the FDA s refusal to file our NDA submission.

There can be no assurance that our nonclinical testing and bioequivalence and/or clinical trials will commence or be completed, that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our current schedule for the development or commercialization of any of our product candidates. For example, in March 2010, we announced that we had received a refusal-to-file letter from the FDA regarding our ANX-530 NDA submission. While we have not met with the FDA to discuss the refusal-to-file letter, we expect the FDA will require additional stability data to accept our application, which data will take time and is costly to generate. If we experience delays in completion of, or if we terminate, our bioequivalence or clinical trials or nonclinical testing, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of bioequivalence or clinical trials or nonclinical testing may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same indications may have been introduced to the market in the interim and established a competitive advantage.

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

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through nonclinical testing and bioequivalence or clinical trials that each product is safe and effective for use in each target indication. Success in nonclinical testing and/or bioequivalence trials does not ensure that subsequent or large-scale trials will be successful. Additionally, throughout development, we must provide adequate assurance to the FDA and other regulatory authorities that we can consistently produce our product candidates in conformance with current good manufacturing practices, or cGMP, and other regulatory standards. Bioequivalence and clinical trial results are frequently susceptible to varying interpretations and regulatory authorities may disagree on what are appropriate methods for analyzing data, which may delay, limit or prevent regulatory approvals. For instance, with respect to our bioequivalence trial of ANX-530, the FDA may perform its bioequivalence analysis based on a patient population other than the population on which we based our analysis, which may result in the FDA determining that ANX-530 and Navelbine are not bioequivalent, requiring that we evaluate additional patients, re-perform the study or take other remedial action. In addition, because we are using a different third-party manufacturer for the commercial manufacture of ANX-530 than we used for the manufacture of the ANX-530 used in our bioequivalence trial and certain changes were required in transferring the manufacturing process, the FDA may require us to perform additional nonclinical or clinical studies before accepting our ANX-530 NDA or approving ANX-530 for marketing and sale in the U.S. Further, the ANX-530 bioequivalence trial was open-label, meaning physician-investigators, as well as patients, may have been aware of which drug was being administered. There is a risk of investigator bias in reporting adverse events as a result of the study s open-label nature, including bias that may have increased the reporting of adverse events associated with Navelbine and/or decreased the reporting of adverse events associated with ANX-530.

With respect to ANX-514, despite positive nonclinical testing that indicated bioequivalence between ANX-514 and the reference product, our bioequivalence trial of ANX-514 did not demonstrate bioequivalence between ANX-514 and the reference product based on the FDA s benchmark regulatory standards. In addition, the FDA may inquire regarding the manufacturing source, in-process and product release specifications and overall uniformity of reference product used in the bioequivalence trial of ANX-514, particularly since it was conducted at sites in multiple countries, and we may be unable to provide documentation satisfactory to the FDA with respect to such reference product, which may result in the FDA requiring that we evaluate additional patients, re-perform the study or take other remedial measures. Further, we have licensed certain rights to ANX-514 to a third party and have limited control over any nonclinical or clinical studies such third party, or a future third-party licensee, may conduct. If data from investigations of ANX-514 sponsored by a third-party licensee identify a safety or efficacy concern with respect to ANX-514, or the lack of comparable pharmacokinetics between ANX-514 and Taxotere, such data could have an adverse effect on the U.S. regulatory process.

The length of time necessary to complete bioequivalence or clinical trials and manufacturing development work and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and is difficult to predict accurately. For instance, with respect to ANX-514, the form of API used in the manufacture of ANX-514 for purposes of our bioequivalence study of ANX-514 will not be the same form of API used in the manufacture of ANX-514 for purposes of process validation batches or commercial supply. To ensure the comparability of the ANX-514 used in the bioequivalence study and the ANX-514 intended for commercial sale, the FDA may require that we evaluate both forms of ANX-514 in additional patients, re-perform the bioequivalence study or take other remedial actions. We may have insufficient quantities of both forms of ANX-514 and could incur substantial cost and delay in acquiring such quantities, in addition to the time and expense associated with conducting the evaluation, re-performing the study or taking other remedial measures.

In addition, delays or rejections may be encountered based upon changes in FDA policy for drug approval during the period of product development and FDA regulatory review of each submitted NDA. For example, while we have not yet met with the FDA to discuss the refusal-to-file letter we announced in March 2010 that we had received regarding our December 2009 ANX-530 NDA submission, we believe a change in regulatory policy, which may not have been

formalized or publicly disseminated, may have been a factor underlying the FDA s refusal to file our NDA submission. There is a significant risk that any of our product candidates could fail to show anticipated results in human trials, as was the case in our bioequivalence study of ANX-514, or manufacturing development, and, as a result, we may not continue their development. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope requested will delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

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

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

In addition, any third parties with which we establish marketing, distribution or sales arrangements may have significant control over important aspects of the commercialization of our products, including market identification, marketing methods, pricing, composition of sales force and promotional activities. If we retain third-party service providers to perform functions related to the sale and distribution of our products, key aspects of those functions that would be out of our direct control could include warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management. In this event, we would place substantial reliance on third-party providers to perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter natural or other disasters at their facilitates, our ability to deliver product to meet commercial demand could be significantly impaired. In addition, we may use third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to enter into or maintain commercial arrangements for these services on reasonable timelines or terms, or at all. Even if we are successful in establishing and maintaining these arrangements, there can be no assurance that we will be able to control the amount and timing of resources that any third party may devote to our products or prevent any third party from pursuing alternative technologies or products that could result in the development of products that compete with, or the withdrawal of support for, our products.

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

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

- our product s perceived advantages over existing treatment methods (including relative convenience and ease of administration and prevalence and severity of any adverse side effects);
- claims or other information (including limitations or warnings) in our product s approved labeling;
- the resources we devote to marketing our products and restrictions on promotional claims we can make with respect to our products;
- reimbursement and coverage policies of government and other third-party payors;
- pricing and cost-effectiveness;

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

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

availability of alternative treatments; and

the prevalence of off-label substitution of chemically equivalent products or alternative treatments.

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

In addition, FDA approval of our product candidates pursuant to a Section 505(b)(2) regulatory strategy, which is the strategy we currently are pursuing for ANX-530, may limit our ability to differentiate our products from competitor products since the basis of such strategy is the bioequivalence of our products to the reference products, unless the FDA allows us to include certain data in our products labels. Even if our products demonstrate clinical or pharmacoeconomic benefits relative to competing products, we may be unable to market our products based on these benefits.

If we fail to obtain a unique HCPCS product code for ANX-530, it is unlikely we will be able to sell that product at a price that exceeds its manufacturing, marketing and distribution costs. Even if we obtain unique HCPCS product codes for our products, if our products are perceived to provide little or no advantage relative to competing products or for other reasons, we may be required to price our products at levels that do not cover our costs to manufacture, market and distribute the products or provide any profit, or to price our products at levels at which they are not competitive.

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

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

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

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Even if we successfully establish a long-term relationship with our current CMO for ANX-530 on commercially acceptable terms, that CMO may be unable to successfully and consistently manufacture ANX-530 at commercial scale. Both us and our current CMO have limited experience manufacturing ANX-530. Because data from a single bioequivalence trial of ANX-530 may be sufficient to support approval of the ANX-530 NDA, our and our current CMO s ability to gain experience manufacturing ANX-530, in particular at various scales, has been limited. If our current CMO is unable to manufacture ANX-530 successfully and consistently at commercial scale and within established parameters, we may be unable to validate our manufacturing process, even if the FDA otherwise would approve our NDA, and we would therefore be unable to sell ANX-530. Both us and our current CMO have similarly limited experience with ANX-514.

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

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

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

If any of our product candidates should be approved, any problems or delays experienced in their manufacturing processes may impair our ability to provide commercial quantities of the products, which would limit our ability to sell the products and would adversely affect our business. It could take significant time to redesign our manufacturing processes or identify alternative suppliers in response to problems we may encounter as we manufacture our products, if such alternative processes and suppliers are available at all. Even if we are able to identify alternative suppliers, they may be unwilling to manufacture our products on commercially reasonable terms. Neither ANX-530 nor ANX-514 have been manufactured at the scales we believe will be necessary to maximize their commercial value to us and, accordingly, we may encounter difficulties in production while scaling-up initial production and may not succeed in scaling-up initial production.

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Any new supplier of products or component materials, including API, would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such products or ingredients. The FDA may require us to conduct additional bioequivalence or clinical trials, collect stability data and provide additional information concerning any new supplier, or change in a validated manufacturing process, before we could distribute products from that supplier or revised process. For example, if FDA requires substantial stability or other data from the new manufacturer, which data will take time and is costly to generate, it could cause interruptions in our ability to meet commercial demand, if any.

In addition, obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new supplier to bear significant additional costs which may be passed on to us.

We rely significantly on third parties to conduct our nonclinical testing and bioequivalence and clinical studies and other aspects of our development programs and if those third parties do not satisfactorily perform their contractual obligations or meet anticipated deadlines, the development of our product candidates could be adversely affected.

We do not employ personnel or possess the facilities necessary to conduct many of the activities associated with our programs, particularly since we implemented severe cost-cutting measures in late 2008 and early 2009. We engage consultants, advisors, CROs, CMOs and others to design, conduct, analyze and interpret the results of nonclinical tests and bioequivalence and clinical studies in connection with the research and development of our product candidates. As a result, many important aspects of our product candidates development are outside our direct control. There can be no assurance that such third parties will perform all of their obligations under arrangements with us or will perform those obligations satisfactorily.

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

For instance, we lack the internal capabilities to fully analyze the data from our bioequivalence study of ANX-514 and rely on multiple third-party consultants to help us interpret and understand the data. Because of the impact different analyses of the data may have on our business, we believe an employee likely would approach the data and analysis in a substantially more rigorous, thoughtful and creative manner than a consultant or contractor.

If we receive regulatory approval for one or more of our product candidates, we may face competition from generic products, which could exert downward pressure on the pricing and market share of our products and limit our ability to generate revenues.

Many of the currently marketed and anticipated products against which our product candidates may compete are, or we anticipate will be, available as generics. For instance, ANX-530 will compete against Navelbine, for which generic equivalents are already available. ANX-514 will compete against Taxotere. We anticipate that ANX-514 will also compete against other formulations of docetaxel and that generic equivalents of Taxotere will enter the market in November 2013 or May 2014 (depending on whether a period of pediatric exclusivity is granted in the future), or sooner if manufacturers of generic equivalents of Taxotere prevail in current or any future patent infringement litigation resulting from their assertions in certifications to the FDA that their products will not infringe any unexpired Taxotere patents or that such unexpired patents are invalid. Even if we obtain unique HCPCS product codes for our products, the existence of generic products could make it more difficult for our branded products, to gain or maintain market share and could cause prices for our products to drop, each of which could adversely affect our business.

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If we receive regulatory approval for one or more of our product candidates, we may face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products.

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

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

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

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing bioequivalence or clinical trials;
- refuse to approve pending applications or supplements to approved applications;
- impose restrictions or affirmative obligations on our or our CMO s operations, including costly new manufacturing requirements;
- close the facilities of a CMO; or
- seize or detain products or require a product recall.

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

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. In particular, other countries may not have a comparable regulatory procedure as is available under Section 505(b)(2) of FDCA. Even if a country did have a comparable procedure, that country may require a more robust data package than the bioequivalence data package that we submitted in support of the ANX-530 NDA. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S., as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that our

product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

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

Undesirable side effects caused by our product candidates could interrupt, delay or halt bioequivalence or clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale.

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

- regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;
- regulatory authorities may withdraw their approval of the product;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; and
- our reputation may suffer.

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

Risks Related to Our Intellectual Property

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

Our success will depend in part on our ability to:

- obtain and maintain patent protection with respect to our products;
- prevent third parties from infringing upon our proprietary rights;
- maintain trade secrets;
- operate without infringing upon the patents and proprietary rights of others; and
- obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, both in the U.S. and in foreign countries.

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

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

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

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

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

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

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

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

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

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

- infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert our management s attention from our core business;
- substantial damages for infringement, including the potential for treble damages and attorneys fees, which we may have to pay if a court decides that the product at issue infringes on or violates the third party s rights;
- a court prohibiting us from selling or licensing the product unless the third party licenses its product rights to us, which it may not be required to do;
- if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross-licenses to our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial funds and time.

No assurance can be given that patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering our products, technology or methods or those of our CMOs or component material suppliers. Because of the number of patents issued and patent applications filed in the pharmaceutical industry, we believe there is a risk that third parties may allege they have patent rights encompassing our products, technology or methods or those of our CMOs or component material suppliers.

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

RISKS RELATED TO OUR INDUSTRY

We expect intense competition in the marketplace for each of our products, if any are approved.

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

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

In particular, 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 eight approved generic versions of vinorelbine. In addition, there is an oral formulation of vinorelbine approved for use in the EU against which we would compete if our emulsion formulation of vinorelbine were approved for use in the EU. 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 (but subject to any period of pediatric exclusivity that may be granted in the future), patent protection ends for Taxotere. We are aware of three 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 or that such unexpired patents are invalid or unenforceable. In addition, a fourth company has submitted an application seeking approval of a generic equivalent of Taxotere and has certified that, after May 2010, its product will not infringe any unexpired Taxotere patents or that such unexpired patents are invalid or unenforceable.

With respect to ANX-530, because we submitted the ANX-530 NDA with only bioequivalence data, our ability to differentiate ANX-530 from competing products will be limited. Even if we believe ANX-530 has demonstrated clinical or pharmacoeconomic benefits relative to competing products, we may be unable to market it based on these benefits. If our products fail to obtain unique HCPCS product 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.

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

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

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

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

- our ability to set a price we believe is fair for our products;
- our ability to generate revenues or achieve or maintain profitability;
- the future revenues and profitability of our potential customers, suppliers and collaborators; and
- the availability to us of capital.

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If we are successful in obtaining FDA approval for ANX-530, we will compete with Navelbine and several generic equivalents of Navelbine. Our ability to commercialize ANX-530 will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish what we believe are appropriate coverage and reimbursement levels for the cost of our products and related treatments. These payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement, particularly for new therapeutic products or if there is a perception that the target indication of the new product is well-served by existing drugs or other treatments. Accordingly, even if coverage and reimbursement are provided, market acceptance of our products would be adversely affected if the amount of coverage and/or reimbursement available for the use of our products proved to be unprofitable for healthcare providers or less profitable than alternative treatments.

There have been federal and state proposals to subject the pricing of healthcare goods and services to government control and to make other changes to the U.S. healthcare system. While we cannot predict the outcome of current or future legislation, we anticipate, particularly given President Obama s focus on healthcare reform, that Congress and state legislatures will introduce initiatives directed at lowering the total cost of healthcare. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain if future legislative proposals, whether domestic or abroad, will be adopted that might affect our products or product candidates or what actions federal, state, or private payors for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Any such healthcare reforms could have a material and adverse effect on the marketability of any products for which we ultimately receive FDA or other regulatory agency approval.

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

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

- decreased demand for our products;
- impairment of our business reputation;
- withdrawal of bioequivalence or clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our products and product candidates.

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

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

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RISKS RELATED TO OUR COMMON STOCK

We currently are not in compliance with NYSE Amex continued listing standards and are at risk of being delisted from the NYSE Amex equities market.

Our common stock currently is listed on the NYSE Amex. The NYSE Amex normally will consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders equity of less than $6.0 million if such issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. In addition, the NYSE Amex will normally consider suspending dealings in, or removing from the list, securities selling for a substantial period of time at a low price per share if the issuer fails to effect a reverse split of such stock within a reasonable time after being notified that the NYSE Amex deems such action to be appropriate under the circumstances. Since October 1, 2007 through the date hereof, the closing price of a share of our common stock has been less than $1.00.

In June 2009, we have received notice from the NYSE Amex staff that we are not in compliance with certain stockholders equity continued listing standards. Specifically, the NYSE Amex staff has noted that we are not in compliance with (1) Section 1003(a)(ii) of the NYSE Amex Company Guide, or the Company Guide, because we reported stockholders equity of less than $4,000,000 and losses from continuing operations and net losses in three of our four most recent fiscal years, or (2) Section 1003(a)(iii) of the Company Guide because we reported stockholders equity of less than $6,000,000 and losses from continuing operations and net losses in our five most recent fiscal years. In addition, the NYSE Amex staff notified us, in accordance with Section 1003(f)(v) of the Company Guide, that it deems it appropriate for us to effect a reverse stock split of our common stock to address its low selling price per share, and that if a reverse stock split is not completed within a reasonable amount of time after June 1, 2009, the NYSE Amex may consider suspending dealings in, or removing from the list, our common stock.

To maintain the listing of our common stock on the NYSE Amex, the NYSE Amex required us to submit a plan advising the exchange of the actions we have taken, or will take, to regain compliance with Sections 1003(a)(ii) and (iii) of the Company Guide by December 1, 2010. On July 1, 2009, we submitted a plan to attempt to resolve our listing deficiencies and regain compliance with the continued listing requirements. On July 31, 2009, the NYSE Amex staff notified us that it determined that our plan makes a reasonable demonstration of our ability to regain compliance with the NYSE Amex s continued listing standards and determined to grant us an extension, until December 1, 2010, for us to regain compliance with the NYSE Amex s continued listing standards. During this extension period, we will be subject to periodic review to determine whether we are making progress consistent with our plan. If we do not show progress consistent with our plan, the NYSE Amex staff will review the circumstances and may immediately commence delisting proceedings. As of December 31, 2009, our stockholders equity was approximately $6.7 million, which meets the NYSE Amex s stockholders equity continued listing standards. However, we have not received notice from the NYSE Amex staff that we have regained compliance with the NYSE Amex s continued listing standards.

The delisting of our common stock from the NYSE Amex likely would reduce the trading volume and liquidity in our common stock and may lead to further decreases in the trading price of our common stock. The delisting of our common stock may also materially impair our stockholders ability to buy and sell shares of our common stock. In addition, the delisting of our common stock could significantly impair our ability to raise capital, which is critical to the execution of our business strategy.

If our common stock were delisted and determined to be a penny stock, a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock in the secondary market.

If our common stock were removed from listing with the NYSE Amex, it may be subject to the so-called penny stock rules. The SEC has adopted regulations that define a penny stock to be any equity security that has a market price per share of less than $5.00, subject to certain exceptions, such as any securities listed on a national securities exchange. For any transaction involving a penny stock, unless exempt, the rules impose additional sales practice requirements on broker-dealers, subject to certain exceptions. If our common stock were delisted and determined to be a penny stock, a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market.

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

The market price for our common stock historically has been highly volatile, and the market for our common stock has from time to time experienced significant price and volume fluctuations that are unrelated to our operating performance. For instance, on October 1, 2007, the market price for our common stock dropped almost 80% following our announcement of the results of our phase 2b clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. Conversely, the market price for our common stock more than doubled over two trading days in late December 2009. The market price of our common stock may fluctuate significantly in response to a number of factors, including:

- the level of our financial resources;
- announcements of entry into or consummation of a financing or strategic transaction;
- changes in the regulatory status of our product candidates, including results of any bioequivalence and clinical trials and other research and development programs;
- FDA or international regulatory actions and regulatory developments in the U.S. and foreign countries;
- announcements of new products or technologies, commercial relationships or other events (including bioequivalence and clinical trial results and regulatory events and actions) by us or our competitors;
- market conditions in the pharmaceutical, biopharmaceutical, specialty pharmaceutical and biotechnology sectors;
- developments concerning intellectual property rights generally or those of us or our competitors;
- litigation or public concern about the safety of our products or product candidates;
- changes in securities analysts estimates of our financial performance or deviations in our business and the trading price of our common stock from the estimates of securities analysts;
- events affecting any future collaborations, commercial agreements and grants;
- fluctuations in stock market prices and trading volumes of similar companies;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders or pursuant to shelf or resale registration statements that register shares of our common stock that may be sold by certain of our current or future stockholders;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- commencement of delisting proceedings by the NYSE Amex;
- additions or departures of key personnel; and
- changes in third-party payor reimbursement policies.

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

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

The market price of our common stock could decline as a result of sales by, or the perceived possibility of sales by, us or our existing stockholders of shares of our common stock. These sales by our existing stockholders might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate. In addition, our currently effective resale registration statements on Form S-3 and registration statement on Form S-1 register a significant number of shares of our common stock and securities convertible into our common stock that may be sold by us or certain of our stockholders, which may increase the likelihood of sales by, or the perception of an increased likelihood of sales by, us or our existing stockholders of shares of our common stock.

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

We are incorporated in Delaware. Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change in control would be beneficial to our stockholders. Our bylaws limit who may call a special meeting of stockholders and establish advance notice requirements for nomination of individuals for election to our board of directors or for proposing matters that can be acted upon at stockholders meetings. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors may use these provisions to prevent changes in the management and control of our company. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future. In addition, provisions of certain compensatory contracts with our management, such as equity award agreements with our executive officers, may have an anti-takeover effect by resulting in accelerated vesting of outstanding equity securities held by these officers. In particular, in the event of a change in control, the vesting of options we granted in July 2009 and January 2010 to our current executives will accelerate with respect to fifty percent of the then unvested shares on the day prior to the date of the change in control and, subject to the respective executive s continuous service, with respect to the remaining fifty percent of the then unvested shares on the one year anniversary of the date of the change in control. As a result, if an acquirer desired to retain the services of one or both of our current executives following an acquisition, it may be required to provide additional incentive to them, which could increase the cost of the acquisition to the acquirer and may deter or affect the terms of the acquisition or potential acquisition.

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

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

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

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Item 1B. Unresolved Staff Comments

We do not have any unresolved comments issued by the SEC Staff.

Item 2. Properties

Our offices are located at 6725 Mesa Ridge Road, San Diego, California 92121. During 2009, our offices consisted of 3,173 square feet of office space, which we used pursuant to a lease that was set to expire on May 31, 2010. The average base rent for this space was approximately $4,400 per month. On December 2009, we amended the lease to extend its term for an additional eight months (i.e., from June 1, 2010 through January 31, 2011). During February 2010, we further amended the lease to lease adjacent office space, consisting of 5,133 square feet, through January 31, 2011, and to terminate our obligations with respect to the office space we were then occupying, effective March 1, 2010. The average base rent for our new space, beginning March 2010, is $7,200 per month. In 2009, because we had significantly down-sized our operations, 3,173 square feet of office space was adequate for our operations. We determined to re-locate to the larger, adjacent office space in February 2010 because, as we began to rebuild our organizational infrastructure, the smaller office space became inadequate for our current and anticipated near-term operations.

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. We are not currently a party to any material pending litigation or other material legal proceeding.

Item 4. [Reserved]

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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. 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			
	2009		2008	
	High	Low	High	Low
First Quarter	$ 0.18	$ 0.09	$ 0.64	$ 0.36
Second Quarter	$ 0.22	$ 0.11	$ 0.54	$ 0.33
Third Quarter	$ 0.20	$ 0.12	$ 0.38	$ 0.18
Fourth Quarter	$ 0.43	$ 0.09	$ 0.21	$ 0.07

As of March 1, 2010, we had approximately 159 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 common stock and do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. In addition, in connection with previous preferred stock financings, we have agreed to charter restrictions on our ability to pay cash dividends or distributions on our common stock for so long as any shares of such preferred stock are outstanding, unless we obtain prior written consent from the holders of such preferred stock, and we may agree to similar restrictions in the future.

We expect to retain all available funds and any future earnings 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

On June 12, 2009, in connection with the closing of our registered direct offering of convertible preferred stock and warrants to purchase common stock, we issued to Rodman & Renshaw, LLC, as partial consideration for its services as placement agent, warrants to purchase an aggregate of up to 901,810 shares of our common stock at an exercise price of $0.15 per share. The warrants became exercisable on December 13, 2009 and may be exercised at any time on or before June 12, 2014.

On July 6, 2009, in connection with the closing of our registered direct offering of convertible preferred stock, we issued to Rodman & Renshaw, LLC, as partial consideration for its services as placement agent, warrants to purchase an aggregate of up to 475,209 shares of our common stock at an exercise price of $0.179 per share. The warrants became exercisable on January 7, 2010 and are exercisable at any time on or before July 6, 2014.

On August 10, 2009, in connection with the closing of our registered direct offering of convertible preferred stock, we issued to Rodman & Renshaw, LLC, as partial consideration for its services as placement agent, warrants to purchase an aggregate of up to 354,615 shares of our common stock at an exercise price of $0.1625 per share. The warrants became exercisable on February 10, 2010 and are exercisable at any time beginning on or before August 10, 2014.

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On October 9, 2009, in connection with the closing of our registered direct offering of convertible preferred stock and warrants to purchase common stock, we issued to Rodman & Renshaw, LLC, as partial consideration for its services as placement agent, warrants to purchase an aggregate of up to 3,600,000 shares of our common stock at an exercise price of $0.235 per share. The warrants are exercisable at any time on or after April 7, 2010 and on or before October 6, 2014.

On January 7, 2010, in connection with the closing of our registered direct offering of convertible preferred stock and warrants to purchase common stock, we issued to Rodman & Renshaw, LLC, as partial consideration for its services as placement agent, warrants to purchase an aggregate of up to 2,492,457 shares of our common stock at an exercise price of $0.4765 per share. The warrants are exercisable at any time on or after July 7, 2010 and on or before June 3, 2014.

The warrants described above were offered and sold by us in reliance upon exemptions from the registration statement requirements by Section 4(2) of the Securities Act of 1933, as amended, as transactions by an issuer not involving a public offering.

Item 6. Selected Financial Data

Under SEC rules and regulations, as a smaller reporting company we are not required to provide the information required by this item.

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 Item 1A Risk Factors in this report.

Overview

We are a development-stage specialty pharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. We seek to improve the performance of existing drugs by addressing limitations associated principally with their safety and use. Our lead product candidates, ANX-530 (vinorelbine emulsion) and ANX-514 (docetaxel emulsion), are novel emulsion formulations of currently marketed chemotherapy drugs.

We have devoted substantially all of our resources to research and development, or R&D, or to acquisition of our product candidates, including our CoFactor program, with respect to which we discontinued all active work in October 2008. We have not yet marketed or sold any products or generated any significant revenue. We have incurred annual net losses since inception. We had an operating net loss of $11.3 million for the year ended December 31, 2009 and cash of approximately $8.7 million and working capital of $6.6 million at December 31, 2009.

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In March 2009, we announced that we and our wholly-owned subsidiary, SD Pharmaceuticals, Inc., entered into a license agreement with respect to ANX-514 with Shin Poong Pharmaceutical Co., Ltd., a company organized under the laws of the Republic of Korea, 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 received an upfront licensing fee of $0.3 million in April 2009 (which we recognized as licensing revenue in the three-month period ended March 31, 2009 because we met the criteria under our revenue recognition policy in that period), a regulatory milestone payment of either $0.2 million or $0.4 million (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, a one-time commercial milestone payment tied to annual net sales of licensed products in an aggregate amount of up to $1.5 million 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 $0.1 million.

Following the completion of our June 2009 financing (discussed below under Recent Financings), we re-started certain development activities that we had suspended in March 2009 to conserve cash while we evaluated strategic options, pursued financing alternatives and considered whether to liquidate our assets and wind-up our operations. Specifically, we re-started the final manufacturing activities related to a new drug application, or NDA, for ANX-530, which we submitted to the U.S. Food and Drug Administration, or FDA, in December 2009. In March 2010, we announced that we had received a refusal-to-file letter from the FDA regarding our ANX-530 NDA submission. In the letter, the FDA indicated that the data included in our December 2009 ANX-530 NDA submission from the intended commercial manufacturing site was insufficient to support a commercially-viable expiration dating period. The FDA identified only this one chemistry, manufacturing and controls, or CMC, reason for the refusal to file. We have requested a face-to-face meeting with the FDA to understand its requirements and define the path to a successful filing of the ANX-530 NDA at the earliest possible time. In addition, we expect to meet with the FDA in the summer of 2010 to discuss the results of our bioequivalence study of ANX-514, following which we will provide an update on planned activities with respect to, or a potential NDA submission timeline for, ANX-514.

We anticipate that our cash as of December 31, 2009, together with the net proceeds from the equity financing we completed in January 2010, will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, we may pursue development activities at levels or on timelines, or we may incur unexpected expenses, that shorten the period through which our operating funds will sustain us. In addition, we may need to raise substantial additional capital to support activities that we believe will enhance the value of our product development programs and increase stockholder value. There can be no assurances that we will be able to obtain additional financing on a timely basis, or at all.

Recent Financings

In June 2009, we completed a registered direct equity financing raising gross proceeds of approximately $2.0 million involving the issuance of 1,993 shares of our 0% Series A Convertible Preferred Stock with a stated value of $1,000 per share, or our Series A Stock, and 5-year warrants to purchase up to an aggregate of 8,116,290 shares of our common stock. In the aggregate, the shares of Series A Stock we issued are convertible into 18,036,199 shares of our common stock. We received approximately $1.7 million in net proceeds from the financing, after deducting the placement agent s fees and expenses and other offering expenses. In December 2009, in connection with the exercise of warrants issued in the June 2009 financing, we issued 6.0 million shares of our common stock and received net proceeds of $0.9 million. In January 2010, in connection with the exercise of warrants issued in the June 2009 financing, we issued an additional 2,116,290 shares of our common stock and received an additional $0.3 million of net proceeds. All of the shares of our Series A Stock and warrants to purchase shares of our common stock issued in the June 2009 financing have been converted or exercised and are no longer outstanding. In connection with the

June 2009 financing, we also issued warrants to purchase up to 901,810 shares of our common stock at an exercise price of $0.15 per share to the placement agent in the financing as additional consideration for its services. The placement agent s warrants became exercisable on December 13, 2009 and may be exercised at any time on or before June 12, 2014.

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In July 2009, we completed a registered direct equity financing raising gross proceeds of approximately $1.4 million involving the issuance of 1,361 shares of our 5% Series B Convertible Preferred Stock with a stated value of $1,000 per share, or our Series B Stock. In the aggregate, the shares of Series B Stock we issued are convertible into 9,504,189 shares of our common stock. Our Series B Stock accrues a cumulative annual dividend of 5% per share until July 6, 2014, and no dividend thereafter. If our Series B Stock is converted at any time prior to July 6, 2014, we will pay the holder an amount equal to the total dividend that would have accrued in respect of the shares converted from the conversion date through July 6, 2014, or $250 per $1,000 of stated value of the shares converted, less any previous dividend paid on such shares before conversion. We received approximately $0.8 million in net proceeds from the July 2009 financing after deducting the $340,250 we placed into an escrow account to pay the aggregate dividend payment in respect of our Series B Stock, placement agent s fees and expenses and other offering expenses. All of the shares of our Series B Stock have been converted into common stock and are no longer outstanding. In connection with the July 2009 financing, we also issued warrants to purchase up to 475,209 shares of our common stock at an exercise price of $0.179 per share to the placement agent in the financing as additional consideration for its services. The placement agent s warrants became exercisable on January 7, 2010 and may be exercised at any time on or before July 6, 2014.

In August 2009, we completed a registered direct equity financing raising gross proceeds of approximately $0.9 million involving the issuance of 922 shares of our 5% Series C Convertible Preferred Stock with a stated value of $1,000 per share, or our Series C Stock. In the aggregate, the shares of Series C Stock we issued are convertible into 7,092,307 shares of our common stock. Our Series C Stock accrues a cumulative annual dividend of 5% per share until February 10, 2012, and no dividend thereafter. If our Series C Stock is converted at any time prior to February 10, 2012, we will pay the holder an amount equal to the total dividend that would have accrued in respect of the shares converted from the conversion date through February 10, 2012, or $125 per $1,000 of stated value of the shares converted, less any previous dividend paid on such shares before conversion. We received approximately $0.7 million in net proceeds from the August 2009 financing after deducting the $115,250 we placed into an escrow account to pay the aggregate dividend payment in respect of our Series C Stock, placement agent s fees and expenses and other offering expenses. All of the shares of our Series C Stock have been converted into common stock and are no longer outstanding. In connection with the August 2009 financing, we also issued warrants to purchase up to 354,615 shares of our common stock at an exercise price of $0.1625 per share to the placement agent in the financing as additional consideration for its services. The placement agent s warrants became exercisable on February 10, 2010 and are exercisable at any time on or before August 10, 2014.

In October 2009, we completed a registered direct equity financing raising gross proceeds of approximately $11.3 million involving the issuance of 11,283 shares of our 4.25660% Series D Convertible Preferred Stock with a stated value of $1,000 per share, or our Series D Stock, and 5-year warrants to purchase up to an aggregate of 19,800,000 shares of our common stock. In the aggregate, the shares of Series D Stock we issued are convertible into 60,000,000 shares of our common stock. Our Series D Stock accrues a cumulative annual dividend of 4.25660% per share until October 9, 2020, and no dividend thereafter. If our Series D Stock is converted at any time prior to October 9, 2020, we will pay the holder an amount equal to the total dividend that would have accrued in respect of the shares converted from the conversion date through October 9, 2020, or $468.23 per $1,000 of stated value of the shares converted, less any previous dividend paid on such shares before conversion. We received approximately $5.1 million in net proceeds from the October 2009 financing after deducting the approximately $5.3 million we placed into an escrow account to pay the aggregate dividend payment in respect of our Series D Stock, placement agent s fees and expenses and other estimated offering expenses. All of the shares of our Series D Stock have been converted into common stock and are no longer outstanding. In December 2009, in connection with the exercise of warrants issued in the October 2009 financing, we issued 14.4 million shares of our common stock and received net proceeds of $2.1 million. We may receive up to an additional $0.8 million of net proceeds from the exercise of the remaining warrants issued in the October 2009 financing. Those warrants, which have an exercise price of $0.1468 per share, are exercisable any time on or before October 9, 2014, subject to certain beneficial ownership limitations. In connection with the October 2009 financing, we also issued warrants to purchase up to 3,600,000 shares of our common stock at an exercise price of $0.235 per share to the placement agent in the financing as additional

consideration for its services. The placement agent s warrants are exercisable at any time on or after April 7, 2010 and on or before October 6, 2014.

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On January 7, 2010, we completed a registered direct equity financing raising gross proceeds of $19.0 million involving the issuance of 19,000 shares of our 3.73344597664961% Series E Convertible Preferred Stock with a stated value of $1,000 per share, or our Series E Stock, and 30-month warrants to purchase up to an aggregate of 12,462,285 shares of our common stock. In the aggregate, the shares of Series E Stock we issued are convertible into 49,849,141 shares of our common stock. Our Series E Stock accrues a cumulative annual dividend of 3.73344597664961% per share until January 7, 2015, and no dividend thereafter. If our Series E Stock is converted at any time prior to January 7, 2015, we will pay the holder an amount equal to the total dividend that would have accrued in respect of the shares converted from the conversion date through January 7, 2015, or $186.67 per $1,000 of stated value of the shares converted, less any previous dividend paid on such shares before conversion. We received approximately $14.0 million in net proceeds from the financing after deducting the approximately $3.5 million we placed into an escrow account to pay the aggregate dividend payment in respect of our Series E Stock, placement agent s fees and expenses and other estimated offering expenses. All of the shares of our Series E Stock have been converted into common stock and are no longer outstanding. We may receive up to approximately $4.4 million of additional proceeds from the exercise of the warrants issued in the January 2010 financing. Those warrants, which have an exercise price of $0.3499 per share, are exercisable any time on or before July 6, 2012, subject to certain beneficial ownership limitations. In connection with the January 2010 financing, we also issued warrants to purchase up to 2,492,457 shares of our common stock at an exercise price of $0.4765 per share to the placement agent in the financing as additional consideration for its services. The placement agent s warrants are exercisable at any time on or after July 7, 2010 and on or before June 3, 2014.

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 financial statements requires management to make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses in these 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 share-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 may enter into revenue arrangements that contain multiple deliverables. In these cases, 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) collectability 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 the license term commences and the revenue recognition criteria are met. 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 the underlying work is performed. 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 is incorporated into products that, or such product candidates, are approved for marketing by the FDA or when other significant risk factors are abated. For accounting purposes, management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain.

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Payments in connection with our bioequivalence and clinical trials are often made under contracts with multiple contract research organizations 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 trial 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. We adopted the Financial Accounting Standards Board s, or FASB s, changes to ASC 805, Business Combinations, effective January 1, 2009. The adoption of the changes to ASC 805 did not have a material effect on our consolidated results of operations or financial position. In accordance with previous accounting guidance effective through December 31, 2008, we accounted for the costs associated with any purchased in-process research and development, or IPR&D, as an expense on the 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.

Share-based Compensation Expenses. Effective January 1, 2006, we account for share-based compensation awards granted to employees, including non-employee members of our board of directors, in accordance with ASC 718, Compensation Stock Compensation. Share-based compensation expense 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 share-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. Although estimates of share-based compensation expenses are significant to our consolidated financial statements, they are not related to the payment of any cash by us.

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

We account for share-based compensation awards granted to non-employees by determining the fair value of the share-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured using the share price and other measurement assumptions as of the earlier 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.

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Income Taxes. We account for income taxes and the related accounts under the liability method in accordance with ASC 740, Income Taxes. 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.

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.

Costs Associated with Exit or Disposal Activities. As part of our efforts to reduce operating costs, we completed the following three work force reductions since the end of the third quarter of 2008, each of which was accounted for in accordance with ASC 420, Exit or Disposal Cost Obligations:

In October 2008, we completed a work force reduction of nine employees. As a result, we recorded severance-related charges including salary, payroll taxes and health benefits of $403,000, of which approximately $384,000 was recorded in R&D and the remainder in selling, general and administrative, or SG&A. In connection with the October 2008 reduction in workforce, severance-related charges of $244,000 were recorded in the fourth quarter of 2008, $120,000 were recorded in the first quarter of 2009, and the remainder were recorded in the second quarter of 2009.

In January 2009, we completed a work force reduction of six employees. As a result, we recorded severance related charges including salary, payroll taxes and health benefits of $193,000, of which $96,000 was recorded in R&D and the remainder in SG&A. In connection with the January 2009 reduction in workforce, severance-related charges of $144,000 were recorded in the first quarter of 2009 and the remainder were recorded in the second quarter of 2009.

In April 2009, we completed a work force reduction of nine employees. As a result, we recorded severance-related charges including salary, payroll taxes and health benefits of $190,000, of which $128,000 was recorded in R&D and the remainder in SG&A. In connection with the April 2009 reduction in workforce, severance-related charges of $114,000 were recorded in the first quarter of 2009 and the remainder were recorded in the second quarter of 2009.

Convertible Instruments. At issuance, we value separately embedded beneficial conversion features present in convertible securities. Embedded beneficial conversion features are recognized by allocating to additional paid-in capital and accumulated deficit that portion of the net proceeds from the sale of the convertible security equal to the intrinsic value of the beneficial conversion feature. Intrinsic value is calculated as the difference, as of the commitment date, between the conversion price of the convertible security and the fair value of the common stock underlying the convertible security, which for us is the closing price of a share of our common stock on the NYSE Amex multiplied by the number of shares of our common stock into which the convertible security is convertible. If the intrinsic value of the beneficial conversion feature is greater than the net proceeds allocated to the convertible security, the amount of the discount assigned to the beneficial conversion feature is limited to the amount of the net proceeds. In our June, July, August and October 2009 registered direct equity financings, we issued convertible preferred stock securities with non-detachable conversion features that were in-the-money as of the commitment date, which we recognized as beneficial conversion features. The convertible preferred stock we issued in these financings subsequently was converted into common stock at fixed conversion rates. The embedded beneficial conversion features were valued separately and recognized by allocating to additional paid-in capital and accumulated deficit a portion of the net proceeds equal to the intrinsic value of the beneficial conversion features.

The foregoing 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 drug products differ depending on the nature of the particular product candidate for which approval is sought. With respect to any product candidate with active ingredients not previously approved by the FDA, a prospective drug product manufacturer is required to submit an NDA that 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 investigational new drug application, or IND, pursuant to which permission is sought to begin clinical testing of the new product candidate. 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 Federal Food, Drug and Cosmetic Act.

Generally, with respect to any product candidate 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 of our R&D programs to pursue and how much funding to direct to each R&D program on an ongoing basis in response to the scientific, nonclinical and clinical success of the underlying product candidate, our ongoing assessment of its market potential and our available resources.

Future expenditures on R&D programs are subject to many uncertainties, including whether we will further develop our product candidates with a partner or independently. At this time, due to such uncertainties and the risks inherent in drug product 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;
- the time and cost of stability studies, including the need to identify critical parameters, methods to evaluate and test these parameters and validation of such methods and tests; and
- the costs, requirements, timing of and the ability to secure regulatory approvals.

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

While many of our R&D expenses are transacted in U.S. dollars, certain significant expenses are required to be paid in foreign currencies and expose us to transaction gains and losses that could result from changes in foreign currency exchange rates. In particular, our current contract manufacturer, which is also our intended commercial manufacturer, for both ANX-530 and ANX-514 is located outside the U.S. and generally we pay for its services, including technology transfer and process development and validation activities related to ANX-514, in Euros. As a result, our exposure to currency risk likely will increase as we move our products towards commercialization and increase the services we request from our current contract manufacturer. We include realized gains and losses from foreign currency transactions in operations as incurred.

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We operate our business and evaluate our company on the basis of a single reportable segment, which is the business of in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. We recognized revenues of $0.3 million and $0.5 million in 2009 and 2008, respectively.

	Operating Expenses Years Ended December 31,	
	2009	2008
Research and development	56%	64%
Selling, general and administrative	43%	35%
Depreciation and amortization	1%	1%
Total operating expenses	100%	100%

Comparison of 2009 and 2008

Revenue. We recognized revenue of $0.3 million for the year ended December 31, 2009 and $0.5 million for the year ended December 31, 2008. Revenue in 2009 represents a nonrefundable license fee under our March 2009 license agreement with respect to ANX-514 with Shin Poong Pharmaceutical Co., Ltd. Revenue in 2008 represents a portion of a $0.6 million settlement payment paid to us by Theragenex, LLC resulting from a claim we made against Theragenex for breach of a license agreement. Under that license agreement Theragenex was required to pay us 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). 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 or more 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,
	2009	2008	2009
External bioequivalence and clinical trial fees and expenses	$ 603,097	$ 3,373,865	$ 23,802,576
External nonclinical study fees and expenses (1)	5,083,474	10,585,695	24,028,948
Personnel costs	779,510	3,237,158	10,290,698
Stock-based compensation expense	41,569	725,465	2,925,730
Total	$ 6,507,650	$ 17,922,183	$ 61,047,952

(1) External nonclinical study fees and expenses

include preclinical, research-related manufacturing, quality assurance and regulatory expenses.

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R&D expenses decreased by $11.4 million, or 64%, to $6.5 million for the year ended December 31, 2009, compared to $17.9 million in 2008. The decrease was primarily due to a $2.9 million decrease in nonclinical expenses related to ANX-514, a $2.5 million decrease in personnel expenses, a $2.0 million decrease in nonclinical expenses related to ANX-530, a $1.8 million decrease in external clinical trial expenses related to the completion of CoFactor studies, a $0.7 million decrease in external clinical trial expenses associated with the completion of patient enrollment in the ANX-514 bioequivalence study in the first quarter of 2009, a $0.7 million decrease in share-based compensation expense, and a $0.4 million decrease in nonclinical expenses related to various other product candidate projects that were discontinued in 2009 as part of cost reduction efforts. We expect 2010 R&D expenses to increase relative to 2009 as we continue to invest in development and preliminary commercialization activities with respect to ANX-530 and ANX-514 and to rebuild our workforce.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses, decreased by $4.7 million, or approximately 49%, to $5.0 million for 2009, compared to $9.7 million for 2008. The decrease was primarily due to a $1.8 million decrease in personnel costs, a $0.9 million decrease in legal and professional services, a $0.6 million decrease in severance related costs, a $0.5 million decrease in consulting, Sarbanes-Oxley compliance and recruiting services, a $0.3 million decrease related to share-based compensation expense, a $0.3 million decrease in travel expenses, a $0.2 million decrease in market research expenses, and a $0.1 million decrease in insurance related expenses.

We expect that, if we maintain our current small number of employees, we will continue to realize SG&A cost savings relative to prior years. However, we expect the amount of such cost-savings to be offset to the extent we rebuild our workforce.

Interest and Other Income/(Expense). Interest income amounted to $7,000 for 2009, compared to $550,000 in 2008. The decrease in interest income of $0.5 million for 2009 was primarily attributable to lower interest rates earned on overall lower invested balances. Other expense was $47,000 in 2009 attributable to losses on the sale of various business assets as compared to $0.1 million other income received in 2008 related to the settlement from Theragenex. Even though we raised a substantial amount of additional capital through our June, July, August and October 2009 and January 2010 registered direct equity financings, we expect that interest income will continue to be low due to negligible interest rates.

Net Loss. Net loss applicable to common stock was $16.2 million, or $0.14 per share, for the year ended December 31, 2009, compared to a net loss applicable to common stock of $26.6 million, or $0.30 per share, for the year ended December 31, 2008. Included in the net loss applicable to common stock for 2009 was a non-cash deemed dividend expense of approximately $4.9 million related to our June, July, August and October 2009 registered direct equity financings. Included in both net loss and net loss applicable to common stock for 2009 were charges associated with our workforce reductions in October 2008 and in January and March 2009.

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 $11.3 million for the year ended December 31, 2009 and cash of approximately $8.7 million and working capital of $6.6 million as of December 31, 2009.

During fiscal 2009, we completed registered direct equity financings involving the issuance of shares of our Series A Stock, Series B Stock, Series C Stock and our Series D Stock. These financings resulted in an aggregate of $15.6 million in gross proceeds and an aggregate of $8.4 million in adjusted net proceeds after deducting the fees and expenses of our placement agent in those financings, our offering expenses and our dividend and related payment obligations. Additionally in December 2009, in connection with the exercise of warrants issued in our June 2009 Series A Stock financing and our October 2009 Series D Stock financing, we issued 6.0 million shares of our common stock and received net proceeds of $0.9 million and issued 14.4 million shares of our common stock and received net proceeds of $2.1 million, respectively. In January 2010, in connection with the exercise of warrants issued in our June 2009 Series A Stock offering, we issued an additional 2.1 million shares of our common stock and received net proceeds of $0.3 million. We may receive up to $0.8 million of additional proceeds from the exercise of the remaining warrants issued in our October 2009 Series D Stock financing; however, the exercise of those warrants is subject to certain beneficial ownership limitations. See Recent Financings, above, for a more detailed discussion regarding these

financings.

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In January 2010, we completed a registered direct equity financing involving the issuance of shares of our Series E Stock. This financing resulted in an aggregate of $19.0 million in gross proceeds and an aggregate of $14.0 million in adjusted net proceeds after deducting the fees and expenses of our placement agent in the Series E Stock offering, our estimated offering expenses and our dividend and related payment obligations. We may receive up to $4.4 million of additional net proceeds from the exercise of warrants issued in this financing; however, the exercise of those warrants is subject to certain beneficial ownership limitations.

For a discussion of our liquidity and capital resources outlook, see Management Outlook below.

Analysis of our 2009 versus 2008 cash flow from operating, investing and financing activities is provided below.

	December 31, 2009	Increase (Decrease) During 2009	December 31, 2008
Cash	$ 8,667,404	$ (1,182,500)	$ 9,849,904
Net working capital	$ 6,618,807	$ 883,288	$ 5,735,519

	Year Ended December 31, 2009	Change Between Periods	Year Ended December 31, 2008
Net cash used in operating activities	$ (12,616,416)	$ 11,171,188	$ (23,787,604)
Net cash provided by investing activities	16,000	(18,840,769)	18,856,769
Net cash provided by financing activities	11,417,916	11,417,916	
Net decrease in cash	$ (1,182,500)	$ (3,748,335)	$ (4,930,835)

Operating activities. Net cash used in operating activities was $12.6 million in 2009, compared to $23.8 million in 2008. The decrease in cash used in operating activities in 2009 was due primarily to the restructuring, cost-cutting and re-prioritization initiatives we implemented beginning in October 2008 through June 2009, specifically our workforce reductions and our discontinuation of active work on all compounds, other than ANX-530 and ANX-514, to which we have or had rights during that period.

Investing activities. Net cash provided by investing activities was $16,000 in 2009, compared to $18.9 million in 2008. The cash provided by investing activities in 2008 was primarily net proceeds from our sale of short-term investments, which we did not have during 2009.

Financing activities. Net cash provided by financing activities was $11.4 million in 2009, compared to $0 in 2008. The cash provided by financing activities in 2009 primarily consisted of proceeds from the issuance of our equity securities in the four financing transactions we completed in 2009. We did not complete any financing transactions in 2008, nor were any of our outstanding warrants or stock options exercised in 2008.

Management Outlook

We anticipate that our cash as of December 31, 2009, plus the funds we raised in the Series E Stock offering that we completed in January 2010, will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, we may determine to grow our organization or product candidate pipeline or pursue development and/or commercialization activities at levels or on timelines that shorten the period through which our operating funds will sustain us. In addition, we will need substantial additional funds to commercialize ANX-530 in the U.S., if an ANX-530 NDA is resubmitted, accepted and, ultimately, approved by the FDA, including acquiring or developing sales, marketing and distribution capabilities and the associated regulatory compliance capabilities. We will also need substantial additional funds to continue the development of ANX-514, including manufacturing process development and validation activities and, potentially, clinical trials designed to differentiate it from potential competitor products.

Currently, we are focused primarily on determining the FDA s requirements for filing an NDA for ANX-530 and discussing with the FDA the results of our bioequivalence study of ANX-514, as well as developing and preliminarily

executing our commercialization plan for ANX-530. Depending on the FDA s requirements for filing an ANX-530 NDA and our success in raising additional capital, we may commence activities enabling us to more aggressively execute our commercialization plan for ANX-530. We are also focused on raising additional capital to fund our operations. In addition, we intend to continue to evaluate strategic and partnering options, including the sale or exclusive license of one or more of our product candidate programs, as well as opportunities to expand our product pipeline.

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Recent Accounting Pronouncements

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Under SEC rules and regulations, as a smaller reporting company we are not required to provide the information required by this item.

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 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, 2009. 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, 2009.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fiscal quarter ended December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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, 2009.

Pursuant to temporary rules of the SEC, 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 Exchange Act 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 or Exchange Act.

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 SEC 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

Item 10. Directors, Executive Officers and Corporate Governance

DIRECTORS

The current members of our board of directors, the year in which they commenced service on our board, the positions they hold and their ages as of March 1, 2010, are as follows:

Name	Age	Position/Committee Membership*	Director Since
Michael M. Goldberg	51	Audit Committee and Compensation Committee (chair)	2004
Odysseas D. Kostas	35	Audit Committee	2010
Jack Lief	63	Chair of the Board, Audit Committee (chair) and Compensation Committee	2006
Mark J. Pykett	45	Nominating & Governance Committee (chair)	2004
Eric K. Rowinsky	53	Nominating & Governance Committee	2008

* Each of the directors served in the capacity set forth in the table for all of 2009, except Dr. Kostas who was appointed to the board and the audit committee in February 2010. Dr. Pykett served on the audit committee during 2009 and until February 2010.

The terms of all our directors will expire at the 2010 annual meeting of our stockholders, or when their successors are elected and qualified. Our directors are elected at each annual meeting of our stockholders to hold office until the next annual meeting of our stockholders.

Audit Committee

We have a standing audit committee as defined in Section 3(a)(58)(A) of the Exchange Act. In addition to being independent under Section 803A(2) of the NYSE Amex Company Guide, all members of the audit committee must meet the additional independence standards for audit committee members set forth in Rule 10A-3 promulgated under the Exchange Act. Our board of directors has determined that the members of our audit committee currently meet the independence standards set forth in Section 803A(2) of the NYSE Amex Company Guide and Rule 10A-3(b)(1) promulgated under the Exchange Act. Mr. Lief qualifies as an audit committee financial expert as defined in

Item 407(d)(5) of Regulation S-K under the Exchange Act.

Biographical Information and Qualifications of Directors

The paragraphs below provide information as of the date of this annual report about each member of our board of directors. The information presented includes each director s principal occupation and business experience during at least the past five years, the names of other publicly held companies at which he currently serves as a director or has served as a director during the past five years, information regarding involvement in certain legal or administrative proceedings during the past ten years, if applicable, and the experience, qualifications, attributes or skills that led our nominating and governance committee and our board of directors to determine that the person should serve on our board of directors as of the date of this annual report.

There are no family relationships among any of our directors and executive officers.

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Michael M. Goldberg, M.D., M.B.A. Dr. Goldberg has served as a director since January 2004. Dr. Goldberg currently is a managing partner of Montaur Capital Partners, an investment firm, a position he has held since January 2007. From August 1990 to January 2007, Dr. Goldberg was chairman and chief executive officer of Emisphere Technologies, Inc., a biopharmaceutical company. Prior to this, Dr. Goldberg was a vice president for The First Boston Corporation, where he was a founding member of the Healthcare Banking Group. He received a B.S. from Rensselaer Polytechnic Institute, an M.D. from Albany Medical College of Union University and an M.B.A. from Columbia University Graduate School of Business. Dr. Goldberg s years of executive experience at a development-stage biopharmaceutical company give him unique insight to our product development, operational and financing challenges and opportunities.

Odysseas D. Kostas, M.D. Dr. Kostas has served as a director since February 2010. Dr. Kostas is currently an attending physician and one of seven hospitalists at Greenwich Hospital, a member of the Yale New Haven Health System and a subsidiary of Greenwich Health Care Services, Inc. He has been at Greenwich Hospital since May 2008. At Greenwich Hospital, Dr. Kostas is a member of various committees that oversee aspects of the hospital s operational decision-making. Since March 2007, Dr. Kostas has provided advisory services to boards of directors of biotechnology companies, primarily in the area of strategic and partnering transactions, including ImClone Systems Incorporated prior to its sale to Eli Lilly and Company. In May 2003, Dr. Kostas founded a private medical practice that he owned and operated, treating over 2,000 patients, until May 2008. Dr. Kostas holds a B.S. in biology from the Massachusetts Institute of Technology and an M.D. from the University of Texas Southwestern Medical School and is board certified in internal medicine. Dr. Kostas years of experience as a practicing physician and with hospital and private practice operational decision-making provides our board with perspective on the potential value of our product candidates and drug development programs to patients and healthcare practitioners, our potential customers.

Jack Lief. Mr. Lief has served as a director since September 2006 and as chair of our board of directors since May 2007. Mr. Lief is a co-founder and since April 1997 has served as president, chief executive officer and a director of Arena Pharmaceuticals, Inc., a publicly held clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. He also has served as Arena s chairman of the board since October 2007. From 1995 to April 1997, Mr. Lief served as an advisor and consultant to numerous biopharmaceutical organizations. From 1989 to 1994, Mr. Lief served as senior vice president, corporate development and secretary of Cephalon, Inc., a biopharmaceutical company. From 1983 to 1989, Mr. Lief served as director of business development and strategic planning for Alpha Therapeutic Corporation, a manufacturer of biological products. Mr. Lief joined Abbott Laboratories, a pharmaceutical company, in 1972, where he served until 1983, most recently as the head of international marketing research. Mr. Lief is a director of Accumetrics, Inc., a developer and marketer of diagnostic tests, ReqMed Company, Ltd., a provider of partnering opportunities, R&D strategies and bio-venture funding, and TaiGen Biotechnology Co., Ltd., a biotechnology company. Mr. Lief is also an executive board member of BIOCOM, a life science industry association representing more than 550 member companies in San Diego and Southern California, and he was the chairman of BIOCOM from March 2005 to March 2006. Mr. Lief holds a B.A. from Rutgers University and an M.S. in psychology (experimental and neurobiology) from Lehigh University. Mr. Lief s extensive and current executive leadership and management experience in biopharmaceutical companies brings to our board of directors the perspective of a leader managing similar drug development, regulatory, commercialization and financing issues as our company. In addition, his over 40 years of experience in the life sciences industry provides unique insight to our board.

Mark J. Pykett, Ph.D., M.B.A., V.M.D. Dr. Pykett has served as a director since February 2004. Dr. Pykett currently is chief executive officer of Talaris Advisors LLC, a privately held integrated, drug development advisory firm, a position he has held since January 2010. From November 2004 until January 2010, Dr. Pykett was president and chief operating officer of Alseres Pharmaceuticals, Inc. (formerly Boston Life Sciences, Inc.), a publicly held company engaged in the development of therapeutic and diagnostic products primarily for disorders in the central nervous system. From May 1996 until April 2003, Dr. Pykett served as president and chief executive officer and a director of Cytomatrix, LLC, a privately held biotechnology company focused on the research, development and commercialization of novel cell-based therapies that Dr. Pykett co-founded. Cytomatrix was acquired by Cordlife, Pte.

Ltd., a subsidiary of CyGenics Ltd., a publicly held biotechnology company listed on the Australian Stock Exchange. From April 2003 to February 2004, Dr. Pykett served as president of Cordlife and then as

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president and director of CyGenics from February 2004 until November 2004. In addition, Dr. Pykett served as a director of Cordlife from April 2003 through November 2005 and a director of Oramax, LLC, a development stage dental implant company developing biomaterials for dental prostheses, from 2000 through 2006. Dr. Pykett held an adjunct faculty position at the Harvard School of Public Health from 1997 to 2004. Dr. Pykett graduated Phi Beta Kappa, summa cum laude from Amherst College, with a veterinary degree, and Phi Zeta, summa cum laude, from the University of Pennsylvania with a doctorate in molecular biology. He also earned an M.B.A., Beta Gamma Sigma, from Northeastern University. Dr. Pykett completed post-doctoral fellowships at the University of Pennsylvania and Harvard University. Dr. Pykett s extensive drug development experience and his years of executive experience at development-stage biopharmaceutical companies provide our board with perspective on drug development and regulatory strategy for our product candidates and insight to our operational and financial challenges and opportunities.

Eric K. Rowinsky, M.D. Dr. Rowinsky has served as a director since February 2008. Dr. Rowinsky currently is a scientific advisor to ImClone Systems Corporation, a wholly-owned subsidiary of Eli Lilly and Company, and an independent consultant to several other biotechnology, venture capital, private equity and consulting companies that focus on, or invest in companies that focus on, the development of cancer therapies. He has been an adjunct professor of medicine (division of medical oncology) at the New York University School of Medicine since September 2008. From February 2005 to December 2009, Dr. Rowinsky served as the chief medical officer of ImClone Systems Incorporated, a biopharmaceutical company focused on advancing oncology care which was acquired by Eli Lilly and Company in November 2008, and additionally served as executive vice president of ImClone from December 2007 to December 2009 and senior vice president from February 2005 to December 2007. His responsibilities at ImClone included managing clinical development, medical affairs, regulatory affairs and corporate strategy. From December 2007 to March 2008, Dr. Rowinsky served on the board of directors of Tapestry Pharmaceuticals, Inc., a biopharmaceutical company focused on the development of cancer therapies. Dr. Rowinsky held the position of director of the Institute of Drug Development (IDD) at the Cancer Therapy and Research Center from 2002 to 2004 and was the director of clinical research at the IDD from 1996 to 2002. In addition, he held the SBC Endowed Chair for Early Drug Development at the IDD. From 1996 to 2006, Dr Rowinsky was also a clinical professor of medicine (division of medical oncology and hematology) at the University of Texas Health Science Center, San Antonio, Texas. Dr. Rowinsky also served as an associate professor of oncology at the Johns Hopkins University School of Medicine from 1988 until 1996. He served on the Board of Scientific Counselors of the National Cancer Institute from 2004 to 2007. Prior to joining ImClone, Dr. Rowinsky was a longstanding National Cancer Institute principal investigator on U01 anticancer drug development grants and a lead investigator on early developmental studies of many classes of cytotoxic agents and targeted therapeutics, including paclitaxel, docetaxel, irinotecan, vinorelbine, topotecan, erlotinib, gefitinib, panitumumab, temsirolimus and ridaforolimus. Dr. Rowinsky is the editor-in-chief of Investigational New Drugs and an associate editor of Cancer Research, Clinical Cancer Research, Annals of Oncology, and several other oncology journals and has published over 295 manuscripts in both the preclinical and clinical research fields. Dr. Rowinsky received a B.A. degree from New York University and an M.D. degree from the Vanderbilt University School of Medicine. Following his residency in internal medicine, he completed fellowship training in medical oncology at the Johns Hopkins University School of Medicine. Dr. Rowinsky s expertise in anticancer drug development, his extensive experience as a member of scientific advisory boards, oncology advisory boards and project advisory boards of pharmaceutical and biotechnology companies, and his experience presenting aspects of several new drug applications to the FDA provide unique insight to our board of directors.

Director Arrangements

Under the terms of the Rights Agreement, dated July 27, 2005, as amended, or the Rights Agreement, we are required to cause our board of directors to nominate to our board of directors an individual, who we refer to as the Purchaser Designee, selected by the Purchasers who at the time own a majority of the Purchased Shares. Odysseas D. Kostas is the current Purchaser Designee. Purchasers, as defined in the Rights Agreement, refers to those entities, including entities affiliated with Carl C. Icahn, that purchased our common stock and warrants in a private transaction in July 2005. Purchased Shares, as defined in the Rights Agreement, refers to those shares of common stock outstanding and issuable upon exercise of warrants issued to the Purchasers in connection with the July 2005 transaction. The

Purchasers right to select a Purchaser Designee for nomination to our board of directors terminates upon the earlier of (i) July 27, 2012, (ii) the date that the Purchasers aggregate holdings of Purchased Shares (either of record or beneficially) is, as a result of sales or other dispositions thereof, equal to less than 50% of the aggregate number of shares purchased by the Purchasers in connection with the July 2005 transaction, and (iii) at the time of a change of control of our company.

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Under the terms of a Third Amendment to Rights Agreement, dated August 26, 2009, the Rights Agreement was amended to allow our board of directors, in the event a director resigns from our board of directors and any resulting vacancy is not filled by a majority of our board of directors then in office, which majority includes the Purchaser Designee, if there is then a Purchaser Designee, to decrease the authorized number of directors to the number of directors then in office (including for this purpose the appointment of a director to fill any vacancy resulting from such resignation) and, from time to time, to increase the number of authorized directors provided that any vacancy created by such an increase is filled by a majority of our board of directors then in office, which majority includes the Purchaser Designee, if there is then a Purchaser Designee. Following the resignation of Mark N.K. Bagnall from of our board of directors in August 2009, our board of directors set the authorized number of directors constituting our board of directors at four. In connection with the appointment of Dr. Kostas to our board of directors in February 2010, our board of directors increased the authorized number of directors constituting our board of directors to five directors.

EXECUTIVE OFFICERS

Our executive officers, their ages and positions held as of March 1, 2010, are as follows:

Name	Age	Position
Brian M. Culley	38	Chief Executive Officer
Patrick L. Keran	38	President and Chief Operating Officer

Biographical Information of Executive Officers

Brian M. Culley, M.A., M.B.A. Mr. Culley joined our company in December 2004 and currently serves as our chief executive officer, a position he has held since February 2010. He has served as our principal executive officer since February 2009. From January 2007 to February 2010, he served as our chief business officer and senior vice president. From February 2006 to January 2007, Mr. Culley served as our senior vice president, business development, and, from December 2004 to February 2006, he served as our vice president, business development. From 2002 until 2004, Mr. Culley managed all strategic collaborations and licensing agreements for iTherx, Inc. (formerly, Immusol, Inc.) in San Diego, where his most recent title was director of business development and marketing. From 1999 until 2000, he was a licensing and marketing associate at the University of California, San Diego, department of technology transfer & intellectual property services and from 1996 to 1999, he was a research associate for Neurocrine Biosciences, Inc., where he performed drug discovery research. Mr. Culley has over 15 years of experience in the biotechnology industry, including deal structure and negotiation, licensing, due diligence, market and competitive research, and venture funding. He received a B.S. in biology from Boston College, a masters in biochemistry from the University of California, Santa Barbara and an M.B.A. from The Johnson School of Business at Cornell University with an emphasis on private equity and entrepreneurship.

Patrick L. Keran, J.D. Mr. Keran joined our company in August 2006 and currently serves as our president and chief operating officer, a position he has held since February 2010. He has also served as our principal financial and accounting officer since July 2009 and as our secretary since September 2006. From August 2006 to February 2010, Mr. Keran served as our general counsel and, from January 2007 to February 2010, he served as our vice president, legal. From April 2004 to August 2006, Mr. Keran was associate general counsel at Isis Pharmaceuticals, a publicly held drug discovery and development company. From February 2003 to April 2004, Mr. Keran practiced corporate law at the law firm of Heller Ehrman LLP, specializing in public and private financings, licensing arrangements, mergers and acquisitions and corporate governance matters. From September 1999 to February 2003, Mr. Keran practiced law at the law firm of Brobeck Phleger & Harrison LLP where he had a similar corporate practice. Mr. Keran is licensed to practice law in the State of California. Mr. Keran received a B.A. from the University of California at San Diego and a J.D. from the University of California at Berkeley, Boalt Hall School of Law.

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SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act and SEC rules require our directors, executive officers and beneficial owners of more than 10% of any class of our equity securities to file with the SEC initial reports of their ownership and reports of changes in ownership of our common stock and other equity securities. These reporting persons are required by SEC rules to furnish us with copies of all Section 16(a) reports they file. Based solely on our review of copies of the Forms 3, 4 and 5 (and any amendments thereto) furnished to us during and with respect to 2009 and written representations from our directors and executive officers, such Section 16(a) filing requirements were complied with during 2009.

CODE OF ETHICS

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller 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.

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Item 11. Executive Compensation

EXECUTIVE COMPENSATION

The following table sets forth information concerning compensation earned for services rendered to us during the years ended December 31, 2009 and December 31, 2008 by (i) each individual serving as principal executive officer during 2009, (ii) the two most highly compensated executive officers, other than the individuals serving as our principal executive officer, who were serving as executive officers as of December 31, 2009, and (iii) the individuals who would have qualified under the foregoing clause (ii) but for the fact that such individuals were not serving as executive officers as of December 31, 2009. Collectively, these individuals are referred to as the named executive officers.

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards (1)	Option Awards (2)	Non-Equity Incentive Plan Compensation (3)	Nonqualified Deferred Compensation Earnings	All Other Compensation (4)	Total
Brian M. Culley	2009	$ 316,817		$ 0	$ 215,900	$ 225,000		$ 962(5)	$ 758,679
Chief Executive Officer	2008	$ 262,500			$ 102,160			$ 14,398	$ 379,058
Patrick L. Keran	2009	$ 290,781		$ 0	$ 215,900	$ 225,000		$ 6,154	$ 737,835
President and	2008	$ 231,000			$ 102,160			$ 14,233	$ 347,393
Chief Operating Officer									
Michele L. Yelmene	2009	$ 102,834		$ 0				$ 94,829(7)	$ 197,663
Former Vice President,	2008	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Regulatory Affairs and Quality (6)									

(1) The amounts in this column represent the grant date fair value of a restricted stock unit award granted to each of the named executive officers on January 30, 2009, calculated in accordance with the provisions of FASB ASC Topic 718. Mr. Culley received 1,200,000 restricted stock

units, Mr. Keran received 850,000 restricted stock units and Ms. Yelmene received 450,000 restricted stock units. Vesting and settlement of the restricted stock unit awards were conditioned upon our consummation of a strategic transaction. The grant date fair value of zero for each of these awards is based on our assessment that achievement of the vesting condition was not probable (assessed as of the grant date). Assuming 100% probability of meeting the vesting condition, the value of the restricted stock unit awards as of the grant date would have been $108,000 for Mr. Culley, $76,500 for Mr. Keran, and $40,500 for Ms. Yelmene. The restricted stock unit awards granted to Mr. Culley and

Mr. Keran were forfeited by them and cancelled in July 2009 and the restricted stock unit award granted to Ms. Yelmene was also cancelled in July 2009 in connection with the termination of her employment. As a result of these cancellations, the officers have not and will not receive any compensation or pecuniary value from these restricted stock unit awards.

(2) The amounts in this column represent the aggregate grant date fair value of option awards granted to the named executive officers in 2009 and 2008, respectively, calculated in accordance with the provisions of FASB ASC Topic 718. For a description of the assumptions used to calculate the grant date fair value of the option awards granted in 2009,

see Note 7 of the Notes to Consolidated Financial Statements contained in this report. For a description of the assumptions used to calculate the grant date fair value of the option awards granted in 2008, see Note 8 of the Notes to Consolidated Financial Statements contained in our annual report on Form 10-K for the year ended December 31, 2008.

(3) We paid the amounts set forth in this column pursuant to the terms of our 2009 mid-year incentive plan. See Narrative to Summary Compensation Table Short-term Non-equity Incentive Plan and Employment Retention and Severance Arrangements below for a description of the material terms of our 2009 mid-year

incentive plan.

(4) Except as otherwise indicated, the amounts in this column consist of (a) matching contributions made pursuant to our tax-qualified 401(k) plan and (b) premiums paid for life insurance policies for the benefit of our executives.

(5) Consists only of the premiums paid for life insurance policies for the benefit of Mr. Culley.

(6) Ms. Yelmene s employment with us ended on July 1, 2009. She has served as a consultant to us since her employment ended pursuant to a consulting agreement, the material terms of which are described below under Narrative to Summary Compensation Table Consulting Arrangements with Michele Yelmene. Compensation

information for Ms. Yelmene for 2008 is not included because she was not a 2008 named executive officer.

(7) Consists of (a) matching contributions pursuant to our 401(k) plan of $4,746, (b) life insurance premiums of $238, (c) accrued vacation benefits paid in connection with termination of employment of $30,220, and (d) consulting fees earned of $59,625.

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Narrative Disclosure to Summary Compensation Table

Base Salary

In July 2009, the compensation committee of our board of directors increased the annual base salaries of Mr. Culley and Mr. Keran to $315,000 and $289,000, respectively, which adjustments were retroactive to January 1, 2009.

Short-term Non-equity Incentive Plan and Employment Retention and Severance Arrangements

Each of Mr. Culley s and Mr. Keran s employment with us is at-will and they may terminate their employment with us at any time with or without prior notice. In July 2009, the compensation committee of our board of directors adopted both a 2009 mid-year incentive plan and a retention and severance plan applicable to Mr. Culley and Mr. Keran. We determined that these plans were necessary to incentivize and retain Mr. Culley and Mr. Keran, who at the time were our only employees, and reinforce their dedication to us during a period when they would otherwise likely seek alternative employment. As a part of adopting these plans, we terminated the retention and incentive agreements that we had entered into with each of Mr. Culley and Mr. Keran in January 2009 and the awards of restricted stock units, representing the right to receive 1,200,000 and 850,000 shares, respectively, of our common stock, that we granted to Mr. Culley and Mr. Keran in January 2009. We did not pay any amounts to either Mr. Culley or Mr. Keran pursuant to the January 2009 retention and incentive agreements before those agreements were terminated.

2009 Mid-Year Incentive Plan. Under our 2009 mid-year incentive plan, each of Mr. Culley and Mr. Keran were eligible for cash incentive awards based 100% on our achievement of corporate performance objectives set by the compensation committee and in effect at the end of 2009. The target award amount for each of Mr. Culley and Mr. Keran was $150,000. The actual payout amount of each award was based on the target amount, subject to increase or decrease by multiplying the target amount by a corporate performance multiplier determined by the compensation committee in the first quarter of 2010 based on its assessment of overall corporate performance in 2009 against the performance objectives. Award multipliers could range from zero to 1.5 and would be the same for each participant. Performance objectives were adopted at the time the plan was adopted, but, pursuant to the terms of the plan, the compensation committee had authority to adjust, re-weight, replace or eliminate any objective that became irrelevant or undesirable during the plan period or if a strategic change or other event affecting one or more of the objectives took place. Given the uncertainty of our ability to continue to operate as a going concern during 2009 and the fact that we were actively seeking strategic partners, the compensation committee determined that providing flexibility as to the performance goals under the plan was important in realizing the objectives of the plan, which were primarily to incentivize our two remaining employees to achieve near-term corporate objectives that would enhance stockholder value and incentivize these employees to remain employed by and dedicated to our company. Although the plan provided flexibility to modify the corporate performance objectives, the objectives set at the time of adoption of the plan were not subsequently changed. The corporate objectives consisted of four equally-weighted goals involving the successful completion of bioequivalence data analysis, acceptance of regulatory documents by the FDA, acceptance by the NYSE Amex of a plan to regain compliance with applicable listing criteria and maintenance of specified levels of working capital at December 31, 2009. In January 2010, the compensation committee determined the award multiplier applicable to Mr. Culley s and Mr. Keran s target award amount under the plan would be 1.5, and, in accordance with the plan, we awarded $225,000 to each of Mr. Culley and Mr. Keran.

Retention and Severance Arrangements. Under the retention and severance plan we adopted in July 2009, if the employment of Mr. Culley or Mr. Keran, as applicable, terminates at any time as a result of an involuntary termination, and Mr. Culley or Mr. Keran, as applicable, delivers and does not revoke a general release of claims, which will also confirm any post-termination obligations and/or restrictions applicable to him, he will be entitled to (i) an amount equal to 12 months of his then-current base salary, less applicable withholdings, and (ii) an amount equal to the estimated cost of continuing his healthcare coverage and the coverage of his dependents who are covered at the time of the involuntary termination under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, for a period equal to 12 months. These severance benefits will be paid in a lump-sum on the date the general release of claims becomes effective. As of December 31, 2009, our aggregate contractual obligation under the retention and severance plan, including applicable payroll and employer taxes, was $350,130 for Mr. Culley and $323,753 for Mr. Keran.

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For purposes of the retention and severance plan, an involuntary termination means (i) without the employee s express written consent, an action by our board of directors or external events causing or immediately portending a material reduction or alteration of the employee s duties, position or responsibilities relative to the employee s duties, position or responsibilities in effect immediately prior to such reduction or alteration, or the removal of the employee from such position, duties or responsibilities; provided, however, that an involuntary termination shall not be deemed to occur (a) with respect to Mr. Culley, if Mr. Culley remains the head of and most senior individual within our company s (or our successor s) business development function and (B) with respect to Mr. Keran, if Mr. Keran remains the head of and most senior individual within our company s (or our successor s) legal function; (ii) without the employee s express written consent, a material reduction by us of the employee s base salary as in effect immediately prior to such reduction; (iii) without the employee s express written consent, the relocation of the employee s principal place of employment with us by more than 50 miles; (iv) any termination of the employee by us without cause (as defined below); or (v) a material breach of the retention and severance plan, including, but not limited to our failure to obtain the assumption of the retention and severance plan by any successors as contemplated in the retention and severance plan. For purposes of the retention and severance plan, Cause means (i) any act of personal dishonesty taken by the employee in connection with his responsibilities as an employee which is intended to result in substantial personal enrichment of the employee; (ii) the employee s conviction of a felony that our board of directors reasonably believes has had or will have a material detrimental effect on our reputation or business; (iii) a willful act by the employee that constitutes misconduct and is materially injurious to us, or (iv) continued willful violations by the employee of the employee s obligations to us after there has been delivered to the employee a written demand for performance from us that describes the basis for our belief that the employee has not substantially performed his duties.

2009 Stock Option Awards

On July 21, 2009, the compensation committee granted to each of Mr. Culley and Mr. Keran a stock option to purchase up to 1,700,000 shares of our common stock. The per share exercise price of these options is $0.13, which was the closing price of our common stock on July 21, 2009. The stock options were granted under our 2008 Omnibus Incentive Plan and have a term of 10 years. Pursuant to the 2008 Omnibus Incentive Plan, the exercise price per share of the options cannot be lowered without prior approval of our stockholders, except in the event of a merger, reorganization, consolidation, recapitalization, dividend or distribution (whether in cash, shares or other property, other than a regular cash dividend), stock split, reverse stock split, spin-off or similar transaction or other change in corporate structure affecting our common stock or the value thereof, in each case as the compensation committee may deem equitable or appropriate.

The stock options become exercisable, subject to Mr. Culley s and Mr. Keran s respective continuous service to us, as to one-fourth of the shares subject to the option on each of January 1, 2010, January 1, 2011, January 1, 2012 and January 1, 2013. However, in the event Mr. Culley or Mr. Keran, as applicable, ceases to provide services to us as an employee by reason of an involuntary termination, exercisability of the then-vested portion of the stock option shall be extended such that the stock option shall be exercisable for a period of 12 months from the date of such involuntary termination. In addition, the vesting and exercisability of each option will accelerate or be extended under certain circumstances, including, (i) in the event of a change in control (as defined in our 2008 Omnibus Incentive Plan), acceleration with respect to 50% of the then unvested shares on the day prior to the date of the change in control and, subject to the respective employee s continuous service, with respect to the remaining 50% of the then unvested shares on the one year anniversary of the date of the change in control, (ii) subject to the preceding clause (i), in the event of a change of control, to the extent the successor company (or a subsidiary or parent thereof) does not assume or substitute for the option, acceleration in full on the day prior to the date of the change in control if the employee is then providing services or was the subject of an involuntary termination in connection with, related to or in contemplation of the change in control and exercisability for a period of 24 months from the date of such involuntary termination, and (iii) subject to the preceding clause (i), in the event of a change of control, to the extent the successor company (or a subsidiary or parent thereof) assumes or substitutes for the option, and in the event of an involuntary termination of the employee within 12 months following the date of the change in control, acceleration in full and exercisability for a period of 24 months from the date of such involuntary termination.

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In January 2010, we modified the stock options granted to Mr. Culley and Mr. Keran in July 2009 such that in the event of an involuntary termination of Mr. Culley or Mr. Keran, as applicable, his stock option will, immediately prior to such involuntary termination, vest and become exercisable with respect to 25% of the total number of shares subject to the applicable option, or 425,000 shares. For purposes of the July 2009 stock options, the definition of involuntary termination is the same as under the retention and severance plan described above, except it does not include clause (v) regarding breach of the retention and severance plan.

We structured the number of shares underlying and the vesting schedule of the July 2009 stock options primarily to retain and incentivize our executives, and not primarily as a form of compensation or to recognize previous individual or corporate performance. In particular, we did not view these awards as typical annual option grants. The compensation committee granted these awards to retain and properly incentivize the individuals capable of maximizing the potential of our assets. Without a substantial opportunity to participate in our future success, we were concerned that we would be unable to retain Mr. Culley and Mr. Keran, who at the time were our only employees. In addition, the annual, cliff-based vesting schedule of the July 2009 stock options was structured to provide substantial retentive value.

As a condition to the grant of the July 2009 stock options, both Mr. Culley and Mr. Keran agreed to terminate the awards of restricted stock units, representing the right to receive 1,200,000 and 850,000 shares, respectively, of our common stock, that we granted to Mr. Culley and Mr. Keran in January 2009.

Other Employment Benefits and Arrangements

Vacation Benefits. Mr. Culley accrues 25 vacation days per year and Mr. Keran accrues 23 vacation days per year, subject to adjustment based on the number of years of the officer s employment with us. As of December 31, 2009, Mr. Culley had accrued 50 vacation days and Mr. Keran had accrued 46 vacation days, which is the maximum amount they can accrue under our vacation benefits policy. Pursuant to our policy, employees may not accrue vacation days in excess of twice their annual vacation accrual rate. Accordingly, until Mr. Culley or Mr. Keran uses his accrued vacation days, he will not accrue additional vacation days unless his annual accrual rate increases. If Mr. Culley s or Mr. Keran s employment with us had terminated as of December 31, 2009, our aggregate vacation benefits payment obligation, including applicable payroll and employer taxes, would have been approximately $61,456 for Mr. Culley and approximately $51,873 for Mr. Keran.

Other Agreements. It is our policy that, at the beginning of employment, all employees sign our standard confidential information, non-solicitation and invention assignment agreement for employees. Under the current version of this agreement, employees agree that, during the period of the employee s service to us and for one year thereafter, the employee will not (a) solicit any employee or consultant of ours to leave the employ of or terminate any relationship with us or (b) solicit the business of any client or customer of ours using our confidential information. Each of Mr. Culley and Mr. Keran have signed one of these agreements.

Consulting Arrangements with Michele Yelmene

Ms. Yelmene served as our vice president, regulatory affairs and quality until July 1, 2009. We had entered into a retention and incentive agreement with Ms. Yelmene in January 2009, but no amounts were due to Ms. Yelmene pursuant to that agreement in connection with the termination of her employment with us in July 2009.

Effective as of July 15, 2009, we entered into a consulting agreement with Ms. Yelmene, pursuant to which she agreed to provide consulting services to us from time to time at a rate of $225 per hour through December 31, 2009. Pursuant to the consulting agreement, Ms. Yelmene s services to us include making herself available to transition her former duties to designated employees or representatives of ours, responding to inquiries of our personnel regarding regulatory, quality-assurance, clinical, manufacturing and related matters, and providing advice and assistance regarding special projects or any other matter consistent with Ms. Yelmene s background, skills and experience as we may request from time to time. Effective as of December 31, 2009, the consulting agreement with Ms. Yelmene was amended to extend the term of the agreement to December 31, 2010. Pursuant to the consulting agreement, as amended, the maximum amount of fees to be incurred by us without specific prior written approval by us is $100,000.

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Outstanding Equity Awards at Fiscal Year-End 2009

The following table sets forth information regarding outstanding equity awards held by our named executive officers at the end of fiscal 2009:

Outstanding Equity Awards at Fiscal Year-End for Fiscal Year 2009

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares of Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Brian M. Culley	100,000			$ 2.30	7/13/2015				
	78,333(1)	1,667(1)		$ 4.75	1/30/2016				
	109,375(2)	40,625(2)		$ 2.75	1/11/2017				
	40,000(3)	160,000(3)		$ 0.54	3/30/2018				
		1,700,000(4)		$ 0.13	7/20/2019				
Patrick L. Keran	83,333(5)	16,667(5)		$ 2.99	8/17/2016				
	36,457(2)	13,543(2)		$ 2.75	1/11/2017				
	40,000(3)	160,000(3)		$ 0.54	3/30/2018				
		1,700,000(4)		$ 0.13	7/20/2019				
Michele L. Yelmene									

(1) Subject to accelerated

vesting in the event of a change in control, as described below under Acceleration of Vesting of Stock Options Granted Under 2005 Equity Incentive Plan, this option vested and became exercisable with respect to 1/4 of the total underlying shares on January 1, 2007 and vests and becomes exercisable with respect to 1/48 of the total underlying shares at the end of each successive calendar month thereafter.

(2) Subject to accelerated vesting in the event of a change in control or an involuntary termination within 24 months of a change in control, as described below under Acceleration of Vesting of Stock Options Granted Under

2005 Equity Incentive Plan, this option vested and became exercisable with respect to 1/4 of the total underlying shares subject to the option on January 1, 2008 and vests and becomes exercisable with respect to 1/48 of the total underlying shares at the end of each successive month thereafter.

(3) Subject to accelerated vesting in the event of a change in control or an involuntary termination within 24 months of a change in control, as described below under Acceleration of Vesting of Stock Options Granted Under 2005 Equity Incentive Plan, this option vested and became exercisable with respect to 1/5 of the total underlying

shares on each of January 1, 2009 and January 1, 2010, and vests and becomes exercisable with respect to 1/5 of the total underlying shares on each of January 1, 2011, January 1, 2012 and January 1, 2013.

(4) Subject to accelerated vesting in the event of a change in control or an involuntary termination, as described above under Narrative Disclosure to Summary Compensation Table 2009 Stock Option Awards, this option vested and became exercisable with respect to 1/4 of the total underlying shares on January 1, 2010 and vests and becomes exercisable with respect to 1/4 of the total underlying shares on each of January 1, 2011, January 1, 2012 and January 1, 2013.

(5) Subject to accelerated vesting in the event of a change in control or an involuntary termination within 24 months of a change in control, as described below under Acceleration of Vesting of Stock Options Granted Under 2005 Equity Incentive Plan, this option vested and became exercisable with respect to 1/4 of the total underlying shares subject to the option on August 7, 2007 and vests and becomes exercisable with respect to 1/48 of the total underlying shares at the end of each successive month thereafter.

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Acceleration of Vesting of Outstanding Stock Options Granted Under 2005 Equity Incentive Plan

All of the stock options held by our named executive officers that were granted before July 2009 were granted under our 2005 Equity Incentive Plan. The stock option agreements governing the options granted to our named executive officers before August 2006 provide that the options will accelerate in full in the event of an acquisition constituting a change of control (as such terms are defined in the stock option agreement) if the option holder remains employed by us as of the closing date of such acquisition and the option is not assumed or replaced by the successor or acquiring entity or the entity in control of such successor or acquiring entity. Otherwise, the option will not accelerate in the event of such an acquisition. The stock option agreements governing the options granted to our named executive officers in and after August 2006 additionally provide that, if following a change of control in which an option is assumed as described above, the option holder is subject to an involuntary termination within 24 months after the closing date of such change in control, the vesting of the assumed option will be accelerated such that the option will vest as of the effective date of such involuntary termination with respect to all shares that would have vested during the period from the date of the option holder s involuntary termination until the date that is 24 months after the closing date of such change in control if such option holder had not been involuntarily terminated. For purposes of these stock option agreements, an involuntary termination is a termination of employment that occurs by reason of dismissal for any reason other than misconduct or of voluntary resignation following: (i) a change in position that materially reduces the level of the employee s responsibility, (ii) a material reduction in the employee s base salary, or (iii) relocation by more than 50 miles; provided that (ii) and (iii) will apply only if the employee has not consented to the change or relocation.

Misconduct means the commission of any act of fraud, embezzlement or dishonesty by the employee, any unauthorized use or disclosure by the employee of confidential information or trade secrets of our company (or any parent or subsidiary), or any other intentional misconduct by the employee adversely affecting our business affairs (or those of any parent or subsidiary) in a material manner. All of the stock option agreements governing the options granted to our named executive officers in January 2007 contain this double trigger acceleration provision. We anticipate continuing to include this or a similar double trigger acceleration provision in most stock option awards made in the future.

Although the terms of the stock options granted to our named executive officers under our 2005 Equity Incentive Plan provide for acceleration of vesting in certain circumstances as described above, our named executive officers would not have realized any value from these options as a result of the acceleration provisions if any of the acceleration scenarios had occurred on December 31, 2009 because none of these options were in-the-money on December 31, 2009, meaning none of them had an exercise price per share less than the market value per share of our common stock. The market value of our common stock is based on the closing market price of our common stock, which was $0.3499 per share on December 31, 2009.

Tax-Qualified Defined Contribution Plan

We have a defined contribution savings plan pursuant to Section 401(k) of the IRC. The plan is for the benefit of all employees and permits voluntary contributions by qualifying employees of up to 100% of eligible compensation, subject to Internal Revenue Service-imposed maximum limits. From January 1, 2008 until May 16, 2009, the terms of the plan required us to make matching contributions equal to 100% of employee contributions up to 6% of eligible compensation, limited by the IRS-imposed maximum. In April 2009, we amended the plan such that we were not required to make matching contributions on any employee contributions made by a highly compensated employee, which included Mr. Culley, Mr. Keran and Ms. Yelmene, from May 16, 2009 through December 31, 2009. We incurred total expenses of approximately $29,661 and $218,150 in employer matching contributions in 2009 and 2008, respectively. In November 2009, we amended the plan to reinstate the 6% matching contribution effective for the plan year beginning January 1, 2010.

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DIRECTOR COMPENSATION

The following table shows compensation information for the individuals who served as our non-employee directors during the year ended December 31, 2009. Directors who are also our employees do not receive any additional compensation for their services as directors. As of the date of this report, none of our directors is also an employee of our company.

Director Compensation for Fiscal Year 2009

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Mark N.K. Bagnall(1)	$ 6,495					$ 191,952(2)	$ 198,447
Alexander J. Denner(3)	$ 11,902						$ 11,902
Michael M. Goldberg	$ 32,500						$ 32.500
Jack Lief	$ 54,000						$ 54,000
Mark J. Pykett	$ 32,500						$ 32,500
Eric K. Rowinsky	$ 26,500					$ 1,050(4)	$ 27,550

(1) Mr. Bagnall resigned from our board of directors effective August 24, 2009. His resignation was not due to a disagreement with us on any matter relating to our operations, policies or practices.

(2) This amount consists of (a) a severance payment of $165,500, (b) a severance-related health benefit allowance of $18,352, and (c) consulting fees of $8,100. See Separation

and Consulting Services Agreements with Mark N.K. Bagnall below for a description of our employment separation and consulting agreements with Mr. Bagnall.

(3) Dr. Denner resigned from our board of directors and the compensation committee effective October 16, 2009. His resignation was not due to a disagreement with us on any matter relating to our operations, policies or practices.

(4) This amount represents fees earned for consulting services provided to us under a consulting agreement with Dr. Rowinsky. See Consulting Services Agreement with Eric K. Rowinsky below for a description of our consulting services agreement with Dr. Rowinsky.

Overview of Non-Employee Director Compensation

Retainer

During 2009, we paid our non-employee directors quarterly cash retainers and board of director and committee meeting fees. The amounts of the quarterly retainers vary depending on the non-employee director s role on our board of directors and its committees, as set forth in the table below:

2009 Quarterly Retainer

	Chairperson	**Member**
Board of Directors	$ 6,250	$ 2,500
Audit Committee	$ 5,000	$ 2,500
Compensation Committee	$ 2,500	$ 1,250
Nominating and Governance Committee	$ 2,500	$ 1,250
Research and Development Committee	$ 2,500	$ 1,250

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In January 2010, our board of directors adopted a compensation policy applicable to all non-employee directors beginning January 1, 2010. Under this new policy, our non-employee directors will continue to be eligible to receive quarterly retainers based on each director s role on our board of directors and its committees, but the amounts of such retainers have changed and are as set forth in the table below:

2010 Quarterly Retainer

	Chairperson	Member
Board of Directors	$ 10,000*	$ 5,000
Audit Committee	$ 1,875	$
Compensation Committee	$ 875	$
Nominating and Governance Committee	$ 875	$
Research and Development Committee**	$ 875	$

* If, in the future, our board of directors appoints a lead independent director, such director s quarterly retainer would be $10,000 per quarter.

** The research and development committee was disbanded by our board of directors in March 2010.

Meeting Fees

In addition to the quarterly retainers, in 2009, we paid $1,000 per meeting to each director who attended in person ($500 for attendance via telephone) a meeting of our board of directors or any committee of our board of directors with a duration of more than 15 minutes. Such meeting fees were not paid in respect of (i) the first four meetings of our board of directors held during each calendar year, (ii) the first four meetings of the audit committee held during each calendar year, (iii) the first two meetings of the compensation committee held during each calendar year or (iv) the first meeting of the nominating and governance committee held during each calendar year.

Pursuant to our new non-employee director compensation policy, beginning January 1, 2010, we pay $1,000 per meeting to each non-employee director for each meeting of our board of directors or any committee of our board of directors attended by such director (whether such attendance is in person or by telephone, videoconference or other comparable communication device).

In addition to the quarterly retainer and meeting fees, we reimburse our directors for travel and other reasonable out-of-pocket expenses related to attendance at our board of directors and committee meetings.

Equity Compensation

Pursuant to the terms of our 2005 Equity Incentive Plan, each of our non-employee directors was automatically granted a nonstatutory option to purchase 50,000 shares of our common stock at the first meeting of our board of

directors following each annual meeting of stockholders, provided that such non-employee director had served on our board of directors for at least the preceding six months. The exercise price per share of each such option was equal to 105% of the per-share fair market value of our common stock on the grant date. Subject to the director s continuous service, each option became exercisable as to 1/12th of the shares underlying the option at the end of each calendar month after its date of grant. The options expire no later than 10 years after the date of grant. In May 2008, our stockholders approved our 2008 Omnibus Incentive Plan. Following adoption of our 2008 Omnibus Incentive Plan, no additional awards (including the automatic options to our non-employee directors described above) have been or will be made under our 2005 Equity Incentive Plan; however, our 2005 Equity Incentive Plan will continue to govern any outstanding awards (including the automatic options to our non-employee directors described above) previously granted under our 2005 Equity Incentive Plan.

Awards under our 2008 Omnibus Incentive Plan are at the discretion of our board of directors or the compensation committee of our board of directors. Unlike our 2005 Equity Incentive Plan, our 2008 Omnibus Incentive Plan does not provide for automatic awards to our directors. During 2009, no stock options or other equity awards were granted to our directors. However, pursuant to the director compensation policy adopted in January 2010, each non-employee director who was a non-employee director on January 25, 2010 was eligible to receive (i) a re-inducement option to purchase 100,000 shares of our common stock and (ii) a make-up option to purchase 100,000 shares of our common stock. The re-inducement and make-up options were approved by our board of directors on January 25, 2010, but the grants were subject to our receipt of a waiver under the Rights Agreement (described under Directors Director Arrangements in Item 10 of this report). Upon our receipt of such waiver on February 2, 2010, the re-inducement and make-up options were granted to each of Mr. Lief and Drs. Goldberg, Pykett and Rowinsky. Each of the re-inducement and make-up options have an exercise price of $0.32 per share, which was the closing price of our common stock on February 2, 2010. Each re-inducement option vests and becomes exercisable in 36 substantially equal monthly installments of 1/36th of the shares subject to the option at the end of each successive month following the date of grant, subject to the director s continuing service (as defined in the 2008 Omnibus Incentive Plan). Each make-up option vests and becomes exercisable in 12 substantially equal monthly installments of 1/12th of the shares subject to the option at the end of each successive month following June 3, 2009, subject to the director s continuing service.

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In addition, our new non-employee director compensation policy provides for annual stock option awards and new director inducement stock option awards. Pursuant to the policy, each non-employee director who is serving as such on the date of each annual meeting of our stockholders shall be eligible to receive an option to purchase 100,000 shares of our common stock, unless such director s initial election or appointment to our board of directors is at such annual meeting of stockholders or on a date that is less than 30 days before such annual meeting. Non-employee directors initially elected or appointed to our board of directors more than 30 days before the date of the next annual meeting of our stockholders shall be eligible to receive a pro-rated annual option based on the number of full 30-day periods between their initial appointment to our board of directors and the next annual meeting of our stockholders. Each annual option shall become vested and exercisable in 12 substantially equal monthly installments of 1/12th of the shares subject to the option at the end of each successive month following the date of the applicable annual meeting of our stockholders, subject to the director s continuing service. Each pro-rated annual option shall become vested and exercisable in such number of substantially equal monthly installments as is equal to the number of full 30-day periods between such new director s initial appointment or election to our board and the date of the next annual meeting of our stockholders. If, on the date of a new director s initial appointment or election the date of the next annual meeting of our stockholders has not been set by our board of directors, the vesting schedule for that director s pro-rated annual option shall be based on the one-year anniversary of the immediately preceding annual meeting of our stockholders. In addition, each newly elected or appointed non-employee director shall also be eligible to receive an inducement option to purchase 100,000 shares of our common stock in connection with his or her election or appointment to our board of directors. Each inducement option shall become vested and exercisable in 36 substantially equal monthly installments of 1/36th of the shares subject to the option at the end of each successive month following the date of the director s initial appointment or election to our board of directors, subject to the director s continuing service.

Each stock option granted under our non-employee director compensation policy shall be granted under our 2008 Omnibus Incentive Plan, shall have an exercise price per share equal to the fair market value (as defined in the 2008 Omnibus Incentive Plan) of a share of our common stock on the date the option is granted, and shall have a term equal to the shorter of (i) ten years from the date the option is granted and (ii) three years from the date such non-employee director ceases to provide services (as defined in the 2008 Omnibus Incentive Plan) to us for any reason other than such director s death or disability.

Separation and Consulting Services Agreements with Mark N.K. Bagnall

Mark N.K. Bagnall was employed by us from April 2008 to December 2008 as our chief financial officer, executive vice president and treasurer. Mr. Bagnall also served as a member of our board of directors from February 2004 to August 2009. In January 2009, we entered into a Confidential Separation Agreement and General Release of All Claims with Mr. Bagnall, which we refer to herein as the Bagnall Separation Agreement, regarding the terms of his employment separation.

As set forth in the Bagnall Separation Agreement, in exchange for a release of claims and Mr. Bagnall s agreement and representations (as more fully described below), we agreed to provide a severance payment of $165,500 to Mr. Bagnall, and each of us and Mr. Bagnall agreed to enter into a consulting relationship. In addition, we agreed to provide a health benefit allowance of $18,352, which Mr. Bagnall could 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. The severance payment and the health benefit allowance were paid in one lump sum, less applicable payroll deductions and required withholdings, in January 2009. The severance provisions set forth in the Bagnall Separation Agreement supersede and replace the severance provisions set forth in Mr. Bagnall s offer letter from us, which was effective as of April 3, 2008 and amended as of December 11, 2008. Pursuant to the terms of the stock option granted to Mr. Bagnall in April 2008 in connection with the commencement of his employment, 100,000 shares underlying that option vested and became exercisable immediately prior to Mr. Bagnall s involuntary termination in December 2008. As a result of Mr. Bagnall s remaining in continuous service to us after the termination of his employment, this option has continued and will continue to vest until such time as Mr. Bagnall is no longer in continuous service to us.

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Under the Bagnall Separation Agreement, Mr. Bagnall represented that he returned to us all property, data and information belonging to us other than is reasonably required by Mr. Bagnall to perform services as a member of our board of directors or is reasonably related to such services or is needed by Mr. Bagnall to provide services as a consultant to us. Mr. Bagnall agreed not to use or disclose to others any confidential or proprietary information of ours, except, as applicable, in connection with Mr. Bagnall s position as a member of our board of directors or as a consultant to us, in which case such use and disclosure will be governed by such documents, agreements and duties as apply to such positions. Mr. Bagnall further agreed to comply with his continuing obligations under various agreements and other documents as previously executed by him. In addition, Mr. Bagnall agreed that he will not make any voluntary statements, written or oral, or cause or encourage others to make any such statements, that defame, disparage or in any way criticize the personal and/or business reputation, practices or conduct of our company or our employees, officers and directors, among others. Mr. Bagnall also represented that he had not filed any lawsuits, complaints or other accusatory pleadings against us. Finally, Mr. Bagnall agreed, at the end of the consulting period, to extend and reaffirm the promises made by Mr. Bagnall in the Bagnall Separation Agreement, including the release of claims.

In December 2008, we entered into a consulting agreement with Mr. Bagnall. Under the consulting agreement, Mr. Bagnall agreed to provide consulting services on an as-needed basis to assist us in identifying and evaluating strategic options and to respond to inquiries regarding finance and other matters, and we agreed to pay Mr. Bagnall $100 per hour. Either party could terminate the consulting agreement upon written notice. In February 2009, we and Mr. Bagnall amended the consulting agreement to include services related to Mr. Bagnall acting as our interim principal financial and accounting officer, and we agreed to pay Mr. Bagnall $250 per hour for services provided after such amendment, capped at $8,000 in the aggregate. In July 2009, we terminated the consulting agreement with Mr. Bagnall. In August 2009, we entered into a new consulting agreement with Mr. Bagnall. Under the August 2009 consulting agreement, which has a one-year term, we pay Mr. Bagnall at a rate of $250 per hour for services he provides to us, capped at $25,000. We are obligated to request at least four hours of services per month or to pay for a minimum of four hours of services, or $1,000 per month.

Consulting Services Agreement with Eric K. Rowinsky

As of November 23, 2009, we entered into a consulting agreement with Eric K. Rowinsky, a member of our board of directors, pursuant to which Dr. Rowinsky will provide consulting services to us from time to time at our request. His services to us may include responding to inquiries of ours regarding medical and clinical matters with which Dr. Rowinsky has knowledge, attending and participating in, at our request, a meeting with the FDA regarding our ANX-530 NDA, and providing advice and assistance regarding special projects or any other matter consistent with Dr. Rowinsky s background, skills and experience, which are described under Directors Biographical Information and Qualifications of Directors in Item 10 of this report. The consulting agreement has a one-year term. Under the agreement, we pay Dr. Rowinsky at a rate of $350 per hour for the services he provides to us, capped at $100,000.

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

The following table sets forth information regarding beneficial ownership of our common stock as of March 1, 2010 (the Evaluation Date), or an earlier date for information based on filings with the SEC, by (a) each person known to us to beneficially own more than 5% of the outstanding shares of our common stock, (b) each of our directors, (c) each of our named executive officers and (d) all of our directors and executive officers as a group. The information in this table is based solely on statements in filings with the SEC or other reliable information. As of the Evaluation Date, 257,237,572 shares of our common stock were outstanding.

Name and Address of Beneficial Owner (1)(2)	Beneficial Ownership (3)	Percent of Class
Michael M. Goldberg(4)	337,110	*
Odysseas D. Kostas(5)	22,221	*
Jack Lief(6)	238,888	*
Mark J. Pykett(7)	296,888	*
Eric K. Rowinsky(8)	188,888	*
Brian M. Culley(9)	806,875	*
Patrick L. Keran(10)	637,290	*
Michele L. Yelmene		*
All directors and executive officers as a group (7 persons) (11)	2,528,160	1%

* Less than 1%

(1) Unless otherwise indicated, the address of each of the listed persons is c/o ADVENTRX Pharmaceuticals, Inc., 6725 Mesa Ridge Road, Suite 100, San Diego, CA 92121.

(2) We do not know of any person or group of persons that holds 5% or more of our common stock as of the Evaluation Date.

(3) Beneficial ownership of shares is

determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power, or of which a person has the right to acquire ownership within 60 days of the Evaluation Date. Except as otherwise noted, each person or entity has sole voting and investment power with respect to the shares shown. Unless otherwise noted, none of the shares shown as beneficially owned on this table are subject to pledge. In calculating the percentage ownership of each person identified in the table, shares underlying options held by that person that are either currently exercisable or exercisable within 60 days of the Evaluation Date are deemed outstanding. These shares,

however, are not deemed outstanding for the purposes of computing the percentage ownership of any other individual or entity. Percentage ownership for each person is based on the number of shares of our common stock outstanding as of the Evaluation Date, together with the applicable number of shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date for that person or group of persons.

(4) Consists of (a) 311,110 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date and (b) 26,000 shares of common stock held directly by Dr. Goldberg.

(5) Consists of 22,221 shares of common stock

subject to options currently exercisable or exercisable within 60 days of the Evaluation Date.

(6) Consists of 238,888 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date.

(7) Consists of (a) 288,888 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date and (b) 8,000 shares of common stock held by Dr. Pykett and his spouse, as joint tenants.

(8) Consists of 188,888 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date.

(9) Consists of 806,875 shares of common stock

subject to options currently exercisable or exercisable within 60 days of the Evaluation Date.

(10) Consists of 637,290 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date.

(11) Includes 2,494,160 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date.

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EQUITY COMPENSATION PLAN INFORMATION

The following table provides information as of December 31, 2009 regarding equity compensation plans previously approved by our stockholders. We do not have any equity compensation plans that have not been approved by our stockholders.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Security Holders:			
2008 Omnibus Incentive Plan(1)	3,650,000	$ 0.15	14,383,656
2005 Equity Incentive Plan(1)	2,209,000	$ 1.88	0
2005 Employee Stock Purchase Plan(2)	0	$	3,923,634
Equity Compensation Plans Not Approved by Security Holders:			
Total	5,859,000	$ 0.80	18,307,290

(1) In May 2008, our stockholders approved our 2008 Omnibus Incentive Plan, following which no awards have been or will be granted under our 2005 Equity Incentive Plan and no automatic increase will

occur to the maximum number of shares that may be issued pursuant to our 2005 Equity Incentive Plan. However, our 2005 Equity Incentive Plan will continue to govern any outstanding awards previously granted under that plan. In addition, if, after December 31, 2007, any shares of our common stock subject to an award under our 2005 Equity Incentive Plan are forfeited, expire or are settled for cash pursuant to the terms of an award, we may use the shares subject to the award for awards under our 2008 Omnibus Incentive Plan to the extent of the forfeiture, expiration or settlement. The shares of common stock will be added back as one share for every one share of common stock

forfeited, expired or settled for cash if the shares were subject to options or stock appreciation rights granted under our 2005 Equity Incentive Plan and as 1.2 shares for every one share of common stock forfeited, expired or settled for cash if the shares were subject to awards other than options or stock appreciation rights granted under our 2005 Equity Incentive Plan.

(2) Our 2005 Employee Stock Purchase Plan contains a provision for an automatic increase in the number of shares available for grant on the first day of each fiscal year beginning in 2006 and on each anniversary of that date thereafter equal to the lesser of (i) one percent of the number of outstanding shares of our

common stock on such day, (ii) 750,000 and (iii) such other amount as our board of directors may specify prior to the date such annual increase is to take effect.

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

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

We have incorporated into our company s written review and approval policies certain procedures designed to ensure that any proposed transaction in which our company would be a participant and in which any of our directors, executive officers, holders of more than 5% of our common stock, or any member of the immediate family of any of the foregoing, would have a direct or indirect material interest is reviewed by individuals within our company familiar with the requirements of Item 404 of Regulation S-K promulgated by the SEC. If any such proposed transaction would require disclosure pursuant to Item 404(a), it will be presented to the audit committee for review and, if appropriate, approval.

Other than as described below and in Item 11 of this report, since January 1, 2008, there has not been, nor currently are there proposed, any transactions or series of similar transactions in which our company was or is to be a participant and the amount involved exceeds or will exceed 1% of the average of our total assets at December 31, 2008 and 2009, which is approximately $98,682, and in which any of our directors, executive officers, holders of more than 5% of our common stock or any member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest, other than the transactions described below.

Consulting Services Agreement with Talaris Advisors LLC

As of February 1, 2010, we entered into a service agreement with Talaris Advisors LLC, a privately held integrated drug development advisory firm, pursuant to which Talaris will assist us in planning for and conducting a meeting with the FDA to discuss the data from our bioequivalence study of ANX-514 and will provide strategic guidance regarding regulatory strategy for ANX-514 based upon the outcome of the meeting. The agreement has a four-month term, but may be extended by mutual agreement between us and Talaris. Pursuant to the agreement, we will pay Talaris a total of $110,000 for its services and reimburse it for reasonable and necessary direct expenses of up to $9,000 incurred in connection with the performance of its services to us. Mark J. Pykett, a member of our board of directors, is the chief executive officer and a member of Talaris. The dollar value of his interest in these transactions between us and Talaris will not exceed the total value of such transactions as described above.

Separation Arrangements with Former Chief Executive Officer and President

Evan M. Levine was employed by us from October 2002 to October 2008, and he most recently served as our chief executive officer and president. Mr. Levine also served as a member of our board of directors from October 2002 to December 2008. In December 2008, we entered into a Confidential Separation Agreement and General Release of All Claims with Mr. Levine, which we refer to herein as the Levine Separation Agreement, regarding the terms of his employment separation.

As set forth in the Levine Separation Agreement, in exchange for a mutual release of claims and Mr. Levine s agreement and representations (as more fully described below), we agreed to provide a severance payment of $225,000 to Mr. Levine. In addition, we agreed to provide a health benefit allowance of $19,870, which Mr. Levine could 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. The severance payment and the health benefit allowance were paid in one lump sum, less applicable payroll deductions and required withholdings, in January 2009. In addition, pursuant to the Levine Separation Agreement, we agreed to issue 1,000,000 fully-vested shares of its common stock to Mr. Levine, subject to the satisfaction of certain conditions by January 30, 2009, or, if those conditions were not so satisfied, pay Mr. Levine an additional $100,000 in one lump sum, less applicable payroll deductions and required withholdings. In February 2009, because the conditions to our obligation to issue the shares had not been timely satisfied, we paid Mr. Levine an additional $100,000 in one lump sum, less applicable payroll deductions and required withholdings. In November 2008, prior to entering into the Levine Separation Agreement, we paid Mr. Levine a total of $40,000 in four weekly installments ending in December 2008 in exchange for his agreement not to sign a Confidential Separation Agreement and General Release of All Claims that was presented to him on October 19, 2008 to allow time for discussions related to the terms of Mr. Levine s employment separation and release of claims to continue.

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Under the Levine Separation Agreement, Mr. Levine represented that he had returned to us all property, data and information belonging to us, agreed not to use or disclose to others any confidential or proprietary information of ours and agreed to comply with his continuing obligations under various agreements and other documents as previously executed by him. In addition, we and Mr. Levine each agreed that neither will make any voluntary statements, written or oral, or cause or encourage others to make any such statements, that defame, disparage or in any way criticize the personal and/or business reputation, practices or conduct of, respectively, Mr. Levine, on the one hand, or our company or our employees, officers and directors, among others, on the other hand. Each of us and Mr. Levine also represented that neither had filed any lawsuits, complaints or other accusatory pleadings against the other.

Separation and Consulting Services Arrangements with Former Chief Financial Officer and Senior Vice President

Gregory P. Hanson was employed by us from December 2006 to April 2008 as our chief financial officer and senior vice president. In April 2008, we entered into a letter agreement with Mr. Hanson, which we refer to herein as the Hanson Separation Agreement, regarding the terms of his employment separation.

As set forth in the Hanson Separation Agreement, in exchange for a mutual release of claims and Mr. Hanson s agreement and representations (as more fully described below), we paid Mr. Hanson an aggregate of $125,000, which was equal to six months of Mr. Hanson base salary in effect at the time of termination, less applicable payroll deductions and required withholdings, in substantially equal installments beginning in April 2008, in accordance with our standard payroll practices over 13 pay periods. In addition, we paid Mr. Hanson $20,997, less applicable payroll deductions and required withholdings, which we and Mr. Hanson agreed satisfied in full our obligation under our offer letter agreement with Mr. Hanson to pay all costs that we would otherwise have incurred to maintain Mr. Hanson s health, welfare and retirement benefits if Mr. Hanson had continued for six continuous months after Mr. Hanson s termination date. We paid the $20,997 amount in substantially equal installments commencing on and continuing in accordance with the same schedule described above with respect to payment of Mr. Hanson s severance amount. Furthermore, we accelerated the vesting and extended the time to exercise vested shares under the stock option granted to Mr. Hanson in December 2006 in connection with the commencement of his employment. Under this option, Mr. Hanson was granted the right to purchase up to 250,000 shares of our common stock at a price of $2.57 per share, which right was subject to a vesting schedule. As of Mr. Hanson s termination date, this option was vested as to 78,125 shares and unvested as to 171,875 shares. Pursuant to the Hanson Separation Agreement, we accelerated vesting as to 31,250 of the unvested shares, which resulted in this option being vested as to a total of 109,375 shares, and extended the time for Mr. Hanson to exercise the vested shares under this option through September 29, 2008. Mr. Hanson did not exercise the option by September 29, 2008 and, accordingly, it terminated on that date. The closing market price of our common stock on September 29, 2008 was $0.18 per share, while the exercise price of the option was $2.57 per share.

Under the Hanson Separation Agreement, Mr. Hanson represented that he had returned to us all of our property and data that had been in his possession or control and acknowledged that he will continue to be bound by an agreement with us regarding the use and confidentiality of our confidential information and, in particular, that he will hold all of our confidential information in confidence and not directly or indirectly use any aspect of such confidential information. Mr. Hanson also agreed not to make any voluntary statements, written or oral, or cause or encourage others to make any such statements that defame or disparage our company and, among others, our officers and directors.

In addition, in April 2008, we and Mr. Hanson entered into a consulting agreement and related confidential information and invention assignment agreement. Under the consulting agreement, Mr. Hanson agreed to provide consulting services on an as-needed basis and we agreed to pay Mr. Hanson (a) for the first ten hours in a particular calendar month, $250 per hour and (b) for any time beyond ten hours in a particular calendar month, $150 per hour. Either party could terminate the consulting agreement upon written notice, except that Mr. Hanson could not terminate the consulting agreement, other than for our failure to pay Mr. Hanson as set forth in the consulting agreement, prior to December 31, 2008. In 2008, consulting fees to Mr. Hanson under our consulting agreement totaled $375. In 2009, Mr. Hanson did not provide any consulting services to us and we did not pay any amounts to him under the consulting agreement.

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Separation Arrangements with Former Chief Scientific Officer and Senior Vice President

Joan M. Robbins was employed by us from March 2003 to October 2008, and she most recently served as our chief scientific officer and senior vice president. In October 2008, we entered into a Confidential Separation Agreement and General Release of All Claims, which we refer to herein as the Robbins Separation Agreement, regarding the terms of her employment separation.

As set forth in the Robbins Separation Agreement, in exchange for a release of claims and Dr. Robbins agreement to provide certain transition assistance and Dr. Robbins other agreements and representations (as more fully described below), we agreed to provide a severance payment of $123,615 to Dr. Robbins. In addition, we agreed to provide a health benefit allowance of $8,309, which Dr. Robbins could use, at her discretion, to pay the premiums required to continue her group health care coverage under COBRA or any other health care related expenses. We agreed to pay the severance payment and the health benefit allowance in 11 substantially equal installments over a period of five and one-half months, less applicable payroll deductions and required withholdings, beginning in December 2008, conditioned upon Dr. Robbins making herself available as needed during that period to answer business-related questions by telephone or in person as deemed reasonably necessary by us.

Under the Robbins Separation Agreement, Dr. Robbins represented that she had returned to us all property, data and information belonging to us and agreed not to use or disclose to others any of our confidential or proprietary information and agreed to comply with her continuing obligations under various agreements and other documents as previously executed by her. In addition, she agreed to make herself available, as needed, without any additional compensation, to answer business-related questions by telephone or in person as deemed reasonably necessary by us and that she would not make any voluntary statements, written or oral, or cause or encourage others to make any such statements, that defame, disparage or in any way criticize the personal and/or business reputation, practices or conduct of our company or our employees, officers and directors, among others. Dr. Robbins also represented that she had not filed any lawsuits, complaints or other accusatory pleadings against us.

Separation Arrangements with Former President and Chief Medical Officer

Dr. James Merritt was employed by us from September 2006 to January 2008 as our president and chief medical officer. In February 2008, we entered into a letter agreement with Dr. Merritt, which we refer to herein as the Merritt Separation Agreement, regarding the terms of his employment separation.

As set forth in the Merritt Separation Agreement, in exchange for a mutual release, beginning in February 2008, we paid Dr. Merritt an aggregate of $181,250, which was equal to six months of Dr. Merritt s base salary in effect at the time of termination, less applicable state and federal payroll deductions, in substantially equal installments in accordance with our standard payroll practices over 13 pay periods. In addition, we paid Dr. Merritt $16,038, less applicable state and federal payroll deductions, which we and Dr. Merritt agreed satisfied in full our obligation under our offer letter agreement with Dr. Merritt to pay all costs that we would otherwise have incurred to maintain Dr. Merritt s health, welfare and retirement benefits if Dr. Merritt s employment had continued for six continuous months after Dr. Merritt s termination date. We paid the $16,038 amount in substantially equal installments commencing on and continuing in accordance with the same schedule described above with respect to payment of Dr. Merritt s severance amount. Furthermore, we accelerated the vesting and extended the time to exercise vested shares under the stock option granted to Dr. Merritt in September 2006 in connection with the commencement of his employment. Under this option, Dr. Merritt was granted the right to purchase up to 300,000 shares of our common stock at a price of $2.86 per share, which right was subject to a vesting schedule. As of Dr. Merritt s termination date, this option was vested as to 100,000 shares and unvested as to 200,000 shares. Pursuant to the Merritt Separation Agreement, we accelerated vesting as to 31,249 of the unvested shares, which resulted in this option being vested as to a total of 131,249 shares, and extended the time for Dr. Merritt to exercise the vested shares under this option to Noon (Pacific time) on December 31, 2008. Dr. Merritt did not exercise the option by December 31, 2008 deadline and, accordingly, it terminated. The closing market price of our common stock on December 31, 2008 was $0.08 per share, while the exercise price of the option was $2.86 per share. In addition, as of his termination date, Dr. Merritt held another option that was vested as to 8,334 shares. Pursuant to its terms, this option expired, unexercised, on April 28, 2008.

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Under the Merritt Separation Agreement, Dr. Merritt represented that he had returned to us all of our property and data that had been in his possession or control and acknowledged that he is bound by an agreement with us regarding the use and confidentiality of our confidential information.

Indemnification of Officers and Directors

Our amended and restated certificate of incorporation and our bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we entered into indemnification agreements with each of our directors and officers, and we purchased a policy of directors and officers liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances.

DIRECTOR INDEPENDENCE

Our board of directors has determined that each of our current directors, Michael M. Goldberg, Odysseas D. Kostas, Jack Lief, Mark J. Pykett and Eric K. Rowinsky, is an independent director as such term is defined in Section 803A(2) of the NYSE Amex Company Guide. In addition, with respect to Alexander J. Denner, who served as a member of our board of directors until October 16, 2009, our board of directors had determined that he was an independent director during his service as a director in 2009. In evaluating whether Dr. Rowinsky is an independent director, our board of directors considered Dr. Rowinsky s consulting services relationship with us, a description of which is under Director Compensation Consulting Services Agreement with Eric K. Rowinsky in Item 11 of this report. In evaluating whether Dr. Pykett is an independent director, our board of directors considered Talaris Advisors LLC s consulting services relationship with us and Dr. Pykett s relationship with Talaris, a description of which is above under Certain Relationships and Related Transactions. In addition, in evaluating whether Dr. Denner was and Dr. Kostas is an independent director, our board of directors considered that we were required to cause our board of directors to nominate each of them to our board as the Purchaser Designee pursuant to the terms of the Rights Agreement (as described under Directors Director Arrangements in Item 10 of this report), as well as each of Dr. Kostas and Dr. Denner s relationship with certain entities affiliated with Carl C. Icahn, which entities are Purchasers under the Rights Agreement, and such entities (a) ownership position in our company and (b) rights under the Rights Agreement entitling them to, among other things, participate in future sales by us of our securities (as described under Risks Related to Our Business Our ability to raise capital may be limited by contractual restrictions in Item 1A of this report). With respect to Dr. Kostas, our board of directors also considered the consulting services he provided to us in 2008 and the fees we paid to him for those services, which were less than $5,000 in the aggregate. Our board of directors determined that the consulting services relationship between us and each of Dr. Rowinsky, Talaris Advisors LLC and Dr. Kostas, respectively, is not one that would interfere with the exercise of Dr. Rowinsky s, Dr. Pykett s or Dr. Kostas independent judgment in carrying out the responsibilities of a director. Our board of directors also determined that each of Dr. Denner s and Dr. Kostas relationship with certain entities affiliated with Carl C. Icahn, which entities are Purchasers under the Rights Agreement, is not one that would interfere with the exercise of his independent judgment in carrying out the responsibilities of a director.

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Item 14. Principal Accounting Fees and Services

The following table shows the fees paid or accrued by us for the audit and other services provided by J.H. Cohn LLP, our independent registered public accounting firm, for fiscal 2008 and 2009.

	2008	2009
Audit Fees (1)	$ 188,779	$ 217,000
Audit-Related Fees (2)	14,500	8,339
Tax Fees		
All Other Fees		
Total	$ 203,279	$ 225,339

(1) Audit Fees represent fees for professional services provided in connection with the audit of our annual financial statements (including the audit of internal controls over financial reporting under Section 404 of the Sarbanes Oxley Act, if conducted), review of our quarterly financial statements, review of our registration statements on Forms S-3 and S-1, and related services normally provided in connection with statutory and regulatory filings and engagements.

(2) Audit-Related Fees consist primarily of assurance and related services that are reasonably related to the performance of the annual audit or review of our financial statements. During 2008 and 2009, such fees were incurred for consultation in responding to SEC staff comments regarding our financial statements as of and for the year ended December 31, 2007 and our internal control over financial reporting.

Policy Regarding Pre-Approval of Audit and Non-Audit Services by the Company s Independent Registered Public Accounting Firm

We have established a policy that all audit and permissible non-audit services provided by our independent registered public accounting firm will be pre-approved by the audit committee. These services may include audit services, audit-related services, tax services and other services. The audit committee considers whether the provision of each non-audit service is compatible with maintaining the independence of our auditors.

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, 2009 and 2008
Consolidated Statements of Operations for the years ended December 31, 2009 and 2008 and from inception through December 31, 2009
Consolidated Statements of Stockholders Equity (Deficit) and Comprehensive Loss from inception through December 31, 2009
Consolidated Statements of Cash Flows for the years ended December 31, 2009 and 2008 and from inception through December 31, 2009
Notes to Consolidated Financial Statements

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(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)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the registrant dated October 5, 2009
3.3(4)	Certificate of Designation of Preferences, Rights and Limitations of 0% Series A Convertible Preferred Stock
3.4(5)	Certificate of Designation of Preferences, Rights and Limitations of 5% Series B Convertible Preferred Stock
3.5(6)	Certificate of Designation of Preferences, Rights and Limitations of 5% Series C Convertible Preferred Stock
3.6(7)	Certificate of Designation of Preferences, Rights and Limitations of 4.25660% Series D Convertible Preferred Stock
3.7(8)	Certificate of Designation of Preferences, Rights and Limitations of 3.73344597664961% Series E Convertible Preferred Stock
3.8(9)	Amended and Restated Bylaws of the registrant (formerly known as Biokeys Pharmaceuticals, Inc.)
10.1(10)	Securities Purchase Agreement, dated July 21, 2005, among the registrant and the Purchasers (as defined therein)
10.2(10)	Rights Agreement, dated July 27, 2005, among the registrant, the Icahn Purchasers and Viking (each as defined therein)
10.3(11)	First Amendment to Rights Agreement, dated September 22, 2006, among the registrant and the Icahn Purchasers (as defined therein)
10.4(12)	Second Amendment to Rights Agreement, dated February 25, 2008, among the registrant and the Icahn Purchasers (as defined therein)
10.5(13)	Third Amendment to Rights Agreement, dated August 26, 2009, among the registrant and Icahn Purchasers (as defined therein)
10.6(10)	Form of $2.26 Common Stock Warrant issued on July 27, 2005 to Icahn Partners LP, Icahn Partners Master Fund LP, High River Limited Partnership, Viking Global Equities LP and

	VGE III Portfolio Ltd.
10.7(10)	Form of $2.26 Common Stock Warrant issued on July 27, 2005 to North Sound Legacy Institutional Fund LLC and North Sound Legacy International Ltd.
10.8(4)	Engagement Letter Agreement, dated June 7, 2009, by and between the registrant and Rodman & Renshaw, LLC
10.9(4)	Securities Purchase Agreement, date June 8, 2009, governing the issuance and sale of the registrant s 0% Series A Convertible Preferred Stock
10.10(4)	Form of Common Stock Purchase Warrant issued on June 12, 2009 by the registrant to the purchasers of the registrant s 0% Series A Convertible Preferred Stock and to Rodman & Renshaw, LLC
10.11(5)	Engagement Letter Agreement, dated June 26, 2009, by and between the registrant and Rodman & Renshaw, LLC

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Exhibit	Description
10.12(5)	Securities Purchase Agreement, dated June 29, 2009, governing the issuance and sale of the registrant s 5% Series B Convertible Preferred Stock
10.13(5)	Form of Common Stock Purchase Warrant issued on July 6, 2009 by the registrant to Rodman & Renshaw, LLC
10.14(6)	Engagement Letter Agreement, dated August 4, 2009, by and between the registrant and Rodman & Renshaw, LLC
10.15(6)	Securities Purchase Agreement, dated August 5, 2009, governing the issuance and sale of the registrant s 5% Series C Convertible Preferred Stock
10.16(6)	Form of Common Stock Purchase Warrant issued on August 10, 2009 by the registrant to Rodman & Renshaw, LLC
10.17(14)	Engagement Letter Agreement, dated September 24, 2009, by and between the registrant and Rodman & Renshaw, LLC
10.18(7)	Engagement Letter Agreement, dated September 29, 2009, by and between the registrant and Rodman & Renshaw, LLC
10.19(7)	Form of Securities Purchase Agreement, dated October 6, 2009, governing the issuance and sale of the registrant s 4.25660% Series D Convertible Preferred Stock
10.20(7)	Form of Common Stock Purchase Warrant issued on October 9, 2009 by the registrant to the purchasers of the registrant s 4.25660% Series D Convertible Preferred Stock and to Rodman & Renshaw, LLC
10.21(8)	Engagement Letter Agreement, dated January 3, 2010, by and between the registrant and Rodman & Renshaw, LLC
10.22(8)	Securities Purchase Agreement, dated as of January 4, 2010, governing the issuance and sale of the registrant s 3.73344597664961% Series E Convertible Preferred Stock
10.23(8)	Form of Common Stock Purchase Warrant issued on January 7, 2010 by the registrant to the purchasers of the registrant s 3.73344597664961% Series E Convertible Preferred Stock and to Rodman & Renshaw, LLC
10.24#(15)	2005 Equity Incentive Plan
10.25#(16)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan
10.26#(17)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for director option grants beginning in 2008)
10.27#(18)	

	Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for option grants to employees approved in March 2008)
10.28#(2)	Form of Restricted Share Award Agreement under the 2005 Equity Incentive Plan
10.29#(19)	2008 Omnibus Incentive Plan
10.30#(20)	Form of Notice of Grant of Restricted Stock Units under the 2008 Omnibus Incentive Plan (for grants to employees in January 2009)
10.31#(20)	Form of Restricted Stock Units Agreement under the 2008 Omnibus Incentive Plan
10.32#(21)	Form of Non-Statutory Stock Option Grant Agreement (for directors) under the 2008 Omnibus Incentive Plan
10.33#(21)	Form of Non-Statutory/Incentive Stock Option Grant Agreement (for consultants/employees) under the 2008 Omnibus Incentive Plan

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Exhibit	Description
10.34#(22)	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Brian M. Culley in July 2009)
10.35#(22)	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Patrick L. Keran in July 2009)
10.36#(23)	Form of letter, dated January 20, 2010, modifying options granted to Brian M. Culley and Patrick L. Keran in July 2009
10.37#(23)	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Brian M. Culley in January 2010)
10.38#(23)	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Patrick L. Keran in January 2010)
10.39(17)	License Agreement, dated December 10, 2005, among SD Pharmaceuticals, Latitude Pharmaceuticals and Andrew Chen, including a certain letter, dated November 20, 2007, clarifying the scope of rights thereunder
10.40 (24)	License Agreement, dated March 25, 2009, among the registrant, SD Pharmaceuticals, Inc. and Shin Poong Pharmaceutical Co., Ltd.
10.41(25)	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
10.42(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
10.43(26)	Second Amendment to Standard Mutli-Tenant Officer Lease Gross, dated July 22, 2009, by and among Westcore Mesa View, LLC, DD Mesa View LLC and the registrant
10.44(27)	Third Amendment to Standard Multi-Tenant Office Lease Gross, dated December 10, 2009, by and among Westcore Mesa View, LLC, DD Mesa View, LLC and the registrant
10.45	Fourth Amendment to Standard Multi-Tenant Office Lease Gross, dated February 4, 2010, by and among Westcore Mesa View, LLC, DD Mesa View, LLC and the registrant
10.46#(28)	Confidential Separation Agreement and General Release of All Claims, effective December 4, 2008, between the registrant and Joan M. Robbins
10.47#(17)	Letter agreement regarding terms of separation with James A. Merritt, effective as of February 12, 2008
10.48#(29)	Letter Agreement regarding terms of separation with Gregory P. Hanson, dated April 2, 2008

10.49#(29)	Consulting Agreement, dated April 2, 2008, with Gregory P. Hanson
10.50#(21)	Offer letter, dated April 1, 2008, to Mark N.K. Bagnall (including Exhibits A, B and C thereto)
10.51#(24)	Confidential Separation Agreement and General Release of All Claims, effective January 8, 2009, and Consulting Agreement, dated December 31, 2008, between the registrant and Mark N.K. Bagnall
10.52#(30)	Consulting Agreement, dated August 24, 2009, with Mark N.K. Bagnall
10.53#(28)	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
10.54#(31)	Offer letter, dated November 15, 2004, to Brian M. Culley
10.55#(20)	Retention and Incentive Agreement, dated January 28, 2009 between the registrant and Brian M. Culley

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Exhibit	Description
10.56#(24)	Retention and Incentive Agreement, dated January 28, 2009, between the registrant and Patrick L. Keran
10.57#(24)	Retention and Incentive Agreement, dated January 28, 2009, between the registrant and Mark E. Erwin
10.58#(24)	Retention and Incentive Agreement, dated January 28, 2009, between the registrant and Michele L. Yelmene
10.59#	Consulting Agreement, effective as of July 15, 2009, and Amendment to Consulting Agreement, effective as of December 31, 2009, between the registrant and Michele L. Yelmene
10.60#(22)	2009 Mid-Year Incentive Plan for Brian M. Culley and Patrick L. Keran
10.61#(22)	Retention and Severance Plan (as of July 21, 2009) for Brian M. Culley and Patrick L. Keran
10.62#(23)	2010 Incentive Plan for Brian M. Culley and Patrick L. Keran
10.63#	Consulting Agreement, effective as of November 23, 2009, between the registrant and Eric K. Rowinsky
10.64#(32)	Director Compensation Policy, adopted June 21, 2006
10.65#	Director Compensation Policy, adopted January 25, 2010
10.66(33)	Form of Director and Officer Indemnification Agreement
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 by reference 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 October 13, 2009 (SEC file number 001-32157-091115090)

(4)

Filed with the registrant s Current Report on Form 8-K on June 8, 2009 (SEC file number 001-32157-09878961)	

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(5) Filed with the registrant s Current Report on Form 8-K on June 30, 2009 (SEC file number 001-32157-09917820)

(6) Filed with the registrant s Current Report on Form 8-K on August 5, 2009 (SEC file number 001-32157-09989205)

(7) Filed with the registrant s Amendment No. 3 to the Registration Statement on Form S-1 on October 5, 2009 (SEC file number 333-160778-091107945)

(8) Filed with the registrant s Current Report on Form 8-K on January 4, 2010 (SEC file number 001-32157- 10500379)

(9) Filed with the registrant s Current Report on Form 8-K on December 15, 2008 (SEC file number 001-32157-081249921)

(10) Filed with the registrant s Quarterly Report on Form 10-Q on August 12, 2005 (SEC file number 001-32157-051022046)

(11) Filed with the registrant s Current Report on Form 8-K on September 22, 2006 (SEC file number 001-32157-061103268)

(12) Filed with the registrant s Current Report on Form 8-K on February 25,

2008 (SEC file number 001-32157 08638638)

(13) Filed with the registrant s Current Report on Form 8-K on September 1, 2009 (SEC file number 001-32157-091049161)

(14) Filed with the registrant s Amendment No. 2 to the Registration Statement on Form S-1 on September 25, 2009 (SEC file number 333-160778-091087750)

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

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

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

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

(19) Filed with the registrant s Current Report on Form 8-K on June 2, 2008 (SEC file number 001-32157-08874724)

(20) Filed with the registrant s Current Report on Form 8-K on February 2, 2009 (SEC file number

001-32157- 09561715)

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

(22) Filed with the registrant s Current Report on Form 8-K on July 22, 2009 (SEC file number 001-32157-09957353)

(23) Filed with the registrant s Current Report on Form 8-K on January 26, 2010 (SEC file number 001-32157- 10547818)

(24) Filed with the registrant s Quarterly Report on Form 10-Q on May 15, 2009 (SEC file number 001-32157-09878961)

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

(26) Filed with the registrant s Current Report on Form 8-K on August 20, 2009 (SEC file number 001-32157-091025631)

(27) Filed with the registrant s Current Report on Form 8-K on December 24, 2009 (SEC file number 001-32157-091260100)

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(28) Filed with the registrant s Annual Report on Form 10-K on March 27, 2009 (SEC file number 001-32157-09708145)

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

(30) Filed with the registrant s Current Report on Form 8-K on August 28, 2009 (SEC file number 001-32157-091043396)

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

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

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

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

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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.

Date: March 18, 2010

ADVENTRX Pharmaceuticals, Inc.

By: /s/ Brian M. Culley

Brian M. Culley
Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Brian M. Culley and Patrick L. Keran, and each of them acting individually, as his true and lawful attorneys-in-fact and agents, each with full power to act alone, with full powers 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 for 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 any of them or their substitute or resubstitute, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Brian M. Culley Brian M. Culley	Chief Executive Officer (Principal Executive Officer)	March 18, 2010
/s/ Patrick L. Keran Patrick L. Keran	President and Chief Operating Officer (Principal Financial and Accounting Officer)	March 18, 2010
/s/ Jack Lief Jack Lief	Chair of the Board	March 18, 2010
/s/ Michael M. Goldberg Michael M. Goldberg	Director	March 18, 2010
/s/ Odysseas D. Kostas Odysseas D. Kostas	Director	March 18, 2010
/s/ Mark J. Pykett Mark J. Pykett	Director	March 18, 2010
/s/ Eric K. Rowinsky	Director	March 18, 2010

Eric K. Rowinsky

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Index to Consolidated Financial Statements

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

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
ADVENTRX Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of ADVENTRX Pharmaceuticals, Inc. and Subsidiaries (a development stage enterprise) as of December 31, 2009 and 2008, 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, 2009. 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, 2009 and 2008, and their results of operations and cash flows for years then ended and for the period from January 1, 2002 through December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

/s/ J. H. COHN LLP
San Diego, California
March 18, 2010

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

	December 31, 2009	December 31, 2008
Assets		
Current assets:		
Cash	$ 8,667,404	$ 9,849,904
Interest and other receivables	14,841	121,736
Prepaid expenses	290,249	477,902
Total current assets	8,972,494	10,449,542
Property and equipment, net	44,210	199,052
Other assets	10,513	60,664
Total assets	$ 9,027,217	$ 10,709,258
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 385,358	$ 1,721,376
Accrued liabilities	1,379,010	2,077,188
Accrued compensation and payroll taxes	589,319	915,459
Total current liabilities	2,353,687	4,714,023
Commitments and contingencies		
Stockholders equity:		
0% Series A Convertible Preferred Stock, $0.001 par value, 1,993 shares authorized; 1,993 shares issued and 0 shares outstanding as of December 31, 2009 and 0 shares issued and outstanding as of December 31, 2008		
5% Series B Convertible Preferred Stock, $0.001 par value, 1,361 shares authorized; 1,361 shares issued and 0 shares outstanding as of December 31, 2009 and 0 shares issued and outstanding as of December 31, 2008		
5% Series C Convertible Preferred Stock, $0.001 par value, 922 shares authorized; 922 shares issued and 0 shares outstanding as of December 31, 2009 and 0 shares issued and outstanding as of December 31, 2008		
4.25660% Series D Convertible Preferred Stock, $0.001 par value, 11,283 shares authorized; 11,283 shares issued and 0 shares outstanding as of December 31, 2009 and 0 shares issued and outstanding as of December 31, 2008		
Common stock, $0.001 par value; 500,000,000 shares authorized and 205,285,265 shares issued and outstanding at December 31, 2009;	205,286	90,254

200,000,000 shares authorized and 90,252,572 shares issued and outstanding at December 31, 2008		
Additional paid-in capital	148,506,647	131,751,439
Deficit accumulated during the development stage	(142,038,403)	(125,846,458)
Total stockholders equity	6,673,530	5,995,235
Total liabilities and stockholders equity	$ 9,027,217	$ 10,709,258

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, 2009	2008	Inception (June 12, 1996) Through December 31, 2009
Licensing revenue	$ 300,000	$ 500,000	$ 1,300,000
Net sales			174,830
Grant revenue			129,733
Total net revenue	300,000	500,000	1,604,563
Cost of sales			51,094
Gross margin	300,000	500,000	1,553,469
Operating expenses:			
Research and development	6,507,650	17,922,183	68,522,205
Selling, general and administrative	4,998,307	9,719,613	47,967,510
Depreciation and amortization	79,728	168,039	10,877,798
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	11,585,685	27,809,835	143,670,709
Loss from operations	(11,285,685)	(27,309,835)	(142,117,240)
Loss on fair value of warrants			(12,239,688)
Interest income	7,162	549,964	4,589,188
Interest expense			(179,090)
Other income (expense)	(46,535)	112,378	65,845
Loss before income taxes	(11,325,058)	(26,647,493)	(149,880,985)
Provision for income taxes			
Loss before cumulative effect of change in accounting principle	(11,325,058)	(26,647,493)	(149,880,985)
Cumulative effect of change in accounting principle			(25,821)
Net loss	(11,325,058)	(26,647,493)	(149,906,806)

Preferred stock dividends			(621,240)
Deemed dividends on preferred stock	(4,866,887)		(4,866,887)
Net loss applicable to common stock	$ (16,191,945)	$ (26,647,493)	$ (155,394,933)
Loss per common share basic and diluted	$ (0.14)	$ (0.30)	
Weighted average shares outstanding basic and diluted	116,678,997	90,252,572	

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, 2009

	Cumulative convertible preferred stock, series A through C		Cumulative Convertible preferred stock, series A (2009)		Cumulative convertible preferred stock, series B through D (2009)		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)	Comprehensive 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	
							375,891	376	887,874				888,250	

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

offering costs of $76,500				
Issuance of common stock at conversion of notes and interest payable	412,487	412	492,085	492,497
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

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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, 2009

	Cumulative convertible preferred stock, series A through C		Convertible preferred stock, series A (2009)		Cumulative convertible preferred stock, series B through D (2009)		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)	Comprehensive loss
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						
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)

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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, 2009

	Cumulative convertible preferred stock, series A through C		Convertible preferred stock, series A (2009)		Cumulative convertible preferred stock, series B through D (2009)		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)	Comprehensive loss
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						
dends able on erred k		$		$		$		$	$ (256,000)	$	$	$	$ (256,000)	
urchase of ants of									(55,279)				(55,279)	
ants less cise of ants									47,741				47,741	
							218,493	219	(219)					
ance of mon stock ay erred dends chable ants ed with s payable							93,421	93	212,907				213,000	
ance of ants to operating enses									450,000				450,000	
ance of mon stock ay ating enses							106,293	106	167,138				167,138	
ance of erred k to pay	137	1							387,165				387,271	
									136,499				136,500	

ating enses loss						(16,339,120)	(16,339,120)	$ (16,339,
nces at ember 31,	3,337	33	15,005,191	15,005	23,389,818	(24,043,342)	(638,486)	$ (16,339,
dends ble on erred k					(242,400)		(242,400)	
urchase of ants of ants			240,000	240	117,613		117,853	
less cise of ants			100,201	100	(100)			
rcise of ants of erred k at $1.50 share			344,573	345	168,477		168,822	
of erred k at 00 per e	200,000	2,000			298,000		300,000	
version of erred k into mon stock	70,109	701			700,392		701,093	
erred k dends iven	(3,000)	(30)	1,800,000	1,800	(1,770)			
ance of ants to operating enses					335,440		335,440	
ance of mon stock ay					163,109		163,109	
ating enses			6,292	6	12,263		12,269	
ance of erred k to pay	136	1			6,000		6,001	

ating enses ance of k options mployees						329,296		329,296	
loss							(2,105,727)	(2,105,727)	$ (2,105,
nces at ember 31, 2	270,582	2,705	17,496,257	17,496	25,276,138		(26,149,069)	(852,730)	$ (2,105,

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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, 2009

Cumulative convertible preferred stock, series A through C		Convertible preferred stock, series A (2009)		Cumulative convertible preferred stock, series B through D (2009)		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)	Compr
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						lo
	$		$		$		$	(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	

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ng es e of ptions to ees s					286,033			286,033	
						(2,332,077)		(2,332,077)	$ (2,3
es at ber 31,	200,473	2,004	42,491,708	42,492	32,556,963	(28,481,146)		4,120,313	$ (2,3
ishment ends on d stock sion of A					72,800			72,800	
tive d stock sion of B	(473)	(4)	236,500	236	(232)				
d stock s	(200,000)	(2,000)	200,000	200	1,800				
e of s			464,573	465	(465)				
e of s			23,832	23	27,330			27,353	
e of s in ent of a					86,375			86,375	
n stock per			10,417,624	10,419	15,616,031			15,626,450	
t of g and costs					(1,366,774)			(1,366,774)	
e of ptions to ees					524,922			524,922	
tion of stock s					34,747	(6,701,048)	(34,747)	(6,701,048)	$ (6,7
es at ber 31,			53,834,237	53,835	47,553,497	(35,182,194)	(34,747)	12,390,391	$ (6,7

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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, 2009

	Cumulative convertible preferred stock, series A through C		Cumulative Convertible preferred stock, series A (2009)		Cumulative convertible preferred stock, series B through D (2009)		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
s		$		$		$		$	$	$	$ (24,782,646)	$	$ (24,782,646)	$ (24,78
of change value of le-for-sale es										(1,722)			(1,722)	
ue of ssued in ction with hine ng							10,810,809	10,811	(10,811)					
ss exercise ants							149,613	149	(149)					
e of ts							2,258,703	2,259	3,071,179				3,073,438	
e of stock							185,000	185	144,815				145,000	
e of stock to ees									994,874				994,874	
e of stock to ployee									93,549				93,549	
e of n stock to							125,000	125	258,375				258,500	
es at ber 31, s restated							67,363,362	67,364	52,105,329	(1,722)	(59,964,840)	(34,747)	(7,828,616)	$ (24,78

s					(29,331,773)	(29,331,773)	$ (29,33
of change value of le-for-sale es				(368)		(368)	
ss exercise ants	420,161	420	(420)				
e of s, net of ng costs	5,103,746	5,104	7,686,486			7,691,590	
ition of SD ceuticals.	2,099,990	2,100	10,161,852			10,163,952	
common t $2.75 per net 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 mployees	15,000	15	68,635			68,650	
e of stock to ees			1,697,452			1,697,452	
e of stock to mployee			104,225			104,225	
ation of y stock	(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	$ (29,33
ative effect ge in ting le			18,116,751		12,239,688	30,356,439	
s					(22,142,040)	(22,142,040)	$ (22,14
of change value of le-for-sale es				4,792		4,792	

e of stock				
	575,833	576	441,040	441,616
e of stock				
to				
ees			2,414,077	2,414,077

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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, 2009

Cumulative convertible preferred stock, series A through C		Convertible preferred stock, series A (2009)		Cumulative convertible preferred stock, series B through D (2009)		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						
	$		$		$		$	$ 1,908	$	$	$	$ 1,908	
						90,252,572	90,254	130,140,549	2,702	(99,198,965)		31,034,540	$
										(26,647,493)		(26,647,493)	$
									(2,702)			(2,702)	
								1,605,908				1,605,908	
								4,982				4,982	
						90,252,572	90,254	131,751,439		(125,846,458)		5,995,235	$
										(11,325,058)		(11,325,058)	$
		1,993	2					1,735,627				1,735,629	

125										
rred										
k	(1,993)	(2)			18,036,199	18,036	(18,034)			
B k,										
643			1,361	1			833,030			833,031
rred										
k			(1,361)	(1)	9,504,189	9,504	(9,503)			
C k,										
885			922	1			711,198			711,199
rred										
k			(922)	(1)	7,092,307	7,092	(7,091)			
D k,										
			11,283	11			5,124,125			5,124,136
rred										
k			(11,283)	(11)	59,999,998	60,000	(59,989)			
end										
k							1,207,536	(1,207,536)		
end										
k							214,795	(214,795)		
end										
k							186,173	(186,173)		
end										
k							3,258,383	(3,258,383)		
ock										
							585,438			585,438
ants										
					6,000,000	6,000	894,000			900,000
ants										
					14,400,000	14,400	2,099,520			2,113,920

$	$	$ 205,285,265	$ 205,286	$ 148,506,647	$	$ (142,038,403)	$	$ 6,673,530	$

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,		Inception (June 12, 1996) Through December 31,
	2009	2008	2009
Cash flows from operating activities:			
Net loss	$ (11,325,058)	$ (26,647,493)	$ (149,906,807)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	79,728	168,039	10,427,799
(Gain)/loss on disposal of fixed assets	59,114	(3,598)	55,516
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	585,437	1,605,907	8,437,999
Expenses related to options issued to non-employees		4,983	204,664
Expenses paid by issuance of common stock			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)	(1,249,853)
Accretion of discount on investments in securities			(354,641)
Changes in assets and liabilities, net of effect of acquisitions:			
(Increase) decrease in prepaid and other assets	344,699	85,723	(562,972)
Increase (decrease) in accounts payable and accrued liabilities	(2,360,336)	1,221,208	2,530,395
Decrease in long-term liabilities		(14,270)	
Net cash used in operating activities	(12,616,416)	(23,787,604)	(98,439,063)
Cash flows from investing activities:			
Proceeds from sales and maturities of short-term investments		33,243,602	112,788,378
Purchases of short-term investments		(14,355,784)	(111,183,884)
Purchases of property and equipment		(64,955)	(1,030,354)
Proceeds from sale of property and equipment	16,000	33,906	49,906

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

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ADVENTRX Pharmaceuticals, Inc. and Subsidiaries
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	Years Ended December 31, 2009	2008	Inception (June 12, 1996) Through December 31, 2009
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	16,000	18,856,769	1,041,234
Cash flows from financing activities:			
Proceeds from sale of common stock			84,151,342
Proceeds from exercise of stock options			712,367
Proceeds from sale or exercise of warrants	3,013,920		14,396,814
Proceeds from sale of preferred stock	9,820,500		14,021,493
Repurchase of warrants			(55,279)
Payments for financing and offering costs	(1,416,504)		(7,900,313)
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	11,417,916		106,065,233
Net (decrease) increase in cash and cash equivalents	(1,182,500)	(4,930,835)	8,667,404
Cash and cash equivalents at beginning of period	9,849,904	14,780,739	
Cash at end of period	$ 8,667,404	$ 9,849,904	$ 8,667,404

See accompanying notes to consolidated financial statements.

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(1) Description of Business

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation (ADVENTRX, we or the Company), is a development-stage specialty pharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. We seek to improve the performance of existing drugs by addressing limitations associated principally with their safety and use. We have devoted substantially all of our resources to research and development (R&D), or to acquisition of our product candidates. 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, but this subsidiary was dissolved by us in December 2009. In April 2006, we acquired all of the outstanding capital stock of SDP through a merger with our newly created wholly-owned subsidiary, Speed Acquisition, Inc. (the Merger Sub) and changed the name of the Merger Sub to SD Pharmaceuticals, Inc.

(2) Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, SDP and ADVENTRX (Europe) Ltd. up until its dissolution in December 2009. 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.

Cash Equivalents

Cash equivalents consist of highly liquid investments with original maturities of three months or less at the date of purchase. The carrying amounts approximate fair value due to the short maturities of these instruments. At December 31, 2009 and 2008, we did not have any cash equivalents.

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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, 2009 and 2008, our cash was in excess of the Federal Deposit Insurance Corporation limit and we did not have any cash equivalents or investment securities.

During 2009, approximately 28% or $3.5 million of our total vendor payments were made to a manufacturer that provided process development and scale-up manufacturing services that assisted us in completing a New Drug Application (NDA) our lead product candidate, ANX-530, filed with the United States Food and Drug Administration (FDA) in December 2009. These services are continuing for our other lead product candidate, ANX-514. If we were to lose this vendor, our progress toward commercializing our lead product candidates would be severely impeded.

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.

Property and Equipment

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

Impairment of Long-Lived Assets

Long-lived assets with finite lives are evaluated for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the evaluation indicates that intangibles or long-lived assets are not recoverable (i.e., carrying amount is less than the future projected undiscounted cash flows), their carrying amount would be reduced to fair value. Since inception through December 31, 2009, 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 may enter into revenue arrangements that contain multiple deliverables. In these cases, 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) collectability 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 the revenue recognition criteria 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.

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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 is incorporated into products that, or such 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 clinical research organizations (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

We immediately charge the costs associated with purchased in-process research and development (IPR&D) to the 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 incorporated into products 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.

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Stock-Based Compensation

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 on a straight-line basis. Stock-based compensation expense recognized in the consolidated statements of operations for the years ended December 31, 2009 and 2008 is based on awards ultimately expected to vest and has been reduced for estimated forfeitures. This estimate will be revised in subsequent periods if actual forfeitures differ from those estimates. We have no awards with market or performance conditions.

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 basis 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.

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.

We account for interest and penalties related to income tax matters in income tax expense.

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.

Net Loss per Common Share

We calculate basic and diluted net loss per share by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share was calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding during the period. For purposes of this calculation, options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

We have excluded the following options and warrants from the calculation of diluted net loss per common share for 2009 and 2008 because their effect is anti-dilutive:

	2009	2008
Warrants	23,658,733	13,373,549
Options	5,859,000	4,364,833
	29,517,733	17,738,382

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Supplemental Cash Flow Information

	Years Ended December 31, 2009	2008	Inception (June 12, 1996) Through December 31, 2009
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	94,632		97,337
Acquisitions			24,781,555
Payment of dividends			213,000
Financial advisor services in conjunction with private placements	691,812		1,829,268
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 loss on short-term investments		2,702	
Cumulative preferred stock dividends	5,738,500		5,738,500

Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued ASC 105, *Generally Accepted Accounting Principles*, (GAAP) which establishes the FASB Accounting Standards Codification (ASC) as the sole source of authoritative U.S. GAAP other than guidance issued by the SEC. Pursuant to the provisions of ASC 105, the Company has updated references to U.S. GAAP in its financial statements issued effective for the period ended September 30, 2009. The adoption of ASC 105 had no impact on our consolidated results of operations, financial position or cash flows.

In October 2009, the FASB issued Accounting Standard Update (ASU) No. 2009-13, *Revenue Recognition* (ASC 605) *Multiple-Deliverable Revenue Arrangements a consensus of the FASB Emerging Issues Task Force*. The guidance modifies the fair value requirements of ASC subtopic 605-25 *Revenue Recognition Multiple Element Arrangements* by providing principles for allocation of consideration among its multiple elements, allowing more flexibility in

identifying and accounting for separate deliverables under an arrangement. An estimated selling price method is introduced for valuing the elements of a bundled arrangement if vendor-specific objective evidence or third-party evidence of selling price is not available, and significantly expands related disclosure requirements. This updated guidance will be effective for our fiscal year 2010 for revenue arrangements entered into or materially modified during 2010 and may be applied retrospectively or prospectively. We are evaluating the effects, if any, the adoption of the guidance will have on our consolidated financial statements.

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In May 2009, the FASB issued ASC 855, *Subsequent Events*, which established general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued or available to be issued. ASC 855 requires new disclosure in financial statements by providing the date through which reporting entities have evaluated events or transactions that occur after the balance sheet date but before the financial statements are issued or available to be issued. ASC 855 requires public entities, including the Company, to evaluate subsequent events through the date that the financial statements are issued. Financial statements are considered issued when they are widely distributed to stockholders and other financial statement users for general use and reliance in a form and format that complies with U.S. GAAP. ASC 855 was effective for our financial statements issued for the period ended June 30, 2009. The adoption of ASC 855 had no impact on our consolidated results of operations, financial position or cash flows.

In December 2007, the FASB revised the authoritative guidance for business combinations, which establishes principles and requirements for how the acquirer in a business combination (i) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree, (ii) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase and (iii) determines what information to disclose to enable the uses of the financial statements to evaluate the nature and financial effects of the business combination. 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. The guidance was effective for financial statements issued for fiscal year 2009, applied prospectively to business combinations completed on or after January 1, 2009, and did not have a material effect on our consolidated financial statements.

The FASB issued authoritative guidance for fair value measurements in September 2006, which defines fair value, establishes a framework for measuring fair value and expands disclosures about assets and liabilities measured at fair value in the financial statements. We adopted the provisions of the guidance for financial assets and liabilities effective for fiscal year 2008 but elected a partial one-year deferral under the provisions related to nonfinancial assets and liabilities that are measured at fair value on a nonrecurring basis, except those that are recognized or disclosed in the consolidated financial statements on at least an annual basis. Effective in fiscal 2009, we have fully adopted all provisions for fair value measurements, which did not have any impact on our consolidated results of operations or financial condition.

(3) Fair Value Measurements

We adopted the authoritative guidance for fair value measurements and the fair value option for financial assets and financial liabilities beginning January 1, 2009. We did not record an adjustment to retained earnings as a result of the adoption of the guidance for fair value measurements, and the adoption did not have a material effect on our consolidated results of operations. The guidance for the fair value option for financial assets and financial liabilities provides companies the irrevocable option to measure many financial assets and liabilities at fair value with changes in fair value recognized in earnings. We have not elected to measure any financial assets or liabilities at fair value that were not previously required to be measured at fair value.

Fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. The guidance also establishes fair value hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company s assumptions about the factors market participants would use in valuing the asset or liability. The guidance establishes three levels of inputs that may be used to measure fair value as follows:

Level 1 Quoted prices in active markets for identical assets or liabilities.

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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.

At December 31, 2009, we had no financial assets or liabilities required to be measured at fair value.

(4) Property and Equipment

Property and equipment at December 31, 2009 and 2008 were as follows:

	Useful Lives	2009	2008
Office furniture, computer and lab equipment	3 5 years	$ 293,480	$ 720,257
Computer software	3 years	89,422	103,306
		382,902	823,563
Less accumulated depreciation and amortization		(338,692)	(624,511)
Property and equipment, net		$ 44,210	$ 199,052

Depreciation and amortization expense was $79,728 and $168,039 for the years ended December 31, 2009 and 2008, respectively.

(5) Accrued Liabilities

Accrued liabilities at December 31, 2009 and 2008 were as follows:

	2009	2008
Accrued contracts and study expenses	$ 1,144,279	$ 1,620,988
Other accrued liabilities	234,731	434,172
Deferred rent		22,028
Accrued liabilities	$ 1,379,010	$ 2,077,188

(6) Capital Stock and Warrants

Authorized Share Increase

On October 5, 2009, we filed a Certificate of Amendment to our Amended and Restated Certificate of Incorporation of the Company to increase the authorized shares of our common stock from 200,000,000 to 500,000,000.

0% Series A Convertible Preferred Stock

In June 2009, we completed a registered direct equity financing raising gross proceeds of approximately $2.0 million involving the issuance of 1,993 shares of our 0% Series A Convertible Preferred Stock with a stated value of $1,000 per share (Series A Stock), and 5-year warrants to purchase up to 8,116,290 shares of our common stock at an exercise price of $0.15 per share. In the aggregate, the shares of Series A Stock we issued are convertible into 18,036,199

shares of our common stock. We received approximately $1.7 million in net proceeds from the financing, after deducting the placement agent s fees and expenses and other offering expenses. All of the shares of the Series A Stock have been converted into common stock and are no longer outstanding. In December 2009, in connection with the exercise of warrants issued in the June 2009 financing, we issued 6.0 million shares of our common stock and received net proceeds of $0.9 million. In January 2010, in connection with the exercise of the remaining warrants issued in the June 2009 financing, we issued an additional 2,116,290 shares of our common stock and received an additional $0.3 million of net proceeds.

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The convertible feature of our Series A Stock and the terms of the warrants issued in connection with our Series A Stock provide for a rate of conversion or exercise that was below the market value of our common stock at issuance. The convertible feature of our Series A Stock is characterized as a beneficial conversion feature (BCF). The estimated relative fair values of the shares of our Series A Stock and the warrants issued in connection with such stock were calculated as approximately $1.2 million and $531,000, respectively. The value of the BCF was determined using the intrinsic value method and calculated as approximately $1.2 million. Because our Series A Stock did not have a stated redemption date, the value of the BCF was fully realized at the time our Series A Stock was issued. The fair value of the warrants was determined using the Black-Scholes option-pricing model at the date of issuance assuming a five-year term, stock volatility of 197.01%, and a risk-free interest rate of 2.81%. The value of the BCF is treated as a deemed dividend to the holders of our Series A Stock and, due to the potential immediate convertibility of our Series A Stock at issuance, was recorded as an increase to additional paid-in capital and accumulated deficit at the time of issuance.

We also issued warrants to purchase up to 901,810 shares of our common stock at an exercise price of $0.15 per share to the placement agent in the June 2009 financing as additional consideration for its services in connection with the financing. These warrants had a fair value of approximately $132,000 using the Black-Scholes option-pricing model. The warrants became exercisable on December 13, 2009 and are exercisable at any time on or before June 12, 2014.

5% Series B Convertible Preferred Stock

In July 2009, we completed a registered direct equity financing raising gross proceeds of approximately $1.4 million involving the issuance of 1,361 shares of our 5% Series B Convertible Preferred Stock with a stated value of $1,000 per share (Series B Stock). In the aggregate, the shares of Series B Stock we issued are convertible into 9,504,189 shares of our common stock. Our Series B Stock accrues a cumulative annual dividend of 5% per share until July 6, 2014, and no dividend thereafter. If our Series B Stock is converted at any time prior to July 6, 2014, we will pay the holder an amount equal to the total dividend that would have accrued in respect of the shares converted from the conversion date through July 6, 2014, or $250 per $1,000 of stated value of the shares converted, less any previous dividend paid on such shares before conversion. We received approximately $0.8 million in net proceeds from the financing after deducting the $340,250 we placed into an escrow account to pay the aggregate dividend payment in respect of our Series B Stock, placement agent s fees and expenses and other offering expenses. All of the shares of our Series B Stock have been converted into common stock and are no longer outstanding.

The convertible feature of our Series B Stock and the value of the dividend in respect thereof provide for a rate of conversion that was below the market value of our common stock at issuance. The convertible feature of our Series B Stock is characterized as a BCF. The estimated relative fair value of the shares of our Series B Stock was calculated as approximately $1.0 million. The value of the BCF was determined using the intrinsic value method and calculated as approximately $215,000. Because our Series B Stock does not have a stated redemption date, the value of the BCF was fully realized at the time our Series B Stock was issued. The value of the BCF is treated as a deemed dividend to the holders of our Series B Stock and, due to the potential immediate convertibility of our Series B Stock at issuance, was recorded as an increase to additional paid-in capital and accumulated deficit at the time of issuance.

We also issued warrants to purchase up to 475,209 shares of our common stock at an exercise price of $0.179 per share to the placement agent in the July 2009 financing as additional consideration for its services in connection with the financing. These warrants had a fair value of approximately $60,000 using the Black-Scholes option-pricing model at the date of issuance. The warrants became exercisable on January 7, 2010 and are exercisable at any time on or before July 6, 2014.

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5% Series C Convertible Preferred Stock

In August 2009, we completed a registered direct equity financing raising gross proceeds of approximately $0.9 million involving the issuance of 922 shares of our 5% Series C Convertible Preferred Stock with a stated value of $1,000 per share (Series C Stock). In the aggregate, the shares of Series C Stock we issued are convertible into 7,092,307 shares of our common stock. Our Series C Stock accrues a cumulative annual dividend of 5% per share until February 10, 2012, and no dividend thereafter. If our Series C Stock is converted at any time prior to February 10, 2012, we will pay the holder an amount equal to the total dividend that would have accrued in respect of the shares converted from the conversion date through February 10, 2012, or $125 per $1,000 of stated value of the shares converted, less any previous dividend paid on such shares before conversion. We received approximately $0.7 million in net proceeds from the financing after deducting the $115,250 we placed into an escrow account to pay the aggregate dividend payment in respect of our Series C Stock, placement agent s fees and expenses and other offering expenses. All of the shares of our Series C Stock have been converted into common stock and are no longer outstanding.

The convertible feature of our Series C Stock and the value of the dividend in respect thereof provide for a rate of conversion that was below the market value of our common stock at issuance. The convertible feature of our Series C Stock is characterized as a BCF. The estimated relative fair value of the shares of our Series C Stock was calculated as approximately $807,000. The value of the BCF was determined using the intrinsic value method and calculated as approximately $186,000. Because our Series C Stock does not have a stated redemption date, the value of the BCF was fully realized at the time our Series C Stock was issued. The value of the BCF is treated as a deemed dividend to the holders of our Series C Stock and, due to the potential immediate convertibility of our Series C Stock at issuance, was recorded as an increase to additional paid-in capital and accumulated deficit at the time of issuance.

We also issued warrants to purchase up to 354,615 shares of our common stock at an exercise price of $0.1625 per share to the placement agent in the August 2009 financing as additional consideration for its services in connection with the financing. These warrants had a fair value of approximately $48,000 using the Black-Scholes option-pricing model at the date of issuance. The warrants became exercisable on February 10, 2010 and are exercisable at any time on or before August 10, 2014.

4.25660% Series D Convertible Preferred Stock

On October 9, 2009, we completed a registered direct equity financing raising gross proceeds of approximately $11.3 million involving the issuance of 11,283 shares of our 4.25660% Series D Convertible Preferred Stock with a stated value of $1,000 per share (Series D Stock), and 5-year warrants to purchase up to an aggregate of 19,800,000 shares of our common stock. In the aggregate, the shares of Series D Stock we issued are convertible into 60,000,000 shares of our common stock. Our Series D Stock accrues a cumulative annual dividend of 4.25660% per share until October 9, 2020, and no dividend thereafter. If our Series D Stock is converted at any time prior to October 9, 2020, we will pay the holder an amount equal to the total dividend that would have accrued in respect of the shares converted from the conversion date through October 9, 2020, or $468.23 per $1,000 of stated value of the shares converted, less any previous dividend paid on such shares before conversion. We received approximately $5.1 million in net proceeds from the financing after deducting the approximately $5.3 million we placed into an escrow account to pay the aggregate dividend payment in respect of our Series D Stock, placement agent s fees and expenses and other offering expenses. In December 2009, in connection with the exercise of warrants issued in the October 2009 financing, we issued 14.4 million shares of our common stock and received net proceeds of $2.1 million. We may receive an additional $0.8 million of net proceeds from the exercise of the remaining warrants issued in the October 2009 financing. Those warrants, which have an exercise price of $0.1468 per share, are exercisable any time on or before October 9, 2014, subject to certain beneficial ownership limitations. All of the shares of our Series D Stock have been converted into common stock and are no longer outstanding.

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The convertible feature of our Series D Stock and the terms of the warrants issued in connection with our Series D Stock provide for a rate of conversion or exercise that was below the market value of our common stock at issuance. The convertible feature of our Series D Stock is characterized as BCF. The estimated relative fair values of the shares of our Series D Stock and the warrants issued in connection with such stock were calculated as approximately $3.9 million and $1.3 million, respectively. The value of the BCF was determined using the intrinsic value method and calculated as approximately $3.3 million. Because our Series D Stock did not have a stated redemption date, the value of the BCF was fully realized at the time our Series D Stock was issued. The fair value of the warrants was determined using the Black-Scholes option-pricing model at the date of issuance assuming a five-year term, stock volatility of 197.63%, and a risk-free interest rate of 2.36%. The value of the BCF is treated as a deemed dividend to the holders of our Series D Stock and, due to the potential immediate convertibility of our Series D Stock at issuance, was recorded as an increase to additional paid-in capital and accumulated deficit at the time of issuance.

We also issued warrants to purchase up to 3,600,000 shares of our common stock at an exercise price of $0.235 per share to the placement agent in the October 2009 financing as additional consideration for its services in connection with the financing. These warrants had a fair value of approximately $452,000 using the Black-Scholes option-pricing model at the date of issuance. The warrants are exercisable at any time on or after April 7, 2010 and on or before October 6, 2014.

Common Stock Issued for Warrants Exercised

In December 2009, we issued 14.4 million shares of our common stock and received net proceeds of $2.1 million in connection with the exercise of warrants issued in the October 2009 financing, at an exercise price of $0.1468 per share. Additionally in December 2009, we issued 6.0 million shares of our common stock and received net proceeds of $0.9 million in connection with the exercise of warrants issued in the June 2009 financing, at an exercise price of $0.15 per share.

During 2008, we issued no new additional shares of common stock.

Warrants

During 2009, warrants were issued to investors in conjunction with the Series A Stock and Series D Stock financings in June and October 2009, respectively. In addition, warrants were issued to the placement agent in each of the Series A Stock, Series B Stock, Series C Stock and Series D Stock financings in June 2009, July 2009, August 2009 and October 2009, respectively. See details of the equity financings above.

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. At December 31, 2009, outstanding warrants to purchase shares of common stock are as follows:

Warrants		Exercise Price	Expiration Date
10,810,809	$	2.2600	July 2012
2,116,290	$	0.1500	June 2014
901,810	$	0.1500	June 2014
475,209	$	0.1790	July 2012
354,615	$	0.1625	August 2014
5,400,000	$	0.1468	October 2014
3,600,000	$	0.2350	October 2014
23,658,733			

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(7) Equity Incentive Plans

At December 31, 2009, 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, 2009 and 2008 was comprised of the following:

		Years Ended December 31, 2009	2008
Selling, general and administrative expense		$ 543,868	$ 885,426
Research and development expense		41,569	725,464
Stock-based compensation expense before taxes		585,437	1,610,890
Related income tax benefits			
Stock-based compensation expense		$ 585,437	$ 1,610,890
Net stock-based compensation expense per common share	basic and diluted	$ 0.01	$ 0.02
Stock-based compensation expense from:			
Stock options		$ 585,437	