ADVENTRX PHARMACEUTICALS INC
Form 424B5
November 10, 2011

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The information in this prospectus supplement is not complete and may be changed. This prospectus supplement and the accompanying prospectus are not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 10, 2011

PRELIMINARY PROSPECTUS SUPPLEMENT **Filed pursuant to Rule 424(b)(5)**
NO. 4
(To Prospectus dated April 1, 2010) **Registration Statement No. 333-165691**

ADVENTRX Pharmaceuticals, Inc.

[ ] Shares of Common Stock
Warrants to Purchase [ ] Shares of Common Stock
[ ] Shares of Common Stock Underlying the Warrants

We are offering [ ] shares of our common stock, par value $0.001 per share, and warrants to purchase up to [ ] shares of our common stock to investors in this offering. We are also offering an aggregate of [ ] shares of our common stock issuable upon exercise of the warrants. The securities will be sold in multiples of a fixed combination consisting of one share of common stock and a warrant to purchase up to [ ] of a share of common stock. These common stock warrants are exercisable at any time on or after their date of issuance, which will be the closing date of this offering, and on or before the [ ] anniversary of their date of issuance at an exercise price of $[ ] per share. The shares of common stock and the warrants being offered will be issued separately, but can only be purchased together in the fixed combination described above. Each fixed combination will be sold at a price of $[ ].

Our common stock is listed on the NYSE Amex equities market under the symbol ANX. The last reported sale price of our common stock on November 9, 2011 was $0.98 per share. We do not intend to list the warrants on any national securities exchange.

This investment involves a high degree of risk. You should carefully review the risks and uncertainties described under the heading Risk Factors.

	Per Fixed Combination of One Share and a Warrant to Purchase [ ] of a Share	Total
Public offering price	$ [ ]	$ [ ]
Underwriting discounts and/or commissions (1)	$ [ ]	$ [ ]
Proceeds, before expenses, to ADVENTRX Pharmaceuticals, Inc. (2)	$ [ ]	$ [ ]

(1) In connection with the offering of our securities under this prospectus supplement, in consideration for its services, we have also agreed to issue to the representative of the underwriters and/or its designees warrants to purchase up to an aggregate of [ ] shares of our common stock at an exercise price of $[ ] per share. Neither these warrants nor the common stock issuable upon exercise of these warrants are covered by this prospectus supplement. We have also agreed to pay to the representative of the underwriters an expense reimbursement of 0.5% of the gross proceeds of the securities sold hereunder.

(2) Excludes potential proceeds from the exercise of the warrants offered hereby.

Delivery of the shares and warrants being sold in this offering will take place on or about November [ ], 2011, against payment of immediately available funds.

The underwriters may also exercise their option to purchase up to an additional [ ] shares of our common stock and warrants to purchase up to [ ] shares of our common stock at the public offering price per fixed combination, less the

underwriting discounts and commissions, to cover over-allotments, if any, within 45 days of the date of this prospectus supplement.

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

Rodman & Renshaw, LLC

The date of this prospectus supplement is November [ ], 2011.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a shelf registration statement on Form S-3 that we filed with the U.S. Securities and Exchange Commission, or the SEC, using a shelf registration process. This prospectus supplement describes the specific terms of this offering. The accompanying prospectus, including the documents incorporated by reference, provides general information about us, some of which, such as the section therein entitled Plan of Distribution, may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document, this prospectus supplement and the accompanying prospectus, combined.

We urge you to carefully read this prospectus supplement, the accompanying prospectus and the documents incorporated herein and therein, before buying any of the securities being offered under this prospectus supplement. These documents contain information you should consider when making your investment decision.

You should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent any information in this prospectus supplement is inconsistent with the accompanying prospectus, you should rely on the information in this prospectus supplement. The information in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and the documents incorporated by reference therein, except for those documents incorporated by reference therein which we file with the SEC after the date hereof.

You should not assume that the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus is accurate on any date subsequent to the date set forth on the front cover of this prospectus supplement and the accompanying prospectus or on any date subsequent to the date of the document incorporated by reference, as applicable. Our business, financial condition, results of operations and prospects may have changed since those dates.

We are offering to sell, and seeking offers to buy, the securities described in this prospectus supplement only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the offering of the securities in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

We are not making any representation to you regarding the legality of an investment in our securities by you under applicable law. You should consult with your own legal advisors as to the legal, tax, business, financial and related aspect of a purchase of these securities.

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SUMMARY

This summary highlights selected information about us and this offering and does not contain all of the information that you need to consider in making your investment decision. You should carefully read this entire prospectus supplement and the accompanying prospectus, including the risks and uncertainties discussed under the heading Risk Factors beginning on page S-4 of this prospectus supplement, and the information incorporated by reference, including our financial statements, before making an investment decision. When used in this prospectus supplement, the terms ADVENTRX, we, us, our and our company refer to ADVENTRX Pharmaceuticals, Inc. and its consolidated subsidiaries, unless otherwise indicated or the context otherwise requires.

About ADVENTRX Pharmaceuticals, Inc.

We are a specialty pharmaceutical company focused on developing proprietary product candidates. 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®.

We have devoted substantially all of our resources to research and development and 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. We had a loss from operations of $11.0 million for the nine months ended September 30, 2011 and cash, cash equivalents and short-term investments of approximately $38.3 million at September 30, 2011.

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 does not constitute part of this prospectus supplement or any other prospectus supplement.

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The Offering

Securities offered by us:	[ ] shares of common stock; Warrants to purchase up to [ ] shares of common stock; and Up to [ ] shares of common stock issuable upon exercise of the warrants.
Description of warrants:	Each investor will receive a warrant to purchase up to [ ] shares of common stock. These common stock warrants are exercisable at any time on or after their date of issuance, which will be the closing date of this offering, and on or before the [ ] anniversary of their date of issuance at an exercise price of $[ ] per share.
Common stock to be outstanding after this offering (excluding over-allotment option):	[ ] shares, or [ ] shares if the warrants offered hereby are exercised in full
Common stock to be outstanding after this offering if over-allotment option exercised in full:	[ ] shares, or [ ] shares if the warrants offered hereby are exercised in full
Use of proceeds:	We currently intend to use the net proceeds from this offering to fund continued development of our current lead product candidates, including activities necessary to initiate and conduct our planned phase 3 clinical trials of ANX-188 and ANX-514, and for general corporate purposes. Please see Use of Proceeds below.
NYSE Amex Symbol:	ANX
No market for the warrants:	There is no established public trading market for the warrants and we do not intend to apply to list the warrants on any national securities exchange.
Risk Factors:	See Risk Factors below for a discussion of factors that you should carefully read and consider before investing in our securities.

The number of shares of our common stock that will be outstanding immediately after the offering is based on 26,465,709 shares outstanding as of September 30, 2011, and excludes:

- 1,553,692 shares of common stock issuable upon the exercise of stock options issued under our equity incentive plans prior to this offering 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;
- 7,777,988 shares of common stock issuable upon the exercise of warrants issued prior to this offering and outstanding as of September 30, 2011, at a weighted average exercise price of $6.58 per share;
- 13,478,050 shares of common stock that may be issued to the former stockholders of SynthRx, subject to the achievement of performance milestones pursuant to the terms of our merger agreement with SynthRx dated February 12, 2011;

[ ] shares of common stock issuable upon the exercise of the warrants to be issued to the investors in this offering, at an exercise price of $[ ] per share; and

[ ] shares of common stock issuable upon exercise of warrants to be issued to the representative of the underwriters for this offering and/or its designees, which are not covered by this prospectus supplement, at an exercise price of $[ ] per share.

All share and per share information in in this prospectus supplement 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. The information contained in documents incorporated herein by reference that we filed with the SEC before April 23, 2010 has not been revised to reflect

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retroactive application of the 1-for-25 reverse stock split. However, the information in documents that we filed after April 23, 2010 and information in documents that we will file in the future does and will reflect the 1-for-25 reverse stock split.

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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, or the Exchange Act, incorporated by reference in this prospectus supplement and the accompanying prospectus before deciding whether to purchase any of the securities being offered by this prospectus supplement. 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. In October 2011, we met with the FDA to discuss our clinical development plans for ANX-514 and the FDA agreed that our proposed clinical trial, a non-inferiority study with a primary objective of comparing fluid retention following treatment with ANX-514, administered without corticosteroid premedication, and Taxotere, administered with corticosteroid premedication, which would enroll approximately 400 patients, which we refer to as Study 514-02, would generate sufficient clinical data to support approval of ANX-514 without requiring corticosteroid premedication. Despite reaching agreement with the FDA that the results of Study 514-02, together with those of Study 514-01, could support approval of ANX-514 without

requiring corticosteroid premedication, the FDA may, in the future, require additional clinical and/or nonclinical studies to support approval of ANX-514, which would increase development expense and may delay regulatory approval. For example, the FDA may determine that it cannot verify the authenticity of the study drugs used in Study 514-01 and require that the bioequivalence study be repeated prior to approval of 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.

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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 $169.2 million as of September 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 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, cash equivalents and short-term investments as of September 30, 2011, which were approximately $38.3 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

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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 $0.98, which was the closing price of our common stock on November 9, 2011, we could not raise more than approximately $5.2 million without stockholder approval, unless the transaction is deemed a public offering or does not involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. However, certain prior sales by us may be aggregated with any offering we may propose in the near-term, further limiting the amount we could raise in any future offering that is not considered a public offering by the NYSE Amex staff and would involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. The NYSE Amex will also require stockholder approval if the issuance or potential issuance of additional shares will be considered by the exchange staff to result in a change of control of us.

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.

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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 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, cash equivalents and short-term investments as of September 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 any nonclinical testing and/or clinical studies in addition to our planned phase 3 clinical trials that may be required by the FDA to support approval of our lead product candidates or any post-approval clinical studies to support uses of our product candidates in new indications or other label changes intended to expand the scale and scope of their market potential.

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, from time to time we evaluate pipeline expansion opportunities that we believe may increase the value of our

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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, and the amount of new securities issuable in connection with any such transaction may be substantial. 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 shares outstanding as of the date of this prospectus supplement plus shares issued in connection with achievement of the milestones). The issuance of shares in connection with other future strategic transactions, if any, may result in the stockholders who own the majority of our voting securities prior to one or more of such transactions owning less than a majority after such transactions.

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.

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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,

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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. 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 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, 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, 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. Although we have met with the FDA and reached agreement that our proposed 400-patient, non-inferiority study of ANX-514 would generate sufficient additional clinical data to support approval of ANX-514 without requiring corticosteroid premedication, the requirement for this additional clinical study has increased significantly the development time and cost associated with seeking regulatory approval of ANX-514 relative to our previously planned regulatory approval pathway for ANX-514. In addition, if the FDA determines that the authenticity of the study drugs used in Study 514-01 cannot be verified,

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including because of the manner in which reserve samples were selected and maintained, we may be required to repeat the bioequivalence study prior to regulatory approval of ANX-514, and the results of a repeat study may cause the FDA to require clinical studies in addition to the planned non-inferiority study. Further, even though the FDA has confirmed the appropriateness of a Section 505(b)(2) regulatory path for ANX-514, the FDA s views may change and the FDA may not allow us to rely on data regarding the safety and efficacy of Taxotere in its evaluation of an NDA for ANX-514 or the FDA may allow us to rely only on certain subsets of the efficacy data related to Taxotere, in which case we likely would need to conduct substantial, additional clinical and nonclinical work prior to regulatory approval. Furthermore, we may determine to conduct clinical studies with respect to ANX-514 to support uses in new indications or other label changes or for other reasons. With respect to ANX-188, we plan to meet with the FDA to reach agreement on a phase 3 clinical trial protocol for the treatment of pediatric patients with sickle cell disease in acute crisis. Although we believe that a properly designed and executed phase 3 clinical trial will demonstrate that ANX-188 is a safe and effective treatment for patients with sickle cell disease in acute crisis, the FDA may require additional nonclinical testing and/or clinical studies for regulatory approval. In the event our regulatory plan for any of our product candidates becomes more extensive and costly than anticipated, we may determine that the associated time and cost are not financially justifiable and, as a result, discontinue the program. If we discontinue either of our current lead product candidate programs, our business and stock price may suffer.

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 clinical trials and related regulatory filings.

In addition, planned 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.

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Even if we complete a planned clinical trial with successful results, 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 because the authenticity of the drug products used in the trial could not be verified. Thereafter, we discontinued making significant additional capital investments into the Exelbine program and are seeking a partner or outside investor for the program.

In addition to the potential for delays in commencing and completing a 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 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 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 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 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 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 and clinical trials do not ensure that future 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 clinical trials that each product is safe and effective for use in each target indication. Success in nonclinical testing and clinical trials, including 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. 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. In October 2011, we met with the FDA and reached agreement that our proposed Study 514-02 would generate sufficient additional clinical data to support approval of ANX-514 without requiring corticosteroid premedication. However, the FDA s requirements for development activities beyond Study 514-01 will significantly increase the time and cost associated with regulatory approval of ANX-514 relative to our previously planned regulatory approval pathway for ANX-514. In addition, the FDA may inquire regarding the manufacturing source, in-process and product release specifications and overall uniformity of reference product used in Study 514-01, particularly since it was conducted at sites in multiple countries, and we may be unable to provide documentation satisfactory to the FDA with respect to such reference product, which may result in the FDA

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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 non-inferiority 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 non-inferiority 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 the incidence and severity of any adverse side effects);

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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;

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;

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 any of our approved products, we, or our partner or licensee, may be unable to sell those products at a price that exceeds their respective manufacturing, marketing and distribution costs. Even if we, or our partner or licensee, obtain unique HCPCS product codes for one or more of our approved products, if they are perceived to provide little or no advantage relative to competing products or for other reasons, we, or our partner or licensee, as applicable, may be required to price those products at levels that do not cover the costs to manufacture, market and distribute the products or provide any profit, or to price those products at levels at which they are not competitive. For instance, even if Study 514-02 demonstrates that ANX-514 can be administered safely without corticosteroid premedication, and the FDA approves ANX-514 without requiring a high-dose corticosteroid premedication regimen, the medical community and/or third-party payors may not perceive the avoidance of high-dose corticosteroid premedication as a meaningful benefit to patients, which likely would negatively impact adoption of, and the price that we could charge for, ANX-514.

There can be no assurance that, in the future, we will continue to develop or seek regulatory approval for our current lead 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 receipt of a complete response letter from the FDA regarding our Exelbine NDA, 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 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 ant