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Filed pursuant to Rule 424(b)(3)
Registration Statement No. 333-174203

PROSPECTUS

ADVENTRX Pharmaceuticals, Inc.

16,278,901 Shares of Common Stock

This prospectus may be used only in connection with the resale, from time to time, by the selling stockholders identified in this prospectus, of up to 16,278,901 shares of our common stock, which includes:

- 662,078 shares of our common stock issued to the selling stockholders pursuant to the terms of that certain Agreement and Plan of Merger, dated February 12, 2011, by and among the registrant, SRX Acquisition Corporation, SynthRx, Inc. and, solely with respect to Sections 2 and 8 of such agreement, an individual who was a principal stockholder of SynthRx (the "Merger Agreement");
- 200,000 shares of common stock that are currently held in escrow to indemnify us against breaches of representations and warranties and may be released to the selling stockholders pursuant to the terms of the Merger Agreement;
- 1,938,773 shares of common stock issued to the selling stockholders, subject to a repurchase right in favor of our company that lapses upon the achievement of a performance milestone pursuant to the terms of the Merger Agreement; and
- 13,478,050 shares of common stock that may be issued to the selling stockholders, subject to the achievement of performance milestones pursuant to the terms of the Merger Agreement.

The selling stockholders may offer and sell the shares of common stock being offered by this prospectus from time to time in public or private transactions, or both. These sales may occur at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market prices, or at negotiated prices. The selling stockholders may sell shares to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling stockholders, the purchasers of the shares, or both. See "Plan of Distribution" for a more complete description of the ways in which the shares may be sold.

We will not receive any of the proceeds from the sale of the shares by the selling stockholders.

Our common stock is traded on the NYSE Amex equities market under the symbol "ANX." On October 5, 2011, the last reported sale price of our common stock on the NYSE Amex equities market was $0.84.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 6 of this prospectus before you make an investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is October 13, 2011.

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ABOUT THIS PROSPECTUS

This prospectus constitutes part of the registration statement on Form S-3 we filed with the U.S. Securities and Exchange Commission (the "SEC") under the Securities Act of 1933, as amended (the "Securities Act"), utilizing a "shelf" registration or continuous offering process. It omits some of the information contained in the registration statement, including the exhibits to the registration statement, and reference is made to the registration statement for further information with respect to us and the securities being offered by the selling stockholders. The registration statement, including the exhibits, can be read on the SEC's website or at the SEC's offices mentioned under the heading "Where You Can Find More Information." Any statement contained in this prospectus concerning the provisions of any document filed as an exhibit to the registration statement or otherwise filed with the SEC is not necessarily complete, and in each instance, reference is made to the copy of the document as filed.

You should rely only on the information contained or incorporated by reference in this prospectus. Neither we nor the selling stockholders have authorized any other person to provide you with different information. The information contained in this prospectus, and the documents incorporated by reference herein, are accurate only as of the date such information is presented. You should also read this prospectus together with the additional information described under the heading "Where You Can Find More Information." Neither the delivery of this prospectus nor any sale made in connection with this prospectus shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus or that the information contained by reference to this prospectus is correct as of any time after its date.

This prospectus may be amended from time to time to add, update or change information in this prospectus. Any statement contained in this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in such prospectus amendment modifies or supersedes such statement. Any statement so modified will be deemed to constitute a part of this prospectus only as so modified, and any statement so superseded will be deemed not to constitute a part of this prospectus.

We are not, and the selling stockholders are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted.

Trademarks, Trade Names and Service Marks

We own or have rights to use the trademarks, service marks and trade names that we use in conjunction with the operation of our business. Some of the more important trademarks that we own or have rights to use that appear in this prospectus include: Exelbine™ and SYNTHRX®, which are registered or trademarked in the United States. Each trademark, trade name or service mark of any other company appearing in this prospectus is, to our knowledge, owned by such other company.

Company References

In this prospectus, unless otherwise specified or the context otherwise requires, references to "ADVENTRX Pharmaceuticals, Inc.," "ADVENTRX," "we," "us," "our" and "our company" refer to ADVENTRX Pharmaceuticals, Inc. and its consolidated subsidiaries.

SUMMARY

The following summary contains basic information about our company and the offering by the selling stockholders. It does not contain all of the information that is important to you. We encourage you to carefully read this prospectus in its entirety and the documents to which we refer you.

Our Company

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing proprietary product candidates. We have devoted substantially all of our resources to research and development or to acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue and have incurred significant losses since inception. Our current lead product candidates are ANX-188, a novel, purified, rheologic and antithrombotic compound, which we initially are developing as a first-in-class treatment for pediatric patients with sickle cell disease in acute crisis, and ANX-514, a detergent-free formulation of the chemotherapy drug, Taxotere®.

Recent Developments

Exelbine™. In November 2010, we submitted a new drug application, or NDA, for Exelbine (vinorelbine injectable emulsion) to the U.S. Food and Drug Administration, or FDA, and in August 2011, we received a complete response letter from the FDA stating that it could not approve the Exelbine NDA in its present form. In particular, the letter stated that, based on inspections at clinical sites, the authenticity of the drug products used in the pivotal bioequivalence trial could not be verified and that the bioequivalence trial would need to be repeated to address this deficiency. During a meeting with the FDA in September 2011, FDA staff indicated that the failure of the clinical sites to randomly select and retain reserve samples of the test article (Exelbine) and reference standard (Navelbine®) could not be overcome by alternative methods of verifying authenticity and reiterated that the bioequivalence study would need to be repeated. We have discontinued making significant additional capital investments into the Exelbine program and are seeking a partner or outside investor for the program.

ANX-514. In February 2011, we met with the FDA to discuss ANX-514 (docetaxel for injectable emulsion) 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®, a branded formulation of docetaxel, 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 plan to meet with the FDA in the fourth quarter of 2011 to discuss a study in which we compare the safety profiles of ANX-514, without routine administration of corticosteroid premedication, and Taxotere, with routine administration of corticosteroid premedication. We believe this single study will provide sufficient clinical data to support an ANX-514 NDA, should the study demonstrate comparable safety profiles between ANX-514 and Taxotere.

Acquisition of SynthRx. In April 2011, we completed the acquisition (the "Merger") of SynthRx, Inc., a privately-held, Delaware corporation ("SynthRx"), pursuant to the terms of the Agreement and Plan of Merger, dated February 12, 2011 (the "Merger Agreement"), by and among our Company, SRX Acquisition Corporation, a Delaware corporation and wholly owned subsidiary of ours ("Merger Sub"), SynthRx and, solely with respect to Sections 2 and 8 of the Merger Agreement, an individual who is a principal stockholder of SynthRx (the "Stockholders' Agent"), and SynthRx became a wholly owned subsidiary of ours. SynthRx's lead product candidate is a novel, purified, rheologic and antithrombotic compound, poloxamer 188, which we are developing as ANX-188.

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

(i) 1,000,000 shares (the "Fully Vested Shares") of our common stock at the effective time of the Merger; provided, however that, pursuant to the Merger Agreement, 137,922 shares were deducted from the number of Fully Vested Shares issued as a result of certain transaction expenses of SynthRx and 200,000 of the Fully Vested Shares were deposited into escrow (the "Closing Escrow Amount") to indemnify us against breaches of representations and warranties;

(ii) up to 1,938,773 shares of our common stock at the at the effective time of the Merger (the "Subject to Vesting Shares," and together with the 862,078 Fully Vested Shares issued to the former SynthRx stockholders and the escrow agent, the "Closing Shares"), which Subject to Vesting Shares are subject to various repurchase rights by us and fully vest, subject to reduction upon certain events, upon achievement of the First Milestone (defined below);

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

(iv) 3,839,400 shares of our common stock (the "Second Milestone Shares"), issued upon achievement of the Second Milestone (the "Second Milestone Payment"). The "Second Milestone" shall mean the acceptance for review of the ANX-188 NDA by the FDA; and

(v) 8,638,650 shares of our common stock (the "Third Milestone Shares," and together with the First Milestone Shares and the Second Milestone Shares, the "Milestone Shares"), issued upon achievement of the Third Milestone (the "Third Milestone Payment," and together with the First Milestone Payment and the Second Milestone Payment, the "Milestone Payments"). The "Third Milestone" shall mean the approval by the FDA of the ANX-188 NDA.

Notwithstanding anything set forth above, in the event that the issuance of the Milestone Shares (x) violates federal or state securities laws or the listing standards of any national securities exchange to which we are subject at the time of such issuance, or (y) we are unable to obtain the affirmative vote of the holders of a majority of our common stock approving the issuance of the Milestone Shares on or before December 31, 2011, we are required to make the applicable Milestone Payments, or portion thereof, in cash based on the product of (x) the number of shares of our common stock issuable upon achievement of an applicable milestone and (y) the daily volume weighted average of actual closing prices measured in hundredths of cents of our common stock on the NYSE Amex, or such other national securities exchange on which our common stock is then listed, for the ten consecutive trading days immediately prior to the applicable Milestone Payment. Any Milestone Payment made in cash will be payable in quarterly installments. If the First Milestone Payment must be made in cash, such amount will be payable at a rate of $1,000,000 per calendar quarter and, if the Second Milestone Payment or the Third Milestone Payment must be made in cash, such amounts will be payable at a rate of 35% of net sales for the applicable calendar quarter of intravenous injection products in which a purified form of poloxamer 188 is an active ingredient. We cannot determine the amount of the potential cash payments to the former SynthRx stockholders because the amount of such payments, if any, will be determined based on the 10-day volume weighted average of the closing prices of our common stock immediately prior to achievement of the applicable milestone, and the market price of our common stock historically has been, and likely will continue to be, highly volatile.

Pursuant to the Merger Agreement and effective as of immediately following the closing of the Merger on April 8, 2011, Lewis J. Shuster was appointed to our board of directors. Pursuant to the Merger Agreement, we were required to appoint to our board of directors an individual proposed by SynthRx and reasonably acceptable to our company. Mr. Shuster was the individual proposed by SynthRx. Mr. Shuster was not a director, officer, employee or stockholder of SynthRx.

In connection with our 2011 Annual Meeting of Stockholders, we filed a definitive proxy statement that included a proposal requesting our stockholders to approve the issuance of the Milestone Shares, in lieu of cash payments for the Milestone Payments. Our stockholders approved this proposal at the annual meeting, which was held June 15, 2011.

On February 12, 2011, in connection with the Merger Agreement, our company, each of the former principal stockholders of SynthRx and, solely with respect to Section 3(c) thereof, the Stockholders' Agent, entered into a Stockholders' Voting and Transfer Restriction Agreement (the "Voting and Transfer Restriction Agreement"). Pursuant to the terms and conditions of the Voting and Transfer Restriction Agreement, each former principal SynthRx stockholder has agreed to vote all shares of our common stock then beneficially owned by that stockholder with respect to every action or approval by written consent of our stockholders in such manner as directed by us. Notwithstanding the foregoing, until the earlier of: (i) achievement of the Third Milestone and (ii) the four (4) year anniversary of the closing of the Merger, each stockholder party shall be permitted to vote any shares of our common stock that he, she or it beneficially owns in such person'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 eighty percent (80%) of the consideration received by our company (or our stockholders) is non-contingent and paid in cash.

The Voting and Transfer Restriction Agreement also provides that no shares of our common stock that are (i) subject to vesting in accordance with the terms of the Merger Agreement and/or (ii) that have been deposited in escrow may be transferred until such shares have vested and/or are released from escrow, as applicable (and upon such vesting or release, as applicable, such shares

shall be referred to as the "Transferable Shares"). The stockholder parties shall be permitted to transfer any Transferable Shares to an affiliate or pursuant to any private resale transactions or series of transactions undertaken in compliance with the Securities Act, any rules and regulations promulgated thereunder, and any applicable state securities laws; provided, however, that such transferee shall be or shall have become a party to the Voting and Transfer Restriction Agreement and shall have agreed in writing to be bound by all of the terms and conditions thereof.

The Voting and Transfer Restriction Agreement also provides that upon the effectiveness of (x) the Registration Statement of which this prospectus forms a part or (y) upon such Transferrable Shares becoming freely transferable to the public in compliance with Rule 144 promulgated under the Securities Act, the stockholder parties, as a group, shall have the right to transfer on each trading day on any eligible market such aggregate number of Transferable Shares equal to or less than ten percent (10%) of the average daily trading volume of our common stock. In addition, upon the effectiveness of (x) the Registration Statement of which this prospectus forms a part, or (y) upon such Transferrable Shares becoming freely transferable to the public in compliance with Rule 144 promulgated under the Securities Act, the stockholder parties, as a group, shall have the right, exercisable not more than once in any twelve (12)-month period, to transfer Transferable Shares on any eligible market in an amount equal to, in the aggregate, five (5) times the average daily trading volume of our common stock.

ANX-188. SynthRx's lead product candidate is a novel, purified, rheologic and antithrombotic compound, poloxamer 188, which, we are developing as ANX-188. We believe ANX-188 is a late-stage product candidate that restores hydration lattices and minimizes the cascade of adhesive, inflammatory and coagulation responses that cause adhesion of cells, impaired blood flow and tissue ischemia. ANX-188 may have numerous applications as a cytoprotective, rheologic, antithrombotic and anti-inflammatory agent. Initially, we are developing ANX-188 as a first-in-class treatment for pediatric patients with sickle cell disease in acute crisis and, if 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 ANX-188 for that indication in 2012.

Corporate Information

Our company was incorporated in Delaware in December 1995. In October 2000, we merged our wholly owned subsidiary, Biokeys Acquisition Corp., with and into Biokeys, Inc. and changed our name to Biokeys Pharmaceuticals, Inc. In May 2003, we merged Biokeys, Inc., our wholly owned subsidiary, with and into us and changed our name to ADVENTRX Pharmaceuticals, Inc. In April 2006, we acquired SD Pharmaceuticals, Inc., a Delaware corporation, as a wholly owned subsidiary, and, in April 2011, we acquired SynthRx, Inc., a Delaware corporation, as a wholly owned subsidiary.

Our executive offices are located at 12390 El Camino Real, Suite 150, San Diego, California 92130, and our telephone number is (858) 552-0866. Our corporate website is located at www.adventrx.com. We make available free of charge through our corporate Internet website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

The Offering

Securities Offered:	This prospectus may be used only in connection with the resale, from time to time, by the selling stockholders identified in this prospectus, of up to 16,278,901 shares of our common stock, which includes: • 662,078 shares of our common stock issued to the selling stockholders pursuant to the terms of the Merger Agreement; • 200,000 shares of common stock that are currently held in escrow to indemnify us against breaches of representations and warranties and may be released to the selling stockholders pursuant to the terms of the Merger Agreement; • 1,938,773 shares of common stock issued to the selling stockholders, subject to a repurchase right in favor of our company that lapses upon the satisfaction of a performance milestone pursuant to the terms of the Merger Agreement; and • 13,478,050 shares of common stock that may be issued to the selling stockholders, subject to the achievement of performance milestones pursuant to the terms of the Merger Agreement.
Common Stock Outstanding:	26,465,709 shares (as of September 30, 2011)
Use of Proceeds:	The selling stockholders will receive all of the proceeds from the sale of the shares offered for sale under this prospectus. We will receive none of the proceeds from the sale of the shares by the selling stockholders.
NYSE Amex Symbol:	ANX
Risk Factors:	Investing in our securities involves a high degree of risk and purchasers of our securities may lose their entire investment. See "Risk Factors" below and the other information included elsewhere in this prospectus for a discussion of factors you should carefully consider before deciding to invest our securities.

The number of shares of our common stock outstanding as of September 30, 2011 includes 2,800,851 shares of our common stock issued on April 8, 2011 to the selling stockholders and the escrow agent upon completion of our acquisition of SynthRx, Inc. This number does not include:

- 7,777,988 shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2011, at a weighted average exercise price of $6.58 per share;
- 1,553,692 shares of common stock issuable upon exercise of options issued under our equity incentive plans and outstanding as of September 30, 2011, at a weighted average exercise price of $4.75 per share;
- 3,256,014 shares of common stock available as of September 30, 2011 for future issuance under our Amended and Restated 2008 Omnibus Incentive Plan; and
- 13,478,050 shares of common stock that may be issued to the selling stockholders, subject to the achievement of performance milestones pursuant to the terms of the Merger Agreement.

All share and per share information in this prospectus related to dates or periods prior to April 23, 2010 reflects the 1-for-25 reverse split of our outstanding common stock that took place on that date.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risk factors discussed below, together with all the other information contained in any of our filings with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, incorporated by reference into this prospectus, before deciding whether to purchase any of the securities being offered by this prospectus. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or part of your investment.

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 proprietary product candidates, but such product candidates cannot be marketed until the regulatory process is completed and governmental approvals have been obtained. Accordingly, there is no current source of revenues from operations, much less profits, to sustain our present activities, and no revenues from operations will likely be available until, and unless, our product candidates are approved by the FDA or other regulatory agencies and successfully marketed, either by us or a partner, an outcome which we may not achieve.

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

We currently have no products for sale and only two product candidates, ANX-188 and ANX-514, for which we actively are pursuing regulatory approval on an independent basis. 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 these product candidates and our efforts in this regard may prove unsuccessful. Until recently, we were also pursuing FDA approval of Exelbine, our novel emulsion formulation of the chemotherapy drug vinorelbine. In November 2010, we submitted a new drug application, or NDA, for Exelbine (vinorelbine injectable emulsion) to the U.S. Food and Drug Administration, or FDA, and in August 2011, we received a complete response letter from the FDA stating that it could not approve the Exelbine NDA in its present form. In particular, the letter stated that, based on inspections at clinical sites, the authenticity of the drug products used in the pivotal bioequivalence trial could not be verified and that the bioequivalence trial would need to be repeated to address this deficiency. During a meeting with the FDA in September 2011, FDA staff indicated that the failure of the clinical sites to randomly select and retain reserve samples of the test article (Exelbine) and reference standard (Navelbine) could not be overcome by alternative methods of verifying authenticity and reiterated that the bioequivalence study would need to be repeated. Failure to obtain approval of the Exelbine NDA, in particular, as a result of logistical matters that investors may perceive as within our control, and our subsequent discontinuation of the Exelbine program may be viewed negatively and adversely affect investor confidence in our company, which could have a material adverse effect on our stock price and our ability to raise additional capital to pursue development and regulatory approval of our other product candidates.

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 protocol for a pivotal safety study and intend to discuss it with the FDA during the fourth quarter of 2011. We also plan to discuss with the FDA the manner in which reserve samples in Study 514-01 were selected and maintained. 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 bioequivalence studies 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 investment in 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.

If any of our current or future product candidates is approved by the FDA or any foreign regulatory agency, our ability to generate revenues from these products will depend in substantial part on the extent to which they are accepted by the medical community and reimbursed by third-party payors 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 $165.7 million as of June 30, 2011, and we expect to continue to incur substantial operating losses for the foreseeable future, even if we or a future partner of ours is successful in advancing our product candidates to market. We do not expect to generate cash flows from sales of our products unless and until our products are approved for marketing, the 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 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, 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 12 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 and cash equivalents as of June 30, 2011, which were approximately $42.0 million, will be sufficient to fund our currently planned level of operations 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 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 continued volatility of U.S. and international equity markets, may adversely impact our ability to raise additional capital.

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.

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 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 September 30, 2011 and a closing price of $0.84, which was the closing price of our common stock on October 5, 2011, we could not raise more than approximately $4.4 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.

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 and/or marketing of any products or product candidates licensed or sold to third parties may be reduced and thus we may not realize the full value of any such products or product candidates. Debt financings could involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens or make investments and may, among other things, preclude us from making distributions to stockholders (either by paying dividends or redeeming stock) and taking other actions beneficial to our stockholders. In addition, investors could impose more one-sided investment terms and conditions on companies that have or are perceived to have limited remaining funds or limited ability to raise additional funds. The lower our cash balance, the more difficult it is likely to be for us to raise additional capital on commercially reasonable terms, or at all.

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

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. 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.

In addition, we may seek to increase the size of our organization in connection with initiating clinical activities with respect to ANX-188 and ANX-514, should we reach agreement with the FDA regarding clinical studies for those product candidates. Currently, we have only 12 employees and we rely on third parties to perform many essential services for us. The success of our business will depend, in part, on our ability to attract and retain highly qualified personnel, and 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. Recruiting and retaining employees, including senior-level personnel, with relevant product development and regulatory 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 and our highly volatile and currently low stock price. If we cannot attract and retain additional skilled personnel, we may not achieve our development and other goals.

If we are unable to raise sufficient additional capital as needed, we may be forced to reduce our current and/or planned development 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 June 30, 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 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 ANX-514 in new indications or other label changes intended to expand the scale and scope of its market potential, or any clinical and/or nonclinical studies that may be required by the FDA to support approval of ANX-188.

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

During 2010 and the first half of 2011, our business strategy involved a particular focus on expanding our product pipeline through one or more in-license, asset acquisition or merger transactions. Although, currently, we are focused on developing our two lead product candidates, we continue to evaluate strategic transaction opportunities that we believe may increase the value of our company. 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, in addition to the 2,800,851 shares we issued upon the completion of our acquisition of SynthRx, we could issue up to an aggregate of 13,478,050 additional shares of our common stock to SythRx's former stockholders upon achievement of milestones related to the development and regulatory approval of ANX-188 for the treatment of sickle cell crisis in children. If all milestones are achieved without reduction, the number of shares we issue in connection with the SynthRx acquisition would, in the aggregate, represent an approximately 41% 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.

We may evaluate new technologies, product candidates and/or products that we believe have a strategic fit with our current or future business strategy. However, any future strategic transaction, including any in-license, asset acquisition and merger transaction, 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;
- 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 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 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, because our public float was more than $75 million as of June 30, 2011, we will be required, for the first time in several years, to obtain an attestation report from our independent registered public accounting firm as to our year-end assessment of the effectiveness of our internal control over financial reporting, which likely will consume significant additional financial and managerial resources.

We have in the past discovered, and may in the future discover, areas of internal controls that need improvement. For example, during the fourth quarter of 2008, we discovered that we did not correctly apply generally accepted accounting principles relating to accounting for warrant liability because our accounting staff did not have adequate training or expertise, and determined that we had a material weakness in our internal control over financial reporting as of December 31, 2007. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. For a detailed description of this material weakness and our remediation of this material weakness, see “Part II — Item 9A(T) — Controls and Procedures” of our annual report on Form 10-K for the year ended December 31, 2008. If we identify a material weakness in our internal control over financial reporting 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. From July 2009 to March 2011, our

president and chief operating officer, who has no formal education in finance or accounting, served as our principal financial and principal accounting officer. He continues to serve as our principal financial 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 disrupt our business operations and result in setbacks to our development programs. Even though we believe we carry commercially reasonable insurance, we might suffer losses that exceed the coverage available under these insurance policies. In addition, we are not insured against terrorist attacks or earthquakes.

Risks Related to Drug Development and Commercialization

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

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

To varying degrees based on the regulatory plan for each 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, in August 2011, we received a complete response letter from the FDA stating that it could not approve the Exelbine NDA in its present form. In particular, the letter stated that, based on inspections at clinical sites, the authenticity of the drug products used in the pivotal bioequivalence trial could not be verified and that the bioequivalence trial would need to be repeated to address this deficiency. During a meeting with the FDA in September 2011, FDA staff indicated that the failure of the clinical sites to randomly select and retain reserve samples of the test article (Exelbine) and reference standard (Navelbine) could not be overcome by alternative methods of verifying authenticity and reiterated that the bioequivalence study would need to be repeated. As a result, we discontinued making significant additional capital investments into the Exelbine program and are seeking a partner or outside investor for the program. In addition, with respect to ANX-514, the FDA has indicated that, in addition to Study 514-01, a randomized safety study comparing ANX-514 and Taxotere would be required in an appropriate patient population to support approval of ANX-514, which has increased our estimated development time and expense for ANX-514 relative to our prior estimates based on a single bioequivalence study regulatory pathway. Furthermore, even though the FDA has confirmed the appropriateness of a Section 505(b)(2) regulatory path for ANX-514, the FDA's views may change and the FDA may not allow us to rely on data regarding the safety and efficacy of Taxotere in its evaluation of an NDA for ANX-514, in which case we likely would need to conduct substantial, additional clinical and nonclinical work. In this case, we may determine that the associated time and cost are not financially justifiable and, as a result, discontinue our ANX-514 program. If we discontinue our ANX-514 program, our business and stock price may suffer.

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

We 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. For example, while our regulatory strategy for ANX-514 previously had been to demonstrate its bioequivalence to Taxotere in a small, bioequivalence trial 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 protocol for a pivotal safety study and intend to discuss it with the FDA during the fourth quarter of 2011. 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 ANX-514 to support uses in new indications or other label changes or for other reasons. With respect to ANX-188, we plan to meet with the FDA to reach agreement on a single, phase 3 clinical trial protocol that would support approval of ANX-188 for the treatment of pediatric patients with sickle cell disease in acute crisis. Although the safety and efficacy of poloxamer 188 and ANX-188 in sickle cell disease have been evaluated in multiple clinical studies by prior sponsors and we believe that a single, properly designed and executed phase 3 clinical trial will demonstrate that ANX-188 is an effective treatment for patients with sickle cell disease in acute crisis and support approval of an ANX-188 NDA for that indication, the FDA may require additional nonclinical testing and/or clinical studies for regulatory approval.

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, planned bioequivalence or clinical trials may not 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, in August 2011, we received a complete response letter from the FDA stating that the pivotal bioequivalence study of Exelbine would need to be repeated. Thereafter, we discontinued making significant additional capital investments into the Exelbine program and are seeking a partner or outside investor for the program. 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.

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 including in our initial Exelbine NDA submission in December 2009 data that we believe met the filing requirements for a new drug promulgated by the International Conference on Harmonization, or ICH, as well as site-specific stability data from lots manufactured at the intended commercial manufacturing site, we received a refusal-to-file letter from the FDA indicating that the data included in that submission was insufficient to support a commercially-viable expiration dating period. Consequently, we had to wait for 12 months of site-specific stability data from the intended commercial manufacturing site to be generated before resubmitting an NDA for Exelbine, which we did in November 2010. A change in regulatory policy, which may not have been formalized or publicly disseminated, may have been a factor underlying the FDA's refusal to file our December 2009 submission.

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.

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, 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 protocol for a pivotal safety study and intend to discuss it with the FDA during the fourth quarter of 2011. 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 pivotal 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 pivotal safety 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 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.

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

We currently do not have sales, marketing or other commercialization personnel. To commercialize our products, we will have to acquire or develop marketing, distribution 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 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.

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.

If we, or a future partner or licensee, fail to obtain a unique Healthcare Common Procedure Coding System, or HCPCS, product code for Exelbine or ANX-514, we, or our partner or licensee, may be unable to sell those products at a price that exceeds their respective manufacturing, marketing and distribution costs. Even if we, or our partner or licensee, 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, or our partner or licensee, as applicable, may be required to price those products at levels that do not cover the costs to manufacture, market and distribute the products or provide any profit, or to price those products at levels at which they are not competitive.

In addition, FDA approval of Exelbine based on bioequivalence to Navelbine may limit the 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 pivotal safety study 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.

Depending on the outcome of future discussions with the FDA regarding protocol for pivotal clinical studies of ANX-514 and ANX-188 and our analysis of the commercial potential of these product candidates, including as a result of the above-described 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. 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. Additionally, in the future, we may reduce our expenditures on the development and/or the process of seeking regulatory approval of these product candidates while we evaluate whether and on what timeline to move the programs forward. For example, in September 2011, following a meeting with the FDA in which it reiterated its position that the Exelbine NDA could not be approved in its present form and that the bioequivalence study would need to be repeated, we discontinued making significant additional capital investments into the Exelbine program and are seeking a partner or outside investor for the program. In the future, we may devote our resources to identifying, acquiring and developing new product candidates. 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 third parties to conduct manufacturing process development activities and to provide us with materials for clinical trials and, if any of our products are approved, commercial product, and the loss of any of these manufacturers, or their failure to provide to us with an adequate supply of our product candidates in a timely manner and on commercially acceptable terms, or at all, could harm our business.

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

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

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

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

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

If our manufacturers encounter any of these difficulties or otherwise fail to comply with their contractual obligations, our ability to provide sufficient quantities of our product candidates for our planned and 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 our planned and 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. None of our product candidates have been manufactured at the scales we believe will be necessary to maximize their commercial value and, accordingly, we or a future partner of ours may encounter difficulties in production while scaling-up initial production and may not succeed in scaling-up initial production.

Any new supplier of products or component materials, including API, would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such products or ingredients. The FDA may require us to conduct additional 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. We engage consultants, advisors, CROs, CMOs, clinical investigators 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 to a significant degree such activities. As a result, many important aspects of our product candidates' development are and will continue to be outside our direct control. For instance, we lacked the internal capabilities to fully analyze the data from our bioequivalence study of ANX-514 and relied on multiple third-party consultants to help us interpret and understand the data. Because of the impact different analyses of the data may have on our business, an employee may have approached the data and analysis in a substantially more rigorous, thoughtful and creative manner than a consultant or contractor. There can be no assurance that such third parties will perform all of their obligations under arrangements with us or will perform those obligations satisfactorily.

The CROs with which we contract for execution of our clinical studies play a significant role in the conduct of the studies and subsequent collection and analysis of data, and we likely will depend on 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 and/or investigators fail to devote sufficient time and resources to our studies, if they do not comply with all regulatory and contractual requirements or if their performance is substandard, it will delay the approval of our applications to regulatory agencies and the introduction of our products. Moreover, these CROs may have relationships with other commercial entities, some of which may compete with us. If they assist our competitors at our expense, it could harm our competitive position. Failure of these CROs to meet their obligations could adversely affect development of our product candidates. For example, in 2006, we engaged a CRO to assist with the primary conduct of our bioequivalence study of Exelbine, including monitoring participating clinical sites to ensure compliance with regulatory requirements. FDA guidance recommends that clinical sites randomly select and retain reserve samples of study drugs used in bioequivalence studies. However, the clinical sites that participated in our bioequivalence study of Exelbine failed to do so. In August 2011, we received a complete response letter from the FDA stating that the authenticity of the study drugs used in Study 530-01 could not be verified and, consequently, the bioequivalence study would need to be repeated to address that deficiency.

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

The currently marketed reference products against which our emulsion-formulation product candidates would compete are available as generics. For instance, ANX-514 would compete against Taxotere, for which generic equivalents may soon be and reformulations currently are available in the U.S. Even if we obtain a unique HCPCS product code for our products, the existence of generic products could make it more difficult for our branded products to gain or maintain market share and could cause prices for our products to drop, potentially below our cost of goods, which could adversely affect our business.

Even 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, it is possible 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.

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

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. 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 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 phase 3 study of ANX-188 conducted by a prior sponsor, 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 ANX-188 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 ANX-188 or ANX-188 may not receive regulatory approval.

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

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

- 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 ANX-188 for the treatment of sickle cell crisis, we acquired exclusive rights to a variety of issued patents that cover, among other things, poloxamer 188, purified poloxamer 188, methods of treating sickle cell anemia using poloxamer 188 and methods of preparing purified poloxamer 188. However, we expect many of the patents covering ANX-188 for the treatment of sickle cell crisis will expire prior to regulatory approval of ANX-188 for that indication. For exclusivity, we expect to rely primarily on the orphan drug designation that the FDA has granted for poloxamer 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. ANX-188 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 ANX-188, the FDA may approve such other product candidate for marketing during ANX-188's seven year exclusive marketing period.

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

Our 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.

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

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

Our commercial success depends on our ability and the ability of our CMOs and component suppliers to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are or may be developing products. As the biotechnology and pharmaceutical 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.

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.

ANX-514 and Exelbine, if approved, would compete against Taxotere and Navelbine, respectively, as well as their generic equivalents and other formulations of docetaxel and vinorelbine. 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, four non-Taxotere formulations of docetaxel have been approved under NDAs by the FDA. In addition, generic versions of Taxotere may soon be commercially available.

If our emulsion-formulation product candidates receive regulatory approval based on bioequivalence to their currently marketed reference products, our ability to differentiate them from competing products will be limited. Even if we believe they demonstrate clinical, pharmacoeconomic or other benefits relative to competing products, we may be unable to market or promote them based on these benefits. If 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.

With respect to competition for ANX-188 for the treatment of sickle cell crisis, we are aware of numerous companies with product candidates in varying stages of development for the treatment of sickle cell crisis. In addition, we expect advances in the understanding of the signaling pathways associated with sickle cell disease to lead to further interest and development of treatment options. More broadly, ANX-188, if approved for the treatment of sickle cell crisis, would compete against agents designed to treat sickle cell disease, of which sickle cell crisis is a condition. Hydroxyurea, a form of chemotherapy used for myeloproliferative disease, 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 ANX-188, if approved, 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.

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

There have been federal and state proposals to subject the pricing of healthcare goods and services to government control and to make other changes to the U.S. healthcare system. While we cannot predict the outcome of current or future legislation, we anticipate, 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.

Previously, we were not in compliance with certain NYSE Amex stockholders' equity continued listing standards. Specifically, we were not in compliance with (1) Section 1003(a)(ii) of the NYSE Amex Company Guide, or the Company Guide, because we reported stockholders' equity of less than $4,000,000 and losses from continuing operations and net losses in three of our four most recent fiscal years, or (2) Section 1003(a)(iii) of the Company Guide, because we reported stockholders' equity of less than $6,000,000 and losses from continuing operations and net losses in our five most recent fiscal years. In addition, we were notified, in accordance with Section 1003(f)(v) of the Company Guide, that the NYSE Amex determined it was appropriate for us to effect a reverse stock split of our common stock to address our low selling price per share.

In April 2010, we announced that we had resolved the stockholders' equity continued listing deficiencies and we implemented a 1-for-25 reverse split of our common stock, in part to address the NYSE Amex's requirement that we address our low stock price. However, there is no assurance that we will continue to maintain compliance with such standards. For example, we may determine to 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," and recently has traded at under $1.00 per share. The NYSE Amex may again determine that the selling price per share of our common stock is low and require that we effect a reverse stock split of our common stock, which would require stockholder approval that we may be unable to obtain. Our failure to maintain compliance with NYSE Amex continued listing standards could result in the delisting of our common stock from the NYSE Amex.

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

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

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

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

The market price for our common stock historically has been highly volatile, and the market for our common stock has from time to time experienced significant price and volume fluctuations, based both on our operating performance and for reasons that appear to us unrelated to our operating performance. For instance, on August 10, 2011, the market price for our common stock dropped almost 60% following our announcement of our receipt of the complete response letter for our Exelbine NDA, which stated that the FDA could not approve it in its present form. Conversely, the market price for our common stock increased over 66% in a 30-day period in June and July 2011 and more than doubled over two trading days in late December 2009. The market price of our common stock may fluctuate significantly in response to a number of factors, including:

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

- changes in the regulatory status of our product candidates, including results of any 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 August 10, 2011 decline, the realization of any of the foregoing could have a dramatic and adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced 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. Furthermore, in addition to the up to 16,278,901 shares of our common stock that may be offered and sold by the selling stockholders pursuant to the resale registration statement on Form S-3 of which this prospectus forms a part, a significant number of shares of our common stock may be issued by us upon exercise of outstanding warrants pursuant to currently effective registration statements on Form S-3 and an effective registration statement on Form S-1. Collectively, these registration statements may increase the likelihood of sales by, or the perception of an increased likelihood of sales by, us or our existing stockholders of shares of our common stock.

We currently have voting control with respect to more than 10% of our outstanding common stock and we may obtain voting control over a significant additional amount of our outstanding common stock if we issue the milestone-related shares to the former SynthRx stockholders, and we may determine to cause those shares to be voted in such a manner that does not necessarily coincide with the interests of individual stockholders or particular groups of stockholders.

Pursuant to the voting and transfer restriction agreement between us and each of the former principal stockholders of SynthRx, each stockholder party has agreed to vote all shares of our common stock beneficially owned by that party with respect to every action or approval by written consent of our stockholders in such manner as directed by us, except in limited circumstances, and has executed an irrevocable proxy appointing and authorizing us to vote such shares in such manner. If the development of ANX-188 achieves all of the milestones set forth in our merger agreement with SynthRx without reduction, we will issue an additional 13,478,050 shares of our common stock, representing, in the aggregate (and including the shares issued in connection with the closing

of our acquisition of SynthRx) an approximately 41% 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 currently have, and in the future may have even more, significant control over substantially all matters requiring approval by our stockholders, including the election of directors and the approval of certain mergers and other business combination transactions. Even if less than all potential milestone-related shares are issued, our ability to control a potentially significant block of stockholder votes pursuant to the voting and transfer restriction agreement may enable us to substantially affect the outcome of proposals brought before our stockholders. Although our board of directors acts in a manner it believes is in the best interest of our stockholders as a whole, the interests of our stockholders as a whole may not always coincide with the interests of individual stockholders or particular groups of stockholders.

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

We are incorporated in Delaware. Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change in control would be beneficial to our stockholders. Our bylaws limit who may call a special meeting of stockholders and establish advance notice requirements for nomination of individuals for election to our board of directors or for proposing matters that can be acted upon at stockholders' meetings. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors may use these provisions to prevent changes in the management and control of our company. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future. In addition, provisions of certain compensatory contracts with our management, such as equity award agreements, may have an anti-takeover effect by resulting in accelerated vesting of outstanding equity securities held by our executive officers. In particular, in the event of a change in control, the vesting of options we granted since July 2009 to certain key executives will accelerate with respect to fifty percent of the then unvested shares on the day prior to the date of the change in control and, subject to the respective executive's continuous service, with respect to the remaining fifty percent of the then unvested shares on the one year anniversary of the date of the change in control, and could accelerate in full at the time of the change in control if the acquirer does not assume or substitute for the options. As a result, if an acquirer desired to retain the services of one or both of those executives following an acquisition, it may be required to provide additional incentive to them, which could increase the cost of the acquisition to the acquirer and may deter or affect the terms of the potential acquisition.

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the other materials we have filed or will file with the SEC contain forward-looking statements within the meaning of Section 27A of the Securities Act 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 regarding our product candidates, our objectives for future operations and our future financial position. When used in this prospectus or in the other materials we have filed or will file with the SEC, the words "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "expect," "indicate," "seek," "should" or "would" and similar expressions are intended to identify forward-looking statements. Among the factors that could cause or contribute to material differences between our actual results and those indicated from the forward-looking statements are risks and uncertainties inherent in our business, including, but not limited to:

- the extent to which we acquire new technologies, product candidates, products or businesses and our ability to integrate them, including the assets we recently acquired from SynthRx, Inc., successfully into our operations;
- our ability, or that of a future partner, to successfully develop and obtain regulatory approval for our product candidates and, if approved, to successfully commercialize them in the U.S. and/or elsewhere;
- the potential that we may enter into one or more commercial partnerships or other strategic transactions relating to our product candidates, and the terms of any such transactions;
- our ability to obtain additional funding to develop and commercialize our current product candidates and any product candidates or products we may acquire in the future, on a timely basis or on acceptable terms, or at all;
- the extent to which we rebuild our workforce and our ability to attract and retain qualified personnel and manage growth;
- 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 clinical or bioequivalence trials;
- our ability to obtain stockholder approval to complete other product pipeline expansion transactions, 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 develop or acquire sales, marketing and distribution capabilities to commercialize any of our product candidates for which we obtain regulatory approval;
- whether any of our product candidates for which we receive regulatory approval, if any, achieve broad market acceptance;
- 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 rights with respect to our product candidates and proprietary technology;
- claims against us for infringing the proprietary rights of third parties;
- competition in the marketplace for our products, if any are approved;
- 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; and

- 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.

Additional factors that could cause or contribute to such differences include, but are not limited to, those discussed in this prospectus, and in particular, the risks discussed under the heading "Risk Factors" and those discussed in other documents we file with the SEC and incorporate herein. Except as required by law, we do not intend to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus and in the documents incorporated in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on such forward-looking statements.

USE OF PROCEEDS

All shares of our common stock offered by this prospectus are being registered for the accounts of the selling stockholders. We will not receive any of the proceeds from the sale of these shares.

The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees and fees and expenses of our counsel and our accountants.

SELLING STOCKHOLDERS

We are registering up to 16,278,901 shares of our common stock for resale, from time to time, by the selling stockholders identified below, which includes:

- 662,078 shares of our common stock issued to the selling stockholders pursuant to the terms of the Merger Agreement;
- 200,000 shares of common stock that are currently held in escrow to indemnify us against breaches of representations and warranties and may be released to the selling stockholders pursuant to the terms of the Merger Agreement;
- 1,938,773 shares of common stock issued to the selling stockholders, subject to a repurchase right in favor of our company that lapses upon the satisfaction of a performance milestone pursuant to the terms of the Merger Agreement; and
- 13,478,050 shares of common stock that may be issued to the selling stockholders, subject to the achievement of performance milestones pursuant to the terms of the Merger Agreement.

The selling stockholders may sell some, all or none of their shares. We do not know how long the selling stockholders will hold the shares offered under this prospectus before selling them, and we cannot advise you as to whether the selling stockholders will in fact sell any or all of the shares of common stock being offered hereunder. As discussed in this prospectus, the shares of common stock being offered hereunder by the selling stockholders other than Georgia Erbez and Scott-Macon Securities, Inc. are subject to voting and transfer restrictions as set forth in the Voting and Transfer Restriction Agreement. In addition, 13,478,050 of the shares being offered under this prospectus have not been issued as of the date of this prospectus and will be issued by us only if the performance milestones set forth in the Merger Agreement and summarized in this prospectus are achieved. Our stockholders approved the issuance of those shares, in lieu of cash payments, at our 2011 annual meeting of stockholders, which was held June 15, 2011.

The following table sets forth the name of each selling stockholder, the number of shares beneficially owned by such selling stockholder as of September 30, 2011, the total number of shares that may be offered under this prospectus by such selling stockholder, and the number of shares of our common stock and the percentage of our common stock to be owned by such selling stockholder after completion of this offering, assuming that all shares offered hereunder are sold by the selling stockholders. Except as otherwise disclosed in this prospectus (or as disclosed in any document incorporated by reference), none of the selling stockholders has, or within the past three years has had, any position, office or other material relationship with us. Other than the costs of preparing and providing this prospectus and a registration fee to the SEC, we are not paying any costs relating to the sales by the selling stockholders.

Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to this Offering(1)	Number of Shares of Common Stock Being Offered	Number of Shares of Common Stock Beneficially Owned After this Offering(2)	Percentage of Shares of Common Stock Owned After this Offering(1)
Robert L. Hunter (3) 6431 Fannin Street, MSB 2.136 Houston, Texas 77030	310,706	7,639,523	—	—
R. Martin Emanuele (4) 12390 El Camino Real, Suite 150 San Diego, California 92130	139,151	3,421,382	—	—

Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to this Offering(1)	Number of Shares of Common Stock Being Offered	Number of Shares of Common Stock Beneficially Owned After this Offering(2)	Percentage of Shares of Common Stock Owned After this Offering(1)
CytRx Corporation (5) 11726 San Vincente Blvd., Suite 650 Los Angeles, California 90049	126,443	3,108,927	—	—
Mannarsamy Balasubramanian (6) 115 Hill Street Roswell, Georgia 30075	56,550	1,390,425	—	—
Georgia Erbez (7) 1514 Elise Court Walnut Creek, California 94596	67,722	359,322	5,900	*
Scott-Macon Securities, Inc. (8) 800 Third Avenue, 16th Floor New York, New York 10022	61,822	359,322	—	—

* Represents less than one percent (1%).

(1) The number of shares of common stock beneficially owned by each selling stockholder prior to this offering is based upon information provided to us by the selling stockholder. The percentage of common stock owned after the offering is based on 26,465,709 shares of our common stock outstanding as of September 30, 2011. Beneficial ownership is determined in accordance with Rule 13d-3 promulgated by the SEC under the Exchange Act. Unless otherwise noted, each person or group identified possesses sole voting and investment power with respect to the shares, subject to community property laws where applicable.

(2) Assumes the sale of all shares of common stock registered pursuant to this prospectus, although, to our knowledge, none of the selling stockholders is under any obligation to sell any shares of common stock at this time.

(3) The shares of common stock beneficially owned by and the total number of shares of common stock being offered by Dr. Hunter are subject to the voting and transfer restrictions set forth in the Voting and Transfer Restriction Agreement. The total number of shares of common stock being offered by Dr. Hunter includes: (i) 93,858 shares that are subject to and are currently held in escrow to indemnify us against breaches of representations and warranties pursuant to the terms of the Merger Agreement; (ii) 909,847 shares that are subject to a repurchase right in favor of our company that lapses upon the achievement of a performance milestone pursuant to the terms of the Merger Agreement; and (iii) 6,325,112 shares that may be issued to Dr. Hunter subject to the achievement of performance milestones pursuant to the terms of the Merger Agreement.

(4) The shares of common stock beneficially owned by and the total number of shares of common stock being offered by Dr. Emanuele are subject to the voting and transfer restrictions set forth in the Voting and Transfer Restriction Agreement. The total number of shares of common stock being offered by Dr. Emanuele includes: (i) 42,035 shares that are subject to and are currently held in escrow to indemnify us against breaches of representations and warranties pursuant to the terms of the Merger Agreement; (ii) 407,477 shares that are subject to a repurchase right in favor of our company that lapses upon the achievement of a performance milestone pursuant to the terms of the Merger Agreement; and (iii) 2,832,719 shares that may be issued to Dr. Emanuele subject to the achievement of performance milestones pursuant to the terms of the Merger Agreement. Dr. Emanuele has been employed as our Senior Vice President, Development since April 27, 2011.

(5) The shares of common stock beneficially owned by and the total number of shares of common stock being offered by CytRx Corporation are subject to the voting and transfer restrictions set forth in the Voting and Transfer Restriction Agreement. The total number of shares of common stock being offered by CytRx Corporation includes: (i) 38,196 shares that are subject to and are currently held in escrow to indemnify us against breaches of representations and warranties pursuant to the terms of the Merger Agreement; (ii) 370,265 shares that are subject to a repurchase right in favor of our company that lapses upon the achievement of a performance milestone pursuant to the terms of the Merger Agreement; and (iii) 2,574,023 shares that may be issued to CytRx Corporation subject to the achievement of performance milestones pursuant to the terms of the Merger Agreement. Shared voting and dispositive power over the shares of common stock resides with the board of directors of CytRx Corporation. The board of directors of CytRx Corporation consists of Steven A. Kriegsman, Louis Ignarro, Ph.D., Max Link, Ph.D., Joseph Rubinfeld, Ph.D., Marvin R. Selter, Richard L. Wennekamp.

(6) The shares of common stock beneficially owned by and the total number of shares of common stock being offered by Dr. Balasubramanian are subject to the voting and transfer restrictions set forth in the Voting and Transfer Restriction Agreement. The total number of shares of common stock being offered by Dr. Balasubramanian includes: (i) 17,083 shares that are subject to and are currently held in escrow to indemnify us against breaches of representations and warranties pursuant to the terms of the Merger Agreement; (ii) 165,596 shares that are subject to a repurchase right in favor of our company that lapses upon the achievement of a performance milestone pursuant to the terms of the Merger Agreement; and (iii) 1,151,196 shares that may be issued to Dr. Balasubramanian subject to the achievement of performance milestones pursuant to the terms of the Merger Agreement. In April 2011, we engaged Dr. Balasubramanian to provide consulting services to us from time to time in connection with our ANX-188 program.

(7) The number of shares of common stock beneficially owned prior to this offering by Ms. Erbez includes: (i) 4,414 shares that are subject to and are currently held in escrow to indemnify us against breaches of representations and warranties pursuant to the terms of the Merger Agreement and (ii) 42,794 shares that are subject to a repurchase right in favor of our company that lapses upon the achievement of a performance milestone pursuant to the terms of the Merger Agreement. The total number of shares of common stock being offered herein by Ms. Erbez includes the shares described in (i) and (ii) above as well as (iii) 297,500 shares that may be issued to Ms. Erbez subject to the achievement of performance milestones pursuant to the terms of the Merger Agreement. Ms. Erbez is a registered broker with Liberty Tree Advisors, LLC, a member of the Financial Industry Regulatory Authority ("FINRA").

(8) The number of shares of common stock beneficially owned prior to this offering by Scott-Macon Securities, Inc. includes: (i) 4,414 shares that are subject to and are currently held in escrow to indemnify us against breaches of representations and warranties pursuant to the terms of the Merger Agreement and (ii) 42,794 shares that are subject to a repurchase right in favor of our company that lapses upon the achievement of a performance milestone pursuant to the terms of the Merger Agreement. The total number of shares of common stock being offered herein by Scott-Macon Securities, Inc. includes the shares described in (i) and (ii) above as well as (iii) 297,500 shares that may be issued to Scott-Macon Securities, Inc. subject to the achievement of performance milestones pursuant to the terms of the Merger Agreement. Scott-Macon Securities, Inc. is a wholly-owned subsidiary of Scott-Macon, Ltd. Voting and dispositive power over the shares of common stock resides with the board of directors of Scott-Macon, Ltd. The board of directors of Scott-Macon, Ltd. consists of Alfred Scott, Alexander Scott and Robert Dimmitt. Scott-Macon Securities, Inc. is a member of FINRA.

PLAN OF DISTRIBUTION

The selling stockholders and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of the shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts relating to their sales of shares to exceed what is customary in the types of transactions involved.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out its short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed the selling stockholders of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

We will not receive any proceeds from the sale of the shares by the selling stockholders.

LEGAL MATTERS

DLA Piper LLP (US), San Diego, California has passed upon the validity of the common stock on behalf of the Company.

EXPERTS

The consolidated financial statements of ADVENTRX Pharmaceuticals, Inc. as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity (deficit) and comprehensive loss and cash flows for the years then ended and for the period from January 1, 2002 through December 31, 2010 are incorporated by reference herein and in the registration statement in reliance upon the report of J.H. Cohn LLP, an independent registered public accounting firm, given on the authority of said firm as experts in accounting and auditing.

No expert or counsel named in this prospectus as having prepared or certified any part of this prospectus or having given an opinion upon the validity of the securities being registered or upon other legal matters in connection with the registration or offering of the common stock was employed on a contingency basis, or had, or is to receive, in connection with the offering, a substantial interest, direct or indirect, in the registrant or any of its parents or subsidiaries. Nor was any such person connected with the registrant or any of its parents or subsidiaries as a promoter, managing or principal underwriter, voting trustee, director, officer, or employee.

WHERE YOU CAN FIND MORE INFORMATION

We post on our public website (www.adventrx.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to the SEC. Our website and the information contained on that site, or connected to that site, are not incorporated into and are not a part of this prospectus.

You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding us at www.sec.gov.

You should rely only on the information contained in this prospectus or to which we have referred you. We have not authorized any person to provide you with different information or to make any representation not contained in this prospectus.

DOCUMENTS INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference the information contained in documents that we file with them. This means that we can disclose important information to you by referring you to those documents and that the information in this prospectus is not complete. You should read the information incorporated by reference for more detail.

We are incorporating by reference into this prospectus the documents listed below (excluding any information furnished under Items 2.02 or 7.01 in any Current Report on Form 8-K). Any reports filed by us with the SEC after the date of this prospectus and before the date that the offering of the securities by means of this prospectus is terminated will automatically update and, where applicable, supersede any information contained in this prospectus or incorporated by reference in this prospectus. Accordingly, we incorporate by reference into this prospectus the documents listed below:

- Our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the SEC on March 10, 2011 (File No. 001-32157-11679095);
- Our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2011 filed with the SEC on May 9, 2011 (File No. 001-32157-11823538);
- Our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011 filed with the SEC on August 8, 2011 (File No. 001-32157-111017315);
- Our Current Reports on Form 8-K filed with the SEC on January 6, 2011 (File No. 001-32157-11512917), January 7, 2011 (File No. 001-32157-11515655), January 7, 2011 (File No. 001-32157-11515695), January 19, 2011 (File No. 001-32157-11536324), February 14, 2011 (File No. 001-32157-11604349), February 15, 2011 (File No. 001-32157-11613491), March 22, 2011 (File No. 001-32157-11704394), April 11, 2011 (File No. 001-32157-11752769); May 9,

2011 (File No. 001-32157-11823649); May 13, 2011 (File No. 001-32157-11837895); June 3, 2011 (File No. 001-32157-11892227); June 16, 2011 (File No. 001-32157-11915265); June 23, 2011 (File No. 001-32157-11928162); June 29, 2011 (File No. 001-32157-11939023); July 8, 2011 (File No. 001-32157-11959481); August 10, 2011 (File No. 001-32157-111022618); and September 30, 2011 (File No. 001-32157-111117627).

- The description of our common stock contained in our registration statement on Form 8-A filed with the SEC on April 27, 2004; and
- All documents filed by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and before the termination of this offering and also between the date of filing of the initial registration statement and prior to effectiveness of the registration statement.

We will provide each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the information that has been incorporated by reference into this prospectus but not delivered with this prospectus upon written or oral request at no cost to the requester. Requests should be directed to: ADVENTRX Pharmaceuticals, Inc., 12390 El Camino Real, Suite 150, San Diego, California 92130, Attn: Investor Relations, telephone: (858) 552-0866. Copies of any of these documents may also be obtained free of charge through our website at www.adventrx.com.

This prospectus is part of a registration statement on Form S-3 that we filed with the SEC. That registration statement contains more information than this prospectus regarding us and our common stock, including certain exhibits and schedules. You can obtain a copy of the registration statement from the SEC at the address listed above or from the SEC's Internet website.

Any statement contained in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

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16,278,901 Shares

ADVENTRX Pharmaceuticals, Inc.

Common Stock, Par Value $0.001 Per Share

PROSPECTUS

October 13, 2011