ADVENTRX PHARMACEUTICALS INC
Form 10-K
March 08, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2011

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File No. 001-32157

ADVENTRX Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

12390 El Camino Real, Ste 150, San Diego, CA **92130**
(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 LLC

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 ¨ No x

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

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 x No ¨

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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. x

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.

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2011 was approximately $77.9 million 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 by the registrant to own beneficially 10% 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, 2012, the registrant had 47,715,709 shares of its common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement to be filed subsequent to the date hereof with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant s 2012 annual meeting of stockholders are incorporated by reference into Part III of this report. Such definitive proxy statement will be filed with the Commission not later than 120 days after the end of the registrant s fiscal year ended December 31, 2011.

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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 information incorporated herein by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements regarding our business strategy, expectations and plans, our objectives for future operations and our future financial position. When used in this report, the words believe, may, could, will, estimate, continue, anticipate, intend, expect, indicate, seek, should or would and similar expressions are intended to identify forward-looking statements. Among the factors that could cause or contribute to material differences between our actual results and those indicated from the forward-looking statements are risks and uncertainties inherent in our business, including, but are not limited to: our ability to successfully develop, obtain regulatory approval for and then successfully commercialize our product candidates; our ability to obtain additional funding on a timely basis or on acceptable terms, or at all; the potential for us to delay, reduce or discontinue current and/or planned development activities, partner our product candidates at inopportune times or pursue less expensive but higher-risk development paths if we are unable to raise sufficient additional capital as needed; delays in the commencement or completion of a clinical study of or manufacturing and regulatory activities related to our product candidates; suspension or termination of a clinical study; the ability of our product candidates to demonstrate acceptable safety and efficacy in clinical studies; our ability to maintain our relationships with the single-source third-party manufacturers and suppliers for our product candidates and certain of their component materials and the ability of such manufacturers and suppliers to successfully and consistently meet our manufacturing and supply requirements; the satisfactory performance of third parties, including contract research organizations, on whom we rely significantly to conduct our nonclinical testing, clinical studies and other aspects of our development programs; the extent of market acceptance of any of our product candidates for which we receive regulatory approval; the extent to which we acquire new technologies and/or product candidates and our ability to integrate them successfully into our operations; the potential that we may enter into one or more commercial partnerships or other strategic transactions relating to our product candidates, and the terms of any such transactions; the extent to which we increase our workforce and our ability to attract and retain qualified personnel and manage growth; competition in the marketplace for our products, if any are approved; our ability to protect our intellectual property rights with respect to our product candidates and proprietary technology; claims against us for infringing the proprietary rights of third parties; healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent our products commercial success; potential product liability exposure and, if successful claims are brought against us, liability for a product or product candidate; our ability to maintain compliance with NYSE Amex continued listing standards and maintain the listing of our common stock on the NYSE Amex or another national securities exchange; and other risks and uncertainties described in Part I, Item 1A Risk Factors of this report.

We have based the forward-looking statements we make 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. In light of these risks and uncertainties and our assumptions, the forward-looking events and circumstances discussed in this report and in the information incorporated herein by reference may not occur. We cannot guarantee future results, events, levels of activity, performance or achievement. Accordingly, you are cautioned not to place undue reliance on forward-looking statements. 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.

PART I

Item 1. Business.

Overview

We are a biopharmaceutical company focused on developing proprietary product candidates. Our lead product candidate is ANX-188, a rheologic, antithrombotic and cytoprotective agent that improves microvascular blood flow and has potential application in treating a wide range of diseases and conditions, such as complications arising from sickle cell disease. We also are developing ANX-514, a novel, detergent-free formulation of the chemotherapy drug docetaxel. We are a development-stage company and have not yet marketed or sold any products or generated any significant revenue.

Business Strategy

Our goal is to be a successful biopharmaceutical company through the development of proprietary product candidates. Currently, we are focused in the areas of hematology (in particular, the treatment of diseases and conditions resulting from microvascular-flow abnormalities) and oncology. Critical components of our business strategy include the following:

Seek regulatory approval of ANX-188 in the U.S. We are focusing our resources primarily on ANX-188, including initiating a phase 3 study in 2012 for the treatment of patients with complications arising from sickle cell disease. In addition, we plan to conduct a number of smaller-scale clinical studies to further assess the efficacy, safety and tolerability of ANX-188, and we expect these studies to overlap the planned phase 3 study.

Determine the optimal development path for ANX-514. We are evaluating the optimal development path for ANX-514, including options for investigating its potential clinical benefits, and, in conjunction, may conduct additional nonclinical and/or clinical studies. In particular, we are evaluating methods, including devices that may measure fluid retention more accurately and objectively then assessment through clinical observation, and whether a device may enable us to reduce the size of future studies. In parallel, we are continuing certain manufacturing development activities to support a clinical study.

Pursue additional indications for our product candidates independently and through collaborations. We may seek to increase the value of our product candidates by pursuing approval for additional indications. For example, beyond treating complications related to sickle cell disease, we believe ANX-188 may have clinical benefits in other acute events related to microvascular-flow abnormalities, such as blood transfusions, heart attack, stroke and hemorrhagic shock.

Although our current focus is on the development of ANX-188 as well as ANX-514, from time to time we may evaluate pipeline expansion opportunities that we believe will increase the long-term value of our company.

Product Candidates

ANX-188 (purified poloxamer 188)

Background

ANX-188 is an aqueous solution of a purified form of poloxamer 188. Poloxamer 188, or P188, is a nonionic, block copolymer that has been found to improve microvascular blood flow by reducing viscosity, particularly under low shear conditions, and by reducing adhesive frictional forces.

Non-purified forms of P188 have been used in foods, drugs and cosmetics since the 1950s. In the 1980s, extensive research on the mechanisms and potential clinical applications of P188 was conducted. Research has demonstrated that P188 binds to hydrophobic surfaces that develop when cells are damaged and restores normal hydrated surfaces, while having little or no activity in normal, healthy tissues. Research also has demonstrated that

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P188 prevents adhesion and aggregation of soluble fibrin and formed elements in the blood and maintains the deformability of red blood cells, the non-adhesiveness of unactivated platelets and granulocytes and the normal viscosity of blood. In addition, it is believed that P188 is not metabolized, but is excreted unchanged in the urine with a half-life of approximately four to six hours.

Formulations of P188 (non-purified and purified) have been studied in clinical trials involving nearly 4,000 individuals. It has been evaluated in the clinic to treat acute myocardial infarction, sickle cell disease and malaria, including a 2,950-patient, randomized, controlled study of P188 (non-purified) in acute myocardial infarction. The effectiveness of P188 also has been investigated in nonclinical studies of stroke, hemorrhagic shock, bypass surgery, adult respiratory distress syndrome, neurologic protection in deep hypothermic circulatory arrest, vasospasm, spinal cord injury, angioplasty, frostbite, amniotic fluid embolism, acute ischemic bowel disease and burns.

Our purified form of P188, or purified P188, which is the active ingredient in ANX-188, was designed to eliminate certain low molecular weight substances present in P188 (non-purified), which we believe were primarily responsible for the moderate to moderately severe elevations in serum creatinine levels (acute renal dysfunction) observed in prior clinical studies of P188 (non-purified). Purified P188 has been evaluated in multiple clinical studies by a prior sponsor, including a 255-patient, phase 3 study. In that study, purified P188 was generally well tolerated and there were no clinically significant elevations in serum creatinine among subjects who received purified P188 compared to placebo.

We believe that, as a rheologic, antithrombotic and cytoprotective agent, ANX-188 has potential application in treating a wide range of diseases and conditions resulting from microvascular-flow abnormalities. Initially, we are developing ANX-188 for the treatment of patients suffering from complications arising from sickle cell disease, but we intend to pursue additional indications for ANX-188 independently and/or through collaborations.

Sickle Cell Disease Market and Opportunity

More than $1.0 billion is spent annually in the U.S. to treat patients with sickle cell disease. Sickle cell disease is a genetic disorder characterized by the sickling of red blood cells, which normally are disc-shaped, deformable and move easily through the microvasculature carrying oxygen from the lungs to the rest of the body. Sickled, or crescent-shaped, red blood cells, on the other hand, are rigid and sticky and tend to adhere to each other and the vascular endothelium. Patients with sickle cell disease are known to experience severely painful episodes associated with the obstruction of small blood vessels by sickle-shaped red blood cells. These painful episodes are commonly known as acute crisis or vaso-occlusive crisis. Reduced blood flow to organs and bone marrow during vaso-occlusive crisis not only causes intense pain, but can result in tissue death, or necrosis. The frequency, severity and duration of these acute crises can vary considerably.

We estimate that, in the U.S., sickle cell disease results in over 95,000 hospitalizations and, in addition, approximately 69,000 emergency department treat-and-release encounters each year. When a patient with sickle cell disease makes an institutional visit, vaso-occlusive crisis is the primary diagnosis in approximately 77% of hospital admissions and 64% of emergency room treat-and-release encounters. In addition, although the number is difficult to measure, we estimate that the number of untreated sickle cell crisis events is substantial and in the hundreds of thousands in the U.S. each year. We believe that, if ANX-188 is approved, as people with sickle cell disease are made aware of the new therapy, more people who suffer from acute crisis will seek treatment.

A number of other serious complications can arise from sickle cell disease, including acute chest syndrome, splenic sequestration, priapism, avascular necrosis, central nervous system abnormalities and the need for frequent blood transfusions. Acute chest syndrome is a leading cause of death in patients with sickle cell disease, and we estimate that, in the U.S., there are nearly 10,000 episodes of acute chest syndrome associated with sickle cell disease every year. Up to half of patients diagnosed with acute chest syndrome are hospitalized initially for other reasons, most often vaso-occlusive crisis, and subsequently develop acute chest syndrome. The underlying cause of acute chest syndrome is believed to be pulmonary hypoxia and lung injury, which itself results from varied causes, including pulmonary infection, fat emboli and rib infarction, with the latter two being common complications of vaso-occlusive crisis. Acute chest syndrome typically is characterized by a pulmonary infiltrate evident on a chest radiograph in combination with clinical symptoms, such as fever, cough, chest pain, shortness of breath, wheezing, hypoxemia, increased leukocytosis or worsening anemia.

We are not aware of any currently available therapeutic agents with demonstrated efficacy in shortening the duration or reducing the severity of an ongoing vaso-occlusive crisis or acute chest syndrome episode. Once a vaso-occlusive crisis occurs, treatment typically consists of hydration, oxygenation and analgesia, usually using narcotics. In addition, treatment for acute chest syndrome includes incentive spirometry, administration of antibiotics and bronchodilators and simple and exchange blood transfusion. By improving microvascular blood flow and reducing tissue ischemia, ANX-188 has the potential to reduce the incidence and severity and shorten the duration of vaso-occlusive crisis and/or acute chest syndrome and improve patient outcomes.

Clinical Development of ANX-188 in Patients with Sickle Cell Disease

Prior sponsors have conducted multiple clinical studies of ANX-188 in patients with sickle cell disease, including a phase 3 study in patients experiencing acute vaso-occlusive crisis and a phase 1 study in patients experiencing acute chest syndrome. ANX-188 was found to be generally safe and well-tolerated in these studies.

Phase 3 Study in Treatment of Vaso-occlusive Crisis in Patients with Sickle Cell Disease. A 255-patient, randomized, double-blind, placebo-controlled study of ANX-188 in patients with sickle cell disease experiencing vaso-occlusive crisis was conducted in 1998-1999 and signs of efficacy were observed in the primary endpoint, duration of crisis. However, the study did not meet its primary endpoint. We believe features of the study s design and the study not enrolling the originally-planned number of patients may have diluted the treatment effect or its significance. Notably, in a planned subgroup analysis in children (n=73), in which the effect of confounding factors may have been mitigated (such as chronic pain syndrome, which is less prevalent in children), a statistically significant and greater treatment effect was observed. In terms of safety, there were no differences between the two treatment groups in the overall incidence of adverse events, for adverse events defined as serious, or for adverse events involving any body system for the groups as a whole. This study demonstrated that there were no clinically significant changes in renal function following treatment with ANX-188. The ANX-188 arm was associated with transient, generally mild to moderate elevations in liver function tests (AST (aspartate aminotransferase), ALT (alanine aminotransferase) and total and direct bilirubin), each of which returned to its respective baseline level by the day-35 follow-up visit.

Phase 1 Study in Treatment of Acute Chest Syndrome in Patients with Sickle Cell Disease. A 43-patient, open-label, multicenter, dose-escalation study of ANX-188 in patients experiencing an acute chest syndrome episode was conducted in 1997-1999 and demonstrated that ANX-188 is safe and well-tolerated in adults and children at doses as high as 120 mg/kg/hour over 24 hours administered by continuous IV infusion. The maximum tolerated dose was not identified. This study also demonstrated that there were no clinically significant changes in renal function associated with treatment with ANX-188. Transient, generally mild to moderate elevations in liver function tests (AST, ALT and total and direct bilirubin) were associated with treatment with ANX-188. However, liver function resolved to baseline level usually within 10 days and no later than the day-35 follow-up visit. This study demonstrated dose-related trends for shortening the duration of acute chest syndrome episodes and the duration of hospitalization.

Planned Clinical Studies. In December 2011, we announced that we met with the U.S. Food and Drug Administration, or FDA, to discuss our overall development plans for ANX-188, as well as the design of a phase 3 study for the treatment of patients with sickle cell disease. We have since had additional interaction with the FDA, as well as with key opinion leaders in sickle cell disease, and continue to develop the trial design. Although additional work is necessary to finalize the protocol and primary endpoint, currently, we plan to initiate a phase 3 study of ANX-188 in patients with sickle cell disease in 2012.

In addition, we plan to conduct a number of smaller-scale clinical studies to further assess the efficacy, safety and tolerability of ANX-188, including a pilot phase 2 study in patients with sickle cell disease. We expect these studies to overlap the planned phase 3 study and provide supportive safety and efficacy data.

ANX-514 (docetaxel for injectable emulsion)

Overview

ANX-514 is a novel, detergent-free emulsion formulation of docetaxel, an intravenously-injected chemotherapy drug commonly used to treat solid tumors. Taxotere®, a branded formulation of docetaxel, is approved to treat breast, non-small cell lung, prostate, gastric, and head and neck cancers. The ANX-514 formulation was designed to have efficacy comparable to Taxotere without the non-active, toxic components found in Taxotere and without the corticosteroid premedication regimen required with Taxotere.

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. Certain adverse 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. In addition, adverse side effects can be associated with other drugs required to be administered with the chemotherapy drug. We believe formulating chemotherapy drugs with less toxic components can reduce undesirable side effects and provide other advantages. Novel formulations may provide patients with more tolerable treatment options without compromising the efficacy of a particular drug s active ingredient.

Limitations of Taxotere® and Other Docetaxel Formulations

Despite its demonstrated efficacy and commercial success, the Taxotere formulation has limitations; principally, toxicity associated with its excipient, polysorbate 80, and the corticosteroid premedication regimen intended to ameliorate Taxotere-related toxicities. Docetaxel, the active ingredient in Taxotere, is lipophilic and practically insoluble in water. Successful development of the molecule for intravenous administration involved formulating the active ingredient with polysorbate 80 (1:26 docetaxel:polysorbate 80), a nonionic surfactant used in parenteral drug formulations as a solvent or solubilizing agent for drugs with poor aqueous solubility, and further dilution with ethanol. Currently available formulations of Taxotere also use detergents to solubilize docetaxel.

Taxotere is associated with acute hypersensitivity reactions, ranging widely in incidence and severity. Many patients suffer severe (in rare cases, fatal) hypersensitivity reactions immediately following Taxotere administration. The occurrence of hypersensitivity reactions may be attributed, in part, to the intrinsic toxic effects of polysorbate 80; more specifically, to its oxidation products, which are known to cause histamine release. Even following premedication with corticosteroids, which is required for Taxotere therapy as discussed below, hypersensitivity reactions have been observed, including, in rare cases, fatal anaphylaxis. Notably, Taxotere is contraindicated for patients with a history of hypersensitivity reactions to drugs formulated with polysorbate 80. Taxotere also is associated with fluid retention. The occurrence of fluid retention may be explained, in part, by the fact that polysorbate 80 has been shown to increase membrane permeability.

Taxotere therapy requires premedication with corticosteroids to reduce the severity of hypersensitivity reactions and the incidence and severity of fluid retention. The required premedication regimen for most cancer patients consists of oral corticosteroids, such as dexamethasone at 16 mg per day (e.g., 8 mg twice a day) for three days starting one day prior to Taxotere administration. Glucocorticoids, such as dexamethasone, affect blood-glucose levels, which can be problematic for diabetic patients, and may increase the risk of diabetes, osteoporosis and infection. In addition, while there is evidence supporting the proapoptotic and antiproliferative effect of dexamethasone in lymphoid cells, several *in vitro* and animal studies have determined that dexamethasone may inhibit the effectiveness of chemotherapy in solid tumors.

Potential Benefits of ANX-514

ANX-514 was designed to have clinically comparable release of docetaxel relative to Taxotere while eliminating the presence of polysorbate 80 and ethanol, both of which are used to solubilize docetaxel in the Taxotere formulation. The ANX-514 formulation solubilizes docetaxel using oil droplets comprised of a combination of non-toxic excipients. Docetaxel is contained within these oil droplets and can be administered intravenously without using detergents as pharmaceutical vehicles. Once in central circulation, the emulsion is metabolized rapidly, leaving chemically-identical active ingredient to exert its cytotoxic effect. The rate and extent of absorption of docetaxel from ANX-514 was designed to be comparable to that of Taxotere, resulting in similar clinical outcomes attributable to the active ingredient. Meanwhile, due to the absence of polysorbate 80 and ethanol in the ANX-514 formulation, ANX-514 may demonstrate an improved safety profile relative to Taxotere and other formulations of docetaxel that use detergents as solubilizing agents or that contain alcohol. ANX-514 may reduce the incidence and severity of hypersensitivity reactions and delay the onset of fluid retention.

In addition, dexamethasone premedication intended to address polysorbate 80-mediated hypersensitivity reactions and fluid retention may be unnecessary with detergent-free ANX-514. Avoiding the high-dose corticosteroid premedication required for treatment with Taxotere and other available docetaxel formulations could significantly benefit cancer patients, particularly diabetics or pre-diabetics (those with impaired fasting glucose), who we estimate constitute one-third of the patients who historically received Taxotere. Dexamethasone and other glucocorticoids are associated with development of hyperglycemia. A study published in 2009 in the *Journal of the National Cancer Institute* examined the effect of dexamethasone on blood glucose levels in 39 women being treated for adjuvant breast cancer. All patients received 8 mg of oral dexamethasone per cycle as an antiemetic, while those in a docetaxel arm received a 24 mg cumulative dose, which is half of the cumulative dose indicated with Taxotere. Before chemotherapy, none of the women had blood glucose in either the impaired glucose range or the diabetic range. However, among women who received the higher dose of dexamethasone, there was a statistically significant increase in blood glucose levels in later cycles (cycle 5: $p<0.001$; cycle 6: $p=0.002$). Following the fifth cycle, six women had blood glucose levels in the impaired range and eight women had levels within the diabetic range.

Further, if corticosteroid premedication interferes with the therapeutic activity of docetaxel by protecting the tumor from cytotoxic treatment or enhancing metastases, the removal of the premedication regimen may improve the efficacy of docetaxel treatment. In addition, if ANX-514 is more tolerable than other docetaxel formulations, patients treated with ANX-514 may be able to tolerate a longer duration of therapy, which has the potential to further improve the efficacy of docetaxel treatment.

The Docetaxel Market

Until 2011, Taxotere was the only docetaxel formulation available in the U.S. Based on data from IMS Health, in 2010, sales of Taxotere were $1.2 billion in the U.S. and $2.9 billion worldwide, making it one of the top-selling anti-cancer agents in the world. The expiration in 2010 of U.S. patents covering docetaxel opened the door for new formulations and, since then, several non-Taxotere formulations of docetaxel have been approved by the FDA and generic versions of Taxotere are expected. While we expect substantial price erosion as a result of the introduction of these non-Taxotere and generic formulations, we believe the number of cancer patients treated with docetaxel will continue to grow modestly year over year and that there is significant opportunity for a detergent-free docetaxel formulation, particularly one that allows for the elimination of the corticosteroid premedication required with Taxotere.

Development Strategy; Additional Studies

The first clinical study of ANX-514 sought to demonstrate the bioequivalence of ANX-514 to Taxotere. We refer to that study, which was completed in 2009, as Study 514-01. In May 2009, we announced that bioequivalence, the primary endpoint of Study 514-01, was not demonstrated based on the FDA s benchmark standards. The study data revealed higher median 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, median total docetaxel blood-levels were comparable and remained so through the end of the observation period. Following extensive analysis and modeling of the data from Study 514-01 and published results from other trials using Taxotere, we reached the conclusion that comparable clinical outcomes can be expected following treatment with ANX-514 or Taxotere, despite Study 514-01 not demonstrating bioequivalence using FDA s benchmark standards. However, the FDA determined that, because the maximum plasma concentrations, or C_{max}, for total docetaxel was higher following administration with ANX-514, additional development activities would be required.

In October 2011, we reached agreement with the FDA on a pivotal study for ANX-514 that would support approval of ANX-514 without a corticosteroid premedication regimen. We agreed on a 400-patient, non-inferiority study with a primary objective of comparing fluid retention following treatment with ANX-514, administered without corticosteroid premedication, and Taxotere, administered with corticosteroid premedication. However, the diagnosis and reporting of fluid retention in cancer patients can be subjective and highly variable. Accordingly, we are evaluating methods, including devices, that can assess the incidence of fluid retention in our planned study population more accurately and objectively than the current method of clinical observation. Notably, incorporating into our study a device capable of more precisely measuring fluid retention may increase the fluid retention event rate and allow us to reduce the number of patients needed to demonstrate non-inferiority. Our near-term focus will be to evaluate these methods and devices (including, possibly, in clinical studies) and to discuss with the FDA our findings and whether use of a method or device could reduce the sample size of the previously agreed study design. As we investigate a development path for ANX-514, if we determine the anticipated capital requirements associated with continued development of ANX-514 are not financially justifiable, we may determine to discontinue this program.

Development Outside the U.S.

In March 2009, we announced that we and our wholly-owned subsidiary, SD Pharmaceuticals, Inc., had 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 agreement, we received an upfront licensing fee and are entitled to receive a regulatory milestone payment upon receipt of regulatory approval for marketing a licensed product in South Korea (the amount depends on whether the Korea Food and Drug Administration requires Shin Poong to conduct a bioequivalence or clinical study in human subjects prior to receipt of regulatory approval), one-time commercial milestone payments tied to annual net sales of licensed products 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.

Exelbine (vinorelbine injectable emulsion)

Exelbine 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.

In November 2010, we submitted to the FDA a new drug application, or NDA, for Exelbine seeking approval of Exelbine for the same indications as Navelbine. The NDA included data from an open-label, single-dose, cross-over comparison study of 31 patients that demonstrated the bioequivalence of Exelbine and Navelbine based on federal regulations and FDA guidance regarding bioequivalence studies by a statistical comparison of both the areas under the curve (AUC) and Cmax.

In August 2011, we received a complete response letter from the FDA stating that it could not approve the Exelbine NDA in its present form and that the bioequivalence study would need to be repeated because the authenticity of the drug products used in the bioequivalence trial could not be verified in accordance with FDA standards. Notably, at a meeting with the FDA following our receipt of the complete response letter, FDA staff commented that no clinical deficiencies were noted with the bioequivalence study and that there were no comments regarding our conclusion that Exelbine and Navelbine are bioequivalent. However, we elected to discontinue independent development of Exelbine and are seeking a partner or outside investor for the program to complete the necessary bioequivalence study.

Competition

If regulatory authorities approve the marketing and selling of any of our product candidates, we expect that our products 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 achieves significant commercial success. Most of our competitors, particularly large pharmaceutical companies, have greater clinical, regulatory, manufacturing, marketing, distribution, compliance and financial resources and experience than do we.

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

ANX-188 in Sickle Cell Disease

Currently, there are few options for patients suffering complications arising from sickle cell disease. Patients in acute crisis typically are provided analgesics, such as morphine, for pain. Hydroxyurea, a form of chemotherapy used for myeloproliferative disease, is an approved product that has been shown to decrease the frequency of crisis, but hydroxyurea does not treat the crisis itself. Patients with acute chest syndrome are provided incentive spirometry, antibiotics or bronchodilators. Blood transfusions, which carry risk of infection, allergic reactions and iron overload, also are used to treat patients with acute chest syndrome.

There is substantial interest, however, in developing agents for the treatment of sickle cell disease-related complications. In addition to for-profit commercial enterprises, numerous foundations and interest groups also are committed to treating sickle cell disease and preventing or mitigating vaso-occlusive crisis and acute chest syndrome. We are aware of numerous companies with product candidates in varying stages of development for the treatment of sickle cell crisis, including mechanisms that target the sPLA2 enzyme or P2Y12 ADP receptor, increase oxygen binding of hemoglobin or stimulate production of fetal hemoglobin. Advances in the understanding of the signaling pathways associated with sickle cell disease may lead to further interest and development of treatment options.

More broadly, ANX-188 would compete against agents designed to treat the underlying pathology of sickle cell disease, of which vaso-occlusive crisis and acute chest syndrome are associated complications. Bone marrow and stem cell transplantation have been shown to be effective to treat and, in some cases, cure sickle cell disease, but current methods are not available to the majority of patients due to their high cost, the unavailability of a well-matched donor and the risk of serious complications, including graft vs host disease and infection.

Further, there is increasing interest in developing drugs for rare diseases, which may have the effect of increasing the development of agents to treat sickle cell disease and complications associated with sickle cell disease, including vaso-occlusive crisis. Each of GlaxoSmithKline and Pfizer has formed a unit focused on rare diseases. Legislative action, such as the potential to expand the priority review voucher system to rare pediatric diseases, may further generate interest.

ANX-514

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 and the treatment limitations associated with certain formulations (principally, toxicity associated with non-active components in the formulations), have generated significant interest in reformulating Taxotere and other taxanes. In addition to our approach of emulsifying docetaxel, we are aware of other companies pursuing alternative delivery vehicles, including the use of albumin nanoparticles, prodrugs, polyglutamates, analogs, co-solvents, liposomes, PEGylation and microspheres. For instance, in 2005, the FDA approved Abraxane,® an albumin-bound form of paclitaxel, which belongs to the taxane class. Relative to ANX-514, 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.

More specifically, ANX-514, if approved, would compete against Taxotere, its generic equivalents and other formulations of docetaxel that have been and may be approved by the FDA. U.S. patents covering docetaxel expired in 2010 and several non-Taxotere formulations of docetaxel have been approved by the FDA and launched in the U.S. and we expect additional formulations to continue to enter the market. For instance, in January 2012, a new formulation of docetaxel manufactured by Apotex, Inc. was approved by the FDA.

Further, at least one company has recently developed a new taxane that could compete with ANX-514. In 2010, the FDA approved Jevtana,® the active ingredient of which is cabazitaxel, a microtubule inhibitor belonging to the taxane class. Companies may pursue other taxane analogs that could result in greater efficacy or safety, provide better drug delivery to tumor sites or otherwise improve benefits to patients and healthcare providers, all of which could be competitive with ANX-514.

Finally, ANX-514, if approved, may be displaced by and could compete with non-taxane drugs approved to treat cancer. For instance, in 2010, the FDA approved Provenge® for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. Provenge therefore is approved for

use at an earlier stage of prostate cancer progression than ANX-514 would be approved, if ANX-514 is approved for the same indications for which Taxotere is approved. In addition to Provenge, we are aware of numerous drugs in on-going pivotal studies that are being developed for hormone refractory prostate cancer.

Manufacturing

We do not have and do not intend to establish, our own manufacturing facilities. We meet our requirements for nonclinical and clinical trial material (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. However, we do not yet have any long-term agreements with our current third-party manufacturers and suppliers. We currently meet our needs through individual proposals and purchase orders and typically rely on terms and conditions proposed by the third party or us to govern our rights and obligations under each order (including provisions with respect to intellectual property, if any). We intend to seek to establish long-term supply arrangements in the future, which may require us to agree to minimum volume requirements, exclusivity arrangements and/or other restrictive terms.

There are a limited number of manufacturers with the technical capabilities and desire to perform the specialized, proprietary processes required to produce ANX-188 and ANX-514. For example, production of purified P188, the API for ANX-188, requires application of an extraction process to P188, and production of ANX-514 requires emulsion and lyophilization processes. We do not plan to engage alternatives to our primary manufacturers and key component suppliers for ANX-188 and ANX-514. Therefore, if our primary sources become unable or unwilling to perform, we could experience protracted delays or interruptions in the supply of clinical trial material.

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. As discussed above, our alternatives may be limited due to proprietary technologies or methods used in the manufacture 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-188 in Sickle Cell Disease

Pursuant to an agreement with CytRx Corporation (described below under Licensing Agreements), we have exclusive rights to a variety of issued patents related to poloxamers and their uses. The issued patents cover, among other things, P188, purified P188, methods of treating sickle cell anemia using P188 and methods of preparing purified P188. However, we expect that many of the patents to which we have rights under this license agreement will expire prior to obtaining regulatory approval for ANX-188.

We believe the primary method of exclusivity for ANX-188 for the treatment of sickle cell disease patients in acute crisis will be the orphan drug designation that the FDA has granted for P188. As described below under Government Regulation, if ANX-188 is the first P188 drug product to receive FDA approval for the treatment of sickle cell crisis, the FDA may not approve any other application to market a P188 drug product for sickle cell crisis for a period of seven years, except in limited circumstances, such as another P188 product showing clinical superiority to ANX-188. However, orphan drug designation does not necessarily convey any advantage in, or shorten the duration of, the regulatory review and approval process. In addition, competitors may receive approval of different drugs or biologics for sickle cell crisis or sickle cell disease generally.

We also own certain patent applications related to ANX-188 for the treatment and diagnosis of chronic inflammation due to chronic microvascular diseases and use in increasing the safety and efficacy of blood transfusions and improving oxygenation of jeopardized tissue.

ANX-514

We own world-wide rights (excluding China, Hong Kong, Macau and Taiwan) to patent applications covering the composition and use of ANX-514, subject to the exclusive licenses we have granted to Latitude Pharmaceuticals (described below under Licensing Agreements) and Shin Poong Pharmaceutical Co., Ltd. (described above under Product Candidates ANX-514 Development Outside the U.S.). Patent applications, entitled Low Oil Emulsion Compositions for Delivering Taxoids and Other Insoluble Drugs, currently are pending in the U.S., Canada, India, Japan, South Korea, Mexico and 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, Australia, India, Japan, South Korea, Mexico, 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.

Exelbine

We own world-wide rights (excluding China, Hong Kong, Macau and Taiwan) to patents and patent applications covering the composition and use of our vinorelbine injectable emulsion product candidate, subject to the exclusive license we granted to Latitude Pharmaceuticals (described below under Licensing Agreements). In 2011, the United States Patent and Trademark Office, or USPTO, issued U.S. Patent Nos. 7,871,632 and 8,026,250, entitled Compositions for Delivering Highly Water Soluble Drugs. These patents will expire in November 2027 and July 2024, respectively. In addition, in August 2011, we filed in the USPTO a continuation application in this patent family claiming a priority date of July 12, 2004 drawn to methods for cancer chemotherapy that substantially avoid vein irritation. With respect to patent protection outside the U.S., patents entitled Compositions for Delivering Highly Water Soluble Drugs have issued in Japan and the Eurasian Patent Office and will provide coverage for Exelbine until July 2025. In addition, patent applications entitled Compositions for Delivering Highly Water Soluble Drugs currently are pending in Canada, India, South Korea and the European 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 2025.

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.

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.

Trademarks

We have applied for trademark registration for EXELBINE in the U.S. We are developing commercial names for our other product candidates. All other trademarks, service marks or trade names appearing in this report, including but not limited to Taxotere® and Navelbine®, are the property of their respective owners. Use or display by us of other parties trademarks, service marks, trade names, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark, trade name, trade dress or product owners.

Research and Development

Our research and development expenses were $5.8 million in 2011 and $3.7 million in 2010. In 2011 and 2010, our research and development expenses consisted primarily of costs associated with external nonclinical activities, such as research-related manufacturing, commercial-readiness manufacturing for Exelbine, regulatory-related consulting services and stability testing. See Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations in this report for more information regarding our research and development expenses.

Licensing Agreements

CytRx Corporation

As described below under Acquisition of SynthRx, Inc., we acquired SynthRx in April 2011. Through a prior license agreement between SynthRx and CytRx Corporation, we acquired rights to issued patents related to poloxamers and their uses. The issued patents cover, among other things, P188, purified P188, methods of treating sickle cell anemia using P188 and methods of preparing purified P188. Under this license agreement, as amended, SynthRx has an exclusive license, with the right to grant sublicenses, under specified patents to use, offer and sell covered products in all of the countries in the world and in all fields, except those fields that, at the time of the agreement, were or will be licensed pursuant to certain identified agreements. We believe that the field limitation does not prevent us from developing or commercializing ANX-188 for the treatment of complications arising from sickle cell disease.

In partial consideration of the license grant, SynthRx agreed to pay CytRx certain non-refundable and non-creditable milestone payments based on the approval of each covered product in a major market, which includes the U.S. The amount of each milestone is in the low single-digit millions, half of which is due on the first commercial sale of the approved product and half of which is payable over time based on a percentage of quarterly net sales. In addition, SynthRx would pay a single-digit royalty on net sales of covered products. However, in the event of a sublicense under the specified patents, in lieu of the foregoing milestone and royalty payments, SynthRx, in its sole discretion, may elect to pay CytRx an amount equal to 20% of any sublicensing income received by SynthRx within 30 days of receipt thereof. Sublicense income includes, without limitation, license fees, royalties, milestone payments, license maintenance fees and strategic alliance payments, whether in cash, equity or other property, with the payment to be in the same form as the payment received by SynthRx.

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

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

Acquisition of SynthRx, Inc.

Background and Terms of Merger Agreement

During 2010 and the first half of 2011, our business strategy involved a particular focus on expanding our product pipeline. We retained the investment banking firm Canaccord Genuity Inc. to advise us in this regard and our board of directors formed a special committee to assist it in evaluating potential opportunities. Our management and the special committee, with assistance from Canaccord Genuity, evaluated numerous opportunities with companies with a wide range of development programs. During this process, we identified SynthRx, Inc. as a company whose lead product candidate, which we are now developing as ANX-188, was a strong fit with our pipeline expansion strategy. SynthRx was a private company formed in 2004 to acquire to purified P188 from CytRx Corporation, but after acquiring rights to purified P188, SynthRx did not have the financial resources to pursue its development. The co-founders of SynthRx had been involved with the development of P188 and purified P188 while at CytRx.

In April 2011, we completed the acquisition of SynthRx, Inc. pursuant to an agreement and plan of merger, and SynthRx became a wholly owned subsidiary of ours. The payment terms of the merger agreement were structured such that the majority of the merger consideration would be payable only in the event of achievement of the milestones set forth in the merger agreement. Upon the closing of the merger, we issued 2,800,851 shares of our common stock to the former SynthRx stockholders, up to 1,454,079 of which are subject to repurchase by us in the event development of ANX-188 does not achieve the First Milestone under specified circumstances (described below), and 200,000 of which are subject to escrow until April 2012 to indemnify us against breaches of representations and warranties in the merger agreement, and we assumed $0.3 million of SynthRx s transaction expenses. The merger agreement provides for the issuance of up to 13,478,050 additional shares of our common stock to the former SynthRx stockholders, which we refer to as the Milestone Shares, if and to the extent development of ANX-188 achieves certain milestones, as described below. On June 15, 2011, at our annual meeting of stockholders, our stockholders approved the issuance of the Milestone Shares, in lieu of cash payments, in accordance with the terms of the merger agreement.

The merger agreement sets forth three milestones related to the development of ANX-188, with the achievement of each triggering the vesting of some or all of the 1,454,079 shares that are subject to repurchase by us and/or the issuance by us of a portion of the Milestone Shares. Up to 1,000,000 shares are issuable upon the dosing of the first patient in a phase 3 clinical study that the FDA has indicated may be sufficient to support approval of a NDA covering the use of purified P188 for the treatment of sickle cell crisis in children, which we refer to as the First Milestone; 3,839,400 shares are issuable upon acceptance for review of the NDA by the FDA, which we refer to as the Second Milestone; and 8,638,650 shares are issuable upon approval of the NDA by the FDA, which we refer to as the Third Milestone. The amounts of the 1,454,079 shares and the 1,000,000 shares that potentially vest or become issuable, as applicable, upon achievement of the First Milestone are subject to reduction based on the timing of achievement of the First Milestone and whether and the extent to which the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint exceeds 250 patients, unless otherwise agreed.

Under the terms of the merger agreement, we also agreed, among other things, (a) to use commercially reasonable efforts during the one-year period following the closing of the merger to conduct certain activities related to the development of purified P188, provided that the aggregate cost of such activities does not exceed $1.5 million; (b) to use commercially reasonable efforts until the earlier of achievement of the Third Milestone or the date that is four years after February 12, 2011 to develop an intravenous injection product in which purified P188 is an active ingredient; and (c) until the earlier of the achievement of the Third Milestone and the date that is four years following February 12, 2011, not to consummate a change of control with a third party that involves all or substantially all of SynthRx s assets, except (i) in connection with an Exempt Transaction (as described below) or (ii) with the written consent of SynthRx, which consent shall not be unreasonably withheld, conditioned or delayed. Under the merger agreement, an Exempt Transaction is a change of control that closes prior to achievement of the Third Milestone in which the acquiror agrees in writing to submit a NDA covering the use of purified P188 for the treatment of sickle cell crisis in children, the 188 NDA, for FDA approval (or, if there are unexpected safety or regulatory issues, to conduct activities to address or resolve such issues) until the earlier of (x) the date that, beginning on April 8, 2011 and thereafter, the aggregate expenditure related to the program involving the product candidate on which the 188 NDA is to be based is at least $15.0 million and (y) the fourth anniversary of April 8, 2011; provided, however, such acquiror shall be relieved of such obligations under certain specified conditions.

Voting and Transfer Restriction Agreement

In February 2011, in connection with our execution of the merger agreement, each of the former principal stockholders of SynthRx entered into a stockholders voting and transfer restriction agreement with us. The voting and transfer restriction agreement became effective on the closing date of the merger and will remain in effect until all of the shares of our common stock issued pursuant to the merger agreement to those former SynthRx stockholders and their affiliates have been transferred to non-affiliates.

Pursuant to the terms of the voting and transfer restriction agreement, each stockholder party agreed to vote all shares of our common stock then beneficially owned by that stockholder with respect to every action or approval by written consent of our stockholders in such manner as directed by us, and executed an irrevocable proxy appointing and authorizing us to vote those shares in such manner. Notwithstanding the foregoing, until the earlier of: (a) achievement of the Third Milestone and (b) the four year anniversary of the closing of the merger, each stockholder party will be permitted to vote any shares of our common stock that he, she or it beneficially owns in such stockholder s sole discretion solely with respect to a change of control that involves the transfer of SynthRx s assets to a third party and in which at least 80% of the consideration received by our company (or our stockholders) is non-contingent and paid in cash. As a result of the voting and transfer restriction agreement and the issuance of shares to the stockholder parties to that agreement, we currently have, and in the future may have even more, significant control over substantially all matters requiring approval by our stockholders, including the election of directors. Even if less than all Milestone Shares are actually issued, our ability to control a potentially significant block of stockholder votes pursuant to the voting and transfer restriction agreement may enable us to substantially affect the outcome of proposals brought before our stockholders. In directing how the shares subject to the voting and transfer restriction agreement shall be voted, our board of directors will act in a manner it believes to be in the best interest of our stockholders as a whole.

The voting and transfer restriction agreement also provides that no shares of our common stock that are (a) subject to vesting in accordance with the terms of the merger agreement and/or (b) that have been deposited in escrow may be transferred until such shares have vested and/or are released from escrow, as applicable. We refer to these shares of our common stock that have vested and/or been released from escrow as Transferable Shares. The stockholder parties may transfer any Transferable Shares to an affiliate or pursuant to any private resale transactions or series of transactions undertaken in compliance with applicable securities laws, provided that any such transferee is or becomes a party to the voting and transfer restriction agreement and has agreed in writing to be bound by all the terms and conditions thereof. The voting and transfer restriction agreement also provides that the stockholder parties, as a group, have the right to transfer to non-affiliates, pursuant to an effective resale registration statement or in compliance with Rule 144 promulgated under the Securities Act of 1933, (i) on each trading day, such aggregate number of Transferable Shares as is equal to or less than 10% of the average daily trading volume of our common stock, and (ii) not more than once in any 12-month period, such aggregate amount of Transferable Shares as is equal to five times the average daily trading volume of our common stock. A registration statement on Form S-3 covering the resale of all shares of our common stock issued or issuable to the former SynthRx stockholders pursuant to the merger agreement was declared effective by the Securities and Exchange Commission on October 13, 2011.

Government Regulation

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

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

FDA Approval Process

To obtain approval of a new drug product from the FDA, we must, among other requirements, submit data supporting its 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 FDA approval process relating to new drug products differs depending on the nature of the particular product candidate for which approval is sought. With respect to any product candidate with API not previously approved by the FDA, the sponsor is required to submit an NDA that includes complete reports of pre-clinical, clinical and laboratory studies and extensive manufacturing information to demonstrate the product s safety and effectiveness for its intended use. On the other hand, if the API has been previously approved by the FDA, such as with reformulation product candidates like ANX-514, the sponsor may be able to rely, in part, on the FDA s findings of safety and efficacy with respect to the previously approved product.

The process required by the FDA before a new drug may be marketed in the U.S. generally involves the following:

- completion of nonclinical laboratory and animal testing performed in compliance with FDA regulations;
- submission of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for its intended use;
- submission of an NDA after completion of pivotal clinical trials
- a determination by the FDA within 60 days of its receipt of the NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the API and finished drug product are produced and tested to assess compliance with current good manufacturing practices, or cGMP; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug product in the U.S.

Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

The clinical testing of a drug product candidate generally is conducted in three sequential phases, but the phases may overlap or be combined. The three phases are as follows:

- *Phase 1*. In phase 1 clinical studies, the product is tested in a small number of patients with the target condition or disease or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the product candidate in humans, side effects associated with increasing doses, and, in some cases, to gain early evidence on efficacy. The number of participants included in phase 1 studies is generally in the range of 20 to 80.

Phase 2. In phase 2 studies, in addition to safety, the sponsor evaluates the efficacy of the product candidate on targeted indications to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks. Phase 2 studies typically are larger than related phase 1 but smaller than phase 3 studies and may involve several hundred participants.

Phase 3. Phase 3 studies typically involve an expanded patient population at geographically-dispersed test sites. They are performed after preliminary evidence suggesting effectiveness of the product candidate has been obtained and are designed to further evaluate clinical efficacy and safety, to establish the overall benefit-risk relationship of the product candidate and to provide an adequate basis for product approval. Phase 3 studies usually involve several hundred to several thousand participants.

A clinical study may combine the elements of more than one phase and, the FDA generally requires, two or more phase 3 studies to support approval of a product candidate. A company s designation of a clinical study as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. In addition, a clinical study may contain elements of more than one phase notwithstanding the designation of the study as being of a particular phase.

A pivotal study is a clinical study that is believed to satisfy FDA requirements for the evaluation of a product candidate s safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal studies, to justify regulatory approval. Generally, pivotal studies are also phase 3 studies, but they may be phase 2 studies if the study design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

Clinical trials must be conducted in accordance with the FDA s good clinical practices, or GCP, requirements. The FDA may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at study sites that the IRB oversees and also may halt a study, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group recommends whether or not a trial may move forward at designated check points based on access to certain data from the study. The clinical study sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

As a product candidate moves through the clinical testing 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. We and the third-party manufacturers on which we rely for the manufacture of our product candidates and their respective components (including API) are subject to requirements that drugs be manufactured, packaged and labeled in conformity with 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.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications, together with payment of a user fee, unless waived. An NDA includes all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information on the chemistry, manufacture, controls and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA.

If an NDA 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 s goal is to complete its initial review and respond to the applicant within ten months of submission, unless the application relates to an unmet medical need in a serious or life-threatening indication, in which case the goal may be within six months of NDA submission. However, PDUFA goal dates are not legal mandates and FDA response often occurs several months beyond the original PDUFA goal

date. Further, 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. The NDA review process can, accordingly, be very lengthy. During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive and the FDA and/or any advisory committee it appoints may interpret data differently than the applicant.

After the FDA evaluates the NDA and inspects manufacturing facilities where the drug product and/or its API will be produced, it will either approve commercial marketing of the drug product with prescribing information for specific indications or issue a complete response letter indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA. If the complete response letter requires additional data and the applicant subsequently submits that data, the FDA nevertheless may ultimately decide that the NDA does not satisfy its criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing. Such post-marketing testing may include phase 4 clinical studies and surveillance to further assess and monitor the product s safety and efficacy after approval. Regulatory approval of products for serious or life-threatening indications may require that participants in clinical studies be followed for long periods to determine the overall survival benefit of the drug.

If the FDA approves one of our product candidates, we will be required to comply with a number of post-approval regulatory requirements. We would be required to report, among other things, certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. If we seek to make certain changes to an approved product, such as certain manufacturing changes, we will need FDA review and approval before the change can be implemented. For example, if we change the manufacturer of a product or its API, 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. 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 is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product s safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

We rely, and expect to continue to rely, on third parties for the manufacture of clinical, and future commercial, quantities of our product candidates. Future FDA and state inspections may identify compliance issues at these third-party facilities that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or efficacy data may require changes to a product s approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Many of the foregoing could limit the commercial value of an approved product or require us to commit substantial additional resources in connection with the approval of a product. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA s policies may change, which could delay or prevent regulatory approval of our products under development.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for product candidates containing API that is contained in a previously approved product, 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 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 labeled indications for which the reference product has been approved, as well as for any new indication supported by the NDA. 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).

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. 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 reference product has expired. 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.

Available Special Regulatory Procedures

Formal Meetings and Advice

Companies may request meetings with the FDA to discuss and seek guidance from the agency with respect to development plans and regulatory approval considerations for a product candidate. There are different types of official meetings and each meeting type is subject to different procedures. Conclusions and agreements from each meeting are captured in the official final meeting minutes issued by the FDA.

Advice from the FDA typically is provided based on questions concerning, for example, nonclinical testing and clinical studies, quality (chemistry, manufacturing and controls, or CMC, testing), pharmacovigilance plans and risk-management programs. Such advice is not legally binding on the sponsor. To obtain binding commitments from the FDA, Special Protocol Assessment, or SPA, procedures are available. An SPA is an evaluation by the FDA of a study protocol with the goal of reaching an agreement with the sponsor that the study s design, clinical endpoints and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to efficacy in the indication studied. The FDA s agreement to an SPA is binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the product candidate after clinical studies begin, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

Orphan Drug Designation

The Orphan Drug Act, or ODA, provides for granting special status, referred to as orphan designation, to a drug intended to treat, diagnose or prevent a rare disease or condition that affects fewer than 200,000 people in the U.S. at the time of application for orphan designation. Orphan designation qualifies the sponsor of the product for the tax credit and marketing incentives of the ODA. Orphan designation must be requested by an applicant before submitting its marketing application for that drug for an orphan disease or condition. After the FDA grants orphan designation, the generic identity of the orphan drug and its potential use are disclosed publicly by the FDA. The first sponsor to receive FDA marketing approval for a drug with an orphan designation is entitled to a seven-year

exclusive marketing period in the U.S. for that product for that indication and, typically, a waiver of the prescription drug user fee for its marketing application. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the U.S. during the seven-year exclusive marketing period. Orphan drug exclusive marketing rights may also be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. The approval of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and efficacy of the product candidate must be established through adequate and well-controlled studies.

Legislation similar to the Orphan Drug Act has been enacted in countries other than the U.S., including the European Union. The legislation in the European Union is available for therapies addressing conditions that affect five or fewer out of 10,000 persons. The marketing exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Pediatric Studies

The Pediatric Research Equity Act of 2003, or PREA, which was reauthorized under the Food and Drug Administration Amendments Act of 2007, authorizes the FDA to require pediatric studies for drugs to ensure the drugs safety and efficacy in children. The PREA requires that certain NDAs or supplements to NDAs contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may also require this data for approved drugs that are used in pediatric patients for the labeled indication, or where there may be therapeutic benefits over existing products. The FDA may grant deferrals for submission of data, or full or partial waivers from the PREA. For example, unless otherwise required by regulation, the PREA does not apply to any drug for an indication for which orphan designation has been granted.

Pharmaceutical Pricing and Reimbursement

Significant uncertainty exists as to the reimbursement status of newly approved drug products, including coding, coverage and payment. Sales of any products for which we obtain marketing approval will depend in part on reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Even if reimbursement is provided, market acceptance of our products would be adversely affected if the amount of payment for our products proves to be unprofitable for healthcare providers or less profitable than alternative treatments or if administrative burdens make our products less desirable to use.

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. We expect that federal, state and local governments in the U.S. will continue to consider legislation 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 whether and how future legislation, whether domestic or abroad, could 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.

Other Healthcare Laws and Compliance Requirements

In addition to FDA requirements, several other types of state and federal laws apply and will apply to our operations. These laws include healthcare information and data privacy protection laws and fraud and abuse laws, such as anti-kickback 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. Under the new Physician Payment Sunshine Act requirements, we will be subject to reporting payments made to certain investigators and physicians in the future.

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 promoting their products for uses for which they were not approved and causing the submission of claims for payment for such use under federal healthcare programs. 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.

Government Regulation Outside the U.S.

In addition to regulations in the U.S., we may be subject to a variety of regulations in foreign jurisdictions that govern, among other things, clinical studies and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign jurisdictions prior to the commencement of clinical studies or marketing and sale of the product in those countries. The foreign regulatory approval process includes all of the risks associated with the FDA approval described above. Some foreign jurisdictions have a drug product approval process similar to that in the U.S., which requires the submission of a clinical trial application much like the IND prior to the commencement of clinical studies. In Europe, for example, a clinical trial application, or CTA, must be submitted to each country s national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country s requirements, clinical trial development may proceed.

To obtain regulatory approval of a product candidate under European Union regulatory systems, we would be required to submit a marketing authorization application, which is similar to the NDA, except that, among other things, there are country-specific document requirements. For countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product approval, pricing and reimbursement vary from country to country. 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 future partner of ours. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees

As of March 1, 2012, we have 14 employees, all but one of which are full-time. Our employees are not unionized and we believe that our relationship with our employees is good.

Historically, we operated using a small, efficient base of full-time employees and outsourcing most of our product development activities, including research-related manufacturing and regulatory affairs, and our general and administrative activities, such as finance, accounting, human resources, facilities, internal systems support and investor relations. Our outsourcing strategy has included engaging individual consultants that commit and spend considerable amounts of time in our office to manage key functional areas, including regulatory, CMC and market research and commercial strategy. In 2011, in connection with our acquisition of SynthRx and expectation of initiating clinical studies in 2012, we filled certain key positions with full-time employees. We expect to continue to hire full-time employees as we internalize operations in critical areas, such as clinical operations, CMC and regulatory affairs.

Formation

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.

Available Information

Our website is located at *http://www.adventrx.com*. Information found on our website is not incorporated by reference into this annual report on Form 10-K. We make our filings with the U.S. Securities and Exchange Commission, or SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, available free of charge on or through our website, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Copies of our SEC filings are located at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings at *http://www.sec.gov*.

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 consider carefully 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 we may never achieve profitability. We have devoted our resources to acquiring and developing proprietary product candidates, but such product candidates 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 may not achieve.

The success of our business currently is dependent primarily on the success of ANX-188 and ANX-514 and these product candidates may not receive regulatory approval or be successfully commercialized.

We currently have no products for sale and only two product candidates, ANX-188 and ANX-514 that we actively are developing for regulatory approval. Accordingly, the success of our business currently depends primarily on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize these product candidates and our efforts in this regard may prove unsuccessful. These product candidates require additional development, including phase 3 clinical studies and significant manufacturing activities prior to commencing clinical studies, all of which require us to expend significant resources and with which we have limited experience. Our product candidates may not be successful in clinical studies or, even if successful in clinical studies, may not receive regulatory approval in a timely manner, or at all. If any of our product candidates 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 as well as our ability to market and sell them and ensure that our third-party manufacturers produce sufficient quantities of the products to meet commercial demand, if any.

Our financial resources are limited, we will need to obtain additional funding to pursue our current 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 losses in acquiring and funding the development of our product candidates, accumulating net losses totaling approximately $171.6 million as of December 31, 2011, 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 occurrence and timing of which we cannot predict accurately.

Our future expenditures on our programs are subject to many uncertainties, including whether our product candidates will be developed or commercialized 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 our product candidates, including the number and size of clinical studies necessary to demonstrate the safety and efficacy of a product candidate and the process development, scale-up and other manufacturing and stability activities, and other work required to achieve such approval, as well as the timing of such activities and approval;

- the scope, prioritization and number of development programs we pursue and the rate of progress and costs with respect to each such program;

the extent to which we invest in or acquire new technologies, product candidates, products or businesses and the development requirements with respect to any acquired programs;

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, if we obtain regulatory approval for a product candidate and commercialize it without a partner;

the extent to which we increase our workforce and the costs 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, cash equivalents and short-term investments, which were approximately $50.7 million as of December 31, 2011, 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 and/or pursue development activities for our product candidates at levels or on timelines, or we may incur unexpected expenses, that shorten the period through which our current operating funds will sustain us. We may also seek to expand our product pipeline through acquisition of additional product candidates and/or technologies and the cost to acquire and develop such new product candidates and/or technologies may shorten the period through which our current operating funds will sustain us. For the foreseeable future, we plan to fund our operations through public or private equity and debt financings. We may also seek to raise funds through collaborations, licensing arrangements or other strategic or partnering transactions. However, adequate additional funding may not be available on acceptable terms or on a timely basis, if at all. 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. We believe global economic conditions, including the continued volatility of U.S. and international equity markets, may adversely impact our ability to raise additional capital.

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

Historically, we have raised capital through the sale of our equity securities. Since June 2009, we have completed seven equity financings under shelf registration statements on Form S-3. Using a shelf registration statement on Form S-3 to raise additional capital is generally more timely and cost effective than other means, such as conducting an offering under a Form S-1 registration statement. However, in the future, our ability to raise capital using a shelf registration statement may be limited by, among other things, current SEC rules and regulations. Under current SEC rules and regulations, we must meet certain requirements to use a Form S-3 registration statement to raise capital without restriction as to the amount of the market value of securities sold thereunder. One such requirement is that the market value of our outstanding common stock held by non-affiliates, or public float, be at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3. If we do not meet that requirement, then the aggregate market value of securities sold by us or on our behalf under the Form S-3 during in any 12-month period is limited to an aggregate of one-third of our public float. Moreover, even if we meet the public float requirement at the time we file a Form S-3, SEC rules and regulations require that we periodically re-evaluate the value of our public float, and if, at a re-evaluation date, our public float is less than $75.0 million, we would become subject to the one-third of public float limitation described above.

In addition, under current SEC rules and regulations, in order to use a Form S-3 registration statement if (i) we seek to conduct a primary offering and our public float is not at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3 or (ii) we seek to register the resale of our securities by persons other than us (i.e., a resale offering), then our common stock must be listed and registered on a national securities exchange.

While currently our common stock is listed on the NYSE Amex equities market, there can be no assurance that we will be able to maintain such listing. The NYSE Amex reviews the appropriateness of continued listing of any issuer that falls below the exchange s continued listing standards. Previously, including during part of 2010, we were not in compliance with certain NYSE Amex continued listing standards and were at risk of having our common stock delisted from the NYSE Amex equities market. For additional information regarding this risk, see the risk factor below titled If we are unable to maintain compliance with NYSE Amex continued listing standards, our common stock may be delisted from the NYSE Amex equities market, which would likely cause the liquidity and market price of our common stock to decline.

Our ability to timely raise sufficient additional capital also may be limited by the NYSE Amex s stockholder approval requirements 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 then outstanding common stock, unless the transaction is considered a public offering by the NYSE Amex staff. Based on the number of shares of our outstanding common stock as of March 1, 2012 and on the closing price per share of our common stock on such date, which was $0.64, we could not raise more than approximately $6.1 million without obtaining 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. In addition, certain prior sales by us may be aggregated with any offering we may propose in the future, further limiting the amount we could raise in any future offering that is not considered a public offering by the NYSE Amex staff and involves 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 also requires that we obtain stockholder approval if the issuance or potential issuance of additional shares will be considered by the NYSE Amex staff to result in a change of control of us.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval for a potential transaction, 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 current business strategy, and there is no guarantee our stockholders ultimately would 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 entities affiliated with Carl C. Icahn. Pursuant to the Rights Agreement, dated July 27, 2005, as amended, or the Rights Agreement, we agreed, among other things, to 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). Pursuant to the Rights Agreement, we must notify the Rights Investors of certain proposed transactions on the timeline specified in the Rights Agreement. In many of our prior financing transactions, 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 in a timely manner, or at all, with respect to future financing transactions, we may be unable to consummate a financing that otherwise may be available to us and in the best interest of our company and stockholders. In addition, in connection with our public offering in November 2011, we entered into an underwriting agreement in which we agreed not to engage for 12 months in variable rate transactions, which involve issuances our securities at prices set or reset at some future date.

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 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 and dilute the current and future value of our assets. For example, any licensing arrangement would likely require us to share with our licensees a significant portion of any revenues generated by our licensed technologies. Additionally, our control over the development and/or marketing 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.

If we are unable to raise sufficient additional capital as needed, we may be forced to delay, reduce or discontinue our current and/or planned development activities, partner our product candidates at inopportune times or pursue less expensive but higher-risk development paths.

Although we anticipate that our cash, cash equivalents and short-term investments as of December 31, 2011 will be sufficient to fund our operations at their current levels for at least the next 12 months, we expect to need to raise additional capital in order to execute our current business plan. If we are not able to raise sufficient additional capital, we may be required to delay, reduce or discontinue our development 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 the financial benefits thereof. For example, if we do not have sufficient capital, we may determine not to investigate additional indications or other label changes for a product candidate or to conduct other studies or activities intended to expand the scale and scope of its clinical benefit and market potential. Any such development delays could impair our ability to realize the full clinical and market potential of a product candidate and have a material adverse effect on our business and financial condition.

Our business may suffer if we are unable to retain and attract key personnel and manage internal growth.

Our industry in general and our company in particular historically have experienced a high rate of turnover of management personnel. Our ability to execute on our business strategy and compete in the highly competitive pharmaceutical and biotechnology industries depends on our ability to attract and retain highly qualified personnel for key positions in our company. We are highly dependent on certain personnel, including our chief executive officer, our president and chief operating officer and our senior vice president, development. If we lose any of these key employees, our ability to successfully implement our current business strategy could be seriously harmed. Replacing these key employees may be a difficult, costly and protracted process, particularly due to the fact that we currently do not have other executive officers or personnel to assume all of the responsibilities of these key employees, competition is intense for qualified personnel among pharmaceutical, biotechnology and other businesses and many of the companies against which we compete for qualified personnel have greater financial and other resources than our company, which may make them more attractive employers. All of our employees, including our executive officers, may terminate their employment with us at any time with or without notice.

In addition, we may seek to increase the size of our organization as our development of our product candidates progresses. Currently, we have only a small number of employees and we rely on third parties to perform many essential services for us. The success of our business will depend, in part, on our ability to attract and retain highly qualified personnel and 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

among pharmaceutical and biotechnology companies, universities and other research organizations, particularly in the San Diego, California area. Recruiting and retaining employees, including senior-level personnel, with relevant product development and regulatory experience may be difficult and costly. Our ability to provide competitive compensation to our management and other employees may also be adversely affected by our capital resources and our highly volatile stock price. If we cannot attract and retain additional skilled personnel, we may not achieve our development and other goals. In addition, our outsourcing strategy, which has included engaging consultants that spend considerable time in our office to manage key functional areas, may subject us to scrutiny under labor laws and regulations, which may divert management time and attention and have an adverse effect on our business and financial condition.

If we determine to grow our business through the acquisition of new technologies and/or product candidates, our existing stockholders may experience substantial dilution, we may fail to realize the benefits of any future strategic acquisition or investment and we may incur unexpected costs and disruptions to our business.

Although we are focused on developing our current product candidates, from time to time, we may evaluate pipeline expansion opportunities that we believe will increase the long-term value of our company. The process of identifying, evaluating, negotiating and implementing the purchase or license of new assets is lengthy and complex and may disrupt other development programs and distract our personnel. We have limited experience and resources with respect to identifying, evaluating, negotiating and implementing the acquisition of new assets or rights thereto and integrating them into our current infrastructure. Supplementing our current resources to complete one or more of these transactions may be costly.

We may use cash, shares of our common stock, securities convertible into our common stock or a combination of cash and our securities to pay the purchase price or license fee for any future strategic transaction. The use of cash could negatively impact our financial position and ability to develop our product candidates. The use of shares of our common stock or securities convertible into shares of our common stock would dilute the holdings of our existing stockholders and, given our recent market capitalization, such dilution could be substantial. For example, as consideration for our acquisition of SynthRx, in addition to the 2,800,851 shares we issued to SynthRx s former stockholders in April 2011, we could issue up to an aggregate of 13,478,050 additional shares of our common stock to such persons upon achievement of milestones related to the development and regulatory approval of ANX-188 for the treatment of sickle cell crisis in children. If all milestones are achieved without reduction, the number of shares we issue in connection with the SynthRx acquisition would, in the aggregate, represent an approximately 27% ownership stake in our company (based on shares outstanding as of March 1, 2012 plus shares issued in connection with achievement of the milestones). The issuance of shares in connection with other future strategic transactions, if any, may result in the stockholders who own the majority of our voting securities prior to one or more of such transactions owning less than a majority after such transactions.

Further, strategic transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention to develop and/or commercialize acquired technologies and/or products candidates;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers of any acquired business due to changes in management and ownership; and
- inability to retain key employees of any acquired business.

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Our stockholders will be required to rely on the judgment of our management and board of directors as to which new product candidates and/or technologies we pursue and may have limited or no opportunity to evaluate potential new assets prior to completion of a transaction, including the terms of acquisition, the costs of their future development and their commercial potential. We may devote resources to potential acquisition or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Any technology and/or product candidate that we acquire or to which we acquire rights likely will require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are subject to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe or effective for approval by regulatory authorities and other risks described under the section titled Risks Related to Drug Development and Commercialization.

The use of our net operating loss carry forwards and research and development tax credits has been and may be limited further by changes in ownership within the meaning of IRC Section 382.

Our net operating loss carry forwards and research and development tax credits may expire and not be used. As of December 31, 2011, we had generated federal and California net operating loss carry forwards of approximately $43.9 million and $47.4 million, respectively, which will begin to expire in 2018 and 2012, respectively, if unused. As of December 31, 2011, we had federal and California research and development tax credit carry forwards of approximately $0.3 million and $0.2 million, respectively. The federal research and development credits will begin to expire in 2029. The California research and development credits do not expire.

In addition, our ability to use any tax carry forwards or credits to offset future taxable income, if any, has been limited in the past, and may be limited further in the future, by transactions deemed to be ownership changes of our company. 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 future taxable income is limited if we experience a cumulative change in ownership of more than 50% within a three-year period. During 2010, we completed a formal study to determine whether any ownership change within the meaning of IRC Section 382 occurred during the period from January 1, 2008 through January 7, 2010, and several ownership changes were identified. We determined that our net operating loss carry forwards and research and development credits were significantly adversely affected by the identified ownership changes and adjusted our deferred tax assets accordingly. We currently are conducting a formal study to determine whether any ownership change within the meaning of IRC Section 382 occurred during the period from January 8, 2010 through December 31, 2011. We have not completed this study, but one or more such ownership changes may have occurred as a result of our equity financings during that period. If we determine that an additional ownership change occurred during 2010 or 2011, or if an additional ownership change occurs in the future, the amount of our net operating loss carry forwards and research and development tax credits we could utilize in the future to offset taxable income, if any, could be further 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.

We expend substantial resources to comply with laws and regulations relating to public companies, and any failure to maintain compliance could subject us to regulatory scrutiny and cause investors to lose confidence in our company, which could harm our business and have a material adverse effect on our stock price.

Laws and regulations affecting public companies, including provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the Sarbanes-Oxley Act of 2002, or SOX, and the related rules and regulations adopted by the SEC and by the NYSE Amex have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these rules and respond to their requirements. For example, compliance with Section 404 of SOX, including performing the system and process documentation and evaluation necessary to issue our annual report on the effectiveness of our internal control over financial reporting and obtain the required attestation report from our independent registered public accounting firm, requires us to incur substantial expense and expend significant management time. Further, we have in the past discovered, and may in the future discover, areas of internal controls that need improvement. If we identify deficiencies in our internal controls that are deemed to be material weaknesses, we could become subject to scrutiny by regulatory authorities and lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on our stock price. 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.

In addition, new laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees, and as our executive officers. We cannot predict or estimate the total amount or timing of the costs we may incur to comply with these laws and regulations.

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

Our corporate headquarters are located in a single commercial facility 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 or severe weather conditions, 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 disrupt our business operations and result in setbacks to our development programs. Even though we believe we carry commercially reasonable insurance, we might suffer losses that are not covered by or exceed the coverage available under these insurance policies.

Risks Related to Drug Development and Commercialization

Further clinical testing of our product candidates is required and clinical studies typically involve a lengthy and expensive process with an uncertain outcome.

Clinical testing typically is expensive and can take years to complete, and its outcome is inherently uncertain. Planned clinical studies may not commence on time or be completed on schedule, if at all. The commencement and completion of clinical studies can be delayed for a variety of reasons, including difficulties and delays related to:

- obtaining regulatory approval to commence a clinical study;
- obtaining institutional review board, or IRB, approval to conduct a trial at a prospective site;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, for the conduct of our clinical studies and contract manufacturing organizations, or CMOs, for the production of our clinical trial material, the terms of which agreements 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;
- identifying appropriate study sites and reaching agreement on acceptable terms with prospective study sites and investigators, the terms of which can be subject to extensive negotiation and may vary significantly among study sites;
- identifying and hiring or engaging, as applicable, additional employees or consultants to assist us in managing CRO and/or CMO activities, managing a clinical study and analyzing the data resulting from a study;

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manufacturing sufficient quantities of clinical trial material due, among other things, to lack of availability of capacity at a CMO or of the component materials, including the active pharmaceutical ingredient, or API, or other materials necessary to manufacture our clinical trial material or for various other reasons;

unforeseen results of from other clinical studies or nonclinical testing that require us to amend a study design;

recruiting and enrolling patients to participate in a clinical study; and

having patients complete a study and/or return for and complete post-treatment follow-up.

Patient enrollment, a significant factor in the time required to complete a clinical study, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, competing clinical studies and clinicians and patients perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including therapies being investigated by other companies. Further, completion of a clinical study and/or its results may be adversely affected by failure to retain patients who enroll in a study but withdraw due to adverse side effects, lack of efficacy, improvement in condition before treatment has been completed or for personal issues or who fail to return for or complete post-treatment follow-up.

In addition, a clinical study may be suspended or terminated by us, an IRB, a data safety monitoring board, the FDA or other regulatory authorities due to a number of factors, including:

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

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

unforeseen safety issues, including adverse side effects;

changes in governmental regulations or administrative actions; or

lack of adequate funding to continue the study.

Changes in governmental regulations and guidance relating to clinical studies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit protocols to IRBs for reexamination or renegotiate terms with CROs and study sites and investigators, all of which may impact the costs, timing or successful completion of a trial.

Although we are planning to initiate a phase 3 clinical study of ANX-188 in 2012, the study may not begin on time or be completed in the timeframe we anticipate for a variety of reasons, including one or more of those described above. There can be no assurance that any of our clinical studies will commence or be completed as planned. The length of time necessary to complete clinical studies varies significantly and is difficult to predict accurately. If we experience delays in the completion of a clinical study or if a clinical study is terminated, the commercial prospects for our product candidate may be harmed and our ability to generate product revenues will be delayed. In addition, any delays in completing our clinical studies likely will increase our development costs. Further, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies 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.

Positive results in nonclinical testing and prior clinical studies do not ensure that future clinical studies 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 clinical studies that each product is safe and effective for use in each target indication. Success in nonclinical testing and prior clinical studies does not ensure that subsequent or larger-scale studies will be successful. For example, the positive results generated to date in clinical studies of ANX-188 by prior sponsors do not ensure that our clinical studies will demonstrate that ANX-188 is safe or effective for the indications we are pursuing. In addition, clinical study results frequently are 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, despite positive nonclinical testing that indicated bioequivalence between ANX-514 and the reference product, Taxotere, our bioequivalence study of ANX-514 did not demonstrate bioequivalence between ANX-514 and Taxotere based on the FDA s benchmark regulatory standards and the FDA determined ANX-514 could not be approved based on the findings from that study. Further, we have licensed to a third party certain rights to ANX-514 in South Korea and have limited control over any nonclinical testing or clinical studies that may be conducted by such third party or a future third-party licensee. 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 adversely affect the U.S. regulatory process for ANX-514.

There is a significant risk that any of our product candidates could fail to show anticipated results in clinical studies, as was the case in our bioequivalence study of ANX-514, 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.

We may not achieve our projected development goals in the time frames we announce. Further testing and validation of our product candidates and related manufacturing processes are required and regulatory approval may be delayed or denied, which would delay or prevent us from marketing our product candidates and substantially harm our business.

Human pharmaceutical products generally are subject to rigorous nonclinical testing and clinical studies 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 of our product candidates, 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, alone or with a future partner, will be granted on a timely basis, or at all.

We set goals for and make public statements regarding our estimates of the timing for accomplishing certain objectives material to successful development of our product candidates. The actual timing of these events can vary dramatically due to many factors, including delays or failures in our nonclinical testing, clinical studies and manufacturing and regulatory activities and the uncertainties inherent in the regulatory approval process. For example, although we reached agreement with the FDA on a pivotal clinical study of ANX-514 that would support approval of ANX-514 without a corticosteroid premedication regimen, we do not plan to initiate the agreed-upon study during 2012, but plan to investigate methods, including devices, that can assess the incidence of fluid retention (the primary endpoint previously agreed upon with the FDA) more accurately and objectively than the current method of clinical observation, which may increase the time and cost of seeking regulatory approval for ANX-514 relative to our previously planned pathway. In addition, if the FDA determines that the authenticity of the study drugs used in our bioequivalence study of ANX-514 cannot be verified, including because of the manner in which reserve samples were selected and

maintained, we may be required to repeat the bioequivalence study prior to regulatory approval of ANX-514, and the results of a repeat study may cause the FDA to require additional clinical studies. Further, the FDA may inquire regarding the manufacturing source, in-process and product release specifications and overall uniformity of reference product used in our bioequivalence study, 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 bioequivalence study, conduct clinical studies or take other remedial measures. Further, the form of API used in the manufacture of ANX-514 for our bioequivalence study will not be the same form of API used in the manufacture of ANX-514 for any future clinical studies of ANX-514 or for 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 use in any future clinical study and commercial sale, the FDA may require that we evaluate each form of ANX-514 in additional patients, conduct other clinical studies or take other remedial actions. We may have insufficient quantities of each form 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, conducting other clinical studies or taking other remedial measures. In addition, even though the FDA has confirmed the appropriateness of a Section 505(b)(2) regulatory path for ANX-514, the FDA s views may change and the FDA may not allow us to rely on data regarding the safety and efficacy of Taxotere in its evaluation of an NDA for ANX-514 or the FDA may allow us to rely only on certain subsets of the efficacy data related to Taxotere, in which case we likely would need to conduct substantial, additional clinical and nonclinical work prior to regulatory approval. Furthermore, we may determine to conduct clinical studies with respect to ANX-514 to support uses in new indications or other label changes or for other reasons. With respect to ANX-188, the FDA may require nonclinical testing and/or clinical studies in addition to our planned phase 3 and other clinical studies to demonstrate that ANX-188 is a safe and effective treatment for patients with sickle cell disease in acute crisis. If the development plan for any of our product candidates becomes more extensive and costly than anticipated, we may determine that the associated time and cost are not financially justifiable and, as a result, discontinue the program. If we discontinue either of our current programs, our business and stock price may suffer.

Even if we complete a planned clinical study with successful results, we may not achieve our projected development goals in the time frames we initially anticipate or announce. For example, in August 2011, we received a complete response letter from the FDA stating that it could not approve our NDA for Exelbine in its present form. In particular, the letter stated that, based on inspections at clinical sites, the authenticity of the drug products used in the pivotal bioequivalence trial could not be verified and that the bioequivalence trial would need to be repeated to address this deficiency. As a result, we elected to discontinue independent development of Exelbine.

In addition, changes may occur in regulatory requirements or policy during the period of product development and/or regulatory review of a submitted NDA relating to the data required to be included in marketing applications. For example, despite including in our initial Exelbine NDA submission in December 2009 data that we believe met the filing requirements for a new drug promulgated by the International Conference on Harmonization, or 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 that submission was insufficient to support a commercially-viable expiration dating period. Consequently, we had to wait for 12 months of site-specific stability data from the intended commercial manufacturing site to be generated before resubmitting an NDA for Exelbine, which we did in November 2010. 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 December 2009 submission.

Further, 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. We rely on CMOs for the manufacture of clinical, and future commercial, quantities of our product candidates. If future FDA or other regulatory authority inspections identify cGMP compliance issues at these third-party facilities, production of our clinical trial material or, in the future, commercial product, could be disrupted and require substantial resources to correct.

In connection with any NDA that we file under Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, or FDCA, including an NDA for ANX-514, 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 do not have, and do not intend to establish, manufacturing capabilities and are dependent on third parties to conduct manufacturing process development activities and to provide us with clinical trial materials and, if any of our products are approved, commercial product, and the loss of any of these manufacturers, or their failure to provide to us with an adequate supply of our product candidates in a timely manner and on commercially acceptable terms, or at all, could harm our business.

We do not have any manufacturing capability and, currently, do not have any long-term development or supply agreements with any third-party manufacturer or component supplier. We may not be able to establish these relationships in a timely manner or on commercially acceptable terms, or at all. If we fail to establish and maintain such relationships, we may not be able to complete development of our product candidates or market our products, if approved, on a timely basis, or at all, which would have a material and adverse effect on our business. Even if we successfully establish these relationships with third-party manufacturers and component suppliers on commercially acceptable terms, these manufacturers and suppliers may not perform as agreed or may terminate their agreements with us. Because many of our 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 manufacturers or suppliers experience could delay or interrupt the supply to us of clinical trial materials or commercial 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. Currently, we do not anticipate engaging alternative sources to backup our primary sources of clinical trial material or, as applicable in the future, commercial product. Therefore, if our primary sources become unable or unwilling to perform, we could experience protracted delays or interruptions in the supply of our product candidates for our clinical studies and, ultimately, for commercial sale, which could materially and adversely affect our development programs and commercial activities and operations.

In addition to supplying clinical trial material for our clinical studies, we rely on third-parties to conduct key manufacturing development activities, including qualification of equipment, developing and validating methods, defining critical process parameters, releasing component materials and conducting stability testing, among other things. If these third parties are unable to perform successfully in a timely manner, whether for technical, financial or other reasons, we may be unable to secure clinical trial materials, which likely would delay the initiation, conduct or completion of our clinical studies, which likely would have a material and adverse effect on our business.

Further, there may be a limited number of third-party manufacturers with the technical capabilities and desire to perform the development and supply services that we require. For instance, the API for ANX-188 is a purified form of P188 that is produced through a proprietary extraction process. This extraction process is complex and requires highly specialized equipment and there are a limited number of CMOs capable and willing to perform the process as we require, which makes identifying and establishing relationships with CMOs more difficult and may provide them with substantial leverage over us in any negotiations. In addition, although P188 (non-purified) is widely available, it generally is manufactured to cGMP requirements applicable to excipients, rather than cGMP requirements applicable to API. If the FDA or other regulatory agencies require the ANX-188 active ingredient starting material to be manufactured consistent with cGMP requirements applicable to API, we likely would engage a CMO to manufacture the ANX-188 active ingredient starting material, which would add significant additional cost to the development and commercialization of ANX-188 and likely would adversely affect our ability to develop ANX-188 on a timely and competitive basis, if we are able to find a CMO capable and willing to conduct such activities at all.

All manufacturers of our clinical and commercial products and product candidates, as well as the manufacturers of the active ingredients included in 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 encounter any of these difficulties or otherwise fail to comply with their contractual obligations, we may have insufficient quantities of our product candidates for our planned and any future clinical studies. In addition, any delay or interruption in the supply of supplies necessary or useful to manufacture our product candidates could delay the completion of our planned and any future clinical studies, 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 are approved by the FDA or another regulatory authority, 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 adversely affect our business. Redesigning our manufacturing processes or identifying alternative suppliers in response to problems we may encounter could take significant time, 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. None of our product candidates have been manufactured at the scales we believe will be necessary to maximize their commercial value and, accordingly, we or a future partner of ours may encounter difficulties in attempting to scale-up production and may not succeed in scaling-up production.

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 clinical studies, 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 the FDA requires substantial stability or other data from the new manufacturer, which would take significant time and cost to generate, our ability to meet commercial demand, if any, could be impaired. In addition, obtaining the necessary FDA or other applicable regulatory approvals and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and 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 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. We engage consultants, advisors, CROs, CMOs and others to design, conduct, analyze and interpret the results of nonclinical tests and clinical studies in connection with the research and development of our product candidates, and we expect to continue to outsource a significant amount of such activities. As a result, many important aspects of our product candidates development are and will continue to be outside our direct control. For instance, we lacked the internal capabilities to fully analyze the data from our bioequivalence study of ANX-514 and

relied 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 the success of our business, an employee may have approached the data and analysis in a substantially more rigorous, thoughtful and creative manner than a consultant or contractor. 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 that we engage to execute our clinical studies play a significant role in the conduct of the studies and subsequent collection and analysis of data, and we likely will depend on CROs and clinical investigators to conduct future clinical studies and to assist in analyzing completed studies and developing regulatory strategies for our product candidates. 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 and/or investigators fail to devote sufficient time and resources to our studies, if they do not comply with all regulatory and contractual requirements or if their performance is substandard, it will delay the approval of our applications to regulatory agencies and the introduction of our products. 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. Failure of these CROs to meet their obligations could adversely affect development of our product candidates. For example, in 2006, we engaged a CRO to assist with the primary conduct of our bioequivalence study of Exelbine, including monitoring participating clinical sites to ensure compliance with regulatory requirements. FDA guidance recommends that clinical sites randomly select and retain reserve samples of study drugs used in bioequivalence studies. However, the clinical sites that participated in our bioequivalence study of Exelbine failed to do so. In August 2011, we received a complete response letter from the FDA stating that the authenticity of the study drugs used in Study 530-01 could not be verified and, consequently, the bioequivalence study would need to be repeated to address that deficiency.

If any of our CRO relationships were to terminate, we may not be able to enter into arrangements with alternative CROs on acceptable terms or in a timely manner, or at all. Switching CROs would involve additional cost and divert management time and attention. In addition, there likely would be a transition period when a new CRO commences work. These challenges could result in delays in the commencement or completion of our clinical studies, which could materially impact our ability to meet our desired development timelines and have a material adverse impact on our business and financial condition.

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

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical studies 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. For example, in clinical studies of ANX-188 conducted by a prior sponsor, transient, generally mild to moderate elevations in liver function tests were associated with treatment with ANX-188. If in our clinical studies of ANX-188 we observe more pronounced increases in liver function tests, or we observe other previously unidentified adverse events, whether or not statistically significant, we may be required to conduct additional clinical studies of ANX-188 or ANX-188 may not receive regulatory approval. In addition, if in future clinical studies of ANX-514 we observe adverse events, including as a result of eliminating corticosteroid premedication, we may be required to conduct further studies of ANX-514 or ANX-514 may not receive regulatory approval.

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 studies 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.

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 manufacturing processes, labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information regarding the product. For instance, the FDA may require changes to approved drug labels, require post-approval clinical studies 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 clinical studies;

refuse to approve pending applications or supplements to approved applications;

exclude our product from reimbursement under government healthcare programs, including Medicaid or Medicare;

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.

We currently have no sales or marketing capability and our failure to acquire or 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 other commercialization personnel. To commercialize our products, we will have to acquire or develop marketing, distribution, sales and associated regulatory compliance capabilities, or rely on marketing partners or other 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 at all, or that any internal capabilities or third-party arrangements will be cost-effective. The acquisition or development of commercialization and associated regulatory compliance capabilities likely will require substantial financial and other resources and divert the attention of our management and key

personnel, and, if not completed on time, could delay the launch of a product candidate and otherwise negatively impact our product development and commercialization efforts.

To the extent we establish marketing, distribution or sales arrangements with third parties, those third parties may hold significant control over important aspects of the commercialization of our products, including market identification, marketing methods, pricing, composition of sales force and promotional activities. 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 we retain third-party service providers to perform functions related to the marketing, distribution and sale of our products, key aspects of those functions that may 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, encounter natural or other disasters at their facilities or otherwise fail to perform in a satisfactory manner, or at all, 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.

If any of our product candidates for which we receive regulatory approval do not achieve significant market acceptance among the medical community, patients or third-party payors, 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, if approved, are accepted by the medical community and patients and reimbursed by third-party payors, including government payors. The degree of market acceptance with respect to each of our approved products, if any, will depend upon a number of factors, including:

- the safety and efficacy of our product demonstrated in clinical studies;
- acceptance in the medical and patient communities of our product as a safe and effective treatment;
- the perceived advantages of our product over alternative treatments, including with respect to the incidence and severity of any adverse side effects and the cost of treatment;
- the indications for which our product is approved;
- claims or other information (including limitations or warnings) in our product s approved labeling;
- reimbursement and coverage policies of government and other third-party payors;
- pricing and cost-effectiveness of our product relative to alternative treatments;
- availability of alternative treatments;
- the prevalence of off-label substitution of chemically equivalent products or alternative treatments; and
- the resources we devote to marketing our product and restrictions on promotional claims we can make with respect to the product;

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 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, if we, or a future partner or licensee, fail to obtain a unique Healthcare Common Procedure Coding System, or HCPCS, product code for any of our approved products, we, or our partner or licensee, may be unable to sell those products at a price that exceeds their respective manufacturing, marketing and distribution costs. Sales of pharmaceuticals that patients are restricted from self-administering, such as injectable chemotherapy drugs, are dependent in large part on the availability and rate of reimbursement from third-party payors to the healthcare providers that purchase the drugs and administer them to patients. The HCPCS was established to identify and provide unique codes for healthcare goods and procedures, and virtually all third-party payors, including Medicare and private insurance plans, use it in setting their reimbursement rates. In determining a specific reimbursement rate for a drug, the Centers for Medicare and Medicaid Services, or CMS, publishes an average sales price for the drug based on manufacturer-reported sales data for all drugs within the same HCPCS product code 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 until price equilibrium is reached. If our products are not assigned a unique HCPCS product code, they will not be reimbursed based on a sales price that we set but based on an average of prices of drugs with the same HCPCS product code, which could limit our ability to set an appropriate price for our product and have a material adverse effect on our results of operations.

Even if we, or our partner or licensee, obtain unique HCPCS product codes for one or more of our approved products, if they are perceived to provide little or no advantage relative to competing products or for other reasons, we, or our partner or licensee, as applicable, may be required to price those products at levels that do not cover the costs to manufacture, market and distribute the products or provide any profit, or to price those products at levels at which they are not competitive. For instance, even if future clinical studies demonstrate that ANX-514 can be administered safely without corticosteroid premedication, and the FDA approves ANX-514 without requiring a high-dose corticosteroid premedication regimen, the medical community and/or third-party payors may not perceive the avoidance of high-dose corticosteroid premedication as a meaningful benefit to patients, which likely would negatively impact adoption of, and the sales price for, ANX-514.

There can be no assurance that, in the future, we will continue to develop or seek regulatory approval for our current product candidates as quickly as possible, or at all, if, among other factors, we determine a product candidate may not achieve adequate market acceptance. Additionally, in the future, we may reduce our expenditures on the development and/or the process of seeking regulatory approval of these product candidates while we evaluate whether and on what timeline to move the programs forward.

Even if we receive regulatory approval for one or more of our product candidates, our products may face competition from lower priced alternatives.

The currently marketed reference products against which our emulsion-formulation product candidates would compete are available as generics. For instance, ANX-514 would compete against Taxotere and other formulations of docetaxel, including generic versions of Taxotere. Even if we obtain a unique HCPCS product code 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, potentially below our cost of goods, which would adversely affect our business.

In addition, 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, it is possible other states and local governments may 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 to market one or more of our product candidates 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 commercial potential of our product candidates.

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

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 and other exclusivity 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 biopharmaceutical 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, any patents that are issued to us may be challenged, invalidated, infringed or circumvented, including by our competitors, and rights we have under issued patents may not provide competitive advantages to us.

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

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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, it is possible that inventions relevant to our business could be developed by a person not bound by an invention assignment agreement with us.

With respect to ANX-188 for the treatment of sickle cell crisis, we acquired exclusive rights to a variety of issued patents that cover, among other things, P188, purified P188, methods of treating sickle cell anemia using P188 and methods of preparing purified P188. However, we expect many of the patents covering ANX-188 for the treatment of sickle cell crisis will expire prior to regulatory approval of ANX-188 for that indication. For exclusivity, we expect to rely primarily on the orphan drug designation that the FDA has granted for P188 for the treatment of sickle cell crisis. However, the orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. ANX-188 would not receive the seven-year orphan drug marketing exclusivity if it is not the first P188 drug product to obtain FDA marketing approval for the treatment of sickle cell crisis. In addition, orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. Furthermore, if the FDA later determines another drug or biologic for the treatment of sickle cell crisis to be clinically superior to or different from ANX-188, the FDA may approve such other product candidate for marketing during ANX-188 s seven year exclusive marketing period.

Patent protection for our emulsion-formulation product candidates may be difficult to obtain and any issued claims may be limited because of the nature of patent protection available for these candidates.

Our emulsion-formulation product candidates consist of common excipients that emulsify the underlying chemical entity. We believe the specific combinations of excipients in our formulations are not obvious and that many of the properties that the resulting formulations exhibit are surprising. However, there is substantial prior art involving the emulsification of drugs and a patent examiner may combine numerous disparate references in order to reject our formulations for obviousness. A patent examiner could also determine that, even without combining references, the prior art taught the specific combination of excipients in our formulations or that, for other reasons, such combination was obvious. If our formulations are deemed obvious, the invention would not be patentable.

In addition, while the patent applications and issued patents covering our emulsion-formulation product candidates, including Exelbine and ANX-514, include product claims, they cover only specific formulations of the API, and not the API itself. Such product claims are not as strong as claims covering 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 largely the same formulation 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 industries expand and more patents are issued, the risk increases that we will be subject to claims that our products or product candidates, or their use, 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, or that the use of our products, product candidates or technologies infringe.

We or our CMOs or component material suppliers may be exposed to, or threatened with, litigation by third parties alleging that our products, product candidates and/or technologies infringe their patents and/or other intellectual property rights, or that one or more of the processes for manufacturing our products or any of their respective component materials, or the component materials themselves, or the use of our products, product candidates or technologies, infringe their patents and/or other intellectual property rights. If a third-party patent or other intellectual property right is 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, or at all. In addition, during litigation, the third-party alleging infringement could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using or selling our products, technologies or methods.

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 time and 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 or violates the third party s rights;
- a court prohibiting us from selling or licensing the product unless the third party licenses its intellectual property 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 the third party ; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial expense 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, product candidates or technology or those of our CMOs or component material suppliers or the use of our products, product candidates or technologies. Because of the large number of patents issued and patent applications filed in the biotechnology and pharmaceutical industries, we believe there is a risk that third parties may allege they have patent rights encompassing our products, product candidates or technologies, or those of our CMOs or component material suppliers, or uses of our products, product candidates or technologies.

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. In litigation or administrative proceedings, we may not succeed in causing a court or administrative body to find that one or more of our patents are valid or that an alleged infringer has infringed one or more of our patents. 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 of our product candidates are approved.

The industry in which we operate is highly competitive and rapidly changing. If successfully developed and approved, 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 hematology or oncology or that are pursuing the development of pharmaceuticals that target the same diseases and conditions as are targeted by the products that we are developing. We anticipate that we will face intense and increasing competition in the future as new products enter the market and new technologies become available. Existing products or new products developed by competitors may 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.

With respect to competition for ANX-188 for the treatment of sickle cell crisis, we are aware of numerous companies with product candidates in varying stages of development for the treatment of sickle cell crisis. In addition, we expect advances in the understanding of the signaling pathways associated with sickle cell disease to lead to further interest and development of treatment options. More broadly, ANX-188, if approved for the treatment of sickle cell crisis, would compete against agents designed to treat sickle cell disease, of which sickle cell crisis is a condition. Hydroxyurea, a form of chemotherapy used for myeloproliferative disease, is an approved product that has been shown to decrease the frequency of sickle cell crisis. Blood transfusions also are used to treat patients with sickle cell disease. Bone marrow and stem cell transplantation have also been shown to be effective to treat and, in some cases, cure sickle cell disease. In addition, there is increasing interest in developing drugs for rare diseases, which may have the effect of increasing the development of agents to treat sickle cell disease generally or sickle cell crisis in particular. GlaxoSmithKline and Pfizer each have a unit focused on rare diseases. Legislative action, such as the potential to expand the priority review voucher system to rare pediatric diseases, may generate further interest. If an effective treatment or cure for sickle cell disease or sickle cell crisis receives regulatory approval, the commercial success of ANX-188, if approved, could be severely jeopardized.

ANX-514 and Exelbine, if approved, would compete against Taxotere and Navelbine, respectively, as well as their generic equivalents and other formulations of docetaxel and vinorelbine. If our emulsion-formulation product candidates receive regulatory approval based on bioequivalence to their currently marketed reference products, our ability to differentiate them from competing products will be limited. Even if we believe they demonstrate clinical, pharmacoeconomic or other benefits relative to competing products, we may be unable to market or promote them based on these benefits. If ANX-514 and/or Exelbine receive regulatory approval, but such approval is for less than all of the indications for which Taxotere and Navelbine, respectively, are approved, the commercial success of those products could be significantly limited. If our products do not receive 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 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. For instance, in 2010, the FDA approved Jevtana® for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen. The active ingredient of Jevtana is cabazitaxel, an antineoplastic agent belonging to the taxane class. In addition to our approach of emulsifying docetaxel, other companies may be 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.

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 operate large, well-funded research, development and commercialization programs, have extensive experience in nonclinical testing and clinical studies, obtaining FDA and other regulatory approvals and manufacturing and marketing products, and have products that have been approved or are in late-stage development.

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 technologies 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, if any of our product candidates are approved.

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 an appropriate price 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

our access to additional capital.

Our ability to successfully commercialize our product candidates 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. 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 rates 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 that Congress and state legislatures will continue to 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, if at all.

Our business (in particular, the use of our product candidates in clinical studies 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 clinical study participants;

costs of related litigation;

substantial monetary awards to patients or other claimants;

loss of revenues; and

the inability to commercialize our products and product candidates.

We maintain limited product liability insurance for our clinical studies, but our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all 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 expect that we would 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.

RISKS RELATED TO OUR COMMON STOCK

If we are unable to maintain compliance with NYSE Amex continued listing standards, our common stock may be delisted from the NYSE Amex equities market, which would likely cause the liquidity and market price of our common stock to decline.

Our common stock currently is listed on the NYSE Amex equities market. The NYSE Amex will consider suspending dealings in, or delisting, securities of an issuer that does not meet its continued listing standards, including specified stockholders equity levels. In addition, the NYSE Amex will consider suspending dealings in, or delisting, 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.

Previously, we were not in compliance with certain NYSE Amex stockholders equity continued listing standards. Specifically, we were 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, we were notified, in accordance with Section 1003(f)(v) of the Company Guide, that the NYSE Amex determined it was appropriate for us to effect a reverse stock split of our common stock to address our low selling price per share.

In April 2010, we announced that we had resolved the stockholders equity continued listing deficiencies and we implemented a 1-for-25 reverse split of our common stock, in part to address the NYSE Amex s requirement that we address our low stock price. However, there is no assurance that we will continue to maintain compliance with such standards. For example, we may determine to pursue development or other activities or grow our organization or product pipeline or at levels or on timelines that reduces our stockholders equity below the level required to maintain compliance with NYSE Amex continued listing standards. In addition, the market price for our common stock historically has been highly volatile, as more fully described below under the risk titled The market price of our common stock historically has been and likely will continue to be highly volatile, and recently has traded at under $1.00 per share. The NYSE Amex may again determine that the selling price per share of our common stock is low and require that we effect a reverse stock split of our common stock, which would require stockholder approval that we may be unable to obtain. Our failure to maintain compliance with NYSE Amex continued listing standards could result in the delisting of our common stock from the NYSE Amex.

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 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 current 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.

The market price of our common stock historically has been and likely will 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, based both on our operating performance and for reasons that appear to us unrelated to our operating performance. For instance, on August 10, 2011, the market price for our common stock dropped almost 60% following our announcement of our receipt of the complete response letter for our Exelbine NDA, which stated that the FDA could not approve it in its present form. Conversely, the market price for our common stock increased over 66% in a 30-day period in June and July 2011 and 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 clinical studies and other research and development programs;
- FDA or international regulatory actions and regulatory developments in the U.S. and foreign countries;
- announcements of new products or technologies, commercial relationships or other events (including clinical study 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;
- 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 us or 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 August 10, 2011 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 a 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 any such 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. Currently, we have an effective primary registration statement on Form S-3 under which we may sell and issue more than $55 million of securities. We also have effective resale registration statements on Form S-3 and an effective registration statement on Form S-1 that 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, including an effective resale registration statement for up to 16,278,901 shares of our common stock that were issued or may be issued in the future to the selling stockholders named therein in connection with our acquisition of SynthRx. Collectively, these registration statements 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.

We currently have voting control with respect to approximately 5% of our outstanding common stock and we may obtain voting control over a significant additional amount of our outstanding common stock if we issue the milestone-related shares to the former SynthRx stockholders, and we may determine to cause those shares to be voted in such a manner that does not necessarily coincide with the interests of individual stockholders or particular groups of stockholders.

Pursuant to the voting and transfer restriction agreement between us and each of the former principal stockholders of SynthRx, each stockholder party has agreed to vote all shares of our common stock beneficially owned by that party with respect to every action or approval by written consent of our stockholders in such manner as directed by us, except in limited circumstances, and has executed an irrevocable proxy appointing and authorizing us to vote such shares in such manner. If the development of ANX-188 achieves all of the milestones set forth in our merger agreement with SynthRx without reduction, we will issue an additional 13,478,050 shares of our common stock, representing, in the aggregate (and including the shares issued in connection with the closing of our acquisition of SynthRx) an approximately 27% ownership stake in our company (based on shares outstanding as of March 1, 2012 plus shares issued in connection with achievement of the milestones). As a result of such issuances and the voting and transfer restriction agreement, we currently have, and in the future may have even more, significant control over substantially all matters requiring approval by our stockholders, including the election of directors and the approval of certain mergers and other business combination transactions. Even if less than all potential milestone-related shares are issued, our ability to control a potentially significant block of stockholder votes pursuant to the voting and transfer restriction agreement may enable us to substantially affect the outcome of proposals brought before our stockholders. Although our board of directors acts in a manner it believes is in the best interest of our stockholders as a whole, the interests of our stockholders as a whole may not always coincide with the interests of individual stockholders or particular groups of stockholders.

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, may have an anti-takeover effect by resulting in accelerated vesting of outstanding equity securities held by our executive officers. In particular, in the event of a change in control, the vesting of options we granted since July 2009 to certain key 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, and could accelerate in full at the time of the change in control if the acquirer does not assume or substitute for the options. As a result, if an acquirer desired to retain the services of one or both of those 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 adversely affect the terms of the 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 our common stock may not appreciate in value.

Item 1B. Unresolved Staff Comments.

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

Item 2. Properties.

We lease approximately 9,300 square feet of office space for our headquarters in San Diego, California. That lease will expire in January 2013, unless we exercise our option to extend it for an additional 12 months. The average rent for this space is approximately $24,500 per month. We believe that the facilities we lease are adequate to meet our current requirements and our requirements for the remaining term of the lease. We have no laboratory, research or manufacturing facilities.

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. Mine Safety Disclosures.

Not applicable.

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 Equities. The following table sets forth the high and low sale prices for our common stock in each full quarterly period within the two most recent fiscal years. The prices in the table below for periods before April 23, 2010 have been adjusted to reflect retrospective application of the 1-for-25 reverse split of our common stock effected on April 23, 2010.

	September 30,	September 30,	September 30,	September 30,
	Sales Price			
	2011		2010	
	High	Low	High	Low
First Quarter	$ 3.45	$ 1.85	$ 13.00	$ 4.00
Second Quarter	$ 3.25	$ 2.08	$ 7.25	$ 1.60
Third Quarter	$ 4.21	$ 0.81	$ 2.35	$ 1.50
Fourth Quarter	$ 1.16	$ 0.56	$ 3.20	$ 1.91

As of March 1, 2012, we had approximately 151 record holders 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. 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.

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. Although currently there are no such restrictions on our ability to pay dividends on our common stock, we may agree to similar restrictions in the future.

Recent Sales of Unregistered Securities

As partial consideration for its services as placement agent or underwriter in connection with registered offerings of our equity securities, we have issued the following common stock purchase warrants to Rodman & Renshaw, LLC, and/or its designee, on the dates indicated:

on June 12, 2009, warrants to purchase an aggregate of up to 36,071 shares of our common stock at an exercise price of $3.75 per share, which warrants became exercisable on December 13, 2009 and may be exercised any time on or before June 12, 2014;

on July 6, 2009, warrants to purchase an aggregate of up to 19,007 shares of our common stock at an exercise price of $4.475 per share, which warrants became exercisable on January 7, 2010 and may be exercised any time on or before July 6, 2014;

on August 10, 2009, warrants to purchase an aggregate of up to 14,183 shares of our common stock at an exercise price of $4.0625 per share, which warrants became exercisable on February 10, 2010 and may be exercised any time beginning on or before August 10, 2014;

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on October 9, 2009, warrants to purchase an aggregate of up to 144,000 shares of our common stock at an exercise price of $5.875 per share, which warrants became exercisable on April 7, 2010 and may be exercised any time on or before October 6, 2014;

on January 7, 2010, warrants to purchase an aggregate of up to 99,696 shares of our common stock at an exercise price of $11.9125 per share, which warrants became exercisable on July 7, 2010 and may be exercised any time on or before June 3, 2014;

on January 11, 2011, warrants to purchase an aggregate of up to 409,228 shares of our common stock at an exercise price of $3.44 per share, which warrants were exercisable upon issuance and may be exercised any time on or before April 1, 2015; and

on November 16, 2011, warrants to purchase an aggregate of up to 1,062,500 shares of our common stock at an exercise price of $1.00 per share, which warrants were exercisable upon issuance may be exercised any time on or before April 1, 2015.

On April 8, 2011, we acquired SynthRx, Inc. and issued an aggregate of 2,800,851 shares of our common stock to the former SynthRx stockholders and U.S. Bank National Association, as escrow agent, in exchange for all of the then-outstanding shares of SynthRx s capital stock. In addition, we agreed to issue up to an aggregate of 13,478,050 shares of our common stock to the former SynthRx stockholders if the development of ANX-188 achieves certain milestones as set forth in the merger agreement. See Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Acquisition of SynthRx, below.

The securities described above were offered and sold by us in reliance upon exemptions from the registration requirements of the Securities Act of 1933, as amended, or the Securities Act. Such securities were issued pursuant to Section 4(2) of the Securities Act, and/or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of the securities represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to warrants or share certificates, as applicable, issued in these transactions. All recipients had adequate access to information about our company. The number of underlying shares and exercise prices of the warrants described above that were issued prior to April 23, 2010 have been adjusted to reflect retrospective application of the 1-for-25 reverse split of our common stock effected on April 23, 2010.

Item 6. Selected Financial Data.

Under SEC rules and regulations, because the aggregate worldwide market value of our common stock held by non-affiliates was more than $75 million, but less than $700 million, as of June 30, 2011, the last business day of our most recently completed second fiscal quarter, we are considered to be an accelerated filer. We were considered to be a smaller reporting company when we determined our filing status for purposes of our annual report on Form 10-K for our fiscal year ended December 31, 2010. SEC rules and regulations provide that a smaller reporting company transitioning to the larger reporting system, as we are doing this year, may finish reporting as a smaller reporting company for the rest of the fiscal year, including in its annual report on Form 10-K, and is not required to satisfy the larger reporting company disclosure requirements until the first quarterly report for the new fiscal year following the determination date. Accordingly, we are not required to provide the information required by this item in this report.

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 biopharmaceutical company focused on developing proprietary product candidates. Our lead product candidate is ANX-188, a rheologic, antithrombotic and cytoprotective agent that improves microvascular blood flow and has potential application in treating a wide range of diseases and conditions, such as complications arising from sickle cell disease. We also are developing ANX-514, a novel, detergent-free formulation of the chemotherapy drug docetaxel.

We have devoted substantially all of our resources to research and development, or R&D, and to acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue and we have incurred significant losses since inception. We incurred losses from operations of $13.4 million and $8.5 million for the years ended December 31, 2011 and December 31, 2010, respectively. Our cash, cash equivalents and short-term investments were $50.7 million at December 31, 2011.

We acquired ANX-188 (purified poloxamer 188) in April 2011 as part of our acquisition of SynthRx, Inc. and are focusing our resources primarily on its development. We believe ANX-188 is a late-stage product candidate that may have numerous applications for the treatment of diseases and conditions resulting from microvascular-flow abnormalities. Initially, we are developing ANX-188 to treat patients suffering from complications arising from sickle cell disease, and we plan to initiate a phase 3 clinical study of ANX-188 in patients with sickle cell disease in 2012. In addition, we plan to conduct a number of smaller-scale clinical studies to further assess the efficacy, safety and tolerability of ANX-188, and expect these studies to overlap the planned phase 3 study.

We also are continuing to develop ANX-514 (docetaxel for injectable emulsion), our detergent-free reformulation of Taxotere® (docetaxel). We are evaluating methods, including devices, that can assess the incidence of fluid retention in cancer patients more accurately and objectively than the current method of clinical observation and plan to discuss with the FDA our findings. We may conduct nonclinical and/or small-scale clinical studies of ANX-514 to investigate the use of such a method or device.

Until late 2011, we also were pursuing FDA approval of Exelbine, our novel emulsion formulation of the chemotherapy drug vinorelbine. In August 2011, we received a complete response letter from the FDA stating that it could not approve our new drug application, or NDA, for Exelbine in its present form and that the pivotal bioequivalence trial included in the NDA would need to be repeated because the authenticity of the drug products used in the study could not be verified in accordance with FDA standards. Consequently, we elected to discontinue independent development of Exelbine and are seeking a partner or outside investor for the program to complete the necessary bioequivalence study.

We anticipate that our cash, cash equivalents and short-term investments as of December 31, 2011 will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, we may pursue development activities for our product candidates, at levels or on timelines, or we may incur unexpected expenses, that shorten the period through which our operating funds will sustain us. We expect to incur significant and increasing losses for the next several years as we advance our product candidates through clinical studies and other development activities and seek regulatory approval to commercialize such product candidates. We will need additional financing to support our planned operating activities. In addition, we may seek to expand our product pipeline through acquisition of additional product candidates and/or technologies. For the foreseeable future, we plan to seek to fund our operations through public or private equity and/or debt financings. We may also seek to raise funds through strategic relationships and/or licensing transactions. Adequate additional financing may not be available to us on acceptable terms or on a timely basis, or at all. Our failure to raise capital as and when needed would have a material and adverse effect on our financial condition and ability to pursue our business strategy.

Acquisition of SynthRx

Merger Consideration. In April 2011, we acquired SynthRx, Inc. as a wholly-owned subsidiary through a merger transaction in exchange for shares of our common stock and rights to additional shares of our common stock upon achievement of specified milestones related to ANX-188. Upon completion of the acquisition, we issued 2,800,851 shares of our common stock to the former SynthRx stockholders, up to 1,454,079 of which are subject to repurchase by us in the event development of ANX-188 does not achieve the First Milestone under specified circumstances, as described below, and 200,000 of which are subject to escrow until April 2012 to indemnify us against breaches of representations and warranties in the merger agreement, and we assumed $0.3 million of SynthRx s transaction expenses. We could issue up to an aggregate of 13,478,050 additional shares of our common stock to the former SynthRx stockholders if the development of ANX-188 achieves certain milestones, as described below. Of the shares issuable in connection with achievement of milestones, up to 1,000,000 shares would be issuable upon the dosing of the first patient in a phase 3 clinical study that the FDA has indicated may be sufficient to support approval of a NDA covering the use of purified P188 for the treatment of sickle cell crisis in children, or the purified P188 NDA, which we refer to as the First Milestone; 3,839,400 shares would be issuable upon acceptance for review of the purified P188 NDA by the FDA, which we refer to as the Second Milestone; and 8,638,650 shares would be issuable upon approval by the FDA of the purified P188 NDA, which we refer to as the Third Milestone. The amounts of the 1,454,079 shares and the 1,000,000 shares that may vest or become issuable, as applicable, upon achievement of the First Milestone are subject to reduction based on the timing of achievement of the First Milestone and whether and the extent to which the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint exceeds 250 patients, unless otherwise agreed.

In-License Agreement with CytRx Corporation. In connection with our acquisition of SynthRx, through a prior license agreement between SynthRx and CytRx Corporation, we acquired rights to a variety of issued patents related to poloxamers and their uses. The issued patents cover, among other things, P188, purified P188, methods of treating sickle cell anemia using P188 and methods of preparing purified P188. Pursuant to this license agreement, we are required to make certain non-refundable and non-creditable milestone payments to CytRx based on the approval of each covered product in a major market, which includes the U.S. The amount of each milestone is in the low single-digit millions, half of which is due on the first commercial sale of the approved product and half of which is payable over time based on a percentage of quarterly net sales. In addition, we would pay a single-digit royalty on net sales of covered products. However, in the event of a sublicense under the specified patents, in lieu of the foregoing milestone and royalty payments, we may elect, in our sole discretion, to pay CytRx an amount equal to 20% of any sublicensing income we receive within 30 days of receipt thereof. Sublicense income includes, without limitation, license fees, royalties, milestone payments, license maintenance fees and strategic alliance payments, whether in cash, equity or other property, with the payment to be in the same form as the payment we receive.

2011 Financings

In 2011, we raised an aggregate of $36.6 million in net proceeds through the following equity financings:

In January 2011, we completed a registered direct equity financing involving the issuance of units consisting of 8,184,556 shares of our common stock, 5-year warrants to purchase up to an aggregate of 2,046,139 shares of our common stock and 1-year warrants to purchase up to an aggregate of 2,046,139 shares of our common stock. The gross proceeds of this financing were $22.5 million, and we received $21.0 million in net proceeds after deducting the fees and expenses of our placement agent and our other offering expenses. The 1-year warrants expired unexercised in January 2012. We may receive up to $5.6 million of additional proceeds from the exercise of the 5-year warrants. The exercise price of the warrants is $2.75 per share, and, subject to certain beneficial ownership limitations, the 5-year warrants are exercisable any time on or before January 11, 2016.

In November 2011, we completed an underwritten public offering of 21,250,000 shares of our common stock and warrants exercisable for up to 10,625,000 additional shares of our common stock. These securities were offered and sold to the public in multiples of a fixed combination consisting of one share and a warrant to purchase up to 0.5 of a share of our common stock. The gross proceeds from this financing were $17.0 million, and we received $15.6 million in net proceeds after deducting the underwriting commissions and our other offering expenses. We may receive up to $11.7 million of additional proceeds from the exercise of the warrants issued to investors in this financing. The warrants have an exercise price of $1.10 per share, and, subject to certain beneficial ownership limitations, the 5-year warrants are exercisable any time on or before November 16, 2016.

Reverse Stock Split

On April 23, 2010, we effected a 1-for-25 reverse split of our common stock, which was authorized by our stockholders at a special meeting held in August 2009. The reverse stock split reduced the number of our issued and outstanding shares of common stock as of April 23, 2010 from approximately 257.3 million shares to approximately 10.3 million shares. All common stock share and per share information included in this report have been restated to reflect retrospective application of the reverse stock split for periods ending or as of a date prior to April 23, 2010, except for par value per share and the number of authorized shares, which were not affected by the reverse stock split.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations included in this annual report is based upon consolidated financial statements that we have prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make a number of estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses in these consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate these estimates and assumptions, including those related to determination of the fair value of contingent consideration, goodwill and acquired in-process research and development, or IPR&D, and recognition of expenses for clinical study accruals and share-based compensation. We base our estimates on historical information, when available, 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 materially from these estimates under different assumptions.

We believe the following accounting policies to be critical to the estimates used in the preparation of our financial statements. The following is not intended to be a comprehensive discussion of all of our significant accounting policies. See the notes accompanying our financial statements appearing in this report for a summary of all of our significant accounting policies and other disclosures required by U.S. GAAP.

Accrued Research and Development Expenses. As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. Many of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The majority of our accrued expenses relate to R&D services and related expenses. Examples of estimated accrued R&D expenses include:

fees paid to contract manufacturing organizations, or CMOs, in connection with process development activities and production of nonclinical and clinical trial material;

fees paid to vendors in connection with nonclinical development activities;

fees paid to consultants for regulatory-related advisory services;

fees paid to contract research organizations, or CROs, in connection with clinical studies; and

fees paid to investigative sites and investigators in connection with clinical studies.

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We base our expenses related to CMOs and CROs on our estimates of the services received and efforts expended pursuant to purchase orders or contracts with multiple service providers that we engage to manufacture our clinical trial material or conduct and manage clinical studies on our behalf. The financial terms of our arrangements with our CMOs and CROs are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful completion of specified process development activities or the successful enrollment of patients and the completion of clinical study milestones. In accruing these service fees, we estimate, as applicable, the time period over which services will be performed (e.g., enrollment of patients, activation of clinical sites, etc.). If the actual timing varies from our estimate, we adjust the accrual accordingly. In addition, there may be instances in which payments made to service providers will exceed the level of services provided and result in a prepayment of R&D expense, which we report as an asset. The actual costs and timing of clinical studies and research-related manufacturing are uncertain and subject to change depending on a number of factors. Differences between actual costs of these services and the estimated costs that we have accrued in a prior period are recorded in the subsequent period in which the actual costs become known to us. Historically, these differences have not resulted in material adjustments, but such differences may occur in the future and have a material impact on our consolidated results of operations or financial position.

Business Combinations. We accounted for the acquisition of SynthRx in accordance with Accounting Standards Codification, or ASC, Topic 805, *Business Combinations*, which requires the purchase price to be measured at fair value. The purchase price consists entirely of shares of our common stock and includes contingent consideration, which becomes vested or issuable, as applicable, upon achievement of the First Milestone, the Second Milestone and the Third Milestone, as discussed above under Acquisition of SynthRx. We calculated the total purchase price by determining the probability-weighted fair value of the shares of our common stock issued, issued subject to repurchase and issuable to the former SynthRx stockholders as of April 8, 2011, the acquisition date. The probability and timing inputs related to the vesting and issuance events were based on estimates and assumptions regarding development of ANX-188, which are highly judgmental due to the inherent unpredictability of drug development, particularly by development-stage companies such as ours. We then allocated the total purchase price to the tangible assets and intangible assets acquired, including IPR&D, and liabilities assumed based on our estimates of their respective fair values as of the acquisition date. We recognized goodwill equal to the excess of the purchase price over the fair value of the tangible and IPR&D assets acquired and liabilities assumed.

The determination and allocation of the purchase price requires us to make significant estimates and assumptions, particularly with respect to the fair values of the contingent consideration and acquired IPR&D. We believe the fair values assigned to the contingent consideration and acquired IPR&D are based on reasonable estimates and assumptions given the available facts and circumstances as of the acquisition date. However, these calculations are highly judgmental and it is possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range of alternative estimated amounts. For instance, we used a discounted cash flow model to determine the fair value of contingent consideration, though other methodologies could have been used. Discounted cash flow models require the use of significant estimates and assumptions, including, but not limited to: the probability of clinical and regulatory success for a product candidate considering its stage of development; the time and resources needed to complete the development and approval of a product candidate, including the inherent difficulties and uncertainties in developing a product candidate, such as obtaining FDA and other regulatory approvals; estimated cash flows projected following the approval of a product candidate in development; the commercial life of the potential approved product and associated risks; and risk associated with uncertainty regarding achievement of the milestone events and, with respect to the First Milestone, the circumstances under which it is achieved. We estimated the time needed to complete the development and approval of ANX-188 based on assumptions regarding its stage of development as of the acquisition date and resources needed to complete its development and approval, taking into account the inherent difficulties and uncertainties in developing product candidates in general and ANX-188 in particular. Changes to any of these estimates and assumptions could significantly impact the fair values recorded for the assets acquired and liabilities assumed in our acquisition of SynthRx, resulting in significant charges to our operations. In addition, unanticipated events and circumstances may occur which may affect the accuracy or validity of such assumptions, estimates or actual results.

Asset and Liability for Contingent Consideration. Our contingent asset and contingent liability are related to our acquisition of SynthRx and the amount of the purchase price, payable in shares of our common stock, that is subject to repurchase and issuance, respectively, contingent upon achievement of the First Milestone and the circumstances under which it is achieved. We remeasure the fair value of this contingent consideration as of the end of each fiscal quarter. Our determination of fair value is highly judgmental in that the number of shares that may be repurchased by us (up to 1,454,079 shares) and the number of shares we may be required to issue (from 250,000 to 1,000,000 shares) reflect our estimates based on assumptions regarding the probability and circumstances of achievement of the First Milestone and these estimates have changed since the acquisition date and may be different in the future. We believe our estimates and assumptions are reasonable based on available facts and circumstances as of each measurement date. The fair value of this contingent consideration is also based on the market price of our common stock. As a proxy, we use the last reported sale price of our common stock on the NYSE Amex equities market on the measurement date (i.e., the last trading day of each quarter), which, given the historic and expected future volatility of our stock price, likely will be different and may vary considerably from one measurement date to the next. Changes in the fair value of this contingent consideration are recognized in earnings, as transaction-related expenses, until the contingent consideration arrangement is settled.

Goodwill and Acquired IPR&D. In accordance with ASC Topic 350, *Intangibles Goodwill and Other*, our goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment annually and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying amount may be impaired. We perform our annual impairment testing on September 30 of each year. We elected to early-adopt Accounting Standards Update No. 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment*, or ASU No. 2011-08, pursuant to which we may first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more likely than not (that is, a likelihood of more than 50%) that goodwill is impaired, and, unless we determine that it is more likely than not goodwill is impaired, we do not perform the two-step impairment test otherwise required under ASC Topic 350. ASU No. 2011-08 does not apply to acquired IPR&D testing. Our determinations as to whether, and, if so, the extent to which, goodwill and acquired IPR&D become impaired are highly judgmental and based on assumptions regarding our projected future operating results, changes in the manner of our use of the acquired assets or our overall business strategy and regulatory, market and economic environment and trends.

Share-based Compensation Expenses. 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*. Compensation expense for all share-based awards is based on the estimated fair value of the award on its date of grant and recognized on a straight-line basis over its vesting period. As share-based compensation expense is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. We estimate forfeitures at the time of grant and revise our estimates in subsequent periods if actual forfeitures differ from those estimates. We estimate forfeitures based on historical experience. Although share-based compensation expense can be significant to our consolidated financial statements, it is not related to the payment of any cash by us.

We estimate the grant date fair value of a stock option award using the Black-Scholes option-pricing model, or Black-Scholes model. In determining the grant date fair value of a stock option award under the Black-Scholes model, we must make a number of assumptions, including the term of the award, the volatility of the price of our common stock over the term of the award, the risk-free interest rate and estimated forfeiture rate. Changes in these or other assumptions could have a material impact on the compensation expense we recognize.

Results of Operations Overview

We operate our business and evaluate our company on the basis of a single reportable segment, which is the business of developing proprietary product candidates.

Revenue

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, if any, that we have obtained approval from a regulatory agency to sell one or more of our product candidates, which we cannot predict with certainty will occur.

Operating Expenses

Research and Development 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 outsource a substantial portion of our work and our R&D personnel and consultants work across multiple programs rather than dedicating their time to one particular program. We began maintaining such expenses by type on January 1, 2005. We categorize our R&D expenses as external clinical study fees and expenses, external nonclinical study fees and expenses, personnel costs and share-based compensation expense. The major components of our external clinical study fees and expenses are fees and expenses related to CROs and clinical study investigative sites and investigators. The major components of our external nonclinical study fees and expenses are fees and expenses related to preclinical studies and other nonclinical testing, research-related manufacturing, including process development activities, quality assurance and regulatory affairs services. Research-related manufacturing expenses include costs associated with purchasing active pharmaceutical ingredient (API), conducting process development activities, producing clinical trial material, producing material for stability testing to support regulatory filings, related labeling, testing and release, packaging and storing services and related consulting fees. Personnel costs relate to employee salaries, benefits and related costs.

A general understanding of drug development is critical to understanding our results of operations and, particularly, our R&D expenses. 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 demonstrate the product candidate s safety and effectiveness. Generally, an NDA must be supported by at least phase 1, 2 and 3 clinical studies, with each study typically more expensive and lengthy than the previous study.

Future expenditures on R&D programs are subject to many uncertainties, including the number of clinical studies required to be conducted for each product candidate and whether we will develop a product candidate with a partner or independently. At this time, due to such uncertainties and the risks inherent in 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 clinical studies and research-related manufacturing, can vary significantly among programs as a result of a variety of factors, including:

- the number of studies necessary to demonstrate the safety and efficacy of a product candidate;
- the number of patients who participate in the clinical studies;
- the number and location of sites included in clinical studies and the rate of site approval for in each study;
- the rates of patient recruitment and enrollment;
- the ratio of randomized to evaluable patients;

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with respect to bioequivalence or comparative studies, the availability and cost of reference or control product in the jurisdiction of each site;

the duration of patient treatment and follow-up;

the time and cost of process development activities related to the manufacture of our product candidates and key components thereof;

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 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.

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, we may be obligated to pay in foreign currencies for the services of third-party manufacturers of and component suppliers for our product candidates. As a result, our exposure to currency risk likely will increase in connection with the manufacture of clinical trial material and, if and as applicable, product for commercial sale. We include realized gains and losses from foreign currency transactions in operations as incurred.

We expect our R&D expenses to increase as we seek to progress development of our product candidates, particularly ANX-188. In particular, we anticipate incurring significant R&D expenses in connection with preparing for and conducting our planned phase 3 study of ANX-188 and the additional, smaller-scale clinical studies of ANX-188, which we expect to overlap the phase 3 study. We expect our R&D expenses to increase significantly in 2012 relative to 2011. Our 2011 R&D expenses reflect less than a full year of activity on ANX-188 because we did not commence development of ANX-188 until after we completed our acquisition of SynthRx in April 2011 and SynthRx was not actively developing ANX-188 prior to the acquisition.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses consist primarily of salaries, benefits and related costs for personnel in executive, finance and accounting, legal and market research functions, professional and consulting fees for accounting, legal, investor relations, business development, market research, human resources and information technology services. Other SG&A expenses include facility lease and insurance costs.

We expect SG&A expenses to be flat in 2012 relative to 2011, as we expect that cost-savings realized by discontinuation of Exelbine commercial-readiness activities will be offset in part by increased personnel costs primarily due to increased headcount relative to the first half of 2011.

Transaction-Related Expenses. Transaction-related expenses consist of legal, accounting, financial and business development advisory fees associated with the evaluation of potential acquisition targets and execution of acquisition transactions, including our acquisition of SynthRx. Transaction-related expenses also include any changes in the fair value of the contingent asset and contingent liability related to our acquisition of SynthRx, which we remeasure as of the end of each quarter.

Interest and Other Income/(Expense). Interest and other income/(expense) includes interest income, interest expense, gains and losses from foreign currency transactions and other non-operating gains and losses.

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Results of Operations Comparison of 2011 and 2010

Revenue. We recognized no revenue for the year ended December 31, 2011 and $0.5 million for the year ended December 31, 2010. Revenue in 2010 consisted of two grants awarded under the qualifying therapeutic discovery project established under Section 48D of the Internal Revenue Code as a result of the Patient Protection and Affordable Care Act of 2010 and paid in November 2010.

Operating Expenses. The following table illustrates the types of operating expenses we incurred in 2011 and 2010 and their respective percent of our total operating costs for those periods:

	September 30, Operating Expenses Years Ended December 31, 2011	September 30, 2010
Research and development	43%	41%
Selling, general and administrative	54%	55%
Transaction-related expenses	3%	4%
Depreciation and amortization	0%	0%
Total operating expenses	100%	100%

R&D Expenses. In 2011 and 2010, our R&D expenses consisted primarily of costs associated with external nonclinical activities related to ANX-188, ANX-514 and Exelbine, including research-related manufacturing costs, regulatory-related consulting services and stability testing. Our most significant R&D expenses in 2011 were those relating to Exelbine commercial-readiness manufacturing, which will not be incurred in 2012.

The following table summarizes our consolidated R&D expenses by type for each of the periods listed:

	September 30, Years Ended December 31, 2011	September 30, 2010	September 30, January 1, 2005 through December 31, 2011
External clinical study fees and expenses	$ 751,236	$ 215,486	$ 24,769,298
External nonclinical study fees and expenses	4,212,596	3,225,723	31,467,267
Personnel costs	817,045	253,298	11,361,041
Share-based compensation expense	(22,540)	(5,745)	2,897,445
Total	$ 5,758,337	$ 3,688,762	$ 70,495,051

R&D expenses increased by $2.1 million, or 56.1%, to $5.8 million for the year ended December 31, 2011, compared to $3.7 million for the year ended December 31, 2010. The increase in R&D expenses in 2011 compared to 2010 was due primarily to a $1.0 million increase in external nonclinical study fees and expenses, a $0.6 million increase in personnel costs and a $0.5 million increase in external clinical study fees and expenses. The increase in external nonclinical study fees and expenses was primarily related to research-related manufacturing activities and consulting expenses of $1.0 million for ANX-188 and increased commercial-readiness manufacturing and consulting expenses of $0.5 million for Exelbine. These increases were offset by a $0.5 million decrease in research-related manufacturing activities and consulting expenses for ANX-514, primarily due to decreased activity while we evaluated potential third-party manufacturers for ANX-514 and negotiated arrangements with our chosen vendor. The increase in personnel costs resulted from additional clinical and research-related manufacturing staff hired in 2011. The increase in external clinical study fees and expenses was primarily related to increased clinical consulting expenses of $0.4 million for ANX-188 and increased consulting expenses of $0.1 million for Exelbine related to study site inspections. The decrease in share-based compensation expense is related to a true up of prior expense based on an updated forfeiture analysis.

Selling, General and Administrative Expenses. In 2011 and 2010, our SG&A expenses consisted primarily of consulting fees for finance, accounting, human resources, facilities, internal systems support, business development, commercialization, market research and investor relations functions services, salaries, benefits and related personnel costs for employees and share-based compensation expense.

SG&A expenses increased by $2.2 million, or 44.1%, to $7.2 million for the year ended December 31, 2011, compared to $5.0 million for the same period in 2010. This increase resulted primarily from a $0.9 million increase in commercial-readiness activities for Exelbine, a $0.9 million increase in personnel costs, mainly due to additional staff hired in 2011, a $0.2 million increase in investor relations consulting expenses, a $0.1 million increase in share-based compensation expense and a $0.1 million increase in facility costs.

Transaction-Related Expenses. Transaction-related expenses were $0.4 million for the year ended December 31, 2011, compared to $0.3 million for the year ended December 31, 2010. Transaction-related expenses for the year ended December 31, 2011 consisted of $1.9 million related to legal, accounting, financial and business development advisory fees associated with the evaluation of potential acquisition targets, including SynthRx, and the execution of our acquisition of SynthRx, offset by a $1.5 million reduction due to changes since the acquisition date in the fair value of the contingent asset and contingent liability related to the SynthRx acquisition. The changes in fair value of this contingent consideration were primarily due to the decrease in our stock price at December 31, 2011 relative to April 8, 2011, the acquisition date, and updated estimates regarding the probability and circumstances of achievement of the First Milestone. Transaction-related expenses for the year ended December 31, 2010 consisted of $0.3 million related to legal, financial and business development advisory fees associated with the evaluation of potential acquisition targets, including SynthRx.

Interest and Other Income/(Expense). Interest income amounted to $77,000 for 2011, compared to $93,000 in 2010. The decrease in interest income of $16,000 for 2011 was attributable primarily to lower interest rates on invested balances in 2011 as compared to 2010. Other income was $71,000 in 2011, compared to other expense of $2,000 in 2010. The other income in 2011 was primarily attributable to insurance proceeds. The other expense in 2010 was attributable to losses on the sale of various business assets.

Net Loss. Net loss applicable to common stock was $13.3 million, or $0.47 per share (basic and diluted), for the year ended December 31, 2011, compared to a net loss applicable to common stock of $14.1 million, or $1.07 per share (basic and diluted), for the year ended December 31, 2010. Included in the net loss applicable to common stock for 2010 was non-cash deemed dividend expenses of approximately $5.6 million, related to our January and May 2010 registered direct preferred stock and warrant financings.

Liquidity and Capital Resources

We have a history of annual losses from operations and we have funded our operations primarily through sales of our equity securities. We incurred losses from operations of $13.4 million and $8.5 million for the years ended December 31, 2011 and December 31, 2010, respectively. Our cash, cash equivalents and short-term investments were $50.7 million at December 31, 2011.

In January 2011, we completed a registered direct equity financing involving the issuance of shares of our common stock and common stock purchase warrants. This financing resulted in $22.5 million in gross proceeds, and we received $21.0 million in net proceeds after deducting the fees and expenses of our placement agent and our other offering expenses.

In November 2011, we completed an underwritten public offering involving the issuance of shares of our common stock and common stock purchase warrants. This financing resulted in $17.0 million in gross proceeds, and we received $15.6 million in net proceeds after deducting the underwriting commissions and our other offering expenses.

We may receive up to $0.8 million, $4.4 million, $6.6 million, $5.6 million and $11.7 million of additional net proceeds from the exercise of warrants issued in the registered direct equity financings we completed in October 2009, January and May 2010 and January 2011, and the underwritten public offering we completed in November 2011, respectively; however, the exercise of these warrants is subject to certain beneficial ownership limitations. In addition, we may receive up to $4.8 million of additional net proceeds from the exercise of warrants issued to our placement agent and underwriter, and its designees, as additional consideration for services in connection with certain of our equity financings.

For a more detailed discussion of our 2010 and 2011 equity financings, see Note 8, Capital Stock and Warrants, of the Notes to Consolidated Financial Statements in this report.

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

Analysis of our 2011 versus 2010 cash flow from operating, investing and financing activities is provided below.

	September 30, December 31, 2011	September 30, Increase During 2011	September 30, December 31, 2010
Cash, cash equivalents and short-term investments	$ 50,703,644	$ 22,724,821	$ 27,978,823
Net working capital	$ 49,323,192	$ 22,715,589	$ 26,607,603

	September 30, Year Ended December 31, 2011	September 30, Change Between Periods	September 30, Year Ended December 31, 2010
Net cash used in operating activities	$ (13,466,954)	$ (5,125,717)	$ (8,341,237)
Net cash used in investing activities	(7,543,976)	(7,519,842)	(24,134)
Net cash provided by financing activities	36,604,210	8,927,420	27,676,790
Effect of exchange rate on cash and cash equivalents	(2,156)	(2,156)	
Net increase in cash and cash equivalents	$ 15,591,124	$ (3,720,295)	$ 19,311,419

Operating activities. Net cash used in operating activities was $13.5 million in 2011, compared to $8.3 million in 2010. The increase in cash used in operating activities in 2011 was due primarily to a higher net loss in 2011 as compared to 2010 ($4.8 million), which was attributable primarily to increases in our R&D and SG&A expenses in connection with Exelbine commercial-readiness activities and ANX-188 development activities, and a gain on the change in fair value of contingent consideration related to our SynthRx acquisition ($1.5 million), offset by an increase in accounts payable and accrued liabilities ($0.8 million), a decrease in prepaids in other assets ($0.3 million) and higher share-based compensation expense ($0.1 million).

Investing activities. Net cash used in investing activities was $7.5 million in 2011, compared to $24,134 in 2010. The cash used in investing activities in 2011 was primarily for purchases of certificates of deposit of $7.1 million, purchases of property and equipment of $0.4 million, offset by $13,000 of proceeds from sale of property and equipment. The cash used in investing activities in 2010 was primarily for purchases of property and equipment offset by $4,379 of proceeds from sale of property and equipment.

Financing activities. Net cash provided by financing activities was $36.6 million in 2011, compared to $27.7 million in 2010. The cash provided by financing activities in 2011 and 2010 primarily consisted of proceeds from the issuance of our equity securities in the financing transactions we completed during those periods.

Management Outlook

We anticipate that our cash, cash equivalents and short-term investments as of December 31, 2011 will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, our future capital uses and requirements will be affected by numerous forward-looking factors that, depending on their actual outcome, could shorten or extend the period through which our operating funds will sustain us. These factors include, but are not limited to: the scope, prioritization and number of development programs we pursue; the rate of progress and costs of development and regulatory approval activities associated with our product candidates, including conducting manufacturing process development activities, manufacturing clinical trial material and initiating and conducting clinical studies; the extent to which we acquire new product candidates and/or technologies; the extent to which we partner or collaborate with third parties to develop, seek regulatory approval of and commercialize our product candidates, or sell or license our product candidates to others; and whether any of our product candidates for which we receive regulatory approval, if any, achieve broad market acceptance. In addition, we have a small workforce and rely on third parties to perform many essential services for us, including the manufacture of clinical trial material, the conduct of clinical studies and regulatory

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submissions related to product approval. The timing and extent to which we increase our workforce is difficult to predict as it will be influenced by the rate of progress of development and regulatory approval of our product candidates and whether we partner them, as well as the extent to which we acquire and develop new product candidates and/or technologies. Increases in the size of our workforce would impact the period through which our operating funds will sustain us.

We are focusing our resources primarily on the development of ANX-188 and plan to initiate a phase 3 clinical study of ANX-188 in 2012 for the treatment of patients suffering from complications associated with sickle cell disease. Currently, we are focused on finalizing the trial design and, in parallel, working with third-party manufacturers on process development and production of clinical trial material. In addition, we plan to conduct a number of smaller-scale clinical studies to further assess the efficacy, safety and tolerability of ANX-188, including a pilot phase 2 study in patients with sickle cell disease, and we expect these studies to overlap the planned phase 3 study. Further, we may begin to pursue additional indications for ANX-188, including through nonclinical and/or clinical studies. We have and may continue to increase our workforce in connection with our development of ANX-188. We plan to pursue partnering and other strategic opportunities for development of ANX-188 outside of the U.S. and for additional indications in the U.S. However, partnering and other strategic options may not be available on acceptable terms, or at all.

We are continuing to develop ANX-514 and our near-term focus is to evaluate methods, including devices, that can assess the incidence of fluid retention in cancer patients more accurately and objectively than the current method of clinical observation. We may conduct nonclinical and/or small-scale clinical studies of ANX-514 to investigate the use of such a method or device. In parallel, we are continuing certain manufacturing development activities to support a clinical study. We do not plan to initiate the previously agreed upon 400-patient study during 2012. As we investigate the optimal development path for ANX-514, if we determine the anticipated capital requirements associated with its continued development are not financially justifiable, we may determine to discontinue this program. We expect to continue to pursue partnering and other strategic opportunities for ANX-514, including its sale or exclusive license to a third party. However, partnering and other strategic options may not be available on acceptable terms, or at all.

Although our current focus is on the development of ANX-188 and ANX-514, from time to time, we may evaluate pipeline expansion opportunities that we believe will increase the long-term value of our company. The process of identifying and evaluating various opportunities can be lengthy and complex and divert management s attention from our current development programs. We have limited resources to identify, evaluate and negotiate potential transactions, and supplementing our current resources to complete one or more transactions may be costly. We expect that our capital requirements would increase in future periods if we were to expand our product pipeline.

Although we anticipate that our cash, cash equivalents and short-term investments as of December 31, 2011 will be sufficient to fund our currently planned level of operations for at least the next 12 months, we expect to incur significant and increasing losses for the next several years as we advance our product candidates through clinical studies and other development activities and seek regulatory approval to commercialize such product candidates. We will need additional financing to support our operating activities. In addition, we may seek to expand our product pipeline through acquisition of additional product candidates and/or technologies. For the foreseeable future, we plan to seek to fund our operations through public or private equity and/or debt financings. We may also seek to raise funds through strategic relationships and/or licensing transactions. Even though we were able to raise significant funds in the recent past through equity financings, adequate additional financing may not be available to us in the future on acceptable terms or on a timely basis or at all. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and ability to pursue our business strategy.

Contingent Asset and Contingent Liability

Our contingent asset is the probability-weighted fair value of the shares of our common stock issued to the former SynthRx stockholders on the acquisition date that may be repurchased by us based on our estimates of the probability of achievement of the First Milestone and assumptions regarding the circumstances under which it is achieved. The number of outstanding shares subject to this repurchase right is 1,454,079 shares. Our contingent liability is the probability-weighted fair value of the shares of our common stock issuable to the former SynthRx stockholders upon achievement of the First Milestone based on our assumptions regarding the circumstances of its achievement. The number of shares issuable ranges from 250,000 to 1,000,000 shares. We remeasure the fair value of this contingent consideration as of the last day of each fiscal quarter until the

arrangement is settled. The increase in fair value of the contingent asset and the decrease in fair value of the contingent liability from April 8, 2011, the acquisition date, to December 31, 2011 were primarily due to the decrease in our stock price at December 31, 2011 relative to April 8, 2011 and updated estimates regarding the probability and circumstances of achievement of the First Milestone.

Acquired In-Process Research and Development

Our acquired IPR&D is the estimated fair value of SynthRx s lead product candidate, ANX-188, as of April 8, 2011, the acquisition date. We determined that the estimated fair value of the ANX-188 program was $6.5 million as of the acquisition date using the Multi-Period Excess Earnings Method, or MPEEM, which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset s incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life.

To calculate fair value of the ANX-188 program under the MPEEM, we used probability-weighted cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by development-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to the program and then reduced by a contributory charge on requisite assets employed. Contributory assets included debt-free working capital, net fixed assets and assembled workforce. Rates of return on the contributory assets were based on rates used for comparable market participants. Cash flows were assumed to extend through the market exclusivity period estimated to be provided by orphan drug designation. The resultant cash flows were then discounted to present value using a weighted-average cost of equity capital for companies with profiles substantially similar to that of SynthRx, which we believe represents the rate that market participants would use to value the assets. We compensated for the phase of development of this program by probability-adjusting our estimation of the expected future cash flows. The projected cash flows were based on significant assumptions, such as the time and resources needed to complete the development and approval of ANX-188, estimates of revenue and operating profit related to the program considering its stage of development, the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in drug development such as obtaining marketing approval from the FDA and other regulatory agencies, and risks related to the viability of and potential alternative treatments in any future target markets.

Our deferred income tax liability of $2.6 million as of December 31, 2011 reflects the tax impact of the difference between the book basis and tax basis of the IPR&D acquired in connection with our acquisition of SynthRx. Such deferred tax liability cannot be used to offset deferred tax assets when analyzing our end of year valuation allowance as the acquired IPR&D is considered to have an indefinite life until we complete or abandon development of ANX-188.

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Tax Loss Carry forwards

As of December 31, 2011, we had federal and California net operating loss carry forwards of $43.9 million and $47.4 million, respectively. These tax loss carry forwards will begin to expire in 2018 and 2012, respectively. As of December 31, 2011, we also had federal and California R&D tax credit carry forwards of $0.3 million and $0.2 million, respectively. The federal tax credit carry forwards will begin to expire in 2029. The California tax credit carry forwards do not expire.

In addition, 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 R&D tax credit carry forwards to offset future taxable income is limited if we experience a cumulative change in ownership of more than 50% within a three-year period. During 2010, we completed a formal study to determine whether any ownership change within the meaning of IRC Section 382 occurred during the period from January 1, 2008 through January 7, 2010, and several ownership changes were identified. Upon application of limitations prescribed by IRC Section 382, we identified certain tax attributes that would expire before utilization and adjusted our deferred tax assets for net operating loss and R&D tax credit carry forwards accordingly. We currently are conducting a formal study to determine whether any ownership change within the meaning of IRC Section 382 occurred during the period from January 8, 2010 through December 31, 2011. This study has not yet been completed. If certain events, including additional ownership changes within the meaning of IRC Section 382, are identified through this study as having occurred in the past or these events take place in the future, the amount of remaining tax carry forwards available to offset future taxable

income in future years may be significantly restricted or eliminated. At December 31, 2011, we recorded a 100% valuation allowance against our remaining net operating loss and research and development tax credit carryforwards of approximately $18.2 million, as we believe it is more likely than not that the tax benefits will not be fully realized. In the future, if we determine that a portion of the tax benefits associated with our tax carryforwards will be realized, net income would increase in the period of determination.

Recent Accounting Pronouncements

See Note 2, Summary of Significant Accounting Policies Recent Accounting Pronouncements, of the Notes to Consolidated Financial Statements in this report 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 transitioning to the larger reporting company disclosure requirements, we are not required to provide the information required by this item. See Item 6. Selected Financial Data, above.

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods 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, 2011. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of December 31, 2011 these disclosure controls and procedures were effective at the reasonable assurance level.

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 Exchange Act Rules 13a-15(d) and 15d-15(d) that occurred during the fiscal quarter ended December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 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, 2011.

The effectiveness of our internal control over financial reporting as of December 31, 2011 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in its report, which appears on page F-2 of this annual report.

Item 9B. Other Information.

Not applicable.

PART III

Certain information required by Part III of this report is omitted from this report pursuant to General Instruction G(3) of Form 10-K because we will file a definitive proxy statement pursuant to Regulation 14A for our 2012 annual meeting of stockholders (the Proxy Statement) not later than 120 days after the end of the fiscal year covered by this report, and the information included in the Proxy Statement that is required by Part III of this report is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

Code of Ethics

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

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

Item 11. Executive Compensation.

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

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

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

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

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

Item 14. Principal Accounting Fees and Services.

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

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

(1) Financial Statements. The following reports of PricewaterhouseCoopers and J.H. Cohn LLP and financial statements:

Report of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm

Report of J.H. Cohn LLP, Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2011 and 2010

Consolidated Statements of Operations for the years ended December 31, 2011 and 2010 and from inception through December 31, 2011

Consolidated Statements of Stockholders Equity (Deficit) and Comprehensive Loss from inception through December 31, 2011

Consolidated Statements of Cash Flows for the years ended December 31, 2011 and 2010 and from inception through December 31, 2011

Notes to Consolidated Financial Statements

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

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

(b) Exhibits. The exhibits filed or furnished with this report are set forth on the Exhibit Index immediately following the signature page of this report, which Exhibit Index is incorporated herein by reference.

(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.

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 8, 2012

ADVENTRX Pharmaceuticals, Inc.

By: /s/ Brian M. Culley
Brian M. Culley
Chief Executive Officer and Director

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Brian M. Culley, Patrick L. Keran and Brandi L. Roberts, and each of them acting individually, as his/her true and lawful attorneys-in-fact and agents, each with full power to act alone, with full powers of substitution and resubstitution, for him/her and in his/her 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/she 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, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Brian M. Culley	Chief Executive Officer and Director	March 8, 2012
Brian M. Culley	(Principal Executive Officer)	
/s/ Patrick L. Keran	President and Chief Operating Officer	March 8, 2012
Patrick L. Keran	(Principal Financial Officer)	
/s/ Brandi L. Roberts	Vice President, Finance	March 8, 2012
Brandi L. Roberts	(Principal Accounting Officer)	
/s/ Jack Lief	Chair of the Board	March 8, 2012
Jack Lief		
/s/ David A. Ramsay	Director	March 8, 2012
David A. Ramsay		
/s/ Lewis J. Shuster	Director	March 8, 2012
Lewis J. Shuster		

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.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

ADVENTRX Pharmaceuticals, Inc.

In our opinion, the accompanying consolidated balance sheet as of December 31, 2011 and the related consolidated statements of operations, stockholders equity (deficit) and comprehensive loss and cash flows for the year ended December 31, 2011 and cumulatively for the period from January 1, 2011 to December 31, 2011 present fairly, in all material respects, the financial position of ADVENTRX Pharmaceuticals, Inc. and its subsidiaries (a development stage enterprise) at December 31, 2011, and the results of their operations and their cash flows for the year then ended and, cumulatively, for the period from January 1, 2011 to December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management s Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company s internal control over financial reporting based on our integrated audit. We did not audit the cumulative totals of the Company for the period from June 12, 1996 (date of inception) to December 31, 2010, which totals reflect a deficit of $156,129,121 accumulated during the development stage. The cumulative totals for the period from January 1, 2002 to December 31, 2010, which totals reflect a deficit of $132,085,779, were audited by other auditors whose report, dated March 10, 2011, expressed an unqualified opinion on such cumulative amounts. We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audit of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

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

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

/s/ PricewaterhouseCoopers LLP

San Diego, California

March 8, 2012

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

ADVENTRX Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of ADVENTRX Pharmaceuticals, Inc. and Subsidiaries (a development stage enterprise) as of December 31, 2010, and the related consolidated statements of operations, stockholders equity (deficit) and comprehensive loss and cash flows for the year then ended and for the period from January 1, 2002 through December 31, 2010. 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether 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 audit provides 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, 2010, and their results of operations and cash flows for the year then ended and for the period from January 1, 2002 through December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

/s/ J.H. Cohn LLP

San Diego, California

March 10, 2011

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Consolidated Balance Sheets

	September 30, 2011	September 30, December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 43,569,947	$ 27,978,823
Short-term investments	7,133,697	
Interest and other receivables	17,245	1,980
Contingent asset	815,011	
Prepaid expenses	256,311	428,276
Total current assets	51,792,211	28,409,079
Property and equipment, net	464,465	44,254
In-process research and development	6,549,000	
Goodwill	3,006,883	
Other assets	43,912	33,484
Total assets	$ 61,856,471	$ 28,486,817
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 451,705	$ 479,780
Accrued liabilities	1,120,416	864,857
Accrued compensation and payroll taxes	756,773	456,839
Contingent liability	140,125	
Total current liabilities	2,469,019	1,801,476
Deferred income tax liability	2,608,755	
Total liabilities	5,077,774	1,801,476
Stockholders equity:		
Common stock, $0.001 par value; 500,000,000 shares authorized; 47,715,709 and 15,480,302 shares issued and outstanding at December 31, 2011 and 2010, respectively	47,716	15,480
Additional paid-in capital	226,122,331	182,798,982
Accumulated other comprehensive loss	(2,298)	
Deficit accumulated during development stage	(169,389,052)	(156,129,121)
Total stockholders equity	56,778,697	26,685,341

Total liabilities and stockholders equity	$ 61,856,471	$ 28,486,817

See accompanying notes to consolidated financial statements.

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Consolidated Statements of Operations

	Years Ended December 31,		September 30, Inception (June 12, 1996) Through December 31,
	2011	2010	2011
Licensing revenue	$	$	$ 1,300,000
Net sales			174,830
Grant revenue		488,959	618,692
Total net revenue		488,959	2,093,522
Cost of sales			51,094
Gross margin		488,959	2,042,428
Operating expenses:			
Research and development	5,758,337	3,688,762	77,969,304
Selling, general and administrative	7,190,093	4,989,704	60,147,307
Transaction-related expenses	410,885	330,369	741,254
Depreciation and amortization	37,570	19,821	10,935,188
Write-off of in-process research and development			10,422,130
Goodwill impairment			5,702,130
Equity in loss of investee			178,936
Total operating expenses	13,396,885	9,028,656	166,096,249
Loss from operations	(13,396,885)	(8,539,697)	(164,053,821)
Revaluation of fair value of warrants			(12,239,688)
Interest income	76,587	92,873	4,758,648
Interest expense	(11,010)	(1,629)	(191,729)
Other income (expense)	71,377	(2,469)	134,752
Loss before cumulative effect of change in accounting principle	(13,259,931)	(8,450,922)	(171,591,838)
Cumulative effect of change in accounting principle			(25,821)
Net loss	(13,259,931)	(8,450,922)	(171,617,659)
Preferred stock dividends			(621,240)
Deemed dividends on preferred stock		(5,639,796)	(10,506,683)

Net loss applicable to common stock	$ (13,259,931)	$ (14,090,718)	$ (182,745,582)
Loss per common share basic and diluted	$ (0.47)	$ (1.07)	
Weighted average shares outstanding basic and diluted	28,175,221	13,180,583	

See accompanying notes to consolidated financial statements.

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, 2011

000000	000000	000000	000000	000000	000000	000000	000000	000000	000000	000000 Deficit	000000	000000	00000
Cumulative convertible preferred stock, series A through C		Convertible preferred stock, series A (2009)		Cumulative convertible preferred stock, series B through F (2009 - 2010)		Common stock		Additional	Accumulated other	accumulated during the	Treasury	Total stockholders	
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	paid-in capital	comprehensive income (loss)	development stage	stock, at cost	equity (deficit)	Compreh loss
es at 2, 1996 f oration)	$		$		$		$	$	$	$	$	$	
on stock t par						20		10				10	
ce of on stock t ies ed in ition						68,645	69	4,871		(18,094)		(13,154)	
ce of on stock						80,405	80	2,386		(2,466)			
ss										(259,476)		(259,476)	$ (259
es at mber 31,						149,070	149	7,267		(280,036)		(272,620)	$ (259
on net of g costs 976						40,182	40	1,790,939				1,790,979	
ce of on stock uisition						15,036	15	888,235				888,250	
ity t ncy at ition d to the any										(45,003)		(45,003)	
ss										(1,979,400)		(1,979,400)	$ (1,979
						204,288	204	2,686,441		(2,304,439)		382,206	$ (1,979

es at ber 31,								
sion of ition			(15,036)	(15)	(888,235)	561,166	(327,084)	
ce of on stock version es e			18,011	18	363,982		364,000	
se to warrants					260,000		260,000	
ss						(1,204,380)	(1,204,380)	$ (1,204
es at ber 31,			207,263	207	2,422,188	(2,947,653)	(525,258)	$ (1,204
on stock			27,136	27	134,973		135,000	
se to warrants					212,000		212,000	
ss						(1,055,485)	(1,055,485)	$ (1,055
es at ber 31,			234,399	234	2,769,161	(4,003,138)	(1,233,743)	$ (1,055
red net of g costs ,500	3,200	32			3,123,468		3,123,500	
ce of on stock version es and t e			16,499	16	492,481		492,497	
ce of on stock version es e			2,814	3	83,997		84,000	
ce of on stock e tions			19,804	20	1,202,140		1,202,160	
ce of on stock quisition			280,000	280	9,332,489		9,332,769	
ce of ts for ition					4,767,664		4,767,664	
issued quisition			6,000	6	487,494		487,500	

se to warrants					140,000		140,000	
nds e on red stock					(85,000)		(85,000)	
ss se of nts			23,963	24	(24)			
ss						(3,701,084)	(3,701,084)	$ (3,701
es at mber 31,	3,200	32	583,479	583	22,313,870	(7,704,222)	14,610,263	$ (3,701

See accompanying notes to consolidated financial statements.

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, 2011

00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
										Deficit			
Cumulative convertible preferred stock, series A through C		Convertible preferred stock, series A (2009)		Cumulative convertible preferred stock, series B through F (2009 - 2010)		Common stock		Additional	Accumulated other	accumulated during the	Treasury	Total stockholders	
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	paid-in capital	comprehensive income (loss)	development stage	stock, at cost	equity (deficit)	Comprehen loss
dends able on erred k	$		$		$		$	$ (256,000)	$	$	$	$ (256,000)	
urchase of rants								(55,279)				(55,279)	
of rants								47,741				47,741	
nless cise of rants							8,740	9 (9)					
ance of mon stock ay erred dends							3,737	4 212,996				213,000	
chable rants ed with s payable								450,000				450,000	
ance of rants to operating enses								167,138				167,138	
ance of mon stock ay ating enses							4,252	4 387,267				387,271	
ance of erred k to pay ating enses	137	1						136,499				136,500	
loss										(16,339,120)		(16,339,120)	$ (16,339,1
nces at ember 31, 1	3,337	33					600,208	600 23,404,223		(24,043,342)		(638,486)	$ (16,339,1

dends able on erred k					(242,400)		(242,400)	
urchase of rants								
of rants			9,600	10	117,843		117,853	
nless cise of rants			4,008	4	(4)			
rcise of rants			13,783	14	168,808		168,822	
of erred k at $1.50 share	200,000	2,000			298,000		300,000	
of erred k at 00 per e	70,109	701			700,392		701,093	
version of erred k into mon stock	(3,000)	(30)	72,000	72	(42)			
erred k dends iven					335,440		335,440	
ance of rants to operating enses					163,109		163,109	
ance of mon stock ay rating enses			251		12,269		12,269	
ance of erred k to pay rating enses	136	1			6,000		6,001	
re-based pensation ense - loyee ons					329,296		329,296	
loss						(2,105,727)	(2,105,727)	$ (2,105,7
nces at ember 31, 2	270,582	2,705	699,850	700	25,292,934	(26,149,069)	(852,730)	$ (2,105,7
dends able on erred k					(37,840)		(37,840)	
version of es C erred k into mon stock	(70,109)	(701)	560,874	561	140			
ance of mon stock ay interest			6,633	7	53,484		53,491	

ridge es									
of mon stock .40 per e, net of ance costs			265,630	266	2,597,066		2,597,332		
of mon stock .00 per e, net of ance costs			148,069	148	3,992,701		3,992,849		
nange of rants			9,412	9	49,712		49,721		
ance of mon stock ay rating enses			9,200	9	206,790		206,799		
ance of rants to operating enses					156,735		156,735		
re-based pensation ense - loyee ons					286,033		286,033		
loss						(2,332,077)	(2,332,077)	$	(2,332,0
nces at ember 31, 8	200,473	2,004	1,699,668	1,700	32,597,755	(28,481,146)	4,120,313	$	(2,332,0

See accompanying notes to consolidated financial statements.

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, 2011

000000	000000	000000	000000	000000	000000	000000	000000	000000	000000	000000 Deficit	000000	000000	0
Cumulative convertible preferred stock, series A through C		Convertible preferred stock, series A (2009)		Cumulative convertible preferred stock, series B through F (2009 - 2010)		Common stock		Additional	Accumulated other	accumulated during the		Total stockholders	
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	paid-in capital	comprehensive income (loss)	development stage	Treasury stock, at cost	equity (deficit)	Com
ent													
ck	$		$		$		$	$ 72,800	$	$	$	$ 72,800	
of													
ck	(473)	(4)					9,460	9	(5)				
of ferred	(200,000)	(2,000)					8,000	8	1,992				
rcise							18,583	18	(18)				
							953	1	27,352				27,353
f a									86,375				86,375
mon 0 per							416,705	417	15,626,033				15,626,450
d s									(1,366,774)				(1,366,774)
n tions									524,922				524,922
of k									34,747			(34,747)	
											(6,701,048)		(6,701,048) $
l,							2,153,369	2,153	47,605,179		(35,182,194)	(34,747)	12,390,391 $
											(24,782,646)		(24,782,646) $ (
nge of -sale										(1,722)			(1,722)

l in with	432,432	433	(433)					
rcise	5,985	6	(6)					
	90,348	90	3,073,348				3,073,438	
stock	7,400	7	144,993				145,000	
n otions			994,874				994,874	
n ee			93,549				93,549	
ck to	5,000	5	258,495				258,500	
1, ated	2,694,534	2,694	52,169,999	(1,722)	(59,964,840)	(34,747)	(7,828,616)	$ (
					(29,331,773)		(29,331,773)	$ (
nge of -sale				(368)			(368)	
rcise	16,807	17	(17)					
of sts	204,150	204	7,691,386				7,691,590	
of SD cals.	84,000	84	10,163,868				10,163,952	
mon 5 per s	581,800	582	37,069,629				37,070,211	
stock e	2,406	2	196,672				196,674	
stock	3,700	4	125,747				125,751	
n ee ck	600	1	68,649				68,650	
n otions			1,697,452				1,697,452	
n ee			104,225				104,225	
	(927)	(1)	(34,746)			34,747		

of k							
1, ated	3,587,070	3,587	109,252,864	(2,090)	(89,296,613)	19,957,748	$ (
effect							
			18,116,751		12,239,688	30,356,439	
					(22,142,040)	(22,142,040)	$ (
nge of -sale				4,792		4,792	
stock	23,033	23	441,593			441,616	
n tions			2,414,077			2,414,077	
n ee			1,908			1,908	
1,	3,610,103	3,610	130,227,193	2,702	(99,198,965)	31,034,540	$ (

See accompanying notes to consolidated financial statements.

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, 2011

000000	000000	000000	000000	000000	000000	000000	000000	000000	000000	000000 Deficit	000000	000000	0
Cumulative convertible preferred stock, series A through C		Convertible preferred stock, series A (2009)		Cumulative convertible preferred stock, series B through F (2009 - 2010)		Common stock		Additional	Accumulated other	accumulated during the	Treasury	Total stockholders	
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	paid-in capital	comprehensive income (loss)	development stage	stock, at cost	equity (deficit)	Cor
	$		$		$		$	$	$	$ (26,647,493)	$	$ (26,647,493)	$ (
nge of -sale									(2,702)			(2,702)	
tock													
n tions								1,605,908				1,605,908	
n e								4,982				4,982	
,						3,610,103	3,610	131,838,083		(125,846,458)		5,995,235	$ (
										(11,325,058)		(11,325,058)	$ (
A ck, g ,125		1,993	2					1,735,627				1,735,629	
f erred k		(1,993)	(2)			721,448	721	(719)					
B ck, g ,643				1,361	1			833,030				833,031	
f erred k				(1,361)	(1)	380,168	380	(379)					

C ck, g ,885	922	1			711,198			711,199
f erred k	(922)	(1)	283,692	284	(283)			
D ck, g	11,283	11			5,124,125			5,124,136
f erred k	(11,283)	(11)	2,400,000	2,400	(2,389)			
dend ck					1,207,536	(1,207,536)		
dend ck					214,795	(214,795)		
dend ck					186,173	(186,173)		
dend ck					3,258,383	(3,258,383)		
n tions					585,438			585,438
rants			240,000	240	899,760			900,000
rants			576,000	576	2,113,344			2,113,920
,			8,211,411	8,211	148,703,722	(142,038,403)	6,673,530	$ (
						(8,450,922)	(8,450,922)	$
sh or ares			(31)		(146)			(146)
E ck, g	19,000	19			14,014,705			14,014,724
f erred k	(19,000)	(19)	1,993,965	1,994	(1,975)			
F ck, g	19,217	19			13,344,749			13,344,768
f erred	(19,217)	(19)	5,190,306	5,190	(5,171)			

k						
dend						
ck			2,514,920	(2,514,920)		
dend						
ck			3,124,876	(3,124,876)		
n						
tions			785,943		785,943	
rants						
	84,651	85	317,359		317,444	
,						
	15,480,302	15,480	182,798,982	(156,129,121)	26,685,341	$

See accompanying notes to consolidated financial statements.

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, 2011

000000	000000	000000	000000	000000	000000	000000	000000	000000	000000	000000	000000	000000	000
Cumulative convertible preferred stock, series A through C		Convertible preferred stock, series A (2009)		Cumulative convertible preferred stock, series B through F (2009 - 2010)		Common stock		Additional	Accumulated other	Deficit accumulated during the	Treasury	Total stockholders	
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	paid-in capital	comprehensive income (loss)	development stage	stock, at cost	equity (deficit)	Comp
										(13,259,931)		(13,259,931)	$ (13
of													
sts													
123						8,184,556	8,185	20,951,221				20,959,406	
f													
						2,800,851	2,801	5,882,522				5,885,323	
of													
sts													
196						21,250,000	21,250	15,623,554				15,644,804	
d													
ion													
								866,052				866,052	
s									(2,156)			(2,156)	
e													
									(142)			(142)	
t													
31,													
	$		$		$	47,715,709	$ 47,716	$ 226,122,331	$ (2,298)	$ (169,389,052)	$	$ 56,778,697	$ (13

See accompanying notes to consolidated financial statements.

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Consolidated Statements of Cash Flows

	September 30, 2011	September 30, 2010	September 30, Inception (June 12, 1996) Through December 31, 2011
	Years Ended December 31,		
Cash flows from operating activities:			
Net loss	$ (13,259,931)	$ (8,450,922)	$ (171,617,659)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	37,570	19,821	10,485,190
(Gain) loss on disposal of fixed assets	(2,973)	4,269	56,812
Loss on fair value of warrants			12,239,688
Gain on change in fair value of contingent consideration	(1,459,305)		(1,459,305)
Amortization of debt discount			450,000
Forgiveness of employee receivable			30,036
Impairment loss write-off of goodwill			5,702,130
Share-based compensation expense related to employee stock options and restricted stock issued	866,052	785,943	10,089,994
Expenses related to options issued to non-employees			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
Amortization of premium / (accretion of discount) on investments in securities	11,152		(1,593,342)
Changes in assets and liabilities, net of effect of acquisitions:			
(Increase) decrease in prepaid and other assets	143,955	(148,137)	(567,155)
Increase (decrease) in accounts payable and accrued liabilities	196,526	(552,211)	2,174,710
Net cash used in operating activities	(13,466,954)	(8,341,237)	(120,247,254)

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Consolidated Statements of Cash Flows

	September 30, 2011	September 30, 2010	September 30, Inception (June 12, 1996) Through December 31, 2011
	Years Ended December 31,		
Cash flows from investing activities:			
Proceeds from sales and maturities of short-term investments	$	$	$ 112,788,378
Purchases of short-term investments			(111,183,884)
Purchases of property and equipment	(411,762)	(28,513)	(1,470,629)
Proceeds from sale of property and equipment	12,635	4,379	66,920
Purchases of certificates of deposit	(7,144,849)		(8,161,179)
Maturity of certificates 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 used in investing activities	(7,543,976)	(24,134)	(6,526,876)
Cash flows from financing activities:			
Proceeds from sale of common stock	39,507,529		123,658,871
Proceeds from exercise of stock options			712,367
Proceeds from sale or exercise of warrants		317,444	14,714,258
Proceeds from sale of preferred stock		30,453,227	44,474,720
Repurchase of warrants			(55,279)
Payments for financing and offering costs	(2,903,319)	(3,093,735)	(13,897,367)
Payments on notes payable and long-term debt			(605,909)
Proceeds from issuance of notes payable and detachable warrants			1,344,718
Cash paid in lieu of fractional shares for reverse stock split		(146)	(146)
Net cash provided by financing activities	36,604,210	27,676,790	170,346,233
Effect of exchange rate changes on cash and cash equivalents	(2,156)		(2,156)
Net increase in cash and cash equivalents	15,591,124	19,311,419	43,569,947
Cash and cash equivalents at beginning of period	27,978,823	8,667,404	
Cash and cash equivalents at end of period	$ 43,569,947	$ 27,978,823	$ 43,569,947

See accompanying notes to consolidated financial statements.

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2011

1. Description of Business

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation (ADVENTRX, we or our company), is a biopharmaceutical company focused on developing proprietary product candidates. We have devoted substantially all of our resources to research and development (R&D), and acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue. Through our acquisition of SynthRx, Inc. in 2011 and SD Pharmaceuticals, Inc. in 2006, we have rights to the product candidates we are developing currently. Our lead product candidate is ANX-188, a rheologic, antithrombotic and cytoprotective agent that improves microvascular blood flow, which has potential application in treating a wide range of diseases and conditions, such as complications arising from sickle cell disease. We are also developing ANX-514, novel, detergent-free formulation of the chemotherapy drug docetaxel.

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 April 2006, we acquired SD Pharmaceuticals, Inc. and, in April 2011, we acquired SynthRx, Inc., each as a wholly-owned subsidiary through a merger transaction.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements included in this report include the accounts of ADVENTRX and its wholly-owned subsidiaries, SD Pharmaceuticals, Inc. (SD Pharmaceuticals) and SynthRx, Inc. (SynthRx). All intercompany accounts and transactions have been eliminated in consolidation.

We accounted for the acquisition of SynthRx in accordance with Accounting Standards Codification (ASC) Topic 805, *Business Combinations* (ASC Topic 805). ASC Topic 805 establishes principles and requirements for recognizing and measuring the total consideration transferred to and the assets acquired, liabilities assumed and any non-controlling interests in the acquired target in a business combination. ASC Topic 805 also provides guidance for recognizing and measuring goodwill acquired in a business combination; requires purchased in-process research and development, or IPR&D, to be capitalized at fair value as intangible assets at the time of acquisition; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; expands the definition of what constitutes a business; and requires the acquirer to disclose information that users may need to evaluate and understand the financial effect of the business combination.

On April 23, 2010, we effected a 1-for-25 reverse split of its common stock, which was authorized by our stockholders at a special meeting held in August 2009. All common stock share and per share information in the consolidated financial statements and notes thereto included in this report have been restated to reflect retrospective application of the reverse stock split for all periods presented ending or as of a date prior to April 23, 2010, except for par value per share and the number of authorized shares, which were not affected by the reverse stock split.

Use of Estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles (U.S. GAAP) requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates, including estimates related to contingent consideration, R&D expenses and share-based compensation expenses. We base our estimates on historical experience and various other relevant assumptions we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2011

Fair Value of Financial Instruments

Our short-term investments and our contingent asset and contingent liability are carried at fair value (see Note 5). Cash, cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, are carried at cost, which we believe approximates fair value due to the short-term maturities of these instruments.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less at the date of purchase. Cash equivalents are carried at cost, which we believe approximates fair value due to the short-term maturities of these instruments. At December 31, 2011 and 2010, we had $2.9 million and $0 of cash equivalents, respectively.

Short-Term Investments

We consider income-yielding securities that can be readily converted to cash and have original maturities of more than three months and one year or less at the date of purchase to be short-term investments. All of our short-term investments are marketable securities under the custodianship of a major financial institution and consist primarily of FDIC-insured certificates of deposit.

We account for and report our short-term investments in accordance with ASC 320, *Accounting for Certain Investments in Debt and Equity Securities*. Our short-term investments are classified as available-for-sale securities and carried at fair value based on quoted market prices, with net unrealized gains or losses included in accumulated other comprehensive income (loss), which is a separate component of stockholders equity. Realized gains and realized losses are included in other income (expense), while amortization of premiums and discounts are included in interest expense. Interest and dividends on available-for-sale securities are included in interest income. Marketable securities are evaluated periodically for impairment. If we determine that a decline in market value of any investment is other than temporary, then the investment basis would be written down to fair value and charged to earnings.

Asset and Liability for Contingent Consideration

Our contingent asset and contingent liability are related to our acquisition of SynthRx in April 2011 and the contingent consideration that varies based on achievement and the circumstances of achievement of a milestone associated with the development of ANX-188. We remeasure the fair value of this contingent consideration as of the end of each fiscal quarter. We estimate the fair value of this contingent consideration based on our stock price at the end of the each fiscal quarter and significant estimates and assumptions of management, including the probability that the First Milestone (as defined in Note 3) will be achieved and the estimated number shares expected to vest and become issuable upon achievement of the First Milestone. Changes in the fair value of this contingent consideration are recognized in earnings until the contingent consideration arrangement is settled.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets (generally three to five years). Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter. Repairs and maintenance are expensed as incurred.

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

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Notes to Consolidated Financial Statements

December 31, 2011

Intangible Assets Goodwill and Acquired In-Process Research & Development

Goodwill is the excess of purchase price of an acquired business over the estimated fair values of the assets acquired and liabilities assumed in a business combination and is considered to have an indefinite life. In accordance with U.S. GAAP, goodwill is not amortized, but is tested for impairment annually and in between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying amount may be impaired. We perform our annual goodwill impairment test as of September 30 of each year. We elected to early adopt Accounting Standards Update (ASU) No. 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment* (ASU 2011-08), pursuant to which an entity may first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not (that is, a likelihood of more than 50%) that the fair value of a reporting unit is less than its carrying amount, and is required to perform step one of the two-step annual goodwill impairment test only if the entity determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. We utilized ASU 2011-08 for our September 30, 2011 annual impairment testing. No impairment was noted. Since inception through December 31, 2011, we have recognized an impairment loss of the value of goodwill in the amount of $5.7 million, all of which was recorded in the year ended December 31, 2001.

Intangible assets classified as acquired IPR&D are considered to have indefinite lives until the completion or abandonment of the associated research and development efforts. During the period the assets are considered to be indefinite-lived, they will not be amortized but will be tested for impairment annually and between annual tests if we become aware of an event or a change in circumstances that would indicate a reduction in the fair value of an IPR&D project below its carrying amount. We perform our annual impairment test as of September 30 of each year. No impairment was noted as a result of our September 30, 2011 testing. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed to have finite lives and would then be amortized based on their respective estimated useful lives at that point in time.

For acquisitions prior to January 1, 2009, the estimated fair value of acquired IPR&D was expensed immediately for projects that, as of the acquisition date, had not reached technological feasibility, had no alternative future use and had uncertainty in receiving future economic benefits from the acquired IPR&D. In the year ended December 31, 2006, we recorded $10.4 million of IPR&D expense related to our acquisition of SD Pharmaceuticals.

Concentration of Credit Risk and Significant Sources of Supply

Financial instruments that potentially subject us to concentrations of credit risk are primarily cash, cash equivalents and short-term investments. We have a board-approved investment policy that sets our investment parameters and limitations with objectives of preserving principal and liquidity. Our cash and cash equivalent balances consist primarily of money market accounts under the custodianship of major financial institutions. Short-term investments are invested in accordance with our investment policy. We do not have any financial instruments with off-balance-sheet risk of accounting loss.

We rely on single-source, third-party manufacturers and suppliers for production and supply of key components of our product candidates, and for production of the final drug products themselves. If these single-source, third-party manufacturers and suppliers are unable to continue providing a key component or the final drug products, the initiation or progress of any clinical studies of our product candidates may be severely impeded.

Foreign Currency

Assets and liabilities denominated in foreign currencies are translated at the rate of exchange on the balance sheet date. Revenues and expenses are translated using the average exchange rate for the period. Net gains and losses resulting from the translation of liabilities payable in foreign currencies are recorded in

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

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accumulated other comprehensive income (loss), which is a separate component of stockholders equity. Net foreign currency gains (losses) resulting from transactions in currencies other than the functional currency are included in other income (expense) in our consolidated statement of operations. For the years ended December 31, 2011 and 2010, we recorded net foreign currency gains of $11,000 and $0 respectively. As of December 31, 2011 and 2010, approximately 8% and 15% of our total liabilities, respectively, were denominated in currencies other than the U.S. dollar, which is our functional currency.

Revenue Recognition

We recognize revenues in accordance with authoritative guidance established by U.S. GAAP. Our revenues to date have been generated primarily through licensing agreements and federal government research grants. Licensing agreements may include upfront payments, funding of research and development, milestone payments and royalties.

We consider a variety of factors in determining the appropriate method of accounting under our licensing agreements, including whether the various elements can be separated and accounted for individually as separate units of accounting. Where there are multiple deliverables identified within a licensing agreement that are combined into a single unit of accounting, revenue is deferred and recognized over the expected period of performance. The specific methodology for the recognition of the revenue is determined on a case-by-case basis according to the facts and circumstances of the applicable agreement. Non-refundable license fees are recognized as revenue upon receipt if the licensed assets have stand-alone value, we do not have ongoing involvement or obligations, and we can determine the best estimate of the selling price for any undelivered items. When these criteria are not met, non-refundable license fees are recorded as deferred revenue upon receipt and recognized as revenue over the expected period of performance. Non-refundable license fees for R&D expenses generally are recognized as revenue over the period as the related R&D activities are performed. We evaluate milestone payments under licensing agreements on an individual basis and recognize revenue from non-refundable milestone payments when the earnings process is complete and payment is reasonably assured. Non-refundable milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenue upon achievement of the associated milestone, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with the milestone event. If a milestone payment does not meet these criteria, we recognize revenue using a probability-adjusted performance model over the expected period of performance.

We recognize revenue from federal government research grants during the period in which we receive the grant funds, or their collection is reasonably assured, and we incur the qualified expenditures.

Research and Development Expense

R&D costs are charged to expense as incurred and include, but are not limited to, employee salaries and benefits, nonclinical study costs, clinical study costs, research-related manufacturing and related costs, consulting services fees and share-based compensation cost. Clinical study costs include, but are not limited to, clinical research organization fees, investigator fees, site costs and, as applicable, comparator drug costs. Costs for certain R&D activities, such as research-related manufacturing and clinical studies, are recognized based on an evaluation of the percentage of work completed or the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, duration of the study and/or information provided to us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid expenses or accrued R&D costs.

Advance payments to third parties, including nonrefundable amounts, for goods and services that will be used or rendered for future R&D activities are deferred and capitalized, then expensed as the services are performed or as the underlying goods are delivered. If we do not expect the services to be rendered or goods to be delivered, any remaining capitalized amounts for nonrefundable advance payments are charged to expense immediately.

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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.

Share-Based Compensation

Share-based compensation cost is measured at the grant date, based on the estimated fair value of the award using the Black-Scholes valuation model, and is recognized as expense over the vesting period on a straight-line basis. Share-based compensation expense recognized in the consolidated statements of operations for the years ended December 31, 2011 and 2010 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. None of our outstanding share-based awards have market or performance conditions.

Patent Costs

Legal costs in connection with approved patents and patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. These costs are recorded as selling, general and administrative expenses 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, if any, 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

Basic and diluted net loss per common share was calculated by dividing the net loss applicable to common stock for the period by the weighted-average number of common shares outstanding during the period, without consideration for our outstanding common stock equivalents because their effect would have been anti-dilutive. Common stock equivalents are included in the calculation of diluted earnings per common share only if their effect is dilutive. As of December 31, 2011 and 2010, our outstanding common stock equivalents consisted of options and warrants as follows:

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	September 30, 2011	September 30, 2010
Warrants	19,465,488	4,055,030
Options	2,892,132	403,737
	22,357,620	4,458,767

Supplemental Cash Flow Information

	September 30,	September 30,	September 30, Inception
	Years Ended December 31,		(June 12, 1996) Through December 31,
	2011	2010	2011
Supplemental disclosures of cash flow information:			
Interest paid	$	$ 1,629	$ 180,719
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		7,184	13,674
Acquisitions	5,885,323		30,666,878
Payment of dividends			213,000
Financial advisor services in conjunction with financings	924,017	724,286	3,477,571
Underwriter commissions in conjunction with financings	766,784		766,784
Acquisition of treasury stock in settlement of a claim			34,737
Cancellation of treasury stock			(34,737)
Assumptions of liabilities in acquisitions	295,899		1,531,806
Acquisition of license agreement for long-term debt			161,180
Fair value of contingent liabilities, net of contingent assets, recorded at acquisition date	784,419		784,419
Cashless exercise of warrants			4,312
Dividends accrued			621,040
Trade asset converted to available for sale asset			108,000
Dividends extinguished			408,240
Trade payable converted to note payable			83,948
Issuance of warrants for return of common stock			50,852
Detachable warrants issued with notes payable			450,000
Unrealized (gain) loss on short-term investments	142		142
Cumulative preferred stock dividends		7,763,903	13,502,403

Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board (FASB) issued ASU No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards* (ASU 2011-04). ASU 2011-04 represents the converged guidance of the FASB and the International Accounting Standards

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Board on fair value measurement. The guidance clarifies how a principal market is determined, addresses the fair value measurement of instruments with offsetting market or counterparty credit risks, addresses the concept of valuation premise and highest and best use, extends the prohibition on blockage factors to all three levels of the fair value hierarchy and requires additional disclosures. ASU 2011-04 is effective for interim and annual periods beginning after December 15, 2011 and is applied prospectively. We are currently evaluating the requirements of ASU 2011-04 and have not yet determined its impact on our financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* (ASU 2011-05). The issuance of ASU 2011-05 is intended to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items reported in other comprehensive income. The guidance in ASU 2011-05 supersedes the presentation options in ASC Topic 220 and facilitates convergence of U.S. GAAP and International Financial Reporting Standards (IFRS) by eliminating the option to present components of other comprehensive income as part of the statement of changes in stockholders equity and requiring that all non-owner changes in stockholders equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 is effective for interim periods and years beginning after December 15, 2011. We are required to adopt ASU 2011-05 in the first quarter of 2012, with the exception of the presentation of reclassifications on the face of the financial statements, which has been deferred by the FASB under ASC Update No. 2011-12, *Comprehensive Income (Topic 820): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income*. We do not believe our adoption of the new guidance will have an impact on our consolidated financial position, results of operations or cash flows.

3. Acquisition of SynthRx

On February 12, 2011, we entered into an agreement and plan of merger (the Merger Agreement) to acquire SynthRx, Inc., a privately-held Delaware corporation, in exchange for shares of our common stock as described below. The transaction was completed on April 8, 2011 and SynthRx became a wholly owned subsidiary of ADVENTRX. The acquisition is accounted for as a business combination.

As consideration for the transaction, all shares of SynthRx common stock outstanding immediately prior to the effective time of the merger were cancelled and automatically converted into the right to receive shares of our common stock, in the aggregate, as follows:

(i) 862,078 shares (the Fully Vested Shares) of our common stock, which shares were issued on April 8, 2011 and represent 1,000,000 shares, less 137,922 shares that were deducted as a result of certain expenses of SynthRx, and 200,000 of which were deposited into escrow (the Closing Escrow Amount) to indemnify us against breaches of representations and warranties;

(ii) up to 1,938,773 shares of our common stock, which shares were issued and outstanding on April 8, 2011 (the Subject to Vesting Shares, and together with the 862,078 Fully Vested Shares issued to the former stockholders of SynthRx and the escrow agent, the Closing Shares), which Subject to Vesting Shares are subject to various repurchase rights by us and fully vest, subject to reduction under certain circumstances as follows, upon achievement of the First Milestone (defined below). Up to approximately 75% of the Subject to Vesting Shares, or 1,454,079 shares, are subject to repurchase by us for $0.001 per share based on whether the First Milestone is achieved, the timing of its achievement and whether and the extent to which the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint exceeds 250 patients, unless otherwise agreed;

(iii) up to 1,000,000 shares of our common stock (the First Milestone Shares), which shares will be issued, if at all, upon achievement of the First Milestone; provided, however, that in the event the First Milestone is achieved prior to the first anniversary of the closing of the merger, 20% of the First Milestone Shares shall be deposited into escrow (the First Milestone Escrow Amount, and together with the Closing Escrow Amount, the Escrow Amount). The First Milestone means the dosing of the first patient in a phase 3 clinical study carried out pursuant to a protocol that is mutually agreed to by SynthRx and ADVENTRX; provided, however, that the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint shall not exceed 250 (unless otherwise mutually agreed) (the First Protocol). In the event that the FDA indicates that a single phase 3 clinical study will not be adequate to support approval of a new drug application covering the use of purified P188 for the treatment of sickle cell crisis in children (the 188 NDA), First Milestone shall mean the dosing of the first patient in a phase 3 clinical study carried out pursuant to a protocol that (a) is mutually agreed to by SynthRx and

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ADVENTRX as such and (b) describes a phase 3 clinical study that the FDA has indicated may be sufficient, with the phase 3 clinical study described in the First Protocol, to support approval of the 188 NDA. The amount of shares that becomes issuable upon achievement of the First Milestone may be reduced by up to 75%, or 750,000 shares, based on the timing of achievement of the First Milestone and whether and the extent to which the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint exceeds 250 patients, unless otherwise agreed;

(iv) 3,839,400 shares of our common stock (the Second Milestone Shares), which shares will be issued, if at all, upon achievement of the Second Milestone. The Second Milestone means the acceptance for review of the 188 NDA by the FDA; and

(v) 8,638,650 shares of our common stock (the Third Milestone Shares, and together with the First Milestone Shares and the Second Milestone Shares, the Milestone Shares), which shares will be issued, if at all, upon achievement of the Third Milestone. The Third Milestone means the approval by the FDA of the 188 NDA.

Based on the estimated fair value of the Closing Shares and the Milestone Shares as of April 8, 2011, the acquisition date (which was based upon the number of shares to be issued at the time of achievement of each milestone, the probability of achievement for each milestone, the estimated date of achievement for each milestone and the market price of a share of our common stock), the total purchase price was approximately $6.7 million.

The elements of the total purchase price of the acquisition were as follows:

Event	September 30, Shares Issued / Issuable	September 30, Probability Weighted Fair Value
Initial consideration (Fully Vested Shares)	862,078	$ 2,017,263
Initial consideration (Subject to Vesting Shares)	1,938,773	2,103,375(1)
First Milestone dosing of first patient	1,000,000	1,084,900
Second Milestone NDA acceptance	3,839,400	733,403
Third Milestone FDA approval	8,638,650	730,801
Total	16,278,901	$ 6,669,742

(1) This amount is net of the probability-weighted fair value of the Subject to Vesting Shares that we estimated, as of the acquisition date, ultimately may be repurchased by us ($300,481).

The allocation of the purchase price is based on our estimates of the fair values of tangible and intangible assets acquired, including IPR&D, and liabilities assumed as of the acquisition date. As of December 31, 2011, we had finalized our purchase price allocation. The following table summarizes the estimated fair values of net tangible and intangible assets acquired and liabilities assumed:

September 30,

Net tangible assets acquired	$	18,513
Net tangible liabilities assumed		(295,899)
Acquired intangibles:		
In-process research and development		6,549,000
Goodwill		3,006,883
Deferred income tax liability		(2,608,755)
Total purchase price	$	6,669,742

Acquired In-Process Research and Development

Our acquired IPR&D is the estimated fair value of SynthRx s lead product candidate, ANX-188, as of the acquisition date. We determined that the estimated fair value of the ANX-188 program was $6.5 million as of the acquisition date using the Multi-Period Excess Earnings Method, or MPEEM, which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset s incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life.

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To calculate fair value of the ANX-188 program under the MPEEM, we used probability-weighted cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by development-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to the program and then reduced by a contributory charge on requisite assets employed. Contributory assets included debt-free working capital, net fixed assets and assembled workforce. Rates of return on the contributory assets were based on rates used for comparable market participants. Cash flows were assumed to extend through the market exclusivity period estimated to be provided by orphan drug designation. The resultant cash flows were then discounted to present value using a weighted-average cost of equity capital for companies with profiles substantially similar to that of SynthRx, which we believe represents the rate that market participants would use to value the assets. We compensated for the phase of development of this program by probability-adjusting our estimation of the expected future cash flows. The projected cash flows were based on significant assumptions, such as the time and resources needed to complete the development and approval of ANX-188, estimates of revenue and operating profit related to the program considering its stage of development, the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in drug development, such as obtaining marketing approval from the FDA and other regulatory agencies, and risks related to the viability of and potential alternative treatments in any future target markets.

Goodwill

A value of $3.0 million, representing the difference between the total purchase price and the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed, was recorded as goodwill. We acquired SynthRx to expand our product pipeline, enter into new therapeutic areas and address unmet market needs. These are among the factors that contributed to a purchase price for the SynthRx acquisition that resulted in the recognition of goodwill.

Deferred Income Tax Liability

The $2.6 million recorded for deferred income tax liability resulting from the acquisition reflects the tax impact of the difference between the book basis and tax basis of acquired IPR&D. Such deferred tax liability cannot be used to offset deferred tax assets when analyzing our end of year valuation allowance as the acquired IPR&D is considered to have an indefinite life until we complete or abandon development of ANX-188.

Contingent Asset and Contingent Liability

The number of Subject to Vesting Shares subject to repurchase by us (1,454,079 shares) and the Milestone Shares constitute contingent consideration because our repurchase rights with respect to those Subject to Vesting Shares and our obligation to issue the Milestone Shares are contingent on future events. In order to determine the classification of the fair value of the Milestone Shares as a liability or equity, we reviewed ASC Topic 815-40, *Derivatives and Hedging Contracts in Entity s Own Equity* (ASC 815-40). ASC 815-40 requires that contingent consideration arrangements that include potential net cash settlements or variable provisions should be classified as a liability. Classification as a liability requires fair value measurement initially and subsequently at each reporting date. Changes in the fair value of contingent consideration classified as a liability are recognized in earnings until the contingent consideration arrangement is settled. Classification as equity requires fair value measurement initially and there are no subsequent re-measurements. Settlement of equity-classified contingent consideration is accounted for within equity.

The probability-weighted fair values of the Second Milestone Shares and the Third Milestone Shares were recorded as equity as there is no net cash settlement provision and the number of shares that ultimately may be issued upon achievement of each of those milestones is fixed.

The probability-weighted fair value of the First Milestone Shares was recorded as a liability as there is variability with respect to the number of shares that ultimately may be issued (from 250,000 to 1,000,000 shares) based on the circumstances of achievement of the First Milestone, as described above. This contingent liability is remeasured at each reporting date until the arrangement is settled. Upon achievement of the First Milestone, the contingent liability will be remeasured and any change in its fair value as of the date of achievement will be recognized in earnings as a transaction-related expense, and the contingent liability will be eliminated. The fair value of the issued First Milestone Shares will

be recorded as equity.

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As with the First Milestone Shares, there is variability with respect to the number of Subject to Vesting Shares that we ultimately may repurchase based on whether the First Milestone is achieved and the circumstances of its achievement, as described above. Accordingly, we recorded as a contingent asset the probability-weighted fair value of the Subject to Vesting Shares that we estimated may be repurchased by us. This contingent asset is remeasured at each reporting date until the arrangement is settled. At settlement, the contingent asset will be remeasured and any change in its fair value as of the date of settlement will be recognized in earnings as a transaction-related expense and the contingent asset will be reduced by the fair value of the repurchased Subject to Vesting Shares. The fair value of the repurchased Subject to Vesting Shares will be recorded as equity.

The remeasurement of the contingent asset and contingent liability as of December 31, 2011 resulted in a net $1.5 million reduction to transaction-related expenses for the year ended December 31, 2011.

Pro Forma Information

The following unaudited pro forma information presents the condensed consolidated results of operations of ADVENTRX and SynthRx as if the acquisition had occurred on January 1, 2010:

	September 30, 2011	September 30, 2010
	Year ended December 31,	
Revenues	$	$ 488,959
Loss from operations	(13,795,615)	(8,661,270)
Net loss applicable to common stock	(13,658,635)	(14,212,109)

The pro forma condensed consolidated financial information includes the following adjustments directly attributable to the acquisition:

	September 30, 2011	September 30, 2010
	Year ended December 31,	
Transaction-related expenses	$ 58,887	$ (58,887)

The pro forma information is not necessarily indicative of what the results of operations actually would have been had the acquisition been completed on the date indicated. In addition, it does not purport to project the future operating results of the combined entity. The pro forma condensed consolidated financial information is presented for illustrative purposes only.

The operations of SynthRx were fully integrated into our operations as of the closing of the acquisition. Accordingly, we do not present SynthRx s expenses separately.

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4. Short-term Investments

At December 31, 2011, the fair value of our short-term investments was $7,133,697. The cost basis of such investments was $7,133,839 and unrealized losses were $142.

5. Fair Value of Financial Instruments

Our short-term investments and our asset and liability for contingent consideration are carried at fair value. The fair value of financial assets and liabilities is measured under a framework that establishes levels which are defined as follows: Level 1 fair value is determined from observable, quoted prices in active markets for identical assets or liabilities. Level 2 fair value is determined from quoted prices for similar items in active markets or quoted prices for identical or similar items in markets that are not active. Level 3 fair value is determined using the entity s own assumptions about the inputs that market participants would use in pricing an asset or liability.

The fair values at December 31, 2011 of our short-term investments and our contingent asset and contingent liability related to the SynthRx acquisition are summarized in the following table:

	September 30, Total Fair Value	September 30, December 31, 2011 Fair Value Determined Under: (Level 1)	September 30, (Level 2)	September 30, (Level 3)
Short-term investments	$ 7,133,697	$ 7,133,697	$	$
Contingent asset	$ 815,011	$	$	$ 815,011
Contingent liability	$ (140,125)	$	$	$ (140,125)

A reconciliation of the contingent asset and contingent liability that are measured and recorded at fair value on a recurring basis using significant unobservable inputs (Level 3) in the year ended December 31, 2011 is as follows:

	September 30, Year ended December 31, 2011 Contingent Asset	September 30, Contingent Liability
Beginning balance	$	$
Net purchases, issuances, sales and settlements	300,481	(1,084,900)
Total net unrealized gains (losses) included in earnings	514,530	944,775

	September 30,	September 30,
Total net unrealized gains (losses) included in other comprehensive income		
Transfers into level 3 (gross)		
Transfers out of level 3 (gross)		
Ending balance	$ 815,011	$ (140,125)

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As discussed in Note 2, the fair values of the contingent asset and contingent liability are based on significant estimates and assumptions of management. The fair values of the contingent asset and contingent liability at each remeasurement date are equal to our estimates of the fair value of the Subject to Vesting Shares that may be repurchased by us and the fair value of First Milestone Shares that may be issued by us, respectively. The fair value of these shares is based on our estimates of the probability of achievement of the First Milestone and assumptions regarding the circumstances under which it is achieved, and the market price of our common stock. As discussed in Note 3, we may repurchase up to 75% of the Subject to Vesting Shares, or 1,454,079 shares, for $0.001 per share and the number of First Milestone Shares issuable upon achievement of the First Milestone may be reduced by up to 75%, or from 1,000,000 to 250,000 shares. The changes in fair values of the contingent asset and contingent liability were primarily due to the decrease in our stock price at December 31, 2011 relative to April 8, 2011, the acquisition date, and updated estimates regarding the probability and circumstances of achievement of the First Milestone.

6. Property and Equipment

Property and equipment at December 31, 2011 and 2010 were as follows:

	September 30, Useful Lives	September 30, 2011	September 30, 2010
Office furniture, computer and lab equipment	3 - 5 years	$ 280,839	$ 216,698
Computer software	3 years	63,016	60,841
Leasehold improvements	1 year	34,900	21,733
Equipment in progress	n/a	359,897	
		738,652	299,272
Less accumulated depreciation and amortization		(274,187)	(255,018)
Property and equipment, net		$ 464,465	$ 44,254

Equipment in progress relates to equipment purchased by us for use by a third party vendor in the manufacturing of ANX-514.

Depreciation and amortization expense was $37,570 and $19,821 for the years ended December 31, 2011 and 2010, respectively.

7. Accrued Liabilities

Accrued liabilities at December 31, 2011 and 2010 were as follows:

	September 30, 2011	September 30, 2010
Accrued contracts and study expenses	$ 880,608	$ 381,309
Other accrued liabilities	239,808	483,548

Accrued liabilities	$ 1,120,416	$ 864,857

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8. Capital Stock and Warrants

Reverse Stock Split

At a special meeting of our stockholders held on August 25, 2009, our stockholders approved a proposal to authorize our board of directors, in its discretion, to effect a reverse split of our outstanding common stock without further action by our stockholders. In April 2010, our board of directors approved a 1-for-25 reverse split of our common stock and on April 23, 2010 at 4:01 p.m. Eastern time, the reverse stock split became effective. As a result of the reverse stock split, each 25 shares of our issued and outstanding common stock were automatically reclassified as and changed into one share of our common stock. The reverse stock split reduced the number of our issued and outstanding shares of common stock as of April 23, 2010 from approximately 257.3 million shares to approximately 10.3 million shares. No fractional shares were issued in connection with the reverse stock split. Stockholders who were entitled to fractional shares instead became entitled to receive a cash payment in lieu of receiving fractional shares (after taking into account and aggregating all shares of our common stock then held by such stockholder) equal to the fractional share interest multiplied by $4.6275 (the per share closing price of our common stock (on a post-split basis) as determined by the NYSE Amex on April 23, 2010). The reverse stock split affected all of the holders of our common stock uniformly. Shares of our common stock underlying outstanding options and warrants were proportionately reduced and the exercise prices of outstanding options and warrants were proportionately increased in accordance with the terms of the agreements governing such securities. All common stock share and per share information in the consolidated financial statements and notes thereto included in this report have been restated to reflect retrospective application of the reverse stock split for all periods presented ending or as of a date on or prior to April 23, 2010, except for par value per share and the number of authorized shares, which were not affected by the reverse stock split.

3. ***73344597664961% Series E Convertible Preferred Stock and Warrant Financing***

In January 2010, we completed a registered direct equity financing raising gross proceeds of $19.0 million involving the issuance of units consisting of 19,000 shares of our 3.73344597664961% Series E Convertible Preferred Stock with a stated value of $1,000 per share (Series E Stock) and 30-month warrants to purchase up to an aggregate of 498,488 shares of our common stock. In the aggregate, the shares of Series E Stock we issued were convertible into 1,993,965 shares of our common stock. All of the shares of our Series E Stock have been converted into common stock and are no longer outstanding. Our Series E Stock would have accrued a cumulative annual dividend of 3.73344597664961% per share until January 7, 2015, and no dividend thereafter. In accordance with the terms of the Series E Stock, because the Series E Stock was converted prior to January 7, 2015, we paid the holders an amount equal to the total dividend that would have accrued in respect of the shares converted from the issuance date through January 7, 2015, or $186.67 per $1,000 of stated value of the shares converted. We received approximately $14.0 million in net proceeds from the financing after deducting the approximately $3.5 million we placed into escrow accounts to pay the aggregate dividend payment in respect of our Series E Stock, placement agent s fees and expenses and other offering expenses. 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 $8.75 per share, are exercisable any time on or before July 6, 2012, subject to certain beneficial ownership limitations.

The convertible feature of our Series E Stock and the terms of the warrants issued in connection with our Series E 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 E Stock is characterized as a beneficial conversion feature, or BCF. The estimated relative fair values of the shares of our Series E Stock and the warrants issued in connection with such stock were calculated as approximately $12.4 million and $3.0 million, respectively. The value of the BCF was determined using the intrinsic value method and calculated as approximately $2.5 million. Because our Series E Stock did not have a stated redemption date, the value of the BCF was fully realized at the time our Series E Stock was issued. The fair value of the warrants was

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determined using the Black-Scholes option-pricing model as of the date of issuance assuming a 30-month term, stock volatility of 275.79%, and a risk-free interest rate of 1.325%. The value of the BCF was treated as a deemed dividend to the holders of our Series E Stock and, due to the potential immediate convertibility of our Series E 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 99,696 shares of our common stock at an exercise price of $11.91 per share to the placement agent in the January 2010 financing and its designees as additional consideration for its services in connection with the financing. These warrants had a fair value of approximately $724,000 using the Black-Scholes option-pricing model as of the date of issuance assuming a 4.5-year term, stock volatility of 209.46%, and a risk-free interest rate of 2.37%. The warrants became exercisable on July 7, 2010 and are exercisable at any time on or before June 3, 2014.

2.19446320054018% Series F Convertible Preferred Stock and Warrant Financing

In May 2010, we completed a registered direct equity financing raising gross proceeds of $19.2 million involving the issuance of units consisting of 19,217.13 shares of our 2.19446320054018% Series F Convertible Preferred Stock with a stated value of $1,000 per share (Series F Stock), 5-year warrants to purchase up to an aggregate of 1,816,608 shares of our common stock and 1-year warrants to purchase up to an aggregate of 778,548 shares of our common stock. In the aggregate, the shares of Series F Stock we issued were convertible into 5,190,312 shares of our common stock. All of the shares of our Series F Stock have been converted into common stock and are no longer outstanding. Series F Stock would have accrued a cumulative annual dividend of 2.19446320054018% per share until May 6, 2020, and no dividend thereafter. In accordance with the terms of the Series F Stock, because the Series F Stock was converted prior to May 6, 2020, upon conversion of the shares, we paid the holders an amount equal to the total dividend that would have accrued in respect of the shares converted from the issuance date through May 6, 2020, or $219.45 per $1,000 of stated value of the shares converted, less the amount of any dividend paid on such shares before their conversion. Dividend payments were due on January 1, April 1, July 1 and October 1. Because 2,884.57 shares of our Series F Stock were outstanding at the time of the July 1, 2010 and October 1, 2010 dividend payment dates, we paid aggregate dividends of approximately $25,300 to the holders of those outstanding shares and such previously paid amounts were subtracted from the payments due in respect of those shares at the time of their conversion. We received approximately $13.3 million in net proceeds from the financing after deducting the approximately $4.2 million we placed into escrow accounts to pay the aggregate dividend payment in respect of our Series F Stock, placement agent and financial advisor fees and other offering expenses. The 1-year warrants expired unexercised in May 2011. We may receive up to approximately $6.6 million of additional proceeds from the exercise of the 5-year warrants issued in the May 2010 financing. The exercise price of the warrants is $3.65 per share. Subject to certain beneficial ownership limitations, the 5-year warrants are exercisable any time on or before May 6, 2015.

The convertible feature of our Series F Stock and the terms of the warrants issued in connection with our Series F 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 F Stock is characterized as BCF. The estimated relative fair values of the shares of our Series F Stock and the warrants issued in connection with such stock were calculated as approximately $10.1 million and $4.9 million, respectively. The value of the BCF was determined using the intrinsic value method and calculated as approximately $3.1 million. Because our Series F Stock did not have a stated redemption date, the value of the BCF was fully realized at the time our Series F Stock was issued. The fair value of the 5-year warrants was determined using the Black-Scholes option-pricing model as of the date of issuance assuming a 5-year term, stock volatility of 202%, and a risk-free interest rate of 2%. The fair value of the 1-year warrants was determined using the Black-Scholes option-pricing model as of the date of issuance assuming a 1-year term, stock volatility of 361%, and a risk-free interest rate of 0.4%. The value of the BCF was treated as a deemed dividend to the holders of our Series F Stock and, due to the potential immediate convertibility of our Series F Stock at issuance, was recorded as an increase to additional paid-in capital and accumulated deficit at the time of issuance.

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Common Stock and Warrant Registered Direct Equity Financing

In January 2011, we completed a registered direct equity financing involving the issuance of units consisting of 8,184,556 shares of our common stock, 5-year warrants to purchase up to an aggregate of 2,046,139 shares of our common stock and 1-year warrants to purchase up to an aggregate of 2,046,139 shares of our common stock. The gross proceeds of this financing were $22.5 million, and we received $21.0 million in net proceeds after deducting the fees and expenses of our placement agent and our other offering expenses. The 1-year warrants expired unexercised in January 2012. We may receive up to $5.6 million of additional proceeds from the exercise of the 5-year warrants. The exercise price of the warrants is $2.75 per share. Subject to certain beneficial ownership limitations, the 5-year warrants are exercisable any time on or before January 11, 2016.

Common Stock and Warrant Underwritten Public Offering

In November 2011, we completed an underwritten public offering of 21,250,000 shares of our common stock and warrants to purchase up to 10,625,000 additional shares of our common stock. These securities were offered and sold to the public in multiples of a fixed combination consisting of one share of our common stock and a warrant to purchase up to 0.5 of a share of our common stock. The gross proceeds from this financing were $17.0 million, and we received $15.6 million in net proceeds after deducting the underwriting commissions and our other offering expenses. We may receive up to $11.7 million of additional proceeds from the exercise of the warrants issued to investors in this financing. The exercise price of the warrants is $1.10 per share. Subject to certain beneficial ownership limitations, the warrants are exercisable at any time on or before November 16, 2016.

We also issued warrants to purchase up to 1,062,500 shares of our common stock at an exercise price of $1.00 per share to the underwriter of the offering and its designees as additional underwriting compensation. These compensation warrants are exercisable at any time on or before April 1, 2015.

Common Stock Issued for Warrants Exercised

In January 2010, we issued 84,651 shares of our common stock and received net proceeds of $0.3 million in connection with the exercise of the warrants issued in our June 2009 0% Series A Convertible Preferred Stock and warrant financing at an exercise price of $3.75 per share.

Warrants

During 2010, warrants were issued to investors in conjunction with the Series E Stock and Series F Stock financings in January 2010 and May 2010, respectively. In addition, warrants were issued to the placement agent of the Series E Stock financing, and its designees, in January 2010. See details of the equity financings above.

During 2011, warrants were issued to investors in conjunction with the registered direct equity financing and underwritten public offering in January 2011 and November 2011, respectively. In addition, warrants were issued to the placement agent and the underwriter for these financings and its designees. See details of the equity financings above.

At December 31, 2011, outstanding warrants to purchase shares of common stock are as follows:

Warrants	September 30, Exercise Price		September 30, Expiration Date
432,429	$	56.5000	July 2012

99,696	$	11.9125	June 2014
498,488	$	8.7475	July 2012
144,000	$	5.8750	October 2014
19,007	$	4.4750	July 2014
14,183	$	4.0625	August 2014
36,071	$	3.7500	June 2014

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Warrants	September 30, Exercise Price	September 30, Expiration Date
216,000	$ 3.6700	October 2014
1,816,608	$ 3.6500	May 2015
409,228	$ 3.4400	April 2015
2,046,139	$ 2.7500	January 2012
2,046,139	$ 2.7500	January 2016
1,062,500	$ 1.0000	April 2015
10,625,000	$ 1.1000	November 2016
19,465,488		

9. Equity Incentive Plans

At December 31, 2011, we had the 2005 Equity Incentive Plan (the 2005 Plan), the 2005 Employee Stock Purchase Plan (the Purchase Plan), the 2008 Omnibus Incentive Plan (the Original 2008 Plan) and the Amended and Restated 2008 Omnibus Incentive Plan (the Amended and Restated 2008 Plan) which are described below. The share-based compensation expense from all stock options granted that has been charged to our consolidated statements of operations in the years ended December 31, 2011 and 2010 was comprised of the following:

	September 30, Years Ended December 31, 2011	September 30, 2010
Selling, general and administrative expense	$ 888,592	$ 791,688
Research and development expense	(22,540)	(5,745)
Share-based compensation expense	$ 866,052	$ 785,943

2005 Equity Incentive Plan, 2008 Omnibus Incentive Plan and Amended and Restated 2008 Omnibus Incentive Plan

Our equity-based incentive plans, which are stockholder-approved, are intended to encourage ownership of shares of common stock by our directors, officers, employees, consultants and advisors and to provide additional incentive for them to promote the success of our business through the grant of share-based awards. Each of the 2005 Plan, the Original 2008 Plan and the Amended and Restated 2008 Plan provide for the grant of incentive and non-statutory stock options as well as share appreciation rights, restricted shares, restricted share units, performance units, shares and other share-based awards. Since the Original 2008 Plan was approved by our stockholders in May 2008, no awards have been or will be granted under the 2005 Plan, and, since the Amended and Restated 2008 Plan was approved by our stockholders in June 2011, no awards have been or will be granted under the Original 2008 Plan. Share-based awards are subject to terms and conditions established by our board of directors or the compensation committee of our board of directors.

At December 31, 2010, the maximum aggregate number of shares of our common stock available for grant under the Original 2008 Plan was 405,969 shares. At December 31, 2011, the maximum aggregate number of shares of our common stock available for grant under the Amended and Restated 2008 Plan was 1,917,574 shares and, as discussed above, no shares were available for grant under the Original 2008 Plan. Shares of common stock that are subject to awards granted under the Amended and Restated 2008 Plan shall be counted against the shares available for issuance under this plan as one share for each share subject to a stock option or stock appreciation right and as 1.5 shares for each share subject to an award other than a stock option or a stock appreciation right. If any shares of common stock subject to an award under the Amended and Restated 2008 Plan, the Original 2008 Plan or the 2005 Plan are forfeited, expire or are settled for cash pursuant to the terms of an award, the shares subject to the award may be used again for awards under the Amended and Restated 2008 Plan to the extent of the forfeiture, expiration or settlement. The shares of common stock will be added back as one share for every share of common stock if the shares

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were subject to a stock option or stock appreciation right granted under the Amended and Restated 2008 Plan, the Original 2008 Plan or the 2005 Plan, and as 1.5 shares for every share of common stock if the shares were subject to an award other than a stock option or stock appreciation right. However, the following shares of common stock will not be added to the shares available for issuance under the Amended and Restated 2008 Plan: (i) shares tendered by a participant or withheld by us in payment of the purchase price of a stock option, (ii) shares tendered by a participant or withheld by us to satisfy any tax withholding obligation with respect to an award, (iii) shares subject to a stock appreciation right that are not issued in connection with the stock settlement of the stock appreciation right on exercise thereof, and (iv) shares reacquired by us on the open market or otherwise using cash proceeds from the exercise of stock options. Shares of common stock under awards made in substitution or exchange for awards previously granted, or the right or obligation to make future awards, in each case by a company acquired by us, or with which we combine, will not reduce the number of shares available for issuance under the Amended and Restated 2008 Plan. In addition, if a company acquired by us, or with which we combine, has shares available under a pre-existing plan approved by its stockholders and not adopted in contemplation of such acquisition or combination, the shares available for issuance under such plan (adjusted to reflect the exchange or valuation ratio or other adjustment used in the acquisition or combination) may be used for awards under the Amended and Restated 2008 Plan and will not reduce the number of shares of common stock available for issuance under the Amended and Restated 2008 Plan; provided, however that awards using such available shares shall not be made after the date awards or grants could have been made under the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not our employees or directors prior to the acquisition or combination.

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

We canceled options exercisable for 31,004 and 34,000 shares of common stock in the years ended December 31, 2011 and 2010, respectively, held by employees and non-employee directors whose service to our company terminated during those respective periods. The shares underlying such options were returned to the Original 2008 Plan or the Amended and Restated 2008 Plan, as applicable, and became available for re-issuance pursuant to the terms described above.

During the years ended December 31, 2011 and December 30, 2010, all awards granted under the 2008 Plan and the Amended and Restated 2008 Plan were stock options. A summary of all of our option activity as of December 31, 2011 and 2010 and of changes in options outstanding under the plans during the year ended December 31, 2011 are as follows:

	September 30, Shares	September 30, Weighted-Average Exercise Price	September 30, Weighted-Average Remaining Contractual Years	September 30, Aggregate Intrinsic Value
Outstanding at December 31, 2010	403,737	$ 12.39		
Granted	2,519,399	$ 1.70		
Exercised				
Cancelled/forfeited/expired	(31,004)	$ 35.13		

Outstanding at December 31, 2011	2,892,132	$	2.83	9.35	$
Options exercisable at December 31, 2011	266,956	$	11.21	7.18	$
Vested and expected to vest at December 31, 2011	2,711,783	$	2.91	9.33	$

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The weighted-average grant-date fair value of options granted during the years ended December 31, 2011 and 2010 was $1.52 and $6.41, respectively. As of December 31, 2011, there was approximately $3.8 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a weighted-average period of approximately 3.47 years.

There were no options exercised during the years ended December 31, 2011 and 2010.

Our determination of fair value is affected by our stock price as well as a number of assumptions that require judgment. The fair value of each option award is estimated on the date of grant using the Black-Scholes option-valuation model. The assumptions used in the Black-Scholes option-valuation model for option grants to employees and non-employee directors during the years ended December 31, 2011 and 2010 are as follows:

	Years Ended September 30, 2011	Years Ended December 31, 2010
Risk-free interest rate	1.1 2.4%	1.8 2.7%
Dividend yield	0.0%	0.0%
Expected volatility	125 131%	128 136%
Expected term (in years)	5 6.25 years	5 6 years
Forfeiture rate	4%	11%

The risk-free interest rate assumption is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have not paid any dividends on common stock since our inception and do not anticipate paying dividends on our common stock in the foreseeable future. The expected option term is computed using the simplified method as permitted under the provisions of Staff Accounting Bulletin (SAB) 107. SAB 107 s guidance was extended indefinitely by SAB 110. The expected volatility is based on the historical volatility of our common stock based on the daily close prices. The forfeiture rate is based on the historical forfeiture rate for our unvested stock options.

No options were granted to consultants in 2011 and 2010. In accordance with ASC 718, Compensation Stock Compensation, share-based compensation expense associated with the non-employee director options is included with employee share-based compensation expense.

Employee Stock Purchase Plan

The Purchase Plan was approved by our stockholders in 2005; however, we have not implemented the Purchase Plan. The Purchase Plan, if implemented, allows all eligible employees to purchase shares of common stock at 85% of the lower of the fair market value on the first or the last day of each offering period. Employees may authorize us to withhold up to 15% of their compensation during any offering period, subject to certain limitations. The maximum aggregate number of shares of common stock that may be issued under the Purchase Plan is 216,945 as of December 31, 2011. This maximum number is subject to an annual automatic increase on January 1 of each year equal to the lesser of (i) 1% of the number of outstanding shares of common stock on such day, (ii) 30,000 or (iii) such other amount as our board of directors may specify. At December 31, 2011, no shares of common stock have been issued under the Purchase Plan.

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10. Commitments

Operating Leases

We are obligated under operating leases for office space and equipment. In December 2010, we entered into a lease for office space in San Diego, California to serve as our headquarters, effective January 1, 2011. The average rent for this space was approximately $16,900 per month. In June 2011, we amended our lease to add an additional suite in the same building. This amendment increased our rent to approximately $23,800 per month through January 31, 2012 and approximately $24,500 per month thereafter. The term of the amended lease will expire January 31, 2013, unless we exercise our option to extend the lease an additional 12 months. Since August 2011, we have subleased a portion of our space to another company and receive rental income of $3,100 per month, which offsets our rent expense.

Prior to December 2010, we leased different office space in San Diego, California. During the year ended December 31, 2010, our average monthly office lease payment was $6,400 per month.

We lease copiers, which leases expire in 2015.

Rent expense was approximately $206,000 and $99,000 during the years ended December 31, 2011 and 2010, respectively.

Future rental commitments under all operating leases are as follows:

Year Ending December 31,	September 30,
2012	$ 301,119
2013	32,710
2014	8,250
2015	687
2016	
Total	$ 342,766

11. Out-Licensing Agreements

In June 2010, we announced that we had entered into a license agreement with respect to our know-how to develop, make, use and sell ANX-510, or CoFactor® (5,10-methylenetetrahydrofolate), with Theragence, Inc., a California corporation (Theragence). Pursuant to the agreement, we granted to Theragence an exclusive worldwide license, including the right to grant sublicenses under certain circumstances, to conduct research on and to develop, make, have made, use, offer for sale, sell, have sold and import licensed products in any field or use. We are entitled to receive royalties on net sales of licensed products and commercial milestone payments of up to approximately $30 million based on aggregate gross sales of licensed products in the United States, European Union and Japan. Theragence agreed to use commercially reasonable efforts to research, develop and commercialize at least one licensed product. We discontinued active work on our CoFactor program in October 2008.

In March 2009, we announced that we and our wholly-owned subsidiary, SD Pharmaceuticals, had entered into a license agreement with respect to our product candidate ANX-514 (docetaxel emulsion for injection) with Shin Poong Pharmaceutical Co., Ltd., a company organized under the

laws of the Republic of Korea (Shin Poong), pursuant to which we granted to Shin Poong an exclusive license, including the right to sublicense, to research, develop, make, have made, use, offer for sale, sell and import licensed products, in each case solely for the treatment of cancer by intravenous administration of formulations of docetaxel as emulsified products and solely in South Korea. Under the terms of the agreement, we received an upfront licensing fee of $0.3 million, and are entitled to receive a regulatory milestone payment of either $0.2 million or $0.4 million upon receipt of regulatory approval for marketing a licensed product in South Korea (the amount depends on whether the Korea Food and Drug Administration requires Shin Poong to conduct

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a bioequivalence or clinical study in human subjects prior to receipt of regulatory approval), one-time commercial milestone payments 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. We agreed to pay Shin Poong $0.1 million if the Korea Food and Drug Administration required Shin Poong 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 received the $0.3 million upfront licensing fee in April 2009. We recognized $0.3 million in licensing revenue in the three-month period ended March 31, 2009 because the criteria under our revenue recognition policy were met in that period.

In September 2010, pursuant to the terms of the license agreement, we elected to make the $0.1 million cash payment to Shin Poong in lieu of supplying product for the ANX-514 trial in human subjects required by the Korea Food and Drug Administration.

12. Grant Revenue

In November 2010, the Internal Revenue Service notified us that an aggregate amount of $488,959 in grants had been awarded to us under the qualifying therapeutic discovery project (QTDP) program established under Section 48D of the Internal Revenue Code as a result of the Patient Protection and Affordable Care Act of 2010. We submitted applications in July 2010 for qualified investments we made, or expected to make, in 2009 and 2010 in our ANX-530, or Exelbine , and ANX-514 programs, and a grant in the amount of $244,479 was approved for each of those programs. These grants are not taxable for federal income tax purposes. We received full payment of the grants in November 2010, all of which we recognized as revenue in the three month period ended December 31, 2010 because the criteria under our revenue recognition policy were met in that period.

13. Income Taxes

Due to our historical net loss position, and as we have recorded a full valuation allowance against net deferred tax assets, there is no provision or benefit for income taxes recorded for the years ended December 31, 2011 and 2010.

The income tax provision/(benefit) is different from that which would be obtained by applying the statutory Federal income tax rate of 34% to income before income tax expense. The items causing this difference for the years ended December 31, 2011 and 2010 are as follows:

	September 30, December 31, 2011	September 30, 2010
Income tax benefit at federal statutory rate	$ (4,508,000)	$ (2,873,000)
R & D credit	(155,000)	1,625,000
Stock options	386,000	164,000
Acquisition costs	374,000	
Contingent asset/liability	(496,000)	
Net operating loss true ups		26,574,000
Other	3,000	(163,000)
Change in federal valuation allowance	4,396,000	(25,327,000)

Total	$	$

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of deferred tax assets and liabilities at December 31, 2011 and 2010 are as follows:

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	September 30, 2011	September 30, December 31, 2010
Deferred tax assets:		
Accrued expenses	$ 96,979	$ 57,252
Stock options expense under ASC 718	1,021,202	1,129,227
Net operating loss carry forwards	17,787,621	12,732,504
Income tax credit carry forwards	445,296	202,215
Property and equipment	8,959	6,820
Intangibles	2,212,680	2,246,349
Other	10,490	6,108
Total deferred tax assets	21,583,227	16,380,475
Less: valuation allowance	(21,583,227)	(16,380,475)
Total deferred tax assets, net of valuation allowance	$	$
Deferred tax liabilities:		
Acquired intangibles	(2,608,755)	
Total deferred tax assets/liabilities, net of valuation allowance	$ (2,608,755)	$

We have established a full valuation allowance against our net deferred tax assets due to the uncertainty surrounding the realization of such assets. Management has determined it is more likely than not that the deferred tax assets are not realizable due to our historical loss position.

As a result of our acquisition of SynthRx, we have recorded a deferred tax liability. This deferred tax liability reflects the tax impact of the difference between the book basis and tax basis of acquired IPR&D that has not yet reached feasibility. Such deferred tax liability cannot be used to offset deferred tax assets when analyzing our end of year valuation allowance as the acquired IPR&D is considered to have an indefinite life until we complete or abandon development of ANX-188. The deferred tax liability was recorded as an offset to the goodwill recorded as part of the acquisition.

Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (IRC), our ability to use net operating loss and R&D tax credit carry forwards to offset future taxable income is limited if we experience a cumulative change in ownership of more than 50% within a three-year period. During 2010, we completed a formal study to determine whether any ownership change within the meaning of IRC Section 382 occurred during the period from January 1, 2008 through January 7, 2010, and several ownership changes were identified. Upon application of limitations prescribed by IRC Section 382, we identified certain tax attributes that would expire before utilization and have adjusted our deferred tax assets for net operating loss and R&D tax credit carry forwards accordingly. We currently are conducting a formal study to determine whether any ownership change within the meaning of IRC Section 382 occurred during the period from January 8, 2010 through December 31, 2011. This study has not yet been completed. If certain events, including additional ownership changes within the meaning of IRC Section 382, are identified through this study as having occurred in the past or these events take place in the future, the amount of remaining tax carry forwards available to offset future taxable income in future years may be significantly restricted or eliminated.

The deferred tax asset for net operating losses and the related valuation allowance includes approximately $47,000 related to stock option deductions, the benefit of which may eventually be credited to equity. We recognize windfall tax benefits associated with the exercise of stock options directly to stockholders equity only when realized. Accordingly, as we are in a cumulative loss position, deferred tax assets have not

been recognized for net operating loss carry forwards resulting from windfall tax benefits generated through stock option deductions.

At December 31, 2011, we had federal and California tax loss carry forwards of approximately $43.9 million and $47.4 million, respectively. The federal and California net operating loss carry forwards begin to expire in 2018 and 2012, respectively, if unused. At December 31, 2011, we had federal and California R&D tax credit carry forwards of approximately $300,000 and $220,000, respectively. The federal R&D tax credits will begin to expire in 2029. The California R&D tax credits do not expire.

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In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. As of December 31, 2011, we continue to have no unrecognized tax benefits. There are no unrecognized tax benefits included on the balance sheet that would, if recognized, impact the effective tax rate. We do not anticipate there will be a significant change in unrecognized tax benefits within the next 12 months.

Our policy is to recognize interest and/or penalties related to income tax matters in income tax expense. Because we have generated net operating losses since inception, no tax liability, penalties or interest has been recognized for balance sheet or income statement purposes as of and for the years ended December 31, 2011 and 2010.

We are subject to taxation in the U.S. and the state of California. All of our tax years are subject to examination by the tax authorities due to the carry forward of unutilized net operating losses and R&D tax credits.

14. Litigation

In the normal course of business, we may become subject to lawsuits and other claims and proceedings. Such matters are subject to uncertainty and outcomes are often not predictable with assurance. We are not currently a party to any material pending litigation or other material legal proceeding.

15. 401(k) Plan

We have a defined contribution savings plan pursuant to Section 401(k) of the IRC. The plan is for the benefit of all qualifying employees and permits voluntary contributions by employees up to 100% of eligible compensation, subject to the Internal Revenue Service (IRS)-imposed maximum limits. The terms of the plan require us to make matching contributions equal to 100% of employee contributions up to 6% of eligible compensation, limited by the IRS-imposed maximum. We incurred total expenses of $87,790 and $47,250 in employer matching contributions in 2011 and 2010, respectively.

16. Segment Information

We operate our business on the basis of a single reportable segment, which, fundamentally, is the business of developing proprietary product candidates. We evaluate our Company as a single operating segment. The majority of our operating activities and work performed by our employees are currently conducted from a single location in the U.S. We recognized revenues of $0 and $0.5 million in 2011 and 2010, respectively. Our 2010 revenue was derived from U.S. government grants (see Note 12).

17. Summary of Quarterly Financial Data (unaudited)

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2011 and 2010:

Quarterly statements of operations data

for 2011 (unaudited):	September 30, March 31	September 30, June 30	September 30, September 30	September 30, December 31
	Quarters Ended			
Revenue	$	$	$	$
Loss from operations	(2,994,415)	(4,406,465)	(3,552,845)	(2,443,160)
Net loss	(2,956,439)	(4,392,190)	(3,539,326)	(2,371,976)
Net loss applicable to common stock	(2,956,439)	(4,392,190)	(3,539,326)	(2,371,976)
Basic and diluted net loss per share	$ (0.13)	$ (0.17)	$ (0.13)	$ (0.06)
Basic and diluted weighted average number of shares of common stock outstanding	22,755,463	26,250,259	26,465,709	37,090,709

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for 2010 (unaudited):	September 30, March 31	September 30, June 30	September 30, Quarters Ended September 30	September 30, December 31
Grant revenue	$	$	$	$ 488,959
Gross margin				488,959
Loss from operations	(2,419,885)	(1,942,750)	(1,868,138)	(2,308,924)
Net loss	(2,403,074)	(1,919,442)	(1,843,899)	(2,284,507)
Net loss applicable to common stock	(4,917,994)	(5,044,318)	(1,843,899)	(2,284,507)
Basic and diluted net loss per share	$ (0.48)	$ (0.39)	$ (0.13)	$ (0.15)
Basic and diluted weighted average number of shares of common stock outstanding	10,143,789	12,886,826	14,701,216	14,921,292

Exhibit Index

Exhibit	Description
2.1 (1)	Agreement and Plan of Merger, dated April 7, 2006, among the registrant, Speed Acquisition, Inc., SD Pharmaceuticals, Inc. and certain individuals named therein (including exhibits thereto)
2.2 (2)	Agreement and Plan of Merger, dated February 12, 2011, by and among the registrant, SRX Acquisition Corporation, SynthRx, Inc. and, solely with respect to Sections 2 and 8, the Stockholders Agent
3.1 (3)	Amended and Restated Certificate of Incorporation of the registrant
3.2 (4)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the registrant dated October 5, 2009
3.3 (5)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the registrant, dated April 23, 2010
3.4 (6)	Amended and Restated Bylaws of the registrant (formerly known as Biokeys Pharmaceuticals, Inc.)
10.1 (7)	Securities Purchase Agreement, dated July 21, 2005, among the registrant and the Purchasers (as defined therein)
10.2 (7)	Rights Agreement, dated July 27, 2005, among the registrant, the Icahn Purchasers and Viking (each as defined therein)
10.3 (8)	First Amendment to Rights Agreement, dated September 22, 2006, among the registrant and the Icahn Purchasers (as defined therein)
10.4 (9)	Second Amendment to Rights Agreement, dated February 25, 2008, among the registrant and the Icahn Purchasers (as defined therein)
10.5 (10)	Third Amendment to Rights Agreement, dated August 26, 2009, among the registrant and Icahn Purchasers (as defined therein)
10.6 (7)	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 (7)	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 (11)	Form of Common Stock Purchase Warrant issued on June 12, 2009 by the registrant to Rodman & Renshaw, LLC and its designees
10.9 (12)	Form of Common Stock Purchase Warrant issued on July 6, 2009 by the registrant to Rodman & Renshaw, LLC and its designees
10.10 (13)	Form of Common Stock Purchase Warrant issued on August 10, 2009 by the registrant to Rodman & Renshaw, LLC and its designees
10.11 (14)	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 and 5-year common stock purchase warrants
10.12 (14)	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 and its designees
10.13 (15)	Engagement Letter Agreement, dated January 3, 2010, by and between the registrant and Rodman & Renshaw, LLC

Exhibit	Description
10.14 (15)	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 and 30-month common stock purchase warrants
10.15 (15)	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 and its designees
10.16 (16)	Engagement Letter Agreement, dated April 29, 2010, by and between the registrant and Rodman & Renshaw, LLC
10.17 (16)	Form of Securities Purchase Agreement, dated May 2, 2010 governing the issuance and sale of the registrant s 2.19446320054018% Series F Convertible Preferred Stock and 5-year and 1-year common stock purchase warrants
10.18 (16)	Form of Series A and B Common Stock Purchase Warrants issued on May 6, 2010 by the registrant to the purchasers of the registrant s 2.19446320054018% Series F Convertible Preferred Stock
10.19 (17)	Engagement Letter Agreement, dated January 5, 2011, by and between the registrant and Rodman & Renshaw, LLC
10.20 (17)	Form of Securities Purchase Agreement, dated January 6, 2011 governing the issuance and sale of the registrant s common stock and 5-year and 1-year common stock purchase warrants
10.21 (17)	Form of [Series A/B] Common Stock Purchase Warrant issued on January 11, 2011 by the registrant to the purchasers of the registrant s common stock and to Rodman & Renshaw, LLC
10.22 (18)	Warrant Agent Agreement, dated November 11, 2011, by and between the registrant and American Stock Transfer & Trust Company, including the form of Common Stock Purchase Warrant as Exhibit A
10.23 (18)	Form of Common Stock Purchase Warrant to be issued on November 16, 2011 to Rodman & Renshaw, LLC and its designees
10.24 (2)	Stockholders Voting and Transfer Restriction Agreement, dated February 12, 2011, by and among the registrant, each of the principal stockholders of SynthRx, Inc. and, solely with respect to Section 3(c), the Stockholders Agent
10.25# (19)	2005 Equity Incentive Plan
10.26# (20)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan
10.27# (21)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for director option grants beginning in 2008)
10.28# (22)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for option grants to employees approved in March 2008)
10.29# (3)	Form of Restricted Share Award Agreement under the 2005 Equity Incentive Plan
10.30# (23)	2008 Omnibus Incentive Plan
10.31# (24)	Form of Notice of Grant of Restricted Stock Units under the 2008 Omnibus Incentive Plan (for grants to employees in January 2009)
10.32# (24)	Form of Restricted Stock Units Agreement under the 2008 Omnibus Incentive Plan
10.33# (25)	Form of Non-Statutory Stock Option Grant Agreement (for directors) under the 2008 Omnibus Incentive Plan
10.34# (25)	Form of Non-Statutory/Incentive Stock Option Grant Agreement (for consultants/employees) under the 2008 Omnibus Incentive Plan

Exhibit	Description
10.35# (26)	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Brian M. Culley in July 2009)
10.36# (26)	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Patrick L. Keran in July 2009)
10.37# (27)	Form of letter, dated January 20, 2010, modifying options granted to Brian M. Culley and Patrick L. Keran in July 2009
10.38# (27)	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Brian M. Culley in January 2010)
10.39# (27)	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Patrick L. Keran in January 2010)
10.40# (28)	Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan, effective as of February 1, 2011, by and between the registrant and Brian M. Culley
10.41# (28)	Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan, effective as of February 1, 2011, by and between the registrant and Patrick L. Keran
10.42# (29)	ADVENTRX Pharmaceuticals, Inc. Amended and Restated 2008 Omnibus Incentive Plan
10.43# (29)	Form of [Non-Statutory][Incentive] Stock Option Grant Agreement (for consultants/employees) under the Amended and Restated 2008 Omnibus Incentive Plan
10.44# (29)	Form of Non-Statutory Stock Option Grant Agreement Director under the Amended and Restated 2008 Omnibus Incentive Plan
10.45# (30)	Form of Incentive Stock Option Grant Agreement (for grants to the registrant s Chief Executive Officer and President and Chief Operating Officer made in July 2011) under the Amended and Restated 2008 Omnibus Incentive Plan
10.46#	Form of Senior Executive Incentive Stock Option Grant Agreement (for grants to the registrant s Chief Executive Officer and President and Chief Operating Officer made beginning in December 2011) under the Amended and Restated 2008 Omnibus Incentive Plan
10.47 (21)	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
10.48 (31)	License Agreement, dated March 25, 2009, among the registrant, SD Pharmaceuticals, Inc. and Shin Poong Pharmaceutical Co., Ltd.
10.49 (2)	License Agreement, dated June 8, 2004, between SynthRx, Inc. and CytRx Corporation, as amended by that certain Letter Agreement Re: Amendment to License Agreement, dated August 3, 2006, and that certain Agreement and Amendment No. 2 to License Agreement, dated December 1, 2010
10.50 (32)	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
10.51 (3)	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
10.52 (33)	Second Amendment to Standard Multi-Tenant Office Lease Gross, dated July 22, 2009, by and among Westcore Mesa View, LLC, DD Mesa View LLC and the registrant
10.53 (34)	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
10.54 (35)	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

Exhibit	Description
10.55# (36)	Offer letter, dated November 15, 2004, to Brian M. Culley
10.56# (37)	Offer letter, dated February 11, 2011, to Brandi L. Roberts
10.57# (28)	Offer letter, dated March 28, 2011, to R. Martin Emanuele
10.58#	Offer letter, dated July 21, 2011, to Gregory D. Gorgas
10.59# (24)	Retention and Incentive Agreement, dated January 28, 2009 between the registrant and Brian M. Culley
10.60# (31)	Retention and Incentive Agreement, dated January 28, 2009, between the registrant and Patrick L. Keran
10.61# (35)	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
10.62# (26)	2009 Mid-Year Incentive Plan for Brian M. Culley and Patrick L. Keran
10.63# (26)	Retention and Severance Plan (as of July 21, 2009) for Brian M. Culley and Patrick L. Keran
10.64# (27)	2010 Incentive Plan for Brian M. Culley and Patrick L. Keran
10.65# (38)	2011 Mid-Year Executive Incentive Plan
10.66# (35)	Consulting Agreement, effective as of November 23, 2009, between the registrant and Eric K. Rowinsky
10.67# (39)	Director Compensation Policy, adopted June 21, 2006
10.68# (35)	Director Compensation Policy, adopted January 25, 2010
10.69# (28)	Director Compensation Policy, adopted March 16, 2011
10.70 (40)	Form of Director and Officer Indemnification Agreement
21.1	List of Subsidiaries
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
23.2	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
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

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.

** Pursuant to Rule 406T of regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

(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 Current Report on Form 8-K on April 11, 2011 (SEC file number 001-32157-11752769)

(3) Filed with the registrant s Annual Report on Form 10-K on March 16, 2006 (SEC file number 001-32157-06693266)

(4) Filed with the registrant s Current Report on Form 8-K on October 13, 2009 (SEC file number 001-32157-091115090)

(5) Filed with the registrant s Current Report on Form 8-K on April 26, 2010 (SEC file number 001-32157-10769058)

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

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

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

(9) Filed with the registrant s Current Report on Form 8-K on February 25, 2008 (SEC file number 001-32157 08638638)

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

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

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

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

(14) 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)

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

(16) Filed with the registrant s Current Report on Form 8-K on May 3, 2010 (SEC file number 001-32157-10790486)

(17) Filed with the registrant s Current Report on Form 8-K on January 7, 2011 (SEC file number 001-32157-11515655)

(18) Filed with the registrant s Current Report on Form 8-K on November 14, 2011 (SEC file number 001-32157-111203681)

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

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

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

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

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

(24) Filed with the registrant s Current Report on Form 8-K on February 2, 2009 (SEC file number 001-32157- 09561715)

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

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

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

(28) Filed with the registrant s Quarterly Report on Form 10-Q on May 9, 2011 (SEC file number 001-32157-11823538)

(29) Filed with the registrant s Form S-8 Registration Statement on June 16, 2011 (SEC file number 333-174940-11914946)

(30) Filed with the registrant s Quarterly Report on Form 10-Q on November 8, 2011 (SEC file number 001-32157-111186142)

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

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

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

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

(35) Filed with the registrant s Annual Report on Form 10-K on March 18, 2010 (SEC file number 001-32157-10692317)

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

(37) Filed with the registrant s Current Report on Form 8-K on March 22, 2011 (SEC file number 001-32157-11704394)

(38) Filed with the registrant s Current Report on Form 8-K on July 8, 2011 (SEC file number 001-32157-11959481)

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

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