ADVENTRX PHARMACEUTICALS INC
Form 10-K
March 10, 2011

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

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

For the fiscal year ended December 31, 2010

or

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

For the transition period from _____ to _____

Commission File No. 001-32157

ADVENTRX Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§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. þ

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting

company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company þ

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2010 was approximately $24.0 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 5% or more of the registrant s outstanding common stock have been excluded for purposes of the foregoing calculation on the basis that such persons and entities may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 1, 2011, the registrant had 23,664,858 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 2011 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, 2010.

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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, i indicate, seek, should or would and similar expressions are intended to identify forward-looking statements. Am 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: the extent to which we acquire new technologies, product candidates, products or businesses and our ability to integrate them successfully into our operations; our ability, or that of a future partner, to obtain regulatory approval for our product candidates and, if approved, to successfully commercialize them in the U.S. and/or elsewhere; our ability to obtain stockholder approval of the issuance of milestone-related shares in connection with our acquisition of SynthRx, Inc. on a timely basis, or at all; our ability to obtain stockholder approval to complete any other product pipeline expansion transaction, if necessary, on a timely basis, or at all; the potential that we may enter into a merger or other business combination whereby the stockholders who own the majority of our voting securities prior to the transaction own less than a majority after the transaction; our ability to obtain additional funding on a timely basis or on acceptable terms, or at all; the potential that we may enter into one or more commercial partnerships or other strategic transactions relating to Exelbine and/or ANX-514, and the terms of any such transactions; the extent to which we rebuild our workforce and our ability to attract and retain qualified personnel and manage growth; our ability to develop sales, marketing and distribution capabilities to launch Exelbine, should we obtain regulatory approval to market it, and any other current or future product candidate, should we obtain regulatory approval to market any of them and determine to commercialize any of them without a partner; delays in the commencement or completion of nonclinical testing, bioequivalence or clinical trials of or manufacturing, regulatory or launch activities related to our product candidates; the success of future bioequivalence or clinical trials; whether any of our product candidates for which we receive regulatory approval, if any, achieve broad market acceptance; competition in the marketplace for our products, if any are approved; our ability to maintain our relationships with the single source manufacturers and suppliers for certain of our product candidates and their component materials and the ability of such manufacturers and suppliers to successfully and consistently manufacture and supply, as applicable, our products and their component materials on a commercial scale, if we receive regulatory approval to commercialize our product candidates; the satisfactory performance of third parties on whom we rely significantly to conduct our nonclinical testing and bioequivalence and clinical studies and other aspects of our development programs; undesirable side effects that our product candidates may cause; 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 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.

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PART I

Item 1. Business.

Overview

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing proprietary product candidates. We have not yet marketed or sold any products or generated any significant revenue.

Our lead product candidates, Exelbine (vinorelbine injectable emulsion), or ANX-530, and ANX-514 (docetaxel emulsion for injection), are novel emulsion formulations of currently marketed chemotherapy drugs. We believe Exelbine and ANX-514 may improve the safety of the currently marketed reference products, Navelbine® (vinorelbine tartrate) Injection and Taxotere® (docetaxel) Injection Concentrate, respectively.

In November 2010, we submitted a new drug application, or NDA, for Exelbine to the U.S. Food and Drug Administration, or FDA, and in January 2011, we announced that the FDA accepted the Exelbine NDA for filing and established a Prescription Drug User Fee Act, or PDUFA, goal date of September 1, 2011 to finish its review of the Exelbine NDA.

In February 2011, we met with the FDA to discuss ANX-514 and the data package we presented to FDA to support approval of ANX-514 based on data from our bioequivalence study of ANX-514. The FDA indicated that a randomized safety study comparing ANX-514 and Taxotere would be required to support approval of ANX-514. The study would be primarily descriptive but with a sample size sufficient to demonstrate a comparable safety profile. The FDA recommended that the study also collect data on response rate and duration of response. We are developing a study protocol for submission to the FDA and intend to continue discussions with the FDA regarding the phase 3 clinical study and other requirements for approval of ANX-514.

In 2010, we additionally began to focus on expanding our product pipeline through one or more in-license, asset acquisition or merger transactions. In August 2010, we announced that we engaged the investment banking firm Canaccord Genuity Inc. to advise us in connection with expanding our product pipeline and that our board of directors formed a special committee to assist the board in evaluating potential opportunities in this regard. The special committee, the members of which are Drs. Michael Goldberg, Odysseas Kostas (chair) and Eric Rowinsky, met regularly during the year with management and Canaccord Genuity to identify and evaluate opportunities and determine whether to recommend them to the full board of directors.

Pending Acquisition of SynthRx, Inc.

In February 2011, we entered into an agreement and plan of merger to acquire SynthRx, Inc., a privately-held company developing a purified form of a rheologic and antithrombotic agent, poloxamer 188, or 188, in exchange for shares of our common stock. We expect to consummate the acquisition of SynthRx in the first half of 2011. 188 is a nonionic block copolymer surfactant that adheres to hydrophobic surfaces that develop when cells are damaged. It has been shown to restore hydration lattices and minimize the cascade of adhesive, inflammatory and coagulation responses that cause adhesion of cells, impaired blood flow and tissue ischemia. Improving blood flow in the microvasculature may benefit patients with sickle cell disease in acute crisis, which is associated with microvascular occlusion. As discussed in more detail below, we initially intend to develop purified 188 for the treatment of sickle cell crisis in a pediatric population and, if our acquisition of SynthRx closes and we are able to reach agreement with the FDA on a study protocol on a timely basis, we may initiate a phase 3 clinical trial of purified 188 for that indication in 2012.

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Business Strategy

Our goal is to be a successful specialty pharmaceutical company focused on acquiring, developing and commercializing proprietary product candidates. Currently, we are focused primarily on oncology and, assuming our acquisition of SynthRx closes, disorders and conditions resulting from microvascular-flow abnormalities. However, we may pursue other therapeutic areas. Our near-term goals include consummating our acquisition of SynthRx, preparing for the commercial launch of Exelbine and reaching agreement with the FDA regarding phase 3 clinical study protocols for ANX-514 and purified 188, should the SynthRx acquisition close, and initiating the phase 3 studies. Specifically, with respect to our business strategy, we intend to:

Acquire SynthRx and pursue development of purified 188. We expect to consummate our acquisition of SynthRx in the first half of 2011. We initially intend to develop SynthRx s lead product candidate, purified 188, for the treatment of sickle cell crisis in a pediatric population. If we consummate our acquisition of SynthRx and we are able to reach agreement with the FDA on a study protocol on a timely basis, we may initiate a phase 3 clinical trial of purified 188 for that indication in 2012.

Seek regulatory approval for Exelbine in the U.S. In November 2010, we submitted an NDA for Exelbine to the FDA, and in January 2011, we announced that the FDA accepted the Exelbine NDA for filing and established a PDUFA goal date of September 1, 2011 to finish its review of the Exelbine NDA. We plan to work with the FDA to the extent possible to move Exelbine toward approval.

Reach agreement with FDA regarding a phase 3 safety study for ANX-514. Based on our February 2011 meeting with the FDA to discuss ANX-514, we believe a single, additional, randomized, phase 3 safety study could support FDA approval of ANX-514. We are developing a study protocol for submission to the FDA and intend to continue discussions with the FDA regarding requirements for regulatory approval of ANX-514.

Establish sales and marketing capabilities in the U.S. The oncology marketplace in general, and the anticipated target audience for Exelbine in particular, is concentrated. We believe a meaningful portion of the potential U.S. market for Exelbine can be accessed through an experienced sales force that targets key constituents of the treatment/product-selection decision-making process. In addition, we will evaluate opportunities to leverage an existing sales force by adding complementary products with a similar target audience. We have undertaken and expect to continue to undertake activities to prepare for the commercial launch of Exelbine, including developing and/or acquiring certain internal sales, distribution and marketing and associated regulatory compliance capabilities and contracting with third parties to supplement and enhance our internal capabilities. However, we remain receptive to partnering Exelbine in the U.S. if presented with terms that we believe would increase its value for our stockholders.

Acquire, develop and commercialize additional product candidates, products and/or capabilities. We continue to evaluate opportunities to expand our product pipeline and believe that, due to a challenging capital raising environment, many drug development programs with substantial potential are available at attractive valuations. We may also seek to acquire currently-marketed products that could complement our portfolio and provide a sales and marketing platform for our existing or future product candidates.

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

Opportunities in Cancer Therapy

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

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Exelbine and ANX-514 are designed to improve treatments for cancer patients. Treatment selection for cancer patients depends on the histology, stage and progression of the disease, along with the number and types of prior therapies, if any. Treatment options include surgery, radiation, chemotherapy, hormone therapy and immunotherapy, both alone and in combination with each other. Treatment of cancer with chemicals is referred to as chemotherapy.

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

Our Novel Emulsion Formulations

Background and Opportunity

Reformulating existing pharmaceutical products is an increasingly common product lifecycle-management strategy. Finding new markets for and ways to modify and enhance existing products is often an essential element of pharmaceutical companies efforts to innovate and improve treatment outcomes in the context of patent expirations and competitive pressures.

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

Commercialization

Currently, we intend to build a commercial capability in the U.S. focused on Exelbine, as well as other products that we may develop or acquire. We believe we can achieve our strategic goals through a targeted approach that combines contracting with oncology group purchasing organizations, or GPOs, to help create awareness of our products and deploying a specialized, experienced sales force to call on physicians and nurses at community oncology practices and other organizations with defined characteristics, such as high vinorelbine use.

In preparing for the potential commercial launch of Exelbine, we expect to develop or acquire certain internal marketing, distribution and sales capabilities and associated regulatory compliance capabilities, as well as contract with third parties to supplement and enhance our internal capabilities.

HCPCS Product Codes and Reimbursement

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

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

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

drug and its generic equivalents) until price equilibrium is reached. Most private payors use similar methods for determining reimbursement rates, sometimes based on average wholesale prices or CMS published average sales price.

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A key component to our commercial strategy in the U.S. for Exelbine is to obtain a unique HCPCS product code that is distinct from the HCPCS product code for Navelbine and its generic equivalents. If our products are provided unique HCPCS product codes, they will be reimbursed based on their own sales prices, without including sales prices of the applicable reference product or its generic competition. We believe this will allow for appropriate pricing for our products relative to competitive products.

Exelbine (vinorelbine injectable emulsion)

Background; Limitations of Current Vinorelbine Formulations

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. Generic equivalents of Navelbine have been available in the U.S. since February 2003.

Navelbine and its generic equivalents are vesicants and often associated with injection site reactions, including phlebitis, erythema and pain at the site of injection. As reported in the Navelbine label, injection site reactions occurred in approximately one-third of 365 patients treated in three clinical studies with Navelbine as a single agent, with 5% of these reactions categorized as severe.

Exelbine was designed to be a bioequivalent formulation of Navelbine that may reduce the incidence and severity of injection site reactions to Navelbine. Our formulation emulsifies vinorelbine into a homogeneous suspension of nanoparticles that is designed to reduce the interaction between vinorelbine and the venous endothelium during administration into a peripheral vein, thereby reducing irritation associated with administration of the drug.

Exelbine New Drug Application

We submitted our Exelbine NDA under Section 505(b)(2) of U.S. Federal Food, Drug and Cosmetic Act, or FDCA, which pathway is discussed below under Government Regulations Section 505(b)(2) New Drug Applications. As such, in seeking approval of Exelbine, we are relying in part on the FDA s findings of safety and effectiveness with respect to Navelbine. We are seeking approval of Exelbine for the same indications as Navelbine. Our November 2010 Exelbine NDA included data from one clinical bioequivalence study designed to assess the pharmacokinetic equivalence of Exelbine and Navelbine, the reference drug for Exelbine, as well as 12 months of site-specific stability data from our intended commercial manufacturer to support expiration dating, which fulfilled a request communicated to us by the FDA following our prior submission of the Exelbine NDA in December 2009. In its refusal-to-file letter relating to our December 2009 Exelbine NDA submission, the FDA identified only this one chemistry, manufacturing and controls, or CMC, reason for the refusal to file.

Our decision to continue to develop Exelbine was based in part on positive results from the bioequivalence study we conducted, which was an open-label, single-dose, cross-over comparison of Exelbine and Navelbine. The FDA had indicated to us that data from such a study of approximately 28 patients that demonstrated the bioequivalence of Exelbine to Navelbine would be sufficient to support an NDA. Pharmacokinetic equivalence, the primary endpoint of our bioequivalence study, was observed between Exelbine and Navelbine. Based on federal regulations and FDA guidance regarding bioequivalence studies, pharmacokinetic equivalence was demonstrated by a statistical comparison of both the areas under the curve (AUC) and maximum plasma concentrations (Cmax). In addition, in post hoc analyses, relative to Navelbine, Exelbine demonstrated a statistically significant reduction in injection site reactions. Notably, in our study, the incidence of injection site reactions attributed to Navelbine was consistent with its product label.

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If approved, the drug prescribing information, or label, for Exelbine generally will be the same as for Navelbine, but may reflect differences between Exelbine and Navelbine or data generated during our bioequivalence trial, including comparative adverse event information. Ultimately, because the label for Exelbine, if approved, will be based on discussions with the FDA, we cannot predict with accuracy its final label. After we obtain marketing approval, we may conduct clinical studies while marketing Exelbine to expand its label in ways that might increase its use. If any clinical study we conduct, in addition to our bioequivalence study, is essential to the FDA s approval of an application to use Exelbine to treat a new indication, or to support a label change in product use, Exelbine may be eligible for three years of marketing exclusivity for that indication or use. Marketing exclusivity means that the FDA will not approve an abbreviated NDA, or ANDA (an ANDA is for a generic drug product), or an NDA submitted under Section 505(b)(2) of the FDCA during the exclusivity period based on the conditions of approval of our product.

Market and Opportunity

Based on data from IMS Health, total vinorelbine sold in the U.S. in 2009 was approximately 9.4 million milligrams. We estimate that the current average sales price for generic, or multi-source, vinorelbine in the U.S. is between $1.40 and $1.50 per milligram. The dollar value of the U.S. vinorelbine market has varied since 2003, when generic equivalents first became available in the U.S., in part due to competition among manufacturers of Navelbine and its generic equivalents. For instance, in September 2009, a new manufacturer of generic Navelbine entered the U.S. market. According to industry data, the price for this new entrant s product was lower than alternatives, which induced a lower average sales price for all products sharing the same HCPCS product code. To remain price-competitive and, because practitioners are reimbursed by CMS based on a percentage of average sales price, to prevent practitioners from being reimbursed at a level that is less than the acquisition cost of their product, other manufacturers may further reduce the prices for their products. As a result, each new entrant s pricing strategy may erode the total dollar value of the entire U.S. vinorelbine market.

As more fully described above under HCPCS Product Codes and Reimbursement, if Exelbine is granted a HCPCS product code that is distinct from the HCPCS product code for Navelbine and its generic equivalents, Exelbine would not be impacted directly by pricing competition in the way that products sharing the same HCPCS product code may be impacted. This should provide us the flexibility to establish an appropriate price for Exelbine and one that is different than the prices of multi-source vinorelbine. While we have not determined a price for Exelbine if it were approved by the FDA, we expect decision makers to value its unique formulation as compared to Navelbine and its generic equivalents, and we anticipate pricing Exelbine in the U.S. between $5 and $10 per milligram. If Exelbine is approved, granted a unique HCPCS product code and priced at a premium to multi-source vinorelbine, the potential dollar value of the U.S. Exelbine market likely will be greater than the dollar value of the existing U.S. vinorelbine market, assuming the same volume of vinorelbine demand.

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

FDA Acceptance of Brand Name Exelbine

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

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ANX-514 (docetaxel emulsion for injection)

Background; Limitations of Taxotere

ANX-514 is a novel emulsion formulation of the chemotherapy drug, docetaxel. Taxotere, a branded formulation of docetaxel, is approved to treat breast, non-small cell lung, prostate, gastric and head and neck cancers. Based on data from IMS Health, sales of Taxotere in 2010 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. However, in the U.S., patents covering docetaxel expired in 2010 and generic equivalents of Taxotere are expected to enter the market in 2011.

Despite its demonstrated efficacy and commercial success, the Taxotere formulation has limitations; principally, toxicity associated with its excipient, polysorbate 80. 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.

Taxotere is associated with acute hypersensitivity reactions, ranging widely in incidence and severity. Taxotere also is associated with fluid retention. Many patients suffer severe (in rare cases, fatal) hypersensitivity reactions immediately following Taxotere administration. The occurrence of hypersensitivity reactions has been 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, 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. 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 due to the presence of polysorbate 80 in the Taxotere formulation. The recommended 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, we believe that ANX-514 may also have handling and administration advantages for healthcare practitioners and patients. For example, Taxotere s label indicates foaming may occur when mixing Taxotere and the accompanying diluents due to the presence of polysorbate 80. Our market research suggests foaming is frequent, which can cause delays in administering the drug or disruption during administration if too much foam is present during administration. Polysorbate 80 also is incompatible with plasticized polyvinyl chloride, or PVC, which is used in making the IV bags and tubing commonly used to infuse chemotherapy drugs. Polysorbate 80 can leach diethylhexyl phthalate, a potentially hepatotoxic and carcinogenic acid, from plasticized PVC bags and tubing, resulting in the addition of diethylhexyl phthalate into the infusion solution. Taxotere s label warns against contact between Taxotere and plasticized PVC equipment. As a result, healthcare providers must have available and remember to use more costly non-PVC supplies to prepare and administer Taxotere, the costs of which generally are not separately reimbursed.

Potential Benefits of ANX-514

ANX-514 is a novel formulation of docetaxel that has the potential to improve outcomes for cancer patients. 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. However, the absence of polysorbate 80 and ethanol in the ANX-514 formulation has the potential

to improve the safety profile of ANX-514 relative to Taxotere and other formulations of docetaxel that use detergents as solubilizing agents or that contain alcohol.

A detergent-free docetaxel formulation may provide benefits to cancer patients. ANX-514 may reduce the incidence and severity of hypersensitivity reactions and delay the onset of fluid retention. ANX-514 also may minimize other adverse reactions to polysorbate 80, such as neurotoxicity.

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In addition, high-dose dexamethasone premedication intended to address polysorbate 80-mediated hypersensitivity reactions and fluid retention may be unnecessary with detergent-free ANX-514. Avoiding high-dose premedication could benefit diabetics and pre-diabetics (those with impaired fasting glucose). 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 for antiemsis, while those in a docetaxel arm received the recommended 24 mg cumulative dose. 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.

Nonclinical Efficacy and Safety

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

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

Planned Phase 3 Clinical Study

As with Exelbine, we expect to seek approval of ANX-514 under Section 505(b)(2) of the FDCA. Initially, we intended to demonstrate the bioequivalence of ANX-514 to Taxotere in a single bioequivalence study, which we refer to as Study 514-01, and which we completed in 2009. In May 2009, we announced that pharmacokinetic equivalence, the primary endpoint of Study 514-01, was not demonstrated based on the FDA s benchmark standards. The study data revealed higher average 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, average total docetaxel blood-levels were comparable and remained so through the end of the observation period. Interestingly, the data also revealed lower average blood-levels of unbound, or free, docetaxel in patients receiving ANX-514 relative to those receiving Taxotere.

Following extensive analysis and modeling of the data from Study 514-01 and published results from other trials using Taxotere, we believe that comparable clinical outcomes can be expected following treatment with ANX-514 or Taxotere, despite Study 514-01 not demonstrating pharmacokinetic equivalence using FDA s benchmark standards.

In February 2011, we met with the FDA to discuss ANX-514 and the data package we presented to FDA to support approval of ANX-514. Because the Cmax for total docetaxel was higher following administration with ANX-514 in Study 514-01, the FDA indicated that a randomized safety study comparing ANX-514 and Taxotere would be required in an appropriate patient population to support approval of ANX-514. The study would be primarily descriptive but with a sample size sufficient to demonstrate a comparable safety profile. The FDA recommended that the study also collect data on response rate and duration of response. We are developing a study protocol for submission to the FDA and intend to continue discussions with the FDA regarding the phase 3 clinical study and other requirements for approval of ANX-514.

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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.

Potential New Opportunity Purified Poloxamer 188

Background

Poloxamer 188, or 188, is a nonionic block copolymer surfactant that has been used in foods, drugs and cosmetics since the 1950s. In the 1980s, extensive research on the mechanisms and potential clinical applications of 188 was conducted. Research has demonstrated that 188 adheres 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 188 prevents adhesion and aggregation of soluble fibrin and formed elements in the blood, maintains the deformability of red blood cells, non-adhesiveness of unactiviated platelets and granulocytes and the normal viscosity of blood. In addition, it is believed that 188 is not metabolized, but is excreted unchanged in the urine with a half-life of approximately two hours. Likewise, it is believed that 188 is not absorbed following oral administration, but is recovered unchanged in the stool.

We believe that 188 has numerous potential applications as a cytoprotective, rheologic, antithrombotic and anti-inflammatory agent. 188 has been evaluated in the clinic to treat acute myocardial infarction, sickle cell disease and malaria, including a 2,950-patient, randomized, controlled study in acute myocardial infarction. The effectiveness of 188 also has been observed in studies investigating its application in 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.

Purified 188 is designed to eliminate impurities present in, and associated renal toxicity that was observed in certain prior clinical investigations of, (non-purified) 188. Purified 188 has been evaluated in multiple clinical studies, including a 255-patient, phase 3 study, in which elevated levels of renal toxicity were not observed.

Sickle Cell: Clinical History; Planned Phase 3 Clinical Study

The safety and efficacy of 188 and purified 188 in sickle cell disease have been evaluated in multiple clinical studies, including a 255-patient, randomized, double-blind, placebo-controlled phase 3 study in patients with sickle cell disease in acute vaso-occlusive crisis.

In the phase 3 study, signs of efficacy were observed in the primary endpoint, duration of crisis. However, 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. It was determined that renal function was not influenced by treatment with purified 188. However, the purified 188 arm did exhibit a modest but statistically significant increase in levels of alanine aminotransferase and direct bilirubin, each of which returned to its respective baseline level by the day-35 follow-up visit.

We believe that a properly designed and executed clinical study will demonstrate that purified 188 is an effective treatment for sickle cell crisis. Assuming our acquisition of SynthRx closes, we intend to develop purified 188 for the

treatment of sickle cell crisis in a pediatric population and plan to meet with the FDA to reach agreement on a phase 3 clinical trial protocol.

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Sickle Cell: Market and Opportunity

Vaso-occlusive crisis, caused by sickle-shaped red blood cells that obstruct capillaries and restrict blood flow to an organ, causes pain that is often very severe and results in ischemia (restriction of blood supply), necrosis, and often organ damage. The frequency, severity and duration of these crises can vary considerably. Once vaso-occlusive crisis occurs, treatment consists of maintenance of hydration, oxygenation and analgesia, usually using narcotics. Preventative measures for pulmonary complications, such as incentive spirometry, and blood transfusion also may be used. We are not aware of any currently available agents with demonstrated efficacy in shortening the duration of vaso-occlusive crisis. Patients with sickle cell disease experience an average life expectancy of approximately 40 years.

More than $1.0 billion is spent annually in the U.S. to treat patients with sickle cell disease. We estimate that, in the U.S., sickle cell disease results in over 95,000 hospitalizations and 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 of untreated crisis events is difficult to measure, we estimate that it is substantial and in the hundreds of thousands in the U.S. each year. We believe that, if purified 188 is approved, as people with sickle cell disease are made aware of the new therapy, more people who suffer from vaso-occlusive crisis will seek treatment.

Competition

If regulatory authorities approve the marketing and selling of any of our product candidates, our product candidates will face significant and long-term competition from pharmaceutical companies, pharmaceutical divisions of companies and biotechnology, biopharmaceutical and specialty pharmaceutical companies, among others. This competition likely will become more intense if any of our products or competitor products 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 we do. Many of these companies have commercial arrangements with other companies to supplement their internal capabilities.

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

Exelbine and ANX-514

Exelbine and ANX-514, if approved, may compete against Navelbine and Taxotere, respectively, as well as their generic equivalents and other formulations of vinorelbine and docetaxel that may be approved by the FDA. In addition to Navelbine, in the U.S., currently there are seven commercially available generic versions of vinorelbine. With respect to docetaxel, in the U.S., we believe non-Taxotere formulations of docetaxel will be commercially available in 2011 and that generic equivalents of Taxotere will be commercially available in the near-term, possibly in 2011. However, we are not aware of any docetaxel formulation with near-market potential that is polysorbate 80-free.

Because we have submitted our Exelbine NDA with only bioequivalence data, the ability to differentiate it from competing products will be limited. Even if we believe Exelbine demonstrates clinical, pharmacoeconomic or other benefits relative to competing products, we may be unable to market or promote it based on these benefits. 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 marketed drugs. In particular, the taxanes, the class of drugs of which Taxotere is a member, have experienced substantial commercial success, in part as a result of their effectiveness in treating a wide variety of cancers. This commercial success has generated significant interest in reformulating Taxotere and other taxanes. 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.

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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 might also be applied to vinorelbine. Relative to our formulations, formulations based on one or more of these other methods may result in greater efficacy or safety, provide better drug delivery to tumor sites or otherwise improve benefits to patients and healthcare providers. For instance, there is an oral formulation of vinorelbine approved for use in the EU against which Exelbine would compete if it were approved for use in the EU.

Purified 188 for Sickle Cell Crisis

Currently, most treatment options for sickle cell crisis are focused on symptomatic relief or treatment to address complications, such as morphine or other analgesics for pain. However, there is substantial interest in developing agents for the treatment of sickle cell crisis. In addition to for-profit commercial enterprises, numerous foundations and interest groups also are committed to treating sickle cell disease and preventing and mitigating acute crisis associated with sickle cell disease. 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, purified 188 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, has been shown to decrease the severity of sickle cell disease by reducing the frequency of crisis, but hydroxyurea does not treat the crisis itself. Blood transfusions, which carry risk of allergic reactions and iron overload, also are used to treat sickle cell disease. 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 expensive, require a well-matched donor and come with risk of serious complications including bleeding, pneumonia, and severe infection.

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 recently 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.

Manufacturing

We do not have our own manufacturing facilities. We meet our nonclinical and clinical trial manufacturing requirements (including manufacturing active pharmaceutical ingredient, or API, formulating and assembling final drug product, labeling, testing and release, packaging, storing API and finished drug product and similar activities) by establishing relationships with third-party manufacturers and other service providers to perform these services for us.

In the past, with respect to Exelbine and ANX-514, we relied on individual proposals and purchase orders to meet our needs and typically relied on terms and conditions proposed by the third party or us to govern our rights and obligations under each order (including provisions with respect to intellectual property, if any). In 2008, we entered into a master services agreement with a new contract manufacturer, as well as individual work orders that are governed by the master services agreement, under which the manufacturer provided process development and scale-up activities for Exelbine. We do not have any long-term agreements or commitments for these services. Likewise, we do not have any long-term agreements or commitments with vendors to supply the underlying component materials of Exelbine, some of which are available from only a single supplier. We are in the process of entering into supply arrangements with third parties in connection with the potential commercialization of Exelbine. We also are in the process of evaluating vendors with respect to manufacturing ANX-514.

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Purified 188 is manufactured by applying a proprietary, super-critical fluid extraction (SCFE) process to commercial grade 188, which is available from several manufacturers. We believe multiple vendors have the capability to manufacture both purified 188 drug substance pursuant to this SCFE process and the final, finished drug product. However, prior to manufacturing additional purified 188, including for clinical use, we expect to evaluate critical operating parameters and ranges and, ultimately, to re-validate the SCFE process with the anticipated manufacturers.

As noted above with respect to Exelbine, should any of our product candidates obtain marketing approval, relationships with third-party manufacturers and other service providers in connection with the commercial production of our products would need to be established. There is some flexibility in securing other manufacturers to produce our product candidates; however, our alternatives may be limited due to proprietary technologies or methods used in the manufacture of some of our product candidates. In addition, if we seek to make certain changes to an approved product, such as changing vendors who supply the underlying component materials of our product candidates, we will need FDA review and approval before the change can be implemented. For example, if we change the manufacturer of a product or of the API component of a product, the FDA may require stability or other data from the new manufacturer, which data will take time and is costly to generate, and the delay associated with generating this data may cause interruptions in our ability to meet commercial demand, if any.

Intellectual Property

Exelbine (vinorelbine injectable emulsion)

We own world-wide rights (excluding China, Hong Kong, Macau and Taiwan) to patent applications covering the composition and use of our vinorelbine injectable emulsion product candidate, subject to the exclusive license we granted to Latitude Pharmaceuticals (described below under Licensing Agreement). In January 2011, the United States Patent and Trademark Office, or USPTO, issued patent claims directed to formulations of vinorelbine bitartrate that provide protection for Exelbine. U.S. Patent No. 7,871,632, entitled Compositions for Delivering Highly Water Soluble Drugs, will provide coverage for Exelbine until November 2027. In addition, in December 2010, we filed a continuation application of U.S. Patent No. 7,871,632 in the USPTO claiming a priority date of July 12, 2004 drawn to methods of treatment. With respect to patent protection outside the U.S., patents entitled Compositions for Delivering Highly Water Soluble Drugs have issued in Japan and Russia 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.

ANX-514 (docetaxel emulsion for injection)

We own world-wide rights (excluding China, Hong Kong, Macau and Taiwan) to patent applications covering the composition and use of our docetaxel injectable emulsion product candidate, subject to the exclusive licenses we have granted to Latitude Pharmaceuticals (described below under Licensing Agreements) and Shin Poong Pharmaceutical Co., Ltd. (described above under 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, New Zealand, 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.

Purified 188 for Sickle Cell Crisis

Assuming our acquisition of SynthRx closes, pursuant to an agreement with CytRx Corporation (described below under Licensing Agreements), we will acquire exclusive rights to a variety of issued patents related to poloxamers and their uses. The issued patents cover, among other things, 188, purified 188, methods of treating sickle cell anemia using 188 and methods of preparing purified 188. However, we expect many of the patents covering purified 188 for the treatment of sickle cell crisis will expire prior to regulatory approval of purified 188 for that indication.

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We believe the primary method of exclusivity for purified 188 for the treatment of sickle cell crisis will be the orphan drug designation that the FDA has granted for 188. Accordingly, as described below under Government Regulations, if our product candidate receives the first FDA approval for sickle cell crisis, the FDA may not approve any other application to market 188 for sickle cell crisis for a period of seven years, except in limited circumstances, such as another product showing clinical superiority to 188. However, orphan drug designation does not 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. In addition, if we and the FDA reach agreement that the planned phase 3 study in a pediatric population will satisfy the requirements for pediatric exclusivity, upon FDA approval, we may be granted an additional six months of marketing exclusivity.

Assuming our acquisition of SynthRx closes, we also will acquire ownership of certain patent applications related to 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.

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 Navelbine® and Taxotere®, are the property of their respective owners. Use or display by us of other parties trademarks, service marks, trade names, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark, trade name, trade dress or product owners.

Research and Development

Our research and development expenses were $3.7 million in 2010 and $6.5 million in 2009. Our research and development expenses consist primarily of costs associated with nonclinical activities, such as research-related manufacturing, nonclinical research studies, quality assurance and regulatory activities, salaries and related employee benefits, and costs associated with bioequivalence and clinical trials managed by contract research organizations, or CROs. In 2010, our most significant costs were for consulting services related to the November 2010 Exelbine NDA, stability testing for Exelbine and consulting services related to evaluation of the data from Study 514-01 and research-related manufacturing for ANX-514. In 2009, our most significant costs were for manufacturing, analytical and stability testing for Exelbine and consulting services related to the December 2009 Exelbine NDA. Our research-related manufacturing expenses include purchasing API, manufacturing materials for bioequivalence and clinical trials and stability testing to support regulatory filings, related labeling, testing and release, packaging and storing and related consulting fees. Our bioequivalence and clinical trial expenses include payments to vendors such as CROs, investigators, clinical suppliers and related consulting fees.

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Licensing Agreements

SD Pharmaceuticals

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

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

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

CytRx Corporation

Assuming our acquisition of SynthRx closes, we will acquire a 2004 license agreement between CytRx Corporation and SynthRx. Under the agreement, as amended, CytRx granted to SynthRx an exclusive license, with the right to grant sublicenses, under specified patents to use, offer and sell licensed 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 purified 188 for the treatment of sickle cell crisis.

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 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 due as a royalty on net sales. In addition, SynthRx would pay a single-digit royalty on net sales of licensed 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.

Material Terms of the Pending Acquisition of SynthRx

Under the terms of our merger agreement with SynthRx, in connection with consummation of the merger we would issue 2,938,773 shares of our common stock to SynthRx s stakeholders, of which 200,000 shares would be placed in escrow for 12 months following the closing of the merger to indemnify us against breaches of SynthRx s representations and warranties, and 1,938,773 shares would be subject to repurchase rights by us pending achievement of the first development milestone described below. We would issue up to an aggregate of 13,478,050 additional shares of our common stock to SynthRx s stakeholders if the development of purified 188 achieves certain milestones, as described below, and our stockholders approve the issuance of such milestone-related shares, as required by NYSE Amex rules. If our stockholders do not approve the issuance of the milestone-related shares, under the terms of the merger agreement, we would be required to pay SynthRx s stakeholders in cash the value of the milestone-related shares we would have otherwise issued, with all such cash payments made in quarterly installments and, with respect to the cash value associated with 12,478,050 of the milestone-related shares, payable based on net sales of purified 188. We cannot determine with any degree of certainty the amount of our potential cash payments to SynthRx s stakeholders because the amount of such payments, if applicable, will depend on the 10-day volume weighted average of the closing price of our common stock at the time a milestone is achieved and the market price of our common stock historically has been, and likely will continue to be, highly volatile. 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 new drug application covering the use of purified 188 for the treatment of sickle cell crisis in children, or the 188 NDA, which we refer to as the First Milestone; 3,839,400 shares would be issuable upon acceptance for review of the 188 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 188 NDA, which we refer to as the Third Milestone.

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Under the terms of the merger agreement, we have agreed to use commercially reasonable efforts (a) to request a meeting with the FDA to occur within nine months of the closing of the merger for the purpose of discussing clinical development and regulatory approval of an intravenous injection product in which a purified form of 188 is an active ingredient and (b) during the one-year period following the closing of the merger, to conduct certain activities related to the development of purified 188; provided that the aggregate cost of such activities does not exceed $1.5 million. We have also agreed to use commercially reasonable efforts to develop an intravenous injection product in which a purified form of 188 is an active ingredient until the earlier of achievement of the Third Milestone or the date that is four years after February 12, 2011. In addition, we have agreed not to consummate a change of control with a third party that involves all or substantially all of SynthRx s assets until the earlier of the achievement of the Third Milestone and the date that is four years following February 12, 2011, except (x) in connection with an Exempt Transaction (as described below) or (y) 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 the 188 NDA to the FDA 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 (i) the date that, beginning at the effective time of the merger 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 $15,000,000 and (ii) the fourth anniversary of the effective time of the merger; provided, however, such acquiror shall be relieved of such obligations under certain specified conditions.

In connection with our execution of the merger agreement, each of SynthRx s stockholders entered into a voting and transfer restriction agreement with us, the term of which will commence at the effective time of the merger. Under the voting and transfer restriction agreement, each SynthRx stockholder has agreed to vote all shares of our common stock 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. 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 SynthRx stockholder will be permitted to vote any shares of our common stock beneficially owned by that stockholder 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. In addition, pursuant to the voting and transfer restriction agreement, SynthRx stockholders may not transfer any shares of our common stock that are subject to vesting or that are held in escrow. We refer to shares of our common stock issued to SynthRx stockholders that have vested and/or been released from escrow as Transferable Shares. Transferable Shares may be transferred by their holder to an affiliate of such holder in accordance with applicable securities laws, provided that any such transferee becomes a party to the voting and transfer restriction agreement. The voting and transfer restriction agreement also provides that SynthRx s stockholders, as a group, will have the right to transfer Transferable Shares to non-affiliates pursuant to an effective resale registration statement, which we agreed to file within 120 days of the effective time of the merger, or in compliance with Rule 144 of the Securities Act of 1933, (a) 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 (b) 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.

Prior Cost-Containment and Fundraising Activities

In the past, we spent significant resources on the development of ANX-510, or CoFactor®, including a 300-patient phase 2b clinical trial and a discontinued phase 3 clinical trial. Following our October 2007 announcement that CoFactor did not meet the primary endpoint in the phase 2b clinical trial, in October 2008, we discontinued active work on our CoFactor program. In June 2010, we granted an exclusive worldwide license for CoFactor to Theragence, Inc., which includes 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.

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Beginning in October 2008 and through June 2009, we implemented numerous restructuring, cost-cutting and re-prioritization initiatives to reduce operating costs and to focus on those of our options that we believed maximized the overall value of our company. For instance, in October 2008, in addition to the discontinuation of our CoFactor program, we discontinued active work on all compounds to which we have or had rights and on which we may have previously spent resources developing, other than Exelbine and ANX-514. In addition, during that period, we suspended substantially all fundamental business operations and effected three reductions in our full-time employee workforce while we explored options for capital-raising and/or strategic transactions as well as liquidating our assets and winding-up our operations.

Since June 2009, we have completed seven registered direct financing transactions, raising an aggregate of approximately $56.7 million in net proceeds, after deducting our aggregate dividend and related payment obligations, the fees and expenses of our placement agent and financial advisor in those financings and our other estimated offering expenses. In addition, in December 2009 and January 2010, we raised an aggregate of approximately $3.3 million in net proceeds in connection with the exercise of warrants issued in connection with certain of these financings.

Government Regulations

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

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

FDA Approval Process

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

The process required by the FDA before a new drug may be marketed in the U.S. generally involves the following: (i) completion of nonclinical laboratory and animal testing in compliance with FDA regulations; (ii) submission of an investigational new drug application, or IND, which must become effective before human clinical trials may begin; (iii) performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and (iv) submission and approval of an NDA by the FDA. The sponsor typically conducts human clinical trials in three sequential phases, but the phases may overlap. In phase 1 clinical trials, the product is tested in a small number of patients or healthy volunteers, primarily for safety at one or more doses. In phase 2, in addition to safety, the sponsor evaluates the efficacy of the product on targeted indications, and identifies possible adverse effects and safety risks, in a patient population somewhat larger than in phase 1 clinical trials. Phase 3 clinical trials typically involve additional testing for safety and clinical efficacy in an expanded population at geographically-dispersed test sites. A clinical trial may combine the elements of more than one phase and, typically, two or more phase 3 studies are required. A company s designation of a clinical trial as being of a particular phase is not necessarily indicative that the trial 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 trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase.

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

Clinical trials must be conducted in accordance with the FDA s good clinical practices requirements. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at each clinical site and may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions. It is not possible to estimate with any certainty the time required to complete phase 1, 2 and 3 studies with respect to a given product candidate.

The applicant must submit to the FDA the results of the nonclinical studies and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, in the form of an NDA, including payment of a user fee, unless waived. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under PDUFA, the FDA ordinarily has 10 months in which to complete its initial review of the NDA and respond to the applicant. However, the PDUFA goal dates are not legal mandates and the FDA response often occurs several months beyond the original PDUFA goal date. 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 submission. 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. Data from clinical trials are not always conclusive and the FDA and/or any advisory committee it appoints may interpret data differently than we or any future partner of ours interprets data.

Following completion of the FDA s initial review of the NDA and the clinical and manufacturing procedures and facilities, the FDA will issue a complete response letter, which will either include an approval authorizing commercial marketing of the drug for certain indications or contain the conditions that must be met in order to secure final approval of the NDA. If the FDA s evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for new formulations of previously approved products, a company may file an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA s conclusions from prior review of such studies. The FDA may also require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2). We submitted our Exelbine NDA under Section 505(b)(2), and we expect to submit an NDA under Section 505(b)(2) for ANX-514.

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

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

Orphan Drug Designation

The Orphan Drug Act, or ODA, provides for granting special status, referred to as orphan drug designation, to a drug or biologic 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 drug designation must be requested by the sponsor before submitting its marketing application for that drug or biologic for an orphan indication. After the FDA grants orphan drug designation, the generic identity of the orphan drug or biologic and its potential use are disclosed publicly by the FDA. The first sponsor to receive FDA marketing approval for an orphan drug or biologic 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 or biologic that the FDA considers to be clinically superior to, or different from, another approved orphan drug or biologic, 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 a compound 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 orphan 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.

Fast Track Designation

Pursuant to the Food and Drug Administration Modernization Act of 1997, or the FDAMA, the FDA is required to facilitate the development and expedite review of drugs and biologics intended to treat a serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Under the fast track program, the sponsor of the product candidate may request that the FDA designate the candidate for a specific indication as a fast track drug concurrent with or after the filing of the IND for the product candidate. FDAMA requires the FDA to

determine within 60 days of receipt of the request whether the conditions for fast track designation have been met.

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Fast track designation typically results in greater access to FDA personnel for consultation throughout the development process and adds to existing FDA programs the possibility of a rolling submission for a marketing application, which means the FDA may initiate review of sections of a fast track drug s NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA s time period goal for reviewing an application as specified under PDUFA does not begin until the sponsor submits the complete application. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority Review

Under the FDA policies, a product candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the product candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast track designated drug or biologic candidate would ordinarily meet the FDA s criteria for priority review.

Pediatric Exclusivity

The Best Pharmaceuticals for Children Act, which was signed into law January 4, 2002 and reauthorized under the Food and Drug Administration Amendments Act of 2007, or the FDAAA, provides in some cases an additional six months of exclusivity for new or marketed drugs for specific pediatric studies conducted at the written request of the FDA. A sponsor may attempt to prompt a written request from the FDA by submitting a proposed pediatric study request describing the pediatric study or studies the sponsor proposes to conduct in return for pediatric exclusivity. The FDA may issue a written request in response to a proposed pediatric study request if it finds that the proposed study will provide information that may result in health benefits to children. The written request sent by FDA will outline the nature of the pediatric studies the drug sponsor must conduct to qualify for pediatric exclusivity and a time frame for completion of those studies.

The Pediatric Research Equity Act of 2003, or PREA, which was also reauthorized under the FDAAA, authorizes the FDA to require pediatric studies for drugs to ensure the drugs safety and efficacy in children. 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 PREA. For example, unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan drug designation has been granted.

Other Regulatory Requirements

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

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

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly 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.

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

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

Outside of the U.S., the ability to market our products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process includes all of the risks associated with the FDA approval described above. In addition, the requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, regulatory approval of prices is required in most countries other than the U.S. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or any collaborator of ours.

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Employees

As of March 1, 2011, we have four employees, three of whom are full-time. Our employees are not unionized and we believe that our relationship with our employees is good.

Following the cost-cutting and re-prioritization initiatives we began in October 2008, we have maintained a small, efficient organizational infrastructure, outsourcing substantially all of our product development and commercialization activities, including research-related manufacturing and regulatory affairs, and our general and administrative activities, such as finance, accounting, human resources, facilities, internal systems support, sales and marketing 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 commercial. In connection with preparing for the commercial launch of Exelbine, should it be approved by the FDA, and initiating clinical activities with respect to ANX-514, should we reach agreement with the FDA regarding a phase 3 clinical study, and purified 188, should we consummate our acquisition of SynthRx, we plan to increase our internal capabilities in the near-term.

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.

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Item 1A. Risk Factors.

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

RISKS RELATED TO OUR BUSINESS

Risks Related to Our Capital Requirements, Finances and Operations

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

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

The success of our business currently is dependent primarily on the success of Exelbine 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, Exelbine and ANX-514, for which we are pursuing regulatory approval. Although we have entered into an agreement to acquire SynthRx, Inc. and currently anticipate pursuing the development of purified 188 for the treatment of sickle cell crisis as another of our lead programs after the transaction closes, the transaction may not close. Accordingly, the success of our business currently depends primarily on our ability, ourselves or with a future partner of ours, to obtain regulatory approval for and successfully market and sell Exelbine and ANX-514, and our efforts in this regard may prove unsuccessful. In November 2010, we submitted an NDA to the FDA for Exelbine and, in January 2011, we announced that the FDA had accepted our NDA for filing and established a PDUFA goal date of September 1, 2011 to finish its review. Because the NDA has been accepted for filing, the FDA is conducting an in-depth review of the submission to determine whether to approve Exelbine for commercial marketing in the U.S. for the same indications as Navelbine. If the FDA is not satisfied with the information we have provided, the agency may refuse to approve our NDA or may require us to perform additional studies or provide other information in order to secure approval. The FDA may delay, limit or refuse to approve our NDA for many reasons, including those identified under the section titled Risks Related to Drug Development and Commercialization. The FDA may formally extend its review process by three months or longer if it determines it requires additional time to review additional information that it requests or that we elect to provide during the review process. If we are unable to timely respond to the FDA s requests for additional information, the approval of the Exelbine NDA may be delayed further. In addition, the FDA may fail to meet its review goals. Regulatory approval for Exelbine may not be obtained, and any failure or significant delay in obtaining the required approval could have a material adverse effect on our business and financial condition.

In addition, with respect to ANX-514, following our meeting with the FDA in February 2011, we announced that the FDA determined ANX-514 could not be approved based on the findings from our bioequivalence study of ANX-514, which we refer to as Study 514-01, because the Cmax for total docetaxel was higher in patients who received ANX-514 relative to those who received Taxotere in Study 514-01. The FDA indicated that a randomized safety study comparing ANX-514 and Taxotere would be required in an appropriate patient population to support approval of ANX-514. The FDA recommended that the study also collect data on response rate and duration of response. We are developing a study protocol for submission to the FDA and intend to continue discussions with the FDA regarding the phase 3 clinical study and other requirements for approval of ANX-514. The results of these discussions will determine in large part the timeline for and estimated cost of continued development of ANX-514. Currently, we plan to continue development of ANX-514, but the FDA s requirements for additional clinical and/or nonclinical activities to support approval of ANX-514 may increase estimated development time and expense to the point where we determine to discontinue work on ANX-514 based on our assessment of its commercial value. Even if we continue

development of ANX-514 following further discussions with the FDA, the FDA s requirements may negatively impact our ability to raise additional capital to develop and/or partner ANX-514.

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If any of our current or future product candidates, including purified 188 if our acquisition of SynthRx closes, is approved by the FDA or any foreign regulatory agency, our ability to generate revenues from these products will depend in substantial part on the extent to which they are accepted by the medical community and reimbursed by third-party payors and our ability to ensure that our third-party manufacturer or manufacturers produce sufficient quantities of the products to meet commercial demand, 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 $158.4 million as of December 31, 2010, and we expect to continue to incur substantial operating losses for the foreseeable future, even if we or a future partner of ours is successful in advancing our product candidates to market. We do not expect to generate cash flows from sales of our products unless and until our products are approved for marketing, the timing of which we cannot predict accurately.

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 any nonclinical testing or bioequivalence or clinical studies, process development, scale-up and other manufacturing and stability activities, or other work required to achieve such approval, as well as the timing of such activities and approval;
- the 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 scope, prioritization and number of development and/or commercialization programs we pursue and the rate of progress and costs with respect to such programs;
- the costs related to developing, acquiring and/or contracting for sales, marketing and distribution capabilities and regulatory compliance capabilities, most immediately with respect to Exelbine, if we commercialize any of our product candidates for which we obtain regulatory approval without a partner;
- the timing and terms of any collaborative, licensing and other strategic arrangements that we may establish;
- the extent to which we will need to rebuild our workforce, which currently consists of four employees, 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 as of December 31, 2010, which was approximately $28.0 million, together with the net proceeds from the equity financing we completed in January 2011, will be sufficient to fund our operations at their current levels for at least the next 12 months. However, we may determine to grow our organization and/or pursue development and/or commercialization activities for our current or future product candidates, including purified 188 should we consummate our acquisition of SynthRx, 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 acquire new technologies, product candidates and/or products and the cost to acquire, develop and/or commercialize such new technologies, product candidates and/or products may shorten the period through which our current operating funds will sustain us. We may seek additional funding through public or private sales of our equity securities, debt financings, collaborations, licensing arrangements or other strategic or partnering transactions. However, we may not be able to obtain sufficient additional funding on satisfactory terms, if at all. We believe global economic conditions, including the heightened volatility of U.S. and international equity markets and the recent credit crisis, may adversely impact our ability to raise additional capital.

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

If we consummate the SynthRx acquisition and if our stockholders fail to approve the issuance of the shares of our common stock issuable upon the achievement of milestones related to development and regulatory approval of purified 188, our future liquidity and cash position could be materially impaired, which could have an immediate negative effect on our stock price and require us to raise additional capital.

Under the terms of the merger agreement we entered into with SynthRx, if we consummate the acquisition of SynthRx, we would be required to issue up to an aggregate of 13,478,050 additional shares of our common stock upon the achievement of milestones related to the development and regulatory approval of purified 188 for the treatment of sickle cell crisis in children. Under NYSE Amex rules, our stockholders are required to approve the issuance of shares of common stock issuable by us as consideration in an acquisition if the potential number of such shares could result in an increase in our outstanding shares of 20% or more, which is the case with respect to the milestone-related shares issuable to SynthRx s stakeholders under our merger agreement. We expect to submit a proposal to our stockholders to approve the issuance of the milestone-related shares at our 2011 annual meeting of stockholders. If our stockholders do not approve the issuance of the milestone-related shares at the annual meeting or any special meeting we may call prior to December 31, 2011, under the terms of the merger agreement, we will be required to pay in cash the value of the milestone-related shares we would have otherwise issued. We cannot determine with any degree of certainty the amounts of these potential cash payments because the amounts of such payments, if any, will be based on the 10-day volume weighted average of the closing price of our common stock at the time a milestone is achieved and the market price of our common stock historically has been, and likely will continue to be, highly volatile.

Any obligation to satisfy the milestone-related merger consideration in cash rather than with shares of our common stock, or even the perception of such future obligations, likely would have a material and adverse effect on our cash position, ability to raise capital and stock price. Though recently we have experienced success raising capital, our financial resources are limited and large cash payments could materially impair or entirely deplete our future cash position, as well as any cash equivalents and short-term securities. In addition, cash used to satisfy milestone-related obligations would reduce our available resources to pursue our core business strategy, including our future development and commercialization activities.

Further, the potential for us to satisfy these obligations in cash may cause us to raise additional capital. It can be difficult to raise capital to finance payment or other debt obligations, or where the use of proceeds is for other than fundamental business activities, which may limit our future capital-raising ability, whether or not the intended purpose of the transaction is to satisfy these potential cash payment obligations. In addition, the expectation that we may or will be required to raise additional capital, including to satisfy these potential cash payment obligations, may have the effect of depressing the market price of our common stock for a substantial period of time, including as a result of anticipated dilution, resulting in further dilution than might otherwise be the case in the event we in fact are able to raise additional capital. Furthermore, if we have or are perceived to have insufficient capital to satisfy a cash payment obligation at the time a particular milestone is achieved, the expectation of imminent financing activity may depress our stock price at a time when the purified 188 program is demonstrating success through achievement of the milestone.

If our stockholders do not approve the issuance of the milestone-related shares and we are successful in raising additional capital in anticipation of satisfying these cash payment obligations before particular milestones are achieved, we may raise more capital than ultimately is necessary, subjecting our stockholders to otherwise unnecessary dilution. Alternatively, we may raise insufficient capital to meet a payment obligation. If we wait to raise capital until particular milestones are achieved, investors may impose more onerous terms based on an actual or perceived need to raise capital immediately, if capital is available at all.

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

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

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

Currently, our common stock is listed on the NYSE Amex equities market. The NYSE Amex will review the appropriateness of continued listing of any issuer that falls below the exchange s continued listing standards. Previously, including during part of 2010, we were not in compliance with certain NYSE Amex continued listing standards and were at risk of being 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, we may be delisted from the NYSE Amex equities market, which would likely cause the liquidity and market price of our common stock to decline. If our common stock were delisted from the NYSE Amex, our ability to raise capital on terms and conditions we deem acceptable, if at all, may be materially impaired.

Our ability to timely raise sufficient additional capital also may be limited by the NYSE Amex s requirements relating to stockholder approval for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, the NYSE Amex requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our presently outstanding common stock, unless the transaction is considered a public offering by the NYSE Amex staff. Based on our outstanding common stock as of March 1, 2011 and a closing price of $2.07, which was the closing price of our common stock on March 1, 2011, we could not raise more than approximately $9.8 million without stockholder approval, unless the transaction is deemed a public offering or does not involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. However, certain prior sales by us may be aggregated with any offering we may propose in the near-term, further limiting the amount we could raise in any future offering that is not considered a public offering by the NYSE Amex staff and would involve

the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. The NYSE Amex will also require stockholder approval if the issuance or potential issuance of additional shares will be considered by the exchange staff to result in a change of control of us.

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Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our 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 to, among other things, grant the investors that were party to the Rights Agreement, or the Rights Investors, the right to participate in sales of our securities for up to seven years (with certain enumerated exceptions as set forth in the Rights Agreement). 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.

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

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

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

Currently, we have four employees and we rely on third parties to perform many essential services for us. In connection with preparing for the commercial launch of Exelbine, should our November 2010 Exelbine NDA be approved, and initiating clinical activities with respect to ANX-514, should we reach agreement with the FDA regarding a phase 3 clinical study, and purified 188, should we consummate our acquisition of SynthRx, we plan to increase our internal sales and marketing, finance and accounting, research and development, regulatory, manufacturing, quality, compliance, and other resources in order to manage our expanded operations. We do not expect that our current management, personnel, systems and, potentially, facilities will be adequate to support those

activities. We expect to continue to rely on third parties to perform certain essential services as we develop and/or acquire additional internal capabilities.

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The success of our business will depend, in part, on our ability to attract and retain highly qualified personnel, and on our ability to develop and maintain important relationships with respected service providers and industry-leading consultants and advisors. Competition for these types of personnel and relationships is intense from numerous pharmaceutical and biotechnology companies, universities and other research organizations, particularly in the San Diego, California area. In connection with the cost-cutting measures we implemented in 2008 and 2009, we eliminated, among others, our scientific staff and our manufacturing and regulatory personnel, who had a deep background in our product candidates and our research and development programs. Recruiting and retaining employees, including senior-level personnel, with relevant product development and commercialization experience may be costly and time-consuming. Our ability to provide competitive compensation to our management and other employees may also be adversely affected by our capital resources. If we cannot attract and retain additional skilled personnel, we may not achieve our development and other goals.

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

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

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

Although we anticipate that our cash as of December 31, 2010, together with the net proceeds from the equity financing we completed in January 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 reduce our development and commercialization activities or attempt to continue them by entering into arrangements with partners or others that may not be available on favorable terms, or at all, and may require us to relinquish some or all of our rights to our product candidates or products or the financial benefits thereof. For example, in late 2008, due to an immediate need for additional capital, we discontinued all of our development programs other than with respect to Exelbine and ANX-514 and limited our activities with respect to Exelbine and ANX-514 to those we believed necessary to preparing and submitting NDAs for Exelbine and ANX-514. Going forward, if we do not have sufficient capital, we may determine, for example, not to conduct the randomized safety study comparing ANX-514 and Taxotere, which the FDA has indicated would be required to support approval of ANX-514 or any additional clinical and/or nonclinical studies that may be required by the FDA to support approval of ANX-514, any post-approval clinical studies to support uses of Exelbine in new indications or other label changes intended to expand the scale and scope of its market potential, or, should we consummate our acquisition of SynthRx, any clinical and/or nonclinical studies that may be required by the FDA to support approval of purified 188.

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Our failure to successfully acquire, develop and commercialize additional technologies, product candidates and/or products may impair our ability to grow.

Our current business strategy involves expanding our pipeline of product candidates through one or more in-license, asset acquisition or merger transactions, including our pending acquisition of SynthRx. Because we neither have, nor currently intend to establish, internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies, universities and other research organizations to sell or license technologies, product candidates, products or businesses to us. 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 transactions may be costly. In addition, given our recent market capitalization and our desire to preserve our cash for development activities, any merger or other business combination transaction pursuant to which we acquire additional technologies, product candidates and/or products primarily will involve the issuance of shares of our common stock, or securities convertible into our common stock. For example, if we consummate our acquisition of SynthRx, in connection with the consummation of the transaction we would issue 2,938,773 shares of our common stock to SynthRx s stakeholders. In addition, we could issue up to an aggregate of 13,478,050 additional shares of our common stock to SythRx s stakeholders upon achievement of milestones related to the development and regulatory approval of purified 188 for the treatment of sickle cell crisis in children, if our stockholders approve the issuance of such milestone-related shares, as required by NYSE Amex rules. 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 40% ownership stake in our company (based on currently outstanding shares plus shares issued in connection with the acquisition). 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.

Our success in acquiring or acquiring rights to new technologies, product candidates and/or products may also be adversely affected by competition for the same assets by other companies, including some with substantially greater development and commercialization resources and with a proven record of successfully developing and/or commercializing product candidates. In addition, we may not be able to identify, acquire or acquire the rights to additional technologies, product candidates and/or products on terms that we find acceptable, or at all.

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.

If we acquire or acquire rights to new technologies, product candidates and/or products and fail to integrate them successfully into our operations, we may incur unexpected costs and disruptions to our business.

In addition to our pending acquisition of SynthRx, which we expect to consummate in the first half of 2011, we currently continue to spend significant time and attention identifying and evaluating, and potentially negotiating to acquire or acquire rights to, other technologies, product candidates and/or products that we believe have a strategic fit with our current or future business strategy. However, any strategic transaction, including in-license, asset acquisition and merger transactions, including our acquisition of SynthRx, if it closes, 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, products candidates and/or products;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;

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increased amortization expenses;

difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;

impairment of relationships with key suppliers and/or customers of any acquired businesses due to changes in management and ownership; and

inability to retain key employees of any acquired businesses.

We may devote resources to potential product candidate acquisition or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

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, 2010, we had generated federal and state net operating loss carry forwards of approximately $31.5 million and $34.4 million, respectively, and federal and state research and development tax credit carry forwards of approximately $145,000 and $87,000, respectively. Federal net operating loss carry forwards and research and development tax credits have a 20-year carry forward period and California net operating losses have a carry forward period that varies depending on the year such net operating losses are generated. California research and development tax credits carry forward indefinitely. Our federal net operating loss carry forwards will begin to expire in 2016 and our California net operating loss carry forwards will begin to expire in 2013 if we have not used them prior to that time. Our federal research and development tax credits will begin to expire in 2029.

Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, our ability to use any net operating loss carry forwards and research and development credits to offset taxable income in the future is limited if we experience a cumulative change in ownership of more than 50% within a three-year period. During 2010, we completed an analysis to determine whether any such change in ownership had occurred during the period from January 1, 2008 through January 7, 2010, and identified several changes in ownership within the meaning of IRC Section 382. Upon application of limitations prescribed by IRC Section 382, we determined that our net operating loss carry forwards and research and development credits were significantly adversely affected by the identified changes in control, and we have adjusted our deferred tax assets accordingly. We have not completed an analysis to determine whether any change in ownership within the meaning of IRC Section 382 has occurred since January 7, 2010, but we believe a change in ownership may have occurred as a result of our equity securities financings in May 2010 and January 2011. If any such change in ownership has occurred since January 7, 2010 or were to occur in the future, the amount of our net operating loss carry forwards and research and development tax credits we could utilize annually in the future to offset taxable income could be further significantly restricted or eliminated. Inability to fully utilize our net operating loss carry forwards and research and development tax credits could have an adverse impact on our financial position and results of operations.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to annually furnish a report by our management on our internal control over financial reporting. Such report must contain, among other matters, an assessment by our principal executive officer and our principal financial officer on the effectiveness of our internal control over financial reporting, including a statement as to whether or not our internal control over financial reporting is effective as of the end of our fiscal year. This assessment must include disclosure of any material weakness in our internal control over financial reporting identified by management. Performing the system and process documentation and evaluation needed to comply with Section 404 is both costly and challenging. In addition, under current SEC rules, if our public float is $75 million or more as of the last business day of our most recently completed second fiscal quarter, we will be required to obtain an attestation report from our independent registered public accounting firm as to our assessment of the effectiveness of our internal control over financial reporting for our annual report on Form 10-K for that fiscal year, which likely would consume significant additional financial and managerial resources.

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We have in the past discovered, and may in the future discover, areas of internal controls that need improvement. For example, during the fourth quarter of 2008, we discovered that we did not correctly apply generally accepted accounting principles relating to accounting for warrant liability because our accounting staff did not have adequate training or expertise, and determined that we had a material weakness in our internal control over financial reporting as of December 31, 2007. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. For a detailed description of this material weakness and our remediation of this material weakness, see Part II Item 9A(T) Controls and Procedures of our annual report on Form 10-K for the year ended December 31, 2008. If we identify a material weakness in our internal control over financial reporting in the future, we may not be able to conclude that our internal control over financial reporting is effective, and we may need to implement expensive and time-consuming remedial measures. As a result of reductions in our workforce and other personnel departures that occurred in 2008 and 2009, we have experienced substantial turnover in our personnel responsible for performing activities related to our internal control over financial reporting. Since July 2009, our president and chief operating officer, who has no formal education in finance or accounting, has served as our principal financial and principal accounting officer. We have used third-party contractors in an effort to maintain effective internal control over financial reporting during and since that turn-over period. However, we cannot be certain that a material weakness will not be identified in the future and, if we fail to maintain effective internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on our stock price.

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

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

Our corporate headquarters are located 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 delay our development and potential commercialization efforts. Even though we believe we carry commercially reasonable insurance, we might suffer losses that exceed the coverage available under these insurance policies. In addition, we are not insured against terrorist attacks or earthquakes.

Risks Related to Drug Development and Commercialization

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

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

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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. For example, despite our including in our December 2009 Exelbine NDA 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 the December 2009 submission was insufficient to support a commercially-viable expiration dating period. Likewise, even though the FDA has confirmed the appropriateness of a Section 505(b)(2) regulatory path for Exelbine and ANX-514, the FDA s views may change or the FDA may require additional nonclinical testing or clinical studies to demonstrate their safety. For example, with respect to ANX-514, because the Cmax for total docetaxel was higher in patients who received ANX-514 relative to those who received Taxotere in Study 514-01, the FDA indicated that a randomized safety study comparing ANX-514 and Taxotere would be required in an appropriate patient population to support approval of ANX-514. The FDA recommended that the study also collect data on response rate and duration of response. We are developing a study protocol for submission to the FDA and intend to continue discussions with the FDA regarding the phase 3 clinical study and other requirements for approval of ANX-514. The results of these discussions will determine in large part the timeline for and estimated cost of continued development of ANX-514. Currently, we plan to continue development of ANX-514, but the FDA s requirements for additional development activities to support approval of ANX-514 may increase estimated development time and expense to the point where we determine to discontinue work on ANX-514 based on our assessment of its commercial value. Likewise, if, during its review of our Exelbine NDA, the FDA determines that additional nonclinical testing or clinical studies are necessary for regulatory approval of Exelbine, we may determine that the associated time and cost is not financially justifiable and, as a result, discontinue that program. If we discontinue the development of one or both of these product candidates, our business and stock price may suffer.

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

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

We set goals for and make public statements regarding our estimates of the timing of the accomplishment of objectives material to successful development, approval and future commercialization of our product candidates. The actual timing of these events can vary dramatically due to any number of factors, including delays or failures in our nonclinical testing, bioequivalence and clinical trials and manufacturing, regulatory and commercial launch activities and the uncertainties inherent in the regulatory approval process. While our regulatory strategy for Exelbine and ANX-514 has been to demonstrate the bioequivalence of each to the currently approved reference product in small, bioequivalence trials in humans, in February 2011, we announced that the FDA determined ANX-514 could not be approved based on the findings from Study 514-01 and indicated that a randomized safety study comparing ANX-514 and Taxotere would be required in an appropriate patient population to support approval of ANX-514. The FDA recommended that the study also collect data on response rate and duration of response. We are developing a study protocol for submission to the FDA and intend to continue discussions with the FDA regarding the phase 3 clinical study and other requirements for approval of ANX-514. However, the FDA s requirements for development activities

beyond Study 514-01 will significantly increase the time and cost associated with seeking regulatory approval of ANX-514 relative to our previously planned regulatory approval pathway for ANX-514. In addition, we may determine to conduct clinical studies with respect to Exelbine and ANX-514 to support uses in new indications or other label changes or for other reasons. If we consummate our acquisition of SynthRx, we intend to develop purified 188 for the treatment of sickle cell crisis in a pediatric population and plan to meet with the FDA to reach agreement on a phase 3 clinical trial protocol. Although the safety and efficacy of 188 and purified 188 in sickle cell disease have been evaluated in multiple clinical studies and we believe that a properly designed and executed phase 3 clinical trial will demonstrate that purified 188 is an effective treatment for sickle cell crisis, the FDA may require additional nonclinical testing and/or clinical studies for regulatory approval of purified 188 for the treatment for sickle cell crisis in a pediatric population.

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

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

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

- obtaining regulatory approval to commence a trial;
- identifying appropriate trial sites and reaching agreement on acceptable terms with prospective CROs, trial sites and investigators, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and investigators;
- identifying and hiring or engaging, as applicable, additional employees or consultants to assist us in managing a trial and analyzing the data resulting from a trial;
- manufacturing sufficient quantities of a product candidate;
- obtaining institutional review board, or IRB, approval to conduct a trial at a prospective site;
- recruiting and enrolling patients to participate in trials for a variety of reasons, including competition from other clinical trials for the same indication as our product candidates and the perception that the design of a trial or the proposed treatment regimen is less beneficial to patients than available alternatives; and
- retaining patients who have initiated a trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy, improvement in condition before treatment has been completed or personal issues, or who are lost to further follow-up.

Even if we complete a planned bioequivalence or clinical trial, we may not achieve our projected development, approval, commercialization or other goals in the time frames we initially anticipate or announce. For example, with respect to ANX-514, in February 2011, we announced that because the Cmax for total docetaxel was higher in patients who received ANX-514 relative to those who received Taxotere in Study 514-01, the FDA indicated that a randomized safety study comparing ANX-514 and Taxotere would be required in an appropriate patient population to support approval of ANX-514. As a result of the FDA s additional requirements with respect to the regulatory approval pathway for ANX-514, there is substantial uncertainty as to the cost and timeline to obtaining FDA approval for ANX-514.

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In addition to the potential for delays in commencing and completing a bioequivalence or clinical trial described above, a trial may be suspended or terminated by us, an IRB, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the trial in accordance with regulatory requirements or the trial s protocol;
- inspection of trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the trial.

Additionally, changes in regulatory requirements and guidance relating to bioequivalence or clinical trials may occur and we may need to amend trial protocols to reflect these changes. Amendments may require us to resubmit protocols to IRBs for reexamination or renegotiate terms with CROs, trial sites and trial investigators, all of which may impact the costs, timing or successful completion of a trial. Changes may also occur in regulatory requirements 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 our including in our December 2009 Exelbine NDA data that we believe met the filing requirements for a new drug promulgated by the 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 Exelbine NDA.

There can be no assurance that our nonclinical testing and bioequivalence and/or clinical trials will commence or be completed, that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to anticipated schedules for the development or approval of any of our product candidates. The length of time necessary to complete bioequivalence or clinical trials and manufacturing development work and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and is difficult to predict accurately. If we experience delays in the completion of, or if we terminate, our bioequivalence or clinical trials or nonclinical testing or if we are otherwise unable to adhere to our current schedule for the development of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of bioequivalence or clinical trials or nonclinical testing may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same indications may have been introduced to the market in the interim and established a competitive advantage.

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

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

With respect to ANX-514, despite positive nonclinical testing that indicated bioequivalence between ANX-514 and the reference product, Taxotere, Study 514-01 did not demonstrate pharmacokinetic equivalence between ANX-514 and Taxotere, the primary endpoint of Study 514-01, based on the FDA s benchmark regulatory standards. In February 2011, we announced that the FDA determined ANX-514 could not be approved based on the findings from Study 514-01 and indicated that a randomized safety study comparing ANX-514 and Taxotere would be required in an appropriate patient population to support approval of ANX-514. We are developing a study protocol for submission to the FDA and intend to continue discussions with the FDA regarding the phase 3 clinical study and other requirements for approval of ANX-514. However, the FDA s requirements for development activities beyond Study 514-01 will significantly increase the time and cost associated with regulatory approval of ANX-514 relative to our previously planned regulatory approval pathway for ANX-514. In addition, the FDA may inquire regarding the manufacturing source, in-process and product release specifications and overall uniformity of reference product used in Study 514-01, 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 purposes of Study 514-01 will not be the same form of API used in the manufacture of ANX-514 for purposes of the planned phase 3 study of ANX-514 or for process validation batches or commercial supply. To ensure the comparability of the ANX-514 used in Study 514-01 and the ANX-514 intended for use in the planned phase 3 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. Furthermore, 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 such third party, or a future third-party licensee, may conduct. If data from investigations of ANX-514 sponsored by a third-party licensee identify a safety or efficacy concern with respect to ANX-514, or the lack of comparable pharmacokinetics between ANX-514 and Taxotere, such data could have an adverse effect on the U.S. regulatory

process.

There is a significant risk that any of our product candidates, including purified 188 should our acquisition of SynthRx close, could fail to show anticipated results in human trials, as was the case in our bioequivalence study of ANX-514, or manufacturing development, and, as a result, we may not continue their development. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope requested will delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

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We currently have no sales or marketing capability and our failure to 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, including Exelbine, we will have to acquire or develop marketing, distribution and sales capabilities and associated regulatory compliance capabilities, or rely on marketing partners or other arrangements with third parties for the marketing, distribution and sale of our products. There is no guarantee that we will be able to establish marketing, distribution or sales capabilities or make arrangements with third parties to perform those activities on terms satisfactory to us, or 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, including Exelbine, if approved, and otherwise negatively impact our product development and commercialization efforts.

To the extent we establish marketing, distribution or sales arrangements with any 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, or otherwise do not carry out their contractual duties to us, or encounter natural or other disasters at their facilities, our ability to deliver product to meet commercial demand 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 broad market acceptance (including as a result of our inability to differentiate our products from competitor products or promote any such differences or as a result of failing to obtain reimbursement rates for our products that make our products competitive from the healthcare provider s perspective), the revenues we generate from their sales will be limited and our business may not be profitable.

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

- our product s perceived advantages over existing treatment methods (including relative convenience and ease of administration and prevalence and severity of any adverse side effects);
- claims or other information (including limitations or warnings) in our product s approved labeling;
- the resources we devote to marketing our product and restrictions on promotional claims we can make with respect to the product;
- reimbursement and coverage policies of government and other third-party payors;
- pricing and cost-effectiveness;
- in the U.S., the ability of group purchasing organizations (including distributors and other network providers) to sell our product to their constituencies;

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

availability of alternative treatments; and

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

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

In addition, FDA approval of Exelbine based on bioequivalence to Navelbine may limit our ability to differentiate Exelbine from Navelbine, its generic equivalents and other formulations of vinorelbine that may be approved by the FDA unless the FDA allows us to include certain data in the Exelbine label. Likewise, unless we investigate the potential clinical benefits of the absence of polysorbate 80 in our planned phase 3 clinical trial of ANX-514, our ability to differentiate ANX-514 from Taxotere, its generic equivalents and other formulations of docetaxel that may be approved by the FDA may be limited.

If we fail to obtain a unique Healthcare Common Procedure Coding System, or HCPCS, product code for Exelbine or ANX-514, we may be unable to sell those products at a price that exceeds their respective manufacturing, marketing and distribution costs. Even if we obtain unique HCPCS product codes for Exelbine and ANX-514, if they are perceived to provide little or no advantage relative to competing products or for other reasons, we may be required to price those products at levels that do not cover our 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.

Based on our determinations regarding the commercial potential of Exelbine and ANX-514, including as a result of the above factors, we may determine that the time and cost necessary to continue to develop and/or seek regulatory approval for one or both of these product candidates is not financially justified, particularly with respect to Exelbine, if the FDA requires additional nonclinical testing or bioequivalence or clinical studies beyond the bioequivalence study that we have conducted for that product candidate and, with respect to ANX-514, depending on the outcome of future discussions with the FDA regarding a phase 3 clinical trial study protocol and other requirements for approval of ANX-514. While we evaluate these factors, we may reduce our expenditures on the development and/or the process of seeking regulatory approval of these product candidates. There can be no assurance that, in the future, we will continue to develop or seek regulatory approval for either of these product candidates as quickly as possible, or at all.

In the future, we may devote our resources to identifying, acquiring and developing new product candidates, including purified 188 if we consummate our acquisition of SynthRx. In such event, we will have significant flexibility in determining which new product candidates to pursue. Stockholders will be required to rely on the judgment of our management and our board of directors in this regard and may have limited or no opportunity to evaluate potential new product candidates, including the terms of their acquisition, the costs of their future development and their commercial potential.

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

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

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

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

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

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

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

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

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

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

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

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

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

For instance, we 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 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.

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

Many of the currently marketed and anticipated products against which our product candidates may compete are, or we anticipate will be, available as generics. For instance, Exelbine would compete against Navelbine, for which generic equivalents have been available in the U.S. since 2003. ANX-514 would compete against Taxotere. We anticipate that ANX-514 would also compete against other formulations of docetaxel and we expect that generic equivalents of Taxotere will have entered the market prior to regulatory approval, if any, to market ANX-514. Even if we obtain unique HCPCS product codes for Exelbine and ANX-514, 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 could adversely affect our business.

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

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

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

Even if initial regulatory approval is obtained, the FDA or a foreign regulatory agency may still impose significant restrictions on a product s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or marketing surveillance programs. Our product candidates will also be subject to ongoing FDA requirements related to the labeling, packaging, storage, 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 trials and impose distribution and use restrictions on certain drug products. In addition, approved products, manufacturers and manufacturers facilities are subject to continuing regulatory review and periodic inspections. If previously unknown problems with a product are discovered, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, the FDA may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we or a CMO of ours fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing bioequivalence or clinical trials;
- refuse to approve pending applications or supplements to approved applications;
- 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.

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Even if one or more of our product candidates receive regulatory approval in the U.S., we may never receive approval or commercialize our products outside of the U.S., which would limit our ability to realize the full 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. In particular, other countries may not have a comparable regulatory procedure as is available under Section 505(b)(2) of FDCA. Even if a country did have a comparable procedure, that country may require a more robust data package than the bioequivalence data package for Exelbine that we submitted in November 2010 and was accepted for review by the FDA. 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.

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

Undesirable side effects caused by our product candidates could interrupt, delay or halt bioequivalence or clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. For example, in a prior phase 3 study of purified 188, a modest but statistically significant increase in levels of alanine aminotrasferase and direct bilirubin was observed. If in our planned phase 3 clinical trial of purified 188, should we consummate our acquisition of SynthRx, we observe more pronounced increases in these or other levels, or we observe other previously unidentified adverse events, whether or not statistically significant, we may be required to conduct additional clinical trials of purified 188 or purified 188 may not receive regulatory approval.

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

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

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

Risks Related to Our Intellectual Property

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

Our success will depend in part on our ability to:

- obtain and maintain patent and other exclusivity with respect to our products;
- prevent third parties from infringing upon our proprietary rights;

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

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

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

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

With respect to purified 188 for the treatment of sickle cell crisis, should our acquisition of SynthRx close, we will acquire exclusive rights to a variety of issued patents that cover, among other things, 188, purified 188, methods of treating sickle cell anemia using 188 and methods of preparing purified 188. However, we expect many of the patents covering purified 188 for the treatment of sickle cell crisis will expire prior to regulatory approval of purified 188 for that indication. For exclusivity, we expect to rely primarily on the orphan drug designation that the FDA has granted for 188 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. Our product candidate would not receive the seven-year orphan drug marketing exclusivity if it is not the first to obtain FDA marketing approval. 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 our product, the FDA may approve such other product candidate for marketing during the seven year exclusive marketing period of our product.

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 formulations 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.

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In addition, while the patent applications and the issued patent 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 the same API as our products. Such competitive products may not infringe any patents we may hold in the future covering our specific formulation of the API.

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

Our commercial success depends on our ability and the ability of our CMOs and component suppliers to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are or may be developing products. As the biotechnology and pharmaceutical industry expands and more patents are issued, the risk increases that 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, future litigation by third parties having patent or other intellectual property rights alleging that our products, product candidates and/or technologies infringe their intellectual property rights or that the process of manufacturing our products or any of their respective component materials, or the component materials themselves, or the use of our products, product candidates or technologies, infringe their intellectual property rights. If one of these patents was found to cover our products, product candidates, technologies or their uses, or any of the underlying manufacturing processes or components, we could be required to pay damages and could be unable to commercialize our products or use our technologies or methods unless we are able to obtain a license to the patent or intellectual property right. A license may not be available to us in a timely manner or on acceptable terms, if at all. In addition, during litigation, a patent holder could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using or selling our products, technologies or methods.

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

- infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert our management s attention from our core business;
- substantial damages for infringement, including the potential for treble damages and attorneys fees, which we may have to pay if a court decides that the product at issue infringes or violates the third party s rights;
- a court prohibiting us from selling or licensing the product unless the third party licenses its product rights to us, which it may not be required to do;
- if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross-licenses to our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial 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 number of patents issued and patent applications filed in the pharmaceutical industry, we believe there is a risk that third parties may allege they have patent rights encompassing our products, product candidates or technologies, or those of our CMOs or

component material suppliers, or uses of our products, product candidates or technologies.

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

RISKS RELATED TO OUR INDUSTRY

We expect intense competition in the marketplace for each of our products, if any 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 oncology and/or that are pursuing the development of pharmaceuticals that target the same diseases as are targeted by the products that we currently are, or in the future may be, developing or that focus on reformulating currently approved drugs. We anticipate that we will face intense and increasing competition in the future as new products enter the market and new technologies become available. 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.

Exelbine and ANX-514, if approved, may compete against Navelbine and Taxotere, respectively, as well as their generic equivalents and other formulations of vinorelbine and docetaxel that may be approved by the FDA. In addition to Navelbine, in the U.S., currently there are seven commercially available generic versions of vinorelbine. In addition, there is an oral formulation of vinorelbine approved for use in the EU against which Exelbine would compete if Exelbine were approved for use in the EU. With respect to docetaxel, in the U.S., we believe non-Taxotere formulations of docetaxel will be commercially available in 2011 and that generic equivalents of Taxotere will be commercially available in the near-term, possibly in 2011.

With respect to Exelbine, because we submitted the Exelbine NDA with only bioequivalence data, our ability to differentiate Exelbine from competing products will be limited. Even if we believe Exelbine demonstrates clinical, pharmacoeconomic or other benefits relative to competing products, we may be unable to market or promote it based on these benefits. 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.

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With respect to competition for purified 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, should we consummate our acquisition of SynthRx and receive regulatory approval to market a product based on purified 188 for the treatment of sickle cell disease in children, purified 188 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, has been shown to decrease the severity of sickle cell disease by reducing the frequency of crisis. Blood transfusions also are used to treat 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 further generate interest. If an effective treatment or cure for sickle cell disease or sickle cell crisis receives regulatory approval, the commercial success of any product of ours based on purified 188, should we consummate our acquisition of SynthRx and receive regulatory approval to market it, could be severely jeopardized.

Companies likely to have products that will compete with our product candidates have significantly greater financial, technical and human resources than we do, and are better equipped to develop, manufacture, market and distribute products. Many of these companies have extensive experience in nonclinical testing and clinical trials, obtaining FDA and other regulatory approvals and manufacturing and marketing products, have products that have been approved or are in late-stage development, and operate large, well-funded research, development and commercialization programs. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, academic institutions, government agencies and other public and private research organizations are becoming increasingly aware of the commercial value of their inventions and are actively seeking to commercialize the 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 a price we believe is fair for our products;
- our ability to generate revenues or achieve or maintain profitability;
- the future revenues and profitability of our potential customers, suppliers and collaborators; and
- the availability to us of capital.

If we are successful in obtaining FDA approval for Exelbine, it will compete with Navelbine, its generic equivalents and other formulations of vinorelbine that may be approved by the FDA. Our ability to commercialize Exelbine 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 product. 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.

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There have been federal and state proposals to subject the pricing of healthcare goods and services to government control and to make other changes to the U.S. healthcare system. While we cannot predict the outcome of current or future legislation, we anticipate, particularly given the passage in 2010 of the Patient Protection and Affordable Care Act, that Congress and state legislatures will introduce initiatives directed at lowering the total cost of healthcare. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain if future legislative proposals, whether domestic or abroad, will be adopted that might affect our products or product candidates or what actions federal, state, or private payors for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Any such healthcare reforms could have a material and adverse effect on the marketability of any products for which we ultimately receive FDA or other regulatory agency approval.

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

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

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

We maintain limited product liability insurance for our bioequivalence and clinical trials, but our insurance coverage may not reimburse us or may not be sufficient to reimburse us for 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, we 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 normally will consider suspending dealings in, or removing from the list, securities of an issuer that has stockholders equity of less than $6.0 million if such issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. In addition, the NYSE Amex will normally consider suspending dealings in, or removing from the list, securities selling for a substantial period of time at a low price per share if the issuer fails to effect a reverse split of such stock within a reasonable time after being notified that the NYSE Amex deems such action to be appropriate under the circumstances.

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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. Even though, currently, we are in compliance with NYSE Amex continued listing standards, there is no assurance that we will continue to maintain compliance with such standards. For example, we may determine to grow our organization or product pipeline or pursue development or other activities 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. 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 that are unrelated to our operating performance. For instance, on October 1, 2007, the market price for our common stock dropped almost 80% following our announcement of the results of our phase 2b clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. Conversely, the market price for our common stock more than doubled over two trading days in late December 2009. The market price of our common stock may fluctuate significantly in response to a number of factors, including:

- the level of our financial resources;
- announcements of entry into or consummation of a financing or strategic transaction;

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

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

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

market conditions in the pharmaceutical, biopharmaceutical, specialty pharmaceutical and biotechnology sectors;

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

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 October 1, 2007 decline, the realization of any of the foregoing could have a dramatic and adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced substantial decline in market price. Moreover, regulatory entities often undertake investigations of investor transactions in securities that experience volatility following an announcement of a significant event or condition. Any such litigation brought against us or 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 $85 million of securities. In addition, we 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. 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.

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If our acquisition of SynthRx closes, we may obtain voting control over a significant amount of our outstanding common stock 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 other parties thereto, each other 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 our acquisition of SynthRx closes we will issue 2,938,773 shares of our common stock to SynthRx s stakeholders, representing, in the aggregate, approximately 11% of our company (based on our currently outstanding shares plus shares issued in connection with the closing). If our acquisition of SynthRx closes, our stockholders approve the issuance of the milestone-related shares and development of purified 188 achieves all related milestones 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) an approximately 40% ownership stake in our company (based on our currently outstanding shares plus shares issued in connection with the acquisition). As a result of such issuances and the voting and transfer restriction agreement, we may, at and following the closing of the acquisition, have 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 our current executives will accelerate with respect to fifty percent of the then unvested shares on the day prior to the date of the change in control and, subject to the respective executive s continuous service, with respect to the remaining fifty percent of the then unvested shares on the one year anniversary of the date of the change in control. As a result, if an acquirer desired to retain the services of one or both of our current executives following an acquisition, it may be required to provide additional incentive to them, which could increase the cost of the acquisition to the acquirer and may deter or affect the terms of the 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.

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

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

Item 1B. Unresolved Staff Comments.

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

Item 2. Properties.

We lease approximately 6,500 square feet of office space for our headquarters in San Diego, California subject to a lease arrangement that will expire in January 2012, unless we exercise our option to extend the lease for an additional 12 months. The average base rent for this space is approximately $15,600 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. (Removed and Reserved).

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PART II

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

Market Information

Our common stock trades under the symbol ANX on NYSE Amex Equities. The following table sets forth the high and low closing sale prices for our common stock in each full quarterly period within the two most recent fiscal years as reported in the consolidated transaction reporting system for NYSE Amex Equities. The prices in the table below have been adjusted to reflect retrospective application of the 1-for-25 reverse split of our common stock effected on April 23, 2010.

	Closing Sale Price			
	2010		2009	
	High	Low	High	Low
First Quarter	$ 11.67	$ 5.00	$ 4.50	$ 2.25
Second Quarter	$ 6.80	$ 1.61	$ 5.50	$ 2.76
Third Quarter	$ 2.11	$ 1.53	$ 5.00	$ 3.00
Fourth Quarter	$ 2.99	$ 1.93	$ 10.75	$ 2.25

As of March 1, 2011, we had approximately 143 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. In addition, in connection with previous preferred stock financings, we have agreed to charter restrictions on our ability to pay cash dividends or distributions on our common stock for so long as any shares of such preferred stock are outstanding, unless we obtain prior written consent from the holders of such preferred stock. 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.

We expect to retain all available funds and any future earnings to support operations and fund the development and growth of our business. Our board of directors will determine whether we pay and the amount of future dividends (including cash dividends), if any.

Recent Sales of Unregistered Securities

As partial consideration for its services as placement agent in connection with registered direct offerings of our equity securities, we have issued the following common stock purchase warrants to Rodman & Renshaw, LLC, 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;

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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;

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; and

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.

The warrants described above were offered and sold by us in reliance upon exemptions from the registration statement requirements by Section 4(2) of the Securities Act of 1933, as amended, as transactions by an issuer not involving a public offering. 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, as a smaller reporting company we are not required to provide the information required by this item.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes appearing elsewhere in this report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those identified under Item 1A Risk Factors in this report.

Overview

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing proprietary product candidates. Our lead product candidates, Exelbine (vinorelbine injectable emulsion), or ANX-530, and ANX-514 (docetaxel emulsion for injection), are novel emulsion formulations of currently marketed chemotherapy drugs.

We have devoted substantially all of our resources to research and development, or R&D, or to acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue and we have incurred significant losses since inception. We had a loss from operations of $8.5 million for the year ended December 31, 2010 and cash of approximately $28.0 million at December 31, 2010.

In November 2010, we submitted a new drug application, or NDA, for Exelbine to the U.S. Food and Drug Administration, or FDA, and in January 2011, we announced that the FDA accepted the Exelbine NDA for filing and established a Prescription Drug User Fee Act, or PDUFA, goal date of September 1, 2011 to finish its review of the Exelbine NDA.

In February 2011, we met with the FDA to discuss ANX-514 and the data package we presented to FDA to support approval of ANX-514 based on data from our bioequivalence study of ANX-514. The FDA indicated that a randomized safety study comparing ANX-514 and Taxotere would be required to support approval of ANX-514. The study would be primarily descriptive but with a sample size sufficient to demonstrate a comparable safety profile. The FDA recommended that the study also collect data on response rate and duration of response. We are developing a study protocol for submission to the FDA and intend to continue discussions with the FDA regarding the phase 3 clinical study and requirements for ANX-514 s approval.

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In 2010, we additionally began to focus on expanding our product pipeline through one or more in-license, asset acquisition or merger transactions. In February 2011, we entered into an agreement and plan of merger to acquire SynthRx, Inc., a privately-held Delaware corporation developing a purified form of a rheologic and antithrombotic agent, poloxamer 188, or 188, in exchange for shares of our common stock. We expect to consummate the acquisition of SynthRx in the first half of 2011. As discussed in more detail under Part I, Item 1 Business in this report, we initially intend to develop purified 188 for the treatment of sickle cell crisis in a pediatric population and, if our acquisition of SynthRx closes and we are able to reach agreement with the FDA on a study protocol on a timely basis, we may initiate a phase 3 clinical trial of purified 188 for that indication in 2012. In connection with the consummation of this acquisition, we would issue 2,938,773 shares of our common stock to SynthRx s stakeholders, 1,938,773 of which would be subject to repurchase by us in the event development of purified 188 does not achieve the first milestone described below. We could issue up to an aggregate of 13,478,050 additional shares of our common stock to SynthRx s stakeholders if the development of purified 188 achieves certain milestones, as described below, and our stockholders approve the issuance of such milestone-related shares, as required by NYSE Amex rules. If our stockholders do not approve the issuance of the milestone-related shares, under the terms of the merger agreement, we would be required to pay SynthRx s stakeholders in cash the value of the milestone-related shares we would have otherwise issued, with all such cash payments made in quarterly installments and, with respect to the cash value associated with 12,478,050 of the milestone-related shares, payable based on net sales of purified 188. We cannot determine the amount of our potential cash payments to SynthRx s stakeholders because the amount of such payments, if any, will depend on the 10-day volume weighted average of the closing price of our common stock at the time a milestone is achieved and the market price of our common stock historically has been, and likely will continue to be, highly volatile. 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 new drug application covering the use of purified 188 for the treatment of sickle cell crisis in children, or the 188 NDA, which we refer to as the First Milestone; 3,839,400 shares would be issuable upon acceptance for review of the 188 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 188 NDA, which we refer to as the Third Milestone.

We anticipate that our cash as of December 31, 2010, together with net proceeds from the equity financing we completed in January 2011, will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, we may pursue development and/or commercialization activities for our current or future product candidates, including purified 188 should we consummate the acquisition of SynthRx, at levels or on timelines, or we may incur unexpected expenses, that shorten the period through which our operating funds will sustain us. We may also acquire new technologies, product candidates and/or products and the cost to acquire, develop and/or commercialize such new technologies, product candidates and/or products may shorten the period through which our operating funds will sustain us. In addition, we may seek to raise substantial additional capital to support activities that we believe will enhance the value of our programs and increase stockholder value. We may not be able to obtain additional financing on a timely basis or on acceptable terms, if at all.

Recent Financings

In 2010, we raised an aggregate of $27.4 million in adjusted net proceeds through the issuance and sale of units consisting of convertible preferred stock and warrants to purchase shares of our common stock, and, in January 2011, we raised an additional $21.0 million in net proceeds through the issuance and sale of units consisting of common stock and warrants to purchase common stock as follows:

- In January 2010, we completed a registered direct equity financing involving the issuance of units consisting of shares of our 3.73344597664961% Series E Convertible Preferred Stock, or Series E Stock, which were convertible into an aggregate of 1,993,965 shares of our common stock, and 30-month warrants to purchase up to an aggregate of 498,488 shares of our common stock. The gross proceeds of this financing were $19.0 million, and we received $14.0 million in net proceeds after deducting amounts deposited into escrow accounts to fund our dividend and related payment obligations in respect of the Series E Stock, the fees and expenses of our placement agent, and our other offering expenses. All of the shares of our Series E Stock have been converted into common stock and are no

longer outstanding. We may receive up to $4.4 million of additional proceeds from the exercise of the warrants issued in this financing. Those warrants have an exercise price of $8.75 per share and are exercisable any time on or before July 6, 2012, subject to certain beneficial ownership limitations.

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In May 2010, we completed a registered direct equity financing involving the issuance of units consisting of shares of our 2.19446320054018% Series F Convertible Preferred Stock, or Series F Stock, which were convertible into an aggregate of 5,190,312 shares of our common 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. The gross proceeds of this financing were $19.2 million, and we received $13.3 million in net proceeds after deducting amounts deposited into escrow accounts to fund our dividend and related payment obligations in respect of the Series F Stock, the fees and expenses of our placement agent and financial advisor, and our other offering expenses. All of the shares of our Series F Stock have been converted into common stock and are no longer outstanding. We may receive up to $9.5 million of additional proceeds from the exercise of the warrants issued in this financing. Those warrants have an exercise price of $3.65 per share. The 5-year warrants are exercisable any time on or before May 6, 2015 and the 1-year warrants are exercisable any time on or before May 20, 2011, subject to certain beneficial ownership limitations.

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. We may receive up to $11.3 million of additional proceeds from the exercise of the warrants issued in this financing. Those warrants have an exercise price of $2.75 per share. The 5-year warrants are exercisable any time on or before January 11, 2016 and the 1-year warrants are exercisable any time on or before January 19, 2012, subject to certain beneficial ownership limitations.

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 Estimates

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

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Revenue Recognition. We may enter into revenue arrangements that contain multiple deliverables. In these cases, revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed and determinable; and (4) collectability is reasonably assured.

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

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

We recognize revenues 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.

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

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

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

Purchased In-Process Research and Development. We adopted the Financial Accounting Standards Board s, or FASB s, changes to Accounting Standards Codification, or ASC, 805, Business Combinations, effective January 1, 2009. The adoption of the changes to ASC 805 did not have a material effect on our consolidated results of operations or financial position.

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In accordance with previous accounting guidance effective through December 31, 2008, we accounted for the costs associated with any purchased in-process research and development, or IPR&D, as an expense on the statement of operations upon acquisition. These amounts represented an estimate of the fair value of purchased IPR&D for projects that, as of the acquisition date, had not yet reached technological feasibility, had no alternative future use, and had uncertainty in generating future economic benefits. We determined the future economic benefits from the purchased IPR&D to be uncertain until such technology is incorporated into products approved for marketing by the FDA or when other significant risk factors are abated.

Share-based Compensation Expenses. We account for share-based compensation awards granted to employees, including non-employee members of our board of directors, in accordance with ASC 718, Compensation Stock Compensation. Share-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee s requisite service period. As share-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience. Although estimates of share-based compensation expenses are significant to our consolidated financial statements, they are not related to the payment of any cash by us.

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

We account for share-based compensation awards granted to non-employees by determining the fair value of the share-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured using the share price and other measurement assumptions as of the earlier of (1) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached or (2) the date at which the counterparty s performance is complete.

Income Taxes. We account for income taxes and the related accounts under the liability method in accordance with ASC 740, Income Taxes. Deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts and the income tax bases of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The tax effects from an uncertain tax position can be recognized in our consolidated financial statements only if the position is more likely than not of being sustained upon an examination by tax authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

Costs Associated with Exit or Disposal Activities. As part of our efforts to reduce operating costs, we completed one workforce reduction in the fourth quarter of 2008 and two workforce reductions in the first six months of 2009, each of which was accounted for in accordance with ASC 420, Exit or Disposal Cost Obligations. We recorded severance-related charges, including salary, payroll taxes and healthcare benefits, of $757,000 in the aggregate over three consecutive quarters beginning in the fourth quarter of 2008. We recorded severance-related charges of $350,000 in the first quarter of 2009, of which $237,000 was recorded in research and development and the balance was recorded in selling, general and administrative, and $163,000 in the second quarter of 2009, of which $121,000 was recorded in research and development and the balance was recorded in selling, general and administrative. As of June 30, 2009, all severance-related costs associated with these workforce reductions had been recorded and paid.

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Convertible Instruments. At issuance, we value separately embedded beneficial conversion features present in convertible securities. Embedded beneficial conversion features are recognized by allocating to additional paid-in capital and accumulated deficit that portion of the net proceeds from the sale of the convertible security equal to the intrinsic value of the beneficial conversion feature. Intrinsic value is calculated as the difference, as of the commitment date, between the conversion price of the convertible security and the fair value of the common stock underlying the convertible security, which for us is the closing price of a share of our common stock on the NYSE Amex multiplied by the number of shares of our common stock into which the convertible security is convertible. If the intrinsic value of the beneficial conversion feature is greater than the net proceeds allocated to the convertible security, the amount of the discount assigned to the beneficial conversion feature is limited to the amount of the net proceeds. In our registered direct equity financings that closed in June, July, August and October 2009 and January and May 2010, we issued convertible preferred stock securities with non-detachable conversion features that were in-the-money as of the commitment date, which we recognized as beneficial conversion features. All of the shares of the convertible preferred stock we issued in these financings have been converted into common stock at fixed conversion rates. The embedded beneficial conversion features were valued separately and recognized by allocating to additional paid-in capital and accumulated deficit a portion of the net proceeds equal to the intrinsic value of the beneficial conversion features.

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

Results of Operations

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

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

Future expenditures on R&D programs are subject to many uncertainties, including whether we will further develop our product candidates with a partner or independently. At this time, due to such uncertainties and the risks inherent in drug product development and the associated regulatory process, we cannot estimate with reasonable certainty the duration of or costs to complete our R&D programs or whether or when or to what extent revenues will be generated from the commercialization and sale of any of our product candidates. The duration and costs of our R&D programs, in particular those associated with clinical and bioequivalence trials and research-related manufacturing, can vary significantly among programs as a result of a variety of factors, including:

- the number of trials necessary to demonstrate the safety and efficacy of a product candidate;
- the number of patients who participate in the trials;

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- the number and location of sites included in trials and the rate of site approval for the trial;
- the rates of patient recruitment and enrollment;
- the ratio of randomized to evaluable patients;
- the time and cost of process development activities related to our product candidates;
- the costs of manufacturing our product candidates;
- with respect to bioequivalence or comparative trials, 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 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, in particular any containing new chemical entities, and compliance with applicable regulations requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our R&D expenditures to increase and, in turn, have a material and unfavorable effect on our results of operations. We cannot be certain when, if ever, we will generate revenues from sales of any of our product candidates.

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

We operate our business and evaluate our company on the basis of a single reportable segment, which is the business of acquiring, developing and commercializing proprietary product candidates principally for the treatment of cancer. As a development-stage company, we have not generated any revenue from product sales to date, and we do not expect to generate revenue from product sales until such time that we have obtained approval from a regulatory agency to sell one or more of our product candidates, which we cannot predict will occur.

In 2010 and 2009, our R&D expenses consisted primarily of costs associated with nonclinical activities related to Exelbine and ANX-514, including regulatory-related consulting services, research-related manufacturing services and stability testing and a toxicology study of Exelbine. Our most significant R&D expenses were those relating to the submission and resubmission of our Exelbine NDA to the FDA. Our selling, general and administrative, or SG&A, expenses for the same periods consisted primarily of consultants fees for performing finance, accounting, human resources, facilities, internal systems support, business development, commercialization and investor relations functions activities, salaries, benefits and related personnel costs for employees, including our executive officers, and share-based compensation expense. The following table illustrates the types of operating expenses we incurred in 2010 and 2009 and their respective percent of our total operating costs for those periods:

	Operating Expenses Years Ended December 31,	
	2010	**2009**
Research and development	41%	56%
Selling, general and administrative	59%	43%
Depreciation and amortization	0%	1%
Total operating expenses	100%	100%

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Comparison of 2010 and 2009

Revenue. We recognized revenue of $0.5 million for the year ended December 31, 2010 and $0.3 million for the year ended December 31, 2009. Revenue in 2010 consists 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. Revenue in 2009 consists of a nonrefundable license fee under our March 2009 license agreement with respect to ANX-514 with Shin Poong Pharmaceutical Co., Ltd.

R&D Expenses. We maintain and evaluate our R&D expenses by the type of cost incurred rather than by project. We maintain and evaluate R&D expenses by type primarily because we 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. The following table summarizes our consolidated R&D expenses by type for each of the periods listed:

	Years Ended December 31,		January 1, 2005 through December 31,
	2010	2009	2010
External bioequivalence and clinical trial fees and expenses	$ 215,486	$ 603,097	$ 24,018,062
External nonclinical study fees and expenses (1)	3,225,723	5,083,474	27,254,671
Personnel costs	253,298	779,510	10,543,996
Share-based compensation expense	(5,745)	41,569	2,919,985
Total	$ 3,688,762	$ 6,507,650	$ 64,736,714

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

R&D expenses decreased by $2.8 million, or 43%, to $3.7 million for the year ended December 31, 2010, compared to $6.5 million for the year ended December 31, 2009. The decrease in R&D expenses in 2010 compared to 2009 was due primarily to a $1.9 million decrease in external nonclinical study fees and expenses. This decrease resulted largely from a $2.6 million decrease in costs of research-related manufacturing activities for Exelbine and a $0.1 million decrease in fees for regulatory-related consulting services related to Exelbine, partially offset by a $0.5 million increase in fees for regulatory-related consulting services related to ANX-514 and a $0.3 million increase in toxicology study expenses related to Exelbine. The decrease in personnel costs was attributable primarily to lower headcount in 2010 compared to 2009 and completion in 2009 of severance payments associated with our 2009 and 2008 workforce reductions. The decrease in external bioequivalence and clinical trial fees and expenses in 2010 compared to 2009 was due primarily to the release of residual accruals for expenses related to ANX-510 clinical trials that were completed in the fourth quarter of 2008 and the first quarter of 2009. The decrease in share-based compensation expense resulted primarily from the forfeiture of stock option awards in connection with employee terminations in 2009 and 2008.

We expect R&D expenses to be a significantly larger component of our total operating expenses in 2011 compared to 2010. We expect R&D expenses to increase in 2011 relative to 2010 to support continued development of ANX-514, to pursue development of purified 188, should our acquisition of SynthRx close, and to pursue development of any other technologies and/or product candidates we may acquire, including potentially adding new clinical, regulatory and manufacturing personnel.

Selling, General and Administrative Expenses. SG&A expenses were relatively flat year to year, with an increase of $0.3 million, or approximately 6%, to $5.3 million for the year ended December 31, 2010, compared to $5.0 million for the year ended December 31, 2009. In 2010 compared to 2009, fees for third-party services related to commercial-readiness activities related to Exelbine and identifying and evaluating strategic opportunities for our

product candidates and pipeline expansion increased by $0.3 million, consulting fees related to our finance, accounting, human resources, facilities and internal systems support increased by $0.2 million, our Delaware corporate franchise tax increased by $0.2 million and share-based compensation expense increased by $0.2 million. These increases were partially offset by a $0.5 million decrease in personnel costs, primarily as a result of lower headcount and the absence of severance costs in 2010, and a $0.1 million decrease in professional fees for legal, audit and tax services.

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We expect SG&A expenses to increase in 2011 relative to 2010 as we prepare for the commercial launch of Exelbine and, should it be approved, as we launch Exelbine, and any other products we may acquire, including potentially adding sales and marketing personnel, and to support continued development of ANX-514, pursue development of purified 188, should our acquisition of SynthRx close, and pursue development of any other technologies, product candidates and/or we may acquire.

Interest and Other Income/(Expense). Interest income amounted to $93,000 for 2010, compared to $7,000 in 2009. The increase in interest income of $86,000 for 2010 was primarily attributable to overall higher invested balances, though offset partially by lower interest rates earned. Even though we raised a substantial amount of additional capital through our January and May 2010 and January 2011 registered direct equity financings, we expect that interest income will continue to be low due to negligible interest rates. Other expense was $2,000 in 2010, compared to $47,000 in 2009. Both years expense was attributable to losses on the sale of various business assets.

Net Loss. Net loss applicable to common stock was $14.1 million, or $1.07 per share, for the year ended December 31, 2010, compared to a net loss applicable to common stock of $16.2 million, or $3.47 per share, for the year ended December 31, 2009. Included in the net loss applicable to common stock for 2010 and 2009 were non-cash deemed dividend expenses of approximately $5.6 million and $4.9 million, respectively, related to our January and May 2010 and June, July, August and October 2009 registered direct equity financings. Included in both net loss and net loss applicable to common stock for 2009 were charges associated with our 2009 and 2008 workforce reductions.

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 had a net loss of $8.5 million for the year ended December 31, 2010 and cash of approximately $28.0 million as of December 31, 2010.

In January and May 2010, we completed registered direct equity financings involving the issuance, respectively, of units consisting of shares of our Series E Stock and our Series F Stock and common stock purchase warrants. These financings resulted in an aggregate of $38.2 million in gross proceeds, and we received an aggregate of $27.4 million in net proceeds after deducting amounts deposited into escrow accounts to fund our dividend and related payment obligations in respect of the Series E Stock and Series F Stock, the fees and expenses of our placement agent and financial advisor in the financings, and our other offering expenses. As of December 31, 2010, all of the shares of our Series E Stock and Series F Stock had been converted into common stock and are no longer outstanding.

In January 2010, we received an aggregate of $0.3 million of net proceeds and issued an aggregate of 84,651 shares of our common stock in connection with the exercise of warrants issued in our June 2009 registered direct equity financing.

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, or 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 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.

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.

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We may receive up to $0.8 million, $4.4 million, $9.5 million and $11.3 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, respectively; however, the exercise of these warrants is subject to certain beneficial ownership limitations. In addition, we may receive up to $3.7 million of additional net proceeds from the exercise of warrants issued to our placement agent as additional consideration for services in connection with certain of our registered direct equity financings.

For a more detailed discussion of our 2009 and 2010 equity financings, see Note 6, 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 2010 versus 2009 cash flow from operating, investing and financing activities is provided below.

	December 31, 2010	Increase During 2010	December 31, 2009
Cash	$ 27,978,823	$ 19,311,419	$ 8,667,404
Net working capital	$ 26,607,603	$ 19,988,796	$ 6,618,807

	Year Ended December 31, 2010	Change Between Periods	Year Ended December 31, 2009
Net cash used in operating activities	$ (8,341,237)	$ 4,275,179	$ (12,616,416)
Net cash provided by (used in) investing activities	(24,134)	(40,134)	16,000
Net cash provided by financing activities	27,676,790	16,258,874	11,417,916
Net increase (decrease) in cash	$ 19,311,419	$ 20,493,919	$ (1,182,500)

Operating activities. Net cash used in operating activities was $8.3 million in 2010, compared to $12.6 million in 2009. The decrease in cash used in operating activities in 2010 was due primarily to realization of financial benefit from the restructuring, cost-cutting and re-prioritization initiatives we implemented beginning in October 2008 through June 2009; specifically, our workforce reductions and our discontinuation of active work on all compounds, other than Exelbine and ANX-514, to which we have or had rights during that period.

Investing activities. Net cash used in investing activities was $24,134 in 2010, compared to $16,000 provided by investing activities in 2009. 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. The $16,000 provided by investing activities in 2009 was from proceeds from sale of property and equipment.

Financing activities. Net cash provided by financing activities was $27.7 million in 2010, compared to $11.4 million in 2009. The cash provided by financing activities in 2010 and 2009 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 as of December 31, 2010, together with the net proceeds from the equity financing we completed in January 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 extent to which we acquire new technologies, product candidates, products or businesses; the scope, prioritization and number of development and/or commercialization 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 and manufacturing clinical trial material; the rate of progress and costs to comply with post-approval requirements imposed on our products candidates, should any be approved; the extent to which we partner or collaborate with third parties to develop, seek regulatory approval of and commercialize our product candidates or products, or sell or license our

product candidates or products to others; the costs and timing of acquiring or developing sales, marketing and distribution capabilities and the regulatory compliance and administrative capabilities to commercialize Exelbine in the U.S., regardless of whether Exelbine is ultimately approved by the FDA; the costs and timing of acquiring or developing similar commercialization capabilities for other of our product candidates, including ANX-514, and product candidates or products we may acquire in the future, including purified 188 should our acquisition of SynthRx close; and whether any of our product candidates for which we receive regulatory approval, if any, achieve broad market acceptance. In addition, currently, we have only three full-time employees and one part-time employee and rely on third parties to perform many essential services for us. Increasing the size of our workforce will also impact the period through which our operating funds will sustain us, but the timing and extent to which we do so 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 technologies, product candidates, products or businesses.

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We continue to undertake commercial-readiness activities with respect to Exelbine to prepare for its launch in the U.S., should the FDA approve our Exelbine NDA. In preparing for the potential commercial launch of Exelbine, we expect to develop or acquire internal marketing, distribution and sales capabilities and associated regulatory compliance capabilities, as well as contract with third parties to supplement and enhance our internal capabilities. Such activities may result in a substantial increase in our workforce in 2011. We continue to evaluate the relative benefits of developing or acquiring these capabilities, as well as the use of third parties. Currently, we cannot forecast with any degree of certainty the costs associated with our Exelbine commercial-readiness activities during 2011.

We also continue to develop ANX-514 following our February 2011 meeting with the FDA. We are in the process of developing a protocol for a phase 3 clinical trial of ANX-514 for submission to the FDA. In 2011, we expect to use capital to develop the phase 3 trial protocol, conduct manufacturing process development activities and manufacture clinical trial material that would enable us to initiate a clinical trial of ANX-514 should we reach agreement with the FDA as to the trial protocol. In parallel, we also 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, if at all. As our discussions with the FDA progress, 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. Currently, we cannot forecast with any degree of certainty the costs associated with our continued development of ANX-514 during 2011.

In February 2011, we entered into an agreement and plan of merger to acquire SynthRx, Inc. in exchange for shares of our common stock. We expect to consummate our acquisition of SynthRx in the first half of 2011. As discussed in more detail under Item 1 Business above, we initially intend to develop purified 188 for the treatment of sickle cell crisis in a pediatric population. If our acquisition of SynthRx closes, we intend to meet with the FDA to reach agreement on a protocol for a phase 3 clinical trial of purified 188 for this indication. In parallel, we expect to prepare to initiate the clinical trial, including conducting manufacturing process development activities and manufacturing clinical material, which could enable us to initiate it in 2012. We also expect to increase our workforce in connection with our acquisition of SynthRx. Until we reach agreement with the FDA on a phase 3 trial protocol, we cannot forecast with any degree of certainty the costs that would be associated with our development of purified 188 for the treatment of sickle cell crisis in a pediatric population. However, our preliminary estimate of third party costs related to this development program through submission of an NDA is approximately $15 million to $25 million.

In addition, in connection with the consummation of the SynthRx acquisition, we would issue 2,938,773 shares of our common stock to SynthRx s stakeholders, 1,938,773 of which would be subject to repurchase by us in the event purified 188 does not achieve the First Milestone. We could issue up to an aggregate of 13,478,050 additional shares of our common stock to SynthRx s stakeholders if the development of purified 188 achieves the First, Second and Third Milestones and our stockholders approve the issuance of such milestone-related shares, as required by NYSE Amex rules. If our stockholders do not approve the issuance of the milestone-related shares, under the terms of the merger agreement, we would be required to pay SynthRx s stakeholders in cash the value of the milestone-related shares we would have otherwise issued, with all such cash payments made in quarterly installments and, with respect to the cash value associated with the Second and Third Milestone shares (an aggregate of 12,478,050 shares), payable based on net sales of purified 188. We cannot determine the amount of our potential cash payments to SynthRx s stakeholders because the amount of such payments, if any, will depend on the 10-day volume weighted average of the closing price of our common stock at the time a milestone is achieved and the market price of our common stock historically has been, and likely will continue to be, highly volatile.

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We continue to spend significant time and attention identifying and evaluating additional opportunities to expand our product pipeline and may do so through one or more in-license, asset acquisition or merger transactions. We continue to believe that, due to a challenging capital raising environment, many drug development programs with substantial potential currently are available at attractive valuations. If we seek to expand our product pipeline through a merger or other business combination with one of these companies, given our recent market capitalization and our desire to preserve our cash for development activities, such a transaction may result in our stockholders owning less than a majority of the voting securities of the surviving entity. The process of identifying and evaluating various opportunities may be lengthy and complex and divert management s attention from our current development programs, and we may not be able to acquire or acquire rights to additional technologies, product candidates and/or products on acceptable terms, or at all. We have limited resources to identify, evaluate and negotiate the acquisition of new technologies, product candidates and/or products or rights thereto and to integrate them into our current infrastructure. Supplementing our current resources to complete one or more transactions may be costly. We anticipate that our capital requirements will increase in future periods if we are successful in expanding our product pipeline.

We may also seek or need to raise additional capital through public or private sales of our equity securities or debt financings. However, we may not be able to obtain additional financing on a timely basis or on acceptable terms, if at all.

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 we are not required to provide the information required by this item.

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure 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.

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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, 2010. Based on that evaluation, our principal executive officer and principal financial officer have concluded that these disclosure controls and procedures were effective as of December 31, 2010.

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, 2010 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, 2010.

This annual report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting. Management s report on internal control over financial reporting was not subject to attestation by our independent registered public accounting firm pursuant to the rules of the SEC because we are neither an accelerated filer nor a larger accelerated filer.

Item 9B. Other Information.

Not applicable.

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PART III

Certain information required by Part III is omitted from this report pursuant to General Instruction G(3) of Form 10-K because we will file a definitive proxy statement (the Proxy Statement) within 120 days after the end of our fiscal year pursuant to Regulation 14A for our 2011 annual meeting of stockholders, and such information included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

Code of Ethics

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or persons performing similar functions, as well as all of our other officers, directors and employees. This code of ethics is a part of our code of business conduct and ethics, and 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 report of J.H. Cohn LLP and financial statements:

Report of J.H. Cohn LLP, Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of December 31, 2010 and 2009
Consolidated Statements of Operations for the years ended December 31, 2010 and 2009 and from inception through December 31, 2010

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Consolidated Statements of Stockholders Equity (Deficit) and Comprehensive Loss from inception through December 31, 2010
Consolidated Statements of Cash Flows for the years ended December 31, 2010 and 2009 and from inception through December 31, 2010
Notes to Consolidated Financial Statements

(2) Financial Statement Schedules. See subsection (c) below.
(3) Exhibits. See subsection (b) below.

(b) Exhibits.

Exhibit	Description
2.1(1)	Agreement and Plan of Merger, dated April 7, 2006, among the registrant, Speed Acquisition, Inc., SD Pharmaceuticals, Inc. and certain individuals named therein (including exhibits thereto)
3.1(2)	Amended and Restated Certificate of Incorporation of the registrant
3.2(3)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the registrant dated October 5, 2009
3.3(4)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the registrant, dated April 23, 2010
3.4(5)	Certificate of Designation of Preferences, Rights and Limitations of 0% Series A Convertible Preferred Stock
3.5(6)	Certificate of Designation of Preferences, Rights and Limitations of 5% Series B Convertible Preferred Stock
3.6(7)	Certificate of Designation of Preferences, Rights and Limitations of 5% Series C Convertible Preferred Stock
3.7(8)	Certificate of Designation of Preferences, Rights and Limitations of 4.25660% Series D Convertible Preferred Stock
3.8(9)	Certificate of Designation of Preferences, Rights and Limitations of 3.73344597664961% Series E Convertible Preferred Stock
3.9(10)	Certificate of Designation of Preferences, Rights and Limitations of 2.19446320054018% Series F Convertible Preferred Stock
3.10(11)	Amended and Restated Bylaws of the registrant (formerly known as Biokeys Pharmaceuticals, Inc.)
10.1(12)	Securities Purchase Agreement, dated July 21, 2005, among the registrant and the Purchasers (as defined therein)
10.2(12)	Rights Agreement, dated July 27, 2005, among the registrant, the Icahn Purchasers and Viking (each as defined therein)

10.3(13)	First Amendment to Rights Agreement, dated September 22, 2006, among the registrant and the Icahn Purchasers (as defined therein)
10.4(14)	Second Amendment to Rights Agreement, dated February 25, 2008, among the registrant and the Icahn Purchasers (as defined therein)
10.5(15)	Third Amendment to Rights Agreement, dated August 26, 2009, among the registrant and Icahn Purchasers (as defined therein)
10.6(12)	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.

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Exhibit	Description
10.7(12)	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(5)	Engagement Letter Agreement, dated June 7, 2009, by and between the registrant and Rodman & Renshaw, LLC
10.9(5)	Securities Purchase Agreement, date June 8, 2009, governing the issuance and sale of the registrant s 0% Series A Convertible Preferred Stock and 5-year common stock purchase warrants
10.10(5)	Form of Common Stock Purchase Warrant issued on June 12, 2009 by the registrant to the purchasers of the registrant s 0% Series A Convertible Preferred Stock and to Rodman & Renshaw, LLC
10.11(6)	Engagement Letter Agreement, dated June 26, 2009, by and between the registrant and Rodman & Renshaw, LLC
10.12(6)	Securities Purchase Agreement, dated June 29, 2009, governing the issuance and sale of the registrant s 5% Series B Convertible Preferred Stock
10.13(6)	Form of Common Stock Purchase Warrant issued on July 6, 2009 by the registrant to Rodman & Renshaw, LLC
10.14(7)	Engagement Letter Agreement, dated August 4, 2009, by and between the registrant and Rodman & Renshaw, LLC
10.15(7)	Securities Purchase Agreement, dated August 5, 2009, governing the issuance and sale of the registrant s 5% Series C Convertible Preferred Stock
10.16(7)	Form of Common Stock Purchase Warrant issued on August 10, 2009 by the registrant to Rodman & Renshaw, LLC
10.17(16)	Engagement Letter Agreement, dated September 24, 2009, by and between the registrant and Rodman & Renshaw, LLC
10.18(8)	Engagement Letter Agreement, dated September 29, 2009, by and between the registrant and Rodman & Renshaw, LLC
10.19(8)	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
10.20(8)	Form of Common Stock Purchase Warrant issued on October 9, 2009 by the registrant to the purchasers of the registrant s 4.25660% Series D Convertible Preferred Stock and to Rodman & Renshaw, LLC
10.21(9)	

	Engagement Letter Agreement, dated January 3, 2010, by and between the registrant and Rodman & Renshaw, LLC
10.22(9)	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
10.23(9)	Form of Common Stock Purchase Warrant issued on January 7, 2010 by the registrant to the purchasers of the registrant s 3.73344597664961% Series E Convertible Preferred Stock and to Rodman & Renshaw, LLC
10.24(10)	Engagement Letter Agreement, dated April 29, 2010, by and between the registrant and Rodman & Renshaw, LLC

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Exhibit	Description
10.25(10)	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
10.26(10)	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
10.27(17)	Engagement Letter Agreement, dated January 5, 2011, by and between the registrant and Rodman & Renshaw, LLC
10.28(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
10.29(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
10.30#(18)	2005 Equity Incentive Plan
10.31#(19)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan
10.32#(20)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for director option grants beginning in 2008)
10.33#(21)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan (for option grants to employees approved in March 2008)
10.34#(2)	Form of Restricted Share Award Agreement under the 2005 Equity Incentive Plan
10.35#(22)	2008 Omnibus Incentive Plan
10.36#(23)	Form of Notice of Grant of Restricted Stock Units under the 2008 Omnibus Incentive Plan (for grants to employees in January 2009)
10.37#(23)	Form of Restricted Stock Units Agreement under the 2008 Omnibus Incentive Plan
10.38#(24)	Form of Non-Statutory Stock Option Grant Agreement (for directors) under the 2008 Omnibus Incentive Plan
10.39#(24)	Form of Non-Statutory/Incentive Stock Option Grant Agreement (for consultants/employees) under the 2008 Omnibus Incentive Plan
10.40#(25)	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Brian M. Culley in July 2009)
10.41#(25)	

	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Patrick L. Keran in July 2009)
10.42#(26)	Form of letter, dated January 20, 2010, modifying options granted to Brian M. Culley and Patrick L. Keran in July 2009
10.43#(26)	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Brian M. Culley in January 2010)
10.44#(26)	Form of Incentive Stock Option Grant Agreement under the 2008 Omnibus Incentive Plan (for grant to Patrick L. Keran in January 2010)
10.45(20)	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
10.46 (27)	License Agreement, dated March 25, 2009, among the registrant, SD Pharmaceuticals, Inc. and Shin Poong Pharmaceutical Co., Ltd.
10.47(28)	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

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Exhibit	Description
10.48(2)	First Amendment to the Standard Multi-Tenant Office Lease Gross, dated June 3, 2004 between the registrant and George V. & Ellen M. Casey, Trustees of the Casey Family Trust dated June 22, 1998
10.49(29)	Second Amendment to Standard Mutli-Tenant Office Lease Gross, dated July 22, 2009, by and among Westcore Mesa View, LLC, DD Mesa View LLC and the registrant
10.50(30)	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
10.51(31)	Fourth Amendment to Standard Multi-Tenant Office Lease Gross, dated February 4, 2010, by and among Westcore Mesa View, LLC, DD Mesa View, LLC and the registrant
10.52#(32)	Offer letter, dated November 15, 2004, to Brian M. Culley
10.53#(23)	Retention and Incentive Agreement, dated January 28, 2009 between the registrant and Brian M. Culley
10.54#(27)	Retention and Incentive Agreement, dated January 28, 2009, between the registrant and Patrick L. Keran