ADVENTRX PHARMACEUTICALS INC Form 424B5 January 04, 2010

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PROSPECTUS SUPPLEMENT NO. 4

(To Prospectus dated June 4, 2009)

Filed pursuant to Rule 424(b)(5) Registration Statement No. 333-159376

ADVENTRX Pharmaceuticals, Inc.

15,676 Shares of 3.73344597664961% Series E Convertible Preferred Stock Warrants to Purchase 10,282, 041 Shares of Common Stock 51,410,206 Shares of Common Stock Underlying the Preferred Stock and Warrants

We are offering 15,676 shares of our 3.73344597664961% Series E convertible preferred stock, \$0.001 par value per share, and warrants to purchase up to 10,282,041 shares of our common stock to purchasers in this offering. We are also offering an aggregate of 51,410,206 shares of our common stock issuable upon conversion of the convertible preferred stock and exercise of the warrants. The convertible preferred stock and warrants will be sold in units, with each unit consisting of one share of convertible preferred stock and a warrant to purchase approximately 655.91 shares of common stock. Subject to certain ownership limitations, the convertible preferred stock is convertible at any time at the option of the holder into shares of our common stock at a conversion ratio determined by dividing the stated value of the convertible preferred stock by a conversion price of \$0.38115 per share and will accrue a 3.73344597664961% dividend until January 7, 2015. In the event the convertible preferred stock is converted at any time prior to January 7, 2015, we will pay the holder of such converted convertible preferred stock an amount equal to the total dividend that would accrue on such convertible preferred stock, less any dividend payments previously made with respect to such shares. The warrants are exercisable at any time after their date of issuance and on or before the 30-month anniversary of their initial exercise date at an exercise price of \$0.3499 per share of common stock. Each unit will be sold at a negotiated price of \$1,000. Units will not be issued or certificated. The shares of convertible preferred stock and warrants are immediately separable and will be issued separately.

We will place 18.6672%, or approximately \$2,926,274, of the gross proceeds in an escrow account, which amounts will be released to make the dividend and other payments due on the convertible preferred stock.

Our common stock is listed on the NYSE Amex (formerly, the American Stock Exchange) under the symbol ANX. The last reported sale price of our common stock on December 31, 2009 was \$0.3499 per share. We do not intend to list the preferred stock or 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 beginning on page S-3 of this prospectus supplement.

Rodman & Renshaw, LLC is acting as our placement agent in connection with this offering. The placement agent is not purchasing or selling any of these securities nor is it required to sell any specific number or dollar amount of securities, but has agreed to use its reasonable best efforts to sell the securities offered by this prospectus supplement. We may increase the dollar value of securities we offer under the registration statement(s) of which this prospectus supplement and the accompanying prospectus form a part by up to \$3,901,311. In consideration for its services, we have agreed to pay the placement agent the cash fees set forth in the table below, which shows the cash fees we would pay without and with such increase, and to issue 30-month warrants to the placement agent to purchase up to an aggregate of 2,056,408 shares (or 2,492,457 shares if we effect the increase) of our common stock at an exercise price of \$0.4765 per share. These warrants are not covered by this prospectus supplement.

| | | Maximum | Maximum |
|--|----------|---------------|-----------------|
| | | Amount | Amount |
| | | (without | |
| | Per Unit | increase) | (with increase) |
| Public offering price | \$1,000 | \$ 15,676,000 | \$ 19,000,000 |
| Placement agent fees | \$ 70 | \$ 1,097,320 | \$ 1,330,000 |
| Proceeds, before expenses, to ADVENTRX | | | |
| Pharmaceuticals, Inc. | \$ 930 | \$ 14,578,680 | \$ 17,670,000 |

We expect delivery of the units being sold in this offering to be made to purchasers on or about January 7, 2010, against payment of immediately available funds. Because there is no minimum offering amount required as a condition to closing this offering, the actual public offering price, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the maximum amounts set forth above.

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 January 3, 2010.

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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 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 placement agent has 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 the units, the convertible preferred stock and warrants comprising the units or the underlying common stock 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-3 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 the 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 development-stage specialty pharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. We seek to improve the performance of existing drugs by addressing limitations associated principally with their safety and use. We have not yet marketed or sold any products or generated any significant revenue. 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. Our lead product candidates, ANX-530 and ANX-514, are novel emulsion formulations of currently marketed chemotherapy drugs. We submitted a New Drug Application, or NDA, for ANX-530 to the United States Food and Drug Administration, or FDA, in December 2009. In addition, we continue to evaluate the data from our recently-completed bioequivalence study of ANX-514 and we plan to seek a meeting with the FDA to discuss the results.

Our business was incorporated in Delaware in December 1995. In October 2000, we merged our wholly-owned subsidiary, Biokeys Acquisition Corp., with and into Biokeys, Inc. and changed our name to Biokeys Pharmaceuticals, Inc. In May 2003, we merged Biokeys, Inc., our wholly-owned subsidiary, with and into us and changed our name to ADVENTRX Pharmaceuticals, Inc. In July 2004, we formed a wholly-owned subsidiary, ADVENTRX (Europe) Ltd., in the United Kingdom primarily to facilitate conducting clinical trials in the European Union and to obtain favorable pricing for discussions with the European Medicines Agency. In April 2006, we acquired SD Pharmaceuticals, Inc. as a wholly-owned subsidiary. Our executive offices are located at 6725 Mesa Ridge Road, Suite 100, San Diego, California 92121, 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 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. Information on our website does not constitute part of this prospectus supplement or any other prospectus supplement.

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The Offering

Convertible preferred stock offered by us:

Up to 15,676 shares of convertible preferred stock;

Up to 41,128,165 shares of common stock issuable upon conversion of the convertible preferred stock;

Warrants to purchase up to 10,282,041 shares of common stock; and

Up to 10,282,041 shares of common stock issuable upon exercise of the warrants.

Common stock to be outstanding after this offering:

205,285,265 shares of common stock, or 256,695,471 shares of common stock if the convertible preferred stock and warrants offered hereby are converted and exercised in full.

Make-whole Payment: In the event that the convertible preferred stock is converted at any time prior to January 7,

2015, we will pay to the holder an amount equal to \$186.67 per \$1,000 in stated value of the shares of convertible preferred stock converted, less any dividend payments previously

made with respect to such shares.

Escrow: An amount of the gross proceeds of the offering equal to the aggregate potential

make-whole payment will be deposited with a third party, as escrow agent, to be held until January 7, 2015. Amounts in the escrow account will be released to pay dividends and any make-whole payments with respect to convertible preferred stock converted during the

escrow period.

Use of proceeds: We currently intend to use the net proceeds from this offering to fund activities relating to

the commercial launch of ANX-530, including acquiring or developing sales, marketing and distribution capabilities and the associated regulatory compliance infrastructure, and to continue the development of ANX-514 in the United States, and for general corporate

purposes. Please see Use of Proceeds below.

NYSE Amex Symbol: ANX

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 205,285,265 shares outstanding as of December 31, 2009, and excludes:

5,859,000 shares of common stock issuable upon the exercise of outstanding stock options issued under our equity incentive plans prior to this offering, at a weighted average exercise price of \$0.80 per share;

14,383,656 shares of common stock available for future issuance under our 2008 Omnibus Incentive Plan;

23,658,733 shares of common stock issuable upon the exercise of outstanding warrants issued prior to this offering, at a weighted average exercise price of \$1.13 per share;

12,462,285 shares of common stock issuable upon the exercise of the warrants to be issued to the purchasers in this offering, at an exercise price of \$0.3499 per share, which amount assumes we increase the dollar value of securities in this offering by a total of \$3,901,311; and

2,492,457 shares of common stock issuable upon exercise of warrants to be issued to the placement agent in connection with this offering, which are not covered by this prospectus supplement, at an exercise price of \$0.4765 per share, which amount assumes we increase the dollar value of securities in this offering by a total of \$3,901,311.

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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 or incorporated by reference in this prospectus supplement and the accompanying prospectus, and in our filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act, 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, Operations and Ability to Continue as a Going Concern 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 developing a new generation of therapeutic products, but such products cannot be marketed until the regulatory process is completed and governmental approvals have been obtained. Accordingly, there is no current source of revenues from operations, much less profits, to sustain our present activities, and no revenues from operations will likely be available until, and unless, our product candidates are approved by the U.S. Food and Drug Administration, or FDA, or other regulatory agencies and successfully marketed, either by us or a partner, an outcome which we are not able to guarantee.

Our financial resources are limited, we will require substantial additional funding to continue our business, and, if we are unable to raise sufficient additional capital, we may cease operating as a going concern and liquidate our assets.

We have experienced significant operating losses in funding the development of our product candidates, accumulating net losses totaling approximately \$146.7 million as of September 30, 2009, and we expect to continue to incur substantial operating losses for the foreseeable future, even if we or a future partner of ours is successful in advancing our product candidates to market. As of September 30, 2009, we had approximately \$3.1 million in cash and cash equivalents and 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. We anticipate that our cash and cash equivalents as of September 30, 2009, together with the net proceeds from the equity financing we completed on October 9, 2009, will be sufficient to permit us to conduct our business through December 31, 2010. However, we will need substantial additional funds to commercialize ANX-530, including acquiring or developing sales, marketing and distribution capabilities and the associated regulatory compliance infrastructure, and to continue the development of ANX-514. In addition, we may incur substantial costs in connection with evaluating and negotiating future capital-raising and/or strategic or partnering transactions, the effect of which may be to shorten the period through which our operating funds will sustain us. We cannot currently predict the extent of these costs. Even if we incur costs in pursuing, evaluating and negotiating particular capital-raising and/or strategic or partnering transactions, our efforts may not prove successful.

Our independent auditor s report for the year ended December 31, 2008 includes an explanatory paragraph stating that our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain additional financing or consummate a strategic transaction on commercially reasonable terms, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to seek protection under the provisions of the U.S. Bankruptcy Code or liquidate our assets and dissolve our company. In either case, we may receive less than the value at which our assets are carried on our financial statements. Based on our current working capital and estimated costs of implementing an orderly liquidation of our assets, we do not expect that there will be material cash available for distribution to our stockholders.

Even following the offering described in this prospectus supplement, we may need to raise additional capital to execute our business plans. Our future expenditures on our programs are subject to many uncertainties, including

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

the costs of seeking regulatory approval for our lead product candidates, ANX-530 and ANX-514, including any bioequivalence or clinical studies, process development, scale-up and other manufacturing activities, or other work required to achieve such approval, as well as the timing of such activities and approval;

the timing and terms of any collaborative, licensing and other strategic arrangements that we may establish;

the cost related to establishing or contracting for sales and marketing capabilities and other commercial capabilities;

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the scope, prioritization and number of development and/or commercialization programs we pursue and the rate of progress and costs with respect to such programs;

the extent to which we will need to rebuild our workforce, which currently consists of two full-time employees, and the cost involved in hiring, training and incentivizing new employees;

the extent to which we invest in or acquire new technologies, products or businesses;

the effect of competing technological and market developments; and

the cost involved in establishing, enforcing or defending patent claims and other intellectual property rights. Even if we sell the maximum amount of units offered by this prospectus supplement, including any potential increase to the offering, we may seek additional funding through public or private sales of our equity securities, debt financings, collaborations, licensing arrangements or other strategic 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 recent credit crisis, have adversely impacted our ability to raise additional capital and may continue to do so. In addition, we have been evaluating and continue to evaluate strategic options, including the sale or exclusive license of one or more of our product candidate programs, a strategic business merger and similar transactions. However, to date, discussions with potential strategic transaction partners have been unsuccessful, protracted or on terms that we determined were unacceptable.

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

Although we have an effective shelf registration statement, we may not be able to use that registration statement to raise substantial additional capital, if any. Under current SEC regulations, we will not be eligible to use a registration statement on Form S-3 for primary offerings of our common stock or securities convertible into our common stock unless our common stock is listed and registered on a national securities exchange or unless the aggregate market value of our common stock held by non-affiliates reaches \$75 million or more. The NYSE Amex will review the appropriateness of continued listing of any issuer that falls below the exchange s continued listing standards and may, in its discretion, at any time, and without notice, suspend dealings in, or may remove any security from, listing privileges. The NYSE Amex will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders equity of less than \$6.0 million if such issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. On June 1, 2009, we received notice from the NYSE Amex staff that, based on their review of our Form 10-Q for the period ended March 31, 2009, we are not in compliance with certain stockholders equity continued listing standards. Specifically, the NYSE Amex staff noted that we are not in compliance with Section 1003(a)(ii) of the NYSE Amex 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 with Section 1003(a)(iii) of the Company Guide because we reported stockholders equity of less than \$6,000,000 and losses from continuing operations and net losses in our five most recent fiscal years. In addition, the NYSE Amex staff notified us, in accordance with Section 1003(f)(v) of the Company Guide, that it deems it appropriate for us to effect a reverse stock split of our common stock to address our low selling price per share, and that if a reverse stock split is not completed within a reasonable amount of time after June 1, 2009, the NYSE Amex may consider suspending dealings in, or removing from the list, our common stock. On July 1, 2009, we submitted a plan to attempt to resolve our listing deficiencies and regain compliance with the continued listing requirements. On July 31, 2009, the NYSE Amex staff notified us that it determined that the plan we submitted makes a reasonable demonstration of our ability to regain compliance with the NYSE Amex s continued listing standards and determined to grant us an extension, until December 1, 2010, for us to regain compliance with the NYSE Amex s continued listing standards. See the risk factor below headed, We are currently not in compliance with NYSE Amex continuing listing standards and are at risk of being delisted from the NYSE Amex equities market, for additional information regarding the risk of our common stock being delisted from the NYSE Amex. If our common stock were delisted from the NYSE Amex, our ability to raise capital on terms and conditions we deem acceptable, if at all, may

be materially impaired. Currently, we do not anticipate being eligible to register and list our common stock on any other national securities exchange.

In addition, even if we maintain our listing with the NYSE Amex, under current SEC regulations, at any time during which 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 can raise through primary offerings of our securities in any twelve-month period using a registration statement on Form S-3 will be limited to an aggregate of one-third of our public float; however, the market value of all securities sold by us under our Form S-3 registration statement in the past 12 months will be subtracted from that amount to determine any future amount we can raise using our Form S-3 registration statement. While, as of the date hereof, our public float exceeds \$75.0 million (calculated as set forth in Form S-3 and SEC rules and regulations), SEC rules and regulations require that we periodically re-evaluate the value of our public float. If, at a re-evaluation data, 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 twelve-month period using a registration statement on Form S-3 again will be limited to an aggregate of one-third of our public float as described above. 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.

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In addition, our ability to timely raise sufficient capital may be limited by the requirements of the NYSE Amex 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 deemed a public offering by the NYSE Amex staff. Based on our outstanding common stock as of December 31, 2009 and a closing price of \$0.3499, which was the closing price of our common stock on December 31, 2009, we could not raise more than approximately \$14.4 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 to any offering we may propose in the near-term, further limiting the amount we could raise in any future offering that is not deemed a public offering by the NYSE Amex 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.

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 continue as a going concern, and there is no guarantee our stockholders would ultimately approve a proposed transaction. A public offering under the NYSE Amex rules typically involves broadly announcing the proposed transaction, which often times has the effect of depressing the issuer s stock price. Accordingly, the price at which we could sell our securities in a public offering may be less and the dilution existing stockholders experience may in turn be greater than if we were able to raise capital through other means.

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

We may raise additional capital at any time and may do so through one or more financing alternatives, including public or private sales of our equity securities, debt financings, collaborations, licensing arrangements or other strategic transactions. Each of these financing alternatives carries certain risks. Raising capital through the issuance of common stock may depress the market price of our stock and may substantially dilute our existing stockholders. If we instead seek to raise capital through strategic transactions, such as licensing arrangements or sales of one or more of our technologies or product candidates, we may be required to relinquish valuable rights. For example, any licensing arrangement would likely require us to share a significant portion of any revenues generated by our licensed technologies with our licensees. Additionally, the development of any product candidates licensed or sold to third parties will no longer be in our control and thus we may not realize the full value of any such 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. As we continue to use our cash and cash equivalents to fund our operations, it will likely become increasingly difficult to raise additional capital on commercially reasonable terms, or at all.

If we are unable to raise sufficient additional capital, we may be forced to reduce or abandon on-going and/or planned development and/or commercialization activities, partner our product candidates or products at inopportune times or pursue less-expensive but higher-risk development paths, which we have done in the past. Even following the offering described in this prospectus supplement, we may need to raise additional capital in order to execute our business plans. If we are not able to raise adequate funds to continue our operations at levels we believe would enable us to capitalize on our assets, we may have to abandon some or all of them or attempt to continue our development and commercialization efforts by entering into arrangements with partners or others that, if available at

all, may not be on favorable terms and may require us to relinquish some or all of our rights to our product candidates or the financial benefits thereof, or we may determine to liquidate our assets and may receive less than the value at which our assets are carried on our financial statements.

To conserve funds, we may pursue less expensive but higher-risk development paths. For instance, in the past, we limited our ANX-530 manufacturing activities to the minimum we felt was sufficient to support our development and commercialization goals, in particular, with respect to ANX-530. While we successfully completed certain key manufacturing activities with respect to ANX-530, without extensive manufacturing experience, we may lack the information necessary to increase the scale of our existing processes and may be unable to manufacture successfully at commercial-scale. If we are unable to scale our manufacturing processes, we may be unable to effectively commercialize our products, if approved.

If we are unable to raise sufficient additional capital, we may seek to merge with or be acquired by another company and that transaction may adversely affect our business and the value of our securities.

If we are unable to raise sufficient additional capital, we may seek to merge with another company with a stronger cash position, complementary work force or product candidate portfolio or for other reasons. We believe the market price for our common stock may

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not accurately reflect the value of our business. While we will continue to seek to maximize the value of our business to our stockholders, the most attractive option for doing so may require us to consummate a transaction involving an exchange of our common stock with that of another company.

There are numerous risks associated with merging or being acquired. These risks include, among others, incorrectly assessing the quality of a prospective acquirer or merger-partner, encountering greater than anticipated costs in integrating businesses, facing resistance from employees and being unable to profitably deploy the assets of the new entity. The operations, financial condition, and prospects of the post-transaction entity depend in part on our and our acquirer/merger-partner s ability to successfully integrate the operations related to our product candidates, business and technologies. We may be unable to integrate operations successfully or to achieve expected cost savings and any cost savings which are realized may be offset by losses in revenues or other charges to operations. As a result, our stockholders may not realize the full value of their investment.

If we fail to maintain registration of the shares of common stock issued or issuable pursuant to the exercise of warrants we issued in our July 2005 private placement, we will be required to pay the holders of those securities liquidated damages, which could be material in amount.

The terms of the securities purchase agreement that we entered into in connection with our July 2005 private placement require us to pay liquidated damages to the purchasers of those securities in the event any shares issued or issuable pursuant to the exercise of warrants we issued in the private placement cannot be resold pursuant to our registration statement on Form S-3 (No. 333-127857) filed with and declared effective by the SEC on September 2, 2005. We refer to this as a maintenance failure. For each 30-day period or portion thereof during which a maintenance failure remains uncured, we are obligated to pay each purchaser an amount in cash equal to 1% of the purchaser s aggregate purchase price for any shares of common stock or shares of common stock issuable upon exercise of warrants then held by the purchaser (prorated for any period less than a month), increasing by an additional 1% with regard to each additional 30-day period or portion thereof until the maintenance failure is cured. There is no cap with respect to the total amount of these liquidated damages. The aggregate gross proceeds from our July 2005 private placement were approximately \$20 million. We are required to maintain the registration statement until the earlier of the date (i) all of the securities issued in our July 2005 private placement have been resold and (ii) each purchaser can resell the securities pursuant to Rule 144 under the Securities Act of 1933, as amended, without regard to the adequate current public information, volume, manner of sale or notice filing restrictions. The amount of these liquidated damages could be substantial and could have a material adverse effect on our financial condition.

For additional information, see Note 11 of the Notes to Consolidated Financial Statements, Registration Payment Arrangement, of our annual report on Form 10-K for the year ended December 31, 2008.

We may be unable to retain the services of key personnel, and, even if we are successful in raising additional funds, we may not be successful in rebuilding our workforce to carry out the development and commercialization activities necessary for our product candidates.

We have only two full-time employees and we depend on the services of these employees to continue our business. We do not have a chief executive officer or chief financial officer. Our Chief Business Officer and Senior Vice President currently is acting as our interim principal executive officer and our General Counsel, Secretary and Vice President, Legal currently is acting as our interim principal financial and accounting officer. To the extent we are successful in raising additional funds to continue to advance our product candidates, we will need to expand our financial, regulatory, research and development, manufacturing, commercial, quality, compliance and other resources in order to manage our operations, submit applications to and respond to inquiries from the FDA, commercialize ANX-530, should it be approved, and continue the development of ANX-514. We do not expect that our current management and personnel, systems and facilities will be adequate to support these activities.

The success of our business will depend, in part, on our ability to attract and retain highly qualified management, scientific and other personnel, and on our ability to develop and maintain important relationships with respected service providers and industry-leading consultants and advisors. Competition for these types of personnel and relationships is intense from numerous pharmaceutical and biotechnology companies, universities and other research institutions, particularly in the San Diego, California area. In connection with the cost-cutting measures we implemented in October 2008, January 2009 and March 2009, we eliminated, among others, our scientific staff and

our manufacturing and regulatory personnel, who had a deep background in our product candidates and our research and development programs. Recruiting and retaining employees, including senior-level personnel, with relevant product development experience in cancer and process development experience with emulsified cytotoxic drugs may be costly and time-consuming. Depending on the net proceeds to us from the offering described in this prospectus supplement, our ability to provide competitive compensation to our officers and employees may also be adversely affected by our limited capital resources and anticipated need to raise substantial additional capital to continue our business. We cannot ensure that we will be able to retain existing employees or attract and retain additional skilled personnel on acceptable terms as a result of these factors and, accordingly, we may not achieve our development and commercialization goals.

We have significant incentive and may, under certain circumstances, have significant severance and other obligations under agreements with our current officers.

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In July 2009, we adopted a 2009 mid-year incentive plan and a retention and severance plan, both of which apply to Mr. Culley and Mr. Keran, our two remaining employees. Under the incentive plan, each of Mr. Culley and Mr. Keran are eligible for incentive awards based upon the achievement of corporate performance objectives in effect at the end of 2009. Awards generally will be paid in cash. The potential award of each of Mr. Culley and Mr. Keran will be based 100% on our achievement of corporate objectives and the target award amount for each of them is \$150,000. The target amount of each award may be increased or decreased by multiplying the target amount by a corporate performance multiplier, as will be determined by the compensation committee of our board of directors in the first quarter of 2010. Award multipliers will range from zero to 1.5. Payment of awards under the incentive plan will be made after December 31, 2009 and on or before March 14, 2010. Under the retention plan, if the employment of either of our two remaining employees terminates at any time as a result of an involuntary termination, and such employee delivers and does not revoke a general release of claims, which will also confirm any post-termination obligations and/or restrictions applicable to such employee, such employee will be entitled to an amount equal to twelve (12) months of such employee s then-current base salary, less applicable withholdings, and an amount equal to the estimated cost of continuing such employee s health care coverage and the coverage of such employee s dependents who are covered at the time of the involuntary termination under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, for a period equal to twelve (12) months. These severance benefits will be paid in a lump-sum on the date the general release of claims becomes effective. Our aggregate contractual obligation under the retention plan, including applicable payroll and employer taxes, is approximately \$650,000.

We believe these plans are necessary to incentivize and retain these key employees and reinforce their dedication to us during a period when they would otherwise likely seek alternative employment. Our contractual responsibility for our current and any future incentive and/or severance obligations may cause us to cease or curtail our operations at an earlier date than would otherwise be the case if we were not required to satisfy these obligations. In addition, part or all of the proceeds from a future capital raising transaction may be used to satisfy these obligations.

The use of our net operating loss carryforwards may be limited.

Net operating loss carryforwards may expire and not be used. As of December 31, 2008, we had generated federal net operating loss carryforwards of approximately \$90.4 million and state net operating loss carryforwards of approximately \$41.4 million. Federal net operating loss carryforwards have a 20-year carryforward period and begin to expire in 2020. State net operating loss carryforwards have a ten year carry forward period and begin to expire in 2012.

Pursuant to Section 382 of the Internal Revenue Code, annual use of our net operating loss carryforwards may be limited in the event a cumulative change in ownership of more than 50 percent occurs within a three-year period. We determined that, as of January 1, 2009, no such ownership change had occurred. However, recent and potential future financing events, including this offering, may cause changes in ownership under Section 382, which could cause our net operating loss carryforwards to be subject to limitations and restrictions. If a change in ownership were to occur, our net operating loss carryforwards could be eliminated or restricted. Inability to fully utilize our net operating loss carryforwards 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, 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. In addition, under current SEC rules, we will be required to obtain an attestation from our independent registered public accounting firm as to our internal control over financial reporting for our annual report on Form 10-K for our fiscal year ending December 31, 2009. Performing the system and process documentation and evaluation needed to comply with Section 404 is both costly and challenging. 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 as they related 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 additional material weaknesses are identified in our internal control over financial reporting, neither our management nor our independent registered public accounting firm will be able to assert that our internal control over financial reporting and/or our disclosure controls and procedures are effective, and we could be required to further implement expensive and time-consuming remedial measures. We cannot be certain that any measures we take will ensure that we implement and maintain adequate internal control over financial reporting and that we will remediate the material weakness. As a result of recent reductions in our workforce and other personnel departures, we have experienced substantial turnover in our personnel responsible for performing activities related to our internal control over financial reporting. We have used third-party contractors to maintain effective internal control over financial reporting during this turn-over.

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However, if we fail to maintain effective internal control over financial reporting and/or disclosure controls and procedures we could lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on our stock price.

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

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

Risks Related to Drug Development and Commercialization

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

To varying degrees based on the regulatory plan for each product candidate, the effect of government regulation and the need for FDA and other regulatory agency approval will delay commercialization of our product candidates, impose costly procedures upon our activities, and put us at a disadvantage relative to larger companies with which we compete. There can be no assurance that FDA or other regulatory approval for any product candidates developed by us will be granted on a timely basis, or at all. Even though the FDA has confirmed the appropriateness of a Section 505(b)(2) regulatory path for ANX-530 and ANX-514, the FDA is views may change. If the FDA requires the longer-term regulatory approval pathway associated with traditional drug development for ANX-530 and ANX-514, we may determine that the associated time and cost is not financially justifiable and, as a result, discontinue those programs. If we discontinue the development of one or both of these product candidates, our business and stock price may suffer.

In connection with any NDA that we file under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, we may be required to notify third parties that we have certified to the FDA that any patents listed for the approved drug in the FDA s Orange Book publication are invalid or will not be infringed by the manufacture, use or sale of our drug. 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-530 and ANX-514, only to be subject to significant delay and patent litigation before our products may be commercialized.

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

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

We conduct pre/non-clinical 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 pre/non-clinical activities could occur for a number of reasons, including:

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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;

changes in regulatory requirements or other standards or guidance relating to preclinical testing, including testing of pharmaceutical products in animals;

a lack of availability of animals that are suitable for the types of studies we plan to conduct;

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 preclinical or nonclinical testing that require us to amend study or test designs or delay future testing or bioequivalence or clinical trials and related regulatory filings.

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

obtaining regulatory approval to commence a trial;

identifying appropriate trial sites and reaching agreement on acceptable terms with prospective CROs, trial sites and investigators, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and investigators;

manufacturing sufficient quantities of a product candidate;

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 or personal issues, or who are lost to further follow-up.

For example, in October 2007, we announced results of our phase 2b clinical trial of ANX-510, or CoFactor, for the first-line treatment of metastatic colorectal cancer, which demonstrated that the CoFactor/5-FU arm did not demonstrate statistically significant improved safety in the trial s primary endpoint. In November 2007, we announced that we would discontinue enrolling patients in our phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer and, in October 2008, we announced that we had discontinued active work on all product candidates other than ANX-530 and ANX-514, including CoFactor. In addition, in May 2009, we announced that we did not meet the primary endpoint in our bioequivalence study of ANX-514, resulting in additional uncertainty around the cost and timeline to obtaining FDA approval for that product candidate.

In addition, a trial may be suspended or terminated by us, 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 clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination or renegotiate terms with CROs, trial sites and clinical investigators, all of which may impact the costs, timing or successful completion of a clinical trial.

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There can be no assurance that our preclinical and nonclinical testing and bioequivalence and/or clinical trials will commence or be completed, that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our current schedule for the development or commercialization of any of our product candidates. If we experience delays in completion of, or if we terminate, our bioequivalence or clinical trials or preclinical and nonclinical testing, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of bioequivalence or clinical trials or preclinical and 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 and established a competitive advantage.

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

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through preclinical testing and bioequivalence or clinical trials that each product is safe and effective for use in each target indication. Success in preclinical testing and/or bioequivalence trials does not ensure that subsequent or large-scale trials will be successful. Additionally, throughout development, we must provide adequate assurance to the FDA and other regulatory authorities that we can consistently produce our product candidates in conformance with current good manufacturing practices, or cGMP, and other regulatory standards. Bioequivalence and clinical trial results are frequently susceptible to varying interpretations and regulatory authorities may disagree on what are appropriate methods for analyzing data, which may delay, limit or prevent regulatory approvals. For instance, with respect to our bioequivalence trial of ANX-530, the FDA may perform its pharmacokinetic equivalence analysis based on a patient population other than the population on which we based our analysis, which may result in the FDA determining that ANX-530 and Navelbine® are not bioequivalent, requiring that we evaluate additional patients, re-perform the study or take other remedial action. In addition, the FDA may inquire regarding the manufacturing source, in-process and product release specifications and overall uniformity of reference product used in the bioequivalence trial of ANX-530, particularly since it was conducted at sites in multiple countries, and we may be unable to provide documentation satisfactory to the FDA with respect to such reference product, which may result in the FDA requiring that we evaluate additional patients, re-perform the study or take other remedial measures. Further, the ANX-530 bioequivalence trial was open-label, meaning physician-investigators, as well as patients, may have been aware of which drug was being administered. There is a risk of investigator bias in reporting adverse events as a result of the study s open-label nature, including bias that increased the reporting of adverse events associated with Navelbine and/or that decreased the reporting of adverse events associated with ANX-530. With respect to ANX-514, despite positive preclinical testing that indicated pharmacokinetic equivalence between ANX-514 and the reference product, our bioequivalence trial of ANX-514 did not demonstrate pharmacokinetic equivalence between ANX-514 and the reference product based on benchmark regulatory standards.

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 may be difficult to predict. In addition, delays or rejections may be encountered based upon changes in FDA policy for drug approval during the period of product development and FDA regulatory review of each submitted NDA. There is a significant risk that any of our product candidates could fail to show satisfactory 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.

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

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

our product s perceived advantages over existing treatment methods (including relative convenience and ease of administration and prevalence and severity of any adverse side effects);

claims or other information (including limitations or warnings) in our product s approved labeling;

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, or GPOs (including distributors and other network providers), to sell our products to their constituencies;

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

availability of alternative treatments; and

the prevalence of off-label substitution of chemically equivalent products.

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 of our products may require significant resources and may never be successful.

Under our Section 505(b)(2) regulatory strategy for ANX-530 and ANX-514, because we anticipate submitting NDAs based on pharmacokinetic data, our ability to differentiate our products from competitor products will be limited unless the FDA allows us to include certain data in our products labels. Even if our products demonstrate clinical or pharmacoeconomic benefits, we may be unable to market our products based on these benefits.

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

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

We do not have any manufacturing capability. We rely on third-party manufacturers and component materials suppliers for the manufacture of our product candidates for bioequivalence or clinical trial purposes and we anticipate establishing relationships with third-party manufacturers and component materials suppliers for the commercial production of our products. Currently we do not have any commercial supply agreements or commitments with our third-party manufacturers or component suppliers, and we cannot ensure that we will be able to establish relationships with these parties on commercially acceptable terms, or at all. If we fail to establish and maintain such relationships, we expect it would have a material and adverse effect on our operations. Even if we successfully establish relationships with third-party manufacturers and component suppliers on commercially acceptable terms, our manufacturers and suppliers may not perform as agreed or may terminate their agreements with us. Because many of our single source suppliers provide manufacturing services to a number of other pharmaceutical companies, our suppliers may experience capacity constraints or choose to prioritize one or more of their other customers over us. Any significant problem that our single source manufacturers or suppliers experience could delay or interrupt the supply to us of bioequivalence or clinical trial materials or products until the manufacturer or supplier cures the problem or until we locate an alternative source of supply, if an alternative source is available, and any such delay or interruption could materially and adversely affect our development and commercial activities and operations. For instance, ANX-530 is an emulsified cytotoxic product that must be aseptically-filled. There are a limited number of CMOs capable and willing to manufacture this type of product at the commercial scale at which we anticipate requiring in accordance with our marketing plans for ANX-530, which will make identifying and establishing shortor long-term relationships with willing manufacturers more difficult and provide them with substantial leverage over us in any negotiations. Furthermore, certain of the component materials of ANX-530 are available only from a particular supplier, and currently we do not have any short- or long-term agreements for the supply of those materials. Even if we successfully establish a long-term relationship with our current CMO for ANX-530 on commercially acceptable terms, our CMO may be unable to successfully and consistently manufacture ANX-530 at commercial scale. We and this manufacturer have limited experience manufacturing ANX-530. Because data from a single

bioequivalence trial of ANX-530 may be sufficient to support an NDA for ANX-530, our and our current contract manufacturer s ability to gain experience manufacturing ANX-530, in particular at various scales, has been limited. If our current CMO is unable to manufacture ANX-530 successfully and consistently at commercial scale and within established parameters, we may be unable to validate our manufacturing process, even if the FDA otherwise would approve our NDA, and therefore unable to sell ANX-530. Our current CMO has similarly limited experience with ANX-514.

All manufacturers of our products and product candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program, as well as applicable requirements of foreign regulatory authorities. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products and product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. While we or our representatives generally monitor and audit our manufacturer systems, we have little control over our manufacturers ongoing

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compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval.

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

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

If any of our product candidates should be approved, any problems or delays experienced in their manufacturing processes may impair our ability to provide commercial quantities of the products, which would limit our ability to sell the products and would adversely affect our business. It could take significant time to redesign our manufacturing processes or identify alternative suppliers in response to problems we may encounter as we manufacture our products, if such alternative processes and suppliers are available at all. Even if we are able to identify alternative suppliers, they may be unwilling to manufacture our products on commercially reasonable terms. Neither ANX-530 nor ANX-514 have been manufactured at the scales we believe will be necessary to maximize their commercial value to us and, accordingly, we may encounter difficulties in production while scaling-up initial production and may not be successful at all 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. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new supplier to bear significant additional costs which may be passed on to us. For instance, with respect to ANX-530, the form of API used in the manufacture of ANX-530 for purposes of our bioequivalence study of ANX-530 will not be the same form of API used in the manufacture of ANX-530 for purposes of process validation batches or commercial supply. To ensure the comparability of the ANX-530 used in the bioequivalence study and the ANX-530 intended for commercial sale, FDA may require that we evaluate both forms of ANX-530 in additional patients, re-perform the bioequivalence study or take other remedial actions. We may have insufficient quantities of both forms of ANX-530 and could incur substantial cost and delay in acquiring such quantities, in addition to the time and expense associated with conducting the evaluation, re-performing the study or taking other remedial measures. We rely in part on third parties to conduct our preclinical and nonclinical testing and bioequivalence and clinical

we rely in part on third parties to conduct our preclinical and 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 the activities associated with our programs, particularly since we implemented severe cost-cutting measures in late 2008 and early 2009. We engage consultants, advisors, CROs, CMOs and others to design and conduct preclinical and nonclinical tests and bioequivalence and clinical studies in connection with the research and development of our product candidates. As a result, many important aspects of our product candidates—development are outside our direct control. There can be no assurance that such third parties will perform all of their obligations under arrangements with us or will perform those obligations satisfactorily.

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

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

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

We currently do not have sales, marketing or commercialization personnel. We have limited business development personnel. To commercialize our products, including ANX-530, we will have to acquire or develop sales, marketing and distribution capabilities, or rely on marketing partners or other arrangements with third parties for the marketing, distribution and sale of our products. There is no guarantee that we will be able to establish marketing, distribution or sales capabilities or make arrangements with third parties to perform those activities on terms satisfactory to us, or that any internal capabilities or third party arrangements will be cost-effective. The acquisition or development of a sales and distribution and associated regulatory compliance infrastructure will require substantial resources, which may divert the attention of our management and key personnel and negatively impact our product development efforts. In addition, any third parties with which we establish marketing, distribution or sales arrangements may have significant control over important aspects of the commercialization of our products, including market identification, marketing methods, pricing, composition of sales force and promotional activities. If we retain third-party service providers to perform functions related to the sale and distribution of our products, key aspects of those functions that would be out of our direct control could include warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management. In this event, we would place substantial reliance on third-party providers to perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter natural or other disasters at their facilitates, our ability to deliver product to meet commercial demand could be significantly impaired. In addition, we may use third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms, or at all. Even if we are successful in establishing and maintaining these arrangement, 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 receive regulatory approval for one or more of our product candidates, we may face competition from generic products, which could exert downward pressure on the pricing and market share of our products and limit our ability to generate revenues.

Many of the currently marketed and anticipated products against which our product candidates may compete are, or we anticipate will be, available as generics. For instance, ANX-530 will compete against Navelbine, for which generic equivalents are already available. ANX-514 will compete against Taxotere[®]. We anticipate that ANX-514 will also compete against other formulations of docetaxel and that generic Taxotere will enter the market in November 2013 or May 2014 (depending on whether a period of pediatric exclusivity is granted in the future). Even if we obtain unique HCPCS codes for our products, the existence of generic products could make it more difficult for our branded products, including ANX-530 and ANX-514, to gain or maintain market share and could cause prices for our products to drop, each of which could adversely affect our business.

We may also face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. Proposed federal legislative changes may expand consumers ability to import lower priced versions of our and competing products from Canada. Further, several states and local

governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own products could negatively impact our business and prospects.

Even if we receive regulatory approval in the U.S. for ANX-530 and/or ANX-514, we will likely depend on a limited number of group purchasing organizations for retail distribution of these products, and if we subsequently lose any significant GPO relationship, our business could be harmed.

Our current U.S. commercialization strategy for our lead emulsion formulations initially involves marketing and selling these products through a limited number of GPOs. Even if we are successful in securing relationships with these entities, the subsequent loss of any one or more of these GPO accounts or a material reduction in their participation could harm our business, financial condition or results of operations. In addition, we may face pricing pressure from these GPOs.

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

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

issue warning letters or untitled letters;

impose civil or criminal penalties;

suspend or withdraw regulatory approval;

suspend or terminate any ongoing bioequivalence or clinical trials;

refuse to approve pending applications or supplements to approved applications;

impose restrictions or affirmative obligations on our or our CMO s operations, including costly new manufacturing requirements;

close the facilities of a CMO; or

seize or detain products or require a product recall.

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

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. In particular, other countries may not have a comparable regulatory procedure as is available under Section 505(b)(2) of FDCA. Even if a country did have a comparable procedure, that country may require a more robust data package than the pharmacokinetic data package that we intend to submit in support of NDAs for ANX-530 and ANX-514. 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 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.

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

regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;

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regulatory authorities may withdraw their approval of the product;

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; and

our reputation may suffer.

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

Risks Related to Our Intellectual Property

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

Our success will depend in part on our ability to:

obtain and maintain patent protection with respect to our products;

prevent third parties from infringing upon our proprietary rights;

maintain trade secrets;

operate without infringing upon the patents and proprietary rights of others; and

obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, both in the U.S. and in foreign countries.

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

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

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

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

regulatory approval for products with the same API as our products. Such competitive products may not infringe the patents we hold covering our specific formulations of the API.

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

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

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infringe the rights of others. Because patent applications can take many years to publish and issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our products, product candidates or technologies infringe, or that the process of manufacturing our products or any of their respective component materials, or the component materials themselves, infringe.

We or our CMOs or component material suppliers may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our products, product candidates and/or technologies infringe their intellectual property rights or that the process of manufacturing our products or any of their respective component materials, or the component materials themselves, infringe their intellectual property rights. If one of these patents was found to cover our products, product candidates, technologies or their uses, or any of the underlying manufacturing processes or components, we could be required to pay damages and could be unable to commercialize our products or use our technologies or methods unless we are able to obtain a license to the patent or intellectual property right. A license may not be available to us 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.

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

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

infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert our management s attention from our core business;

substantial damages for infringement, including treble damages and attorneys fees, which we may have to pay if a court decides that the product at issue infringes on or violates the third party s rights;

a court prohibiting us from selling or licensing the product unless the third party licenses its product rights to us, which it may not be required to do;

if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross-licenses to our products; and

redesigning our products or processes so they do not infringe, which may not be possible or may require substantial funds and time.

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

In addition, it may be necessary for us to enforce patents under which we have rights, or to determine the scope, validity and unenforceability of other parties proprietary rights, which may affect our rights. There can be no assurance that our patents would be held valid by a court or administrative body or that an alleged infringer would be found to be infringing. The uncertainty resulting from the mere institution and continuation of any technology-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 all of our product candidates.

The industry in which we operate is highly competitive and rapidly changing. If successfully developed and approved, all of our products will likely compete with existing and new products and therapies and our competitors may succeed in commercializing products more rapidly or effectively than us, which would have a material and adverse effect on our results of operations and financial condition. In addition, there are numerous companies with a focus in oncology and/or that are pursuing the development of pharmaceuticals that target the same diseases as are targeted by the products being developed by us or that focus on reformulating currently approved drugs. We anticipate that we will face intense and increasing competition in the future as new products enter the

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market and advanced technologies become available. There is no assurance that existing products or new products developed by competitors will not be more effective, or more effectively marketed and sold, than those we may market and sell. Competitive products may render our products and product candidates obsolete or noncompetitive. For instance, numerous companies are focused on reformulating currently approved chemotherapeutic agents. In particular, the taxanes, the class of drugs of which Taxotere is a member, have experienced substantial commercial success, in part as a result of their effectiveness in treating a wide variety of cancers, which has generated significant interest in reformulating Taxotere and other taxanes. In addition to our approach of emulsifying docetaxel, other companies are pursuing alternative delivery vehicles, including the use of albumin nanoparticles, prodrugs, polyglutamates, analogs, co-solvents, liposomes and microspheres. Many of these or similar approaches could be applied to vinorelbine. Relative to our formulations, formulations based on one or more of these other methods may result in greater efficacy or safety, provide better drug delivery to tumor sites or otherwise increase benefits to patients and healthcare providers.

In particular, ANX-530 and ANX-514, if approved, may compete against Navelbine and Taxotere, respectively, as well as their generic equivalents and other formulations of vinorelbine and docetaxel. In addition to Navelbine, currently there are at least 6 generic versions of vinorelbine on the market. In addition, there is an oral formulation of vinorelbine approved for use in the European Union, or EU, against which we would compete if our emulsion formulation of vinorelbine were approved for use in the EU. In the U.S., in May 2010 (but subject to any period of pediatric exclusivity that may be granted in the future), patent protection ends for docetaxel and, in November 2013 (but subject to any period of pediatric exclusivity that may be granted in the future), patent protection ends for Taxotere. We are aware of two leading generics companies that each have developed or acquired a formulation of docetaxel and have certified that, after May 2010, their respective formulations of docetaxel will not infringe any unexpired Taxotere patents.

Under our current regulatory strategy, because we anticipate submitting Section 505(b)(2) NDAs with only bioequivalence data, the ability to differentiate our products from competitor products will be limited. Even if we believe our products demonstrate clinical or pharmacoeconomic benefits, we may be unable to market our products based on these benefits. If our products fail to obtain unique HCPCS codes, we may be required to price our products at levels that do not cover our costs to manufacture, market and distribute the products or provide any profit, or to price our products at levels at which they are not competitive.

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

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

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

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

our ability to set a price we believe is fair for our products;

our ability to generate revenues or achieve or maintain profitability;

the future revenues and profitability of our potential customers, suppliers and collaborators; and

the availability to us of capital.

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

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

We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization. In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage and it is uncertain that such increased or additional insurance coverage can be obtained on commercially reasonable terms. Our business (in particular, the use of our product candidates in clinical trials and the sale of our products for which we obtain marketing approval) will expose us to product liability risks. Product liability claims might be brought against us by patients, health care providers, pharmaceutical companies or others selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our products or product candidates;

impairment of our business reputation;

withdrawal of bioequivalence or clinical trial participants;

costs of related litigation;

substantial monetary awards to patients or other claimants;

loss of revenues; and

the inability to commercialize our products and product candidates.

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

We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval of any of our product candidates, but we may be unable to obtain product liability insurance on commercially acceptable terms or may not be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect us against potential losses. Large judgments have been awarded in class action lawsuits based on drugs 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

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

Our common stock currently trades on the NYSE Amex. NYSE Amex will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders equity of less than \$6.0 million if such issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. As of

September 30, 2009, our stockholders equity was approximately \$1.6 million and we have incurred annual net losses since inception. In addition, NYSE Amex will normally consider suspending dealings in, or removing from the list, securities selling for a substantial period of time at a low price per share if the issuer fails to effect a reverse split of such stock within a reasonable time after being notified that the NYSE Amex deems such action to be appropriate under the circumstances. Since October 1, 2007 through the date hereof, the closing price of a share of our common stock has been less than \$1.00.

On June 1, 2009, we received notice from the NYSE Amex staff that, based on their review of our Form 10-Q for the period ended March 31, 2009, we are not in compliance with certain stockholders equity continued listing standards. Specifically, the NYSE Amex staff noted that we are not in compliance with Section 1003(a)(ii) of the NYSE Amex 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

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

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

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

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. Investors in penny stocks should be prepared for the possibility that they may lose their whole investment.

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

On October 1, 2007, the market price for our common stock dropped almost 80% following our announcement of the results of our phase 2b clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. In addition, the market price for our common stock has historically been highly volatile, and the market for our common stock has from time to time experienced significant price and volume fluctuations that are unrelated to our operating performance. The market price of our common stock may fluctuate significantly in response to a number of factors, including:

the level of our financial resources and ability to continue as a going concern;

announcements of entry into or consummation of a financing or strategic transaction;

any decision by us to liquidate our assets and wind-up operations;

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

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

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

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

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

litigation or public concern about the safety of our products or product candidates;

changes in securities analysts estimates of our financial performance or deviations in our business and the trading price of our common stock from the estimates of securities analysts;

events affecting any future collaborations, commercial agreements and grants;

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fluctuations in stock market prices and trading volumes of similar companies;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders or pursuant to shelf or resale registration statements that register shares of our common stock that may be sold by certain of our current or future stockholders;

discussion of us or our stock price by the financial and scientific press and in online investor communities;

commencement of delisting proceedings by the NYSE Amex;

additions or departures of key personnel; and

changes in third party reimbursement policies.

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

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

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

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

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

required to provide additional incentive to them, which could increase the cost of the acquisition to the acquirer and may deter or affect the terms of the acquisition or potential acquisition.

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

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

We have paid no cash dividends on any of our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, with respect to our common stock, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we are subject to various laws and regulations that may restrict our ability to pay dividends and we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, 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.

RISKS RELATED TO THIS OFFERING

Since we have broad discretion in how we use the proceeds from this offering, we may use the proceeds in ways with which you disagree.

Although we describe under the heading Use of Proceeds in this prospectus supplement our currently intended use of the net proceeds from this offering, we cannot estimate the allocation of the net proceeds from this offering among those uses and we reserve the right to change the use of proceeds as a result of certain contingencies, including any future partnering or strategic transaction opportunity. Accordingly, our management will have significant flexibility in applying the net proceeds from this offering. You will be relying on the judgment of our management and our board of directors with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be used in a way that does not improve our operating results or enhance the value of our common stock. In addition, if we are unable to obtain additional capital or complete a strategic transaction on a timely basis, net proceeds from this offering may be used for expenses related to seeking protection under the provisions of the U.S. Bankruptcy Code or conducting an orderly liquidation of our assets and winding up of our corporate affairs. In either case, you could lose part or all of your investment.

Investors in this offering will pay a much higher price than the book value of our stock.

The public offering price of the securities offered hereby is likely to be substantially higher than the book value per share of our common stock. Investors purchasing securities in this offering may, therefore, incur immediate dilution in net tangible book value per share of the common stock issuable upon conversion or exercise of the securities purchased in this offering. See Dilution below for a more detailed discussion of the dilution you will incur in this offering.

Provisions of the Delaware General Corporation Law may prohibit us from making dividend payments with respect to our Series E convertible preferred stock or make-whole payments that may be due to the holders of our Series E convertible preferred stock.

We are incorporated in the State of Delaware and are subject to the provisions of the Delaware General Corporation Law (the DGCL). Section 170 of the DGCL provides, among other things, that a Delaware corporation may declare and pay dividends upon shares of its capital stock out of its surplus, as defined in and computed in accordance with Sections 154 and 244 of the DGCL. As of the date hereof, we have sufficient surplus to make dividend payments with respect to the Series E convertible preferred stock offered by this prospectus supplement, as well as sufficient surplus to make the make-whole payments that may be due to the holders of our Series E convertible preferred stock, should such make-whole payments be deemed a dividend under the DGCL. However, our surplus will decrease as we spend our capital on operational activities, unless our spending is offset by capital-raising transactions. If our surplus is less than then-due dividend payments, including make-whole payments if they are deemed a dividend under the DGCL, we will be prohibited by the DGCL from making the dividend or make-whole payment, which may constitute a violation of our certificate of incorporation or a breach of our contractual obligations to the holders of our Series E convertible preferred stock.

If third parties bring claims against us, the proceeds held in escrow may be reduced and we may not be able to make dividend payments with respect to our Series E convertible preferred stock or make-whole payments that may be due to the holders of our Series E convertible preferred stock.

Our placing of a portion of the proceeds from this offering in escrow may not protect those funds from third party claims against us. We cannot assure you that we will be able to prevent third parties, including other lenders or holders of our debt, from making claims against the escrow account. Additionally, if we are forced to file a bankruptcy case or an involuntary bankruptcy case is filed against us which is not dismissed, the proceeds held in our escrow account may be subject to applicable bankruptcy law, and may be included in our bankruptcy estate and subject to claims of third parties with priority over the claims of the holders of our Series E convertible preferred stock. To the extent bankruptcy claims deplete the amounts held in escrow, we cannot assure that we will able to make dividend payments with respect to our Series E convertible preferred stock or make-whole payments that may be due to the holders of our Series E convertible preferred stock.

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There is no public market for the convertible preferred stock or the warrants being offered by this prospectus supplement.

There is no established trading market for the convertible preferred stock or the warrants being offered by this prospectus supplement and we do not expect a market to develop. In addition, we do not intend to apply to list the convertible preferred stock or the warrants on any securities exchange or automated quotation system. Without an active market, the liquidity of the convertible preferred stock and the warrants will be limited.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and the accompanying prospectus, including the documents that we incorporate herein and therein by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements regarding business strategy, expectations and plans, our objectives for future operations, including product development, and our future financial position. When used in this report, the words believe, may, could, will, estimate, continue, anticipate, intend, expect, indicate and similar expressions are intended forward-looking statements.

We base these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs, including our ability to consummate a strategic transaction or otherwise satisfy our immediate need for additional capital. These forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: the risk that we will pursue development activities at levels or on timelines, or will incur unexpected expenses, that shortens the period through which our operating funds will sustain us; the risk that ADVENTRX will be unable to raise sufficient additional capital to commercialize ANX-530, if an ANX-530 NDA is submitted and approved, or to continue the development of ANX-514; the risk that ADVENTRX will be unable to raise sufficient additional capital on a timely basis to continue as a going concern; the risk that ADVENTRX will seek protection under the provisions of the U.S. Bankruptcy Code; the risk that changes made in transferring the manufacturing process for ANX-530 may result in a lack of comparability between the commercial product and the material used in clinical trials, and that FDA may require ADVENTRX to perform additional non-clinical or clinical studies; the potential for regulatory authorities to require additional preclinical work and/or clinical activities to support regulatory filings, including prior to the submission or the approval of an NDA for ANX-530 and/or ANX-514, which activities may increase the cost and timeline to NDA submission or approval and negatively impact our ability to raise additional capital and/or complete a strategic or partnering transaction; the risk the FDA will determine that ANX-530 and Navelbine and/or ANX-514 and Taxotere are not bioequivalent, including as a result of performing pharmacokinetic equivalence analysis based on a patient population other than the population on which we based our analysis or determining that increased docetaxel blood-levels during and immediately following infusion are clinically relevant; the risk of investigator bias in reporting adverse events as a result of the open-label nature of the ANX-530 bioequivalence study, including bias that increased the reporting of adverse events associated with Navelbine and/or that decreased the reporting of adverse events associated with ANX-530; difficulties or delays in manufacturing, obtaining regulatory approval for and marketing ANX-530 and ANX-514, including validating commercial manufacturing processes and manufacturers, as well as suppliers, and the potential for automatic injunctions regarding FDA approval of ANX-514; the risk that the performance of third parties on whom we rely to conduct our studies or evaluate the data, including clinical investigators, expert data monitoring committees, contract laboratories and contract research organizations, may be substandard, or they may fail to perform as expected; the risk that our significantly reduced workforce and leadership by officers who do not have substantial previous experience in executive leadership roles will negatively impact our ability to raise capital or maintain effective disclosure controls and procedures or internal control over financial reporting; the risk that our common stock will be delisted by the NYSE Amex, including as a result of failing to maintain sufficient stockholders equity or a sufficient stock price; the risk that we will trigger a maintenance failure under that certain Rights Agreement, dated July 27, 2005, as amended, and be required to pay liquidated damages, including as a result of losing our eligibility to use Form S-3 if our common stock is delisted from the NYSE Amex; and other risks and uncertainties discussed under the heading Risk Factors in this prospectus supplement, the accompanying prospectus and in other reports and documents we file with the SEC.

Any forward-looking statement speaks only as of the date on which it is made and, except as required by law, we do not intend to update any forward-looking statements publicly to reflect events or circumstances after the date on which such statement is made or to update the reasons actual results could differ materially from those anticipated in

the forward-looking statements, even if new information becomes available in the future. You should not place undue reliance on any forward-looking statement.

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USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the securities offered under this prospectus supplement, after deducting the placement agent s fees and our estimated offering expenses, but before deducting our dividend and related payment obligations, and excluding the proceeds, if any, from exercise of the warrants issued in this offering, will be approximately \$14.5 million, if we sell the maximum number of units. We may increase the dollar value of securities offered under the registration statement(s) of which this prospectus supplement and the accompanying prospectus form a part. In this event, we estimate that the net proceeds to us from the sale of the securities offered under this prospectus supplement, after deducting the placement agent s fees and our estimated offering expenses, but before deducting our dividend and related payment obligations, and excluding the proceeds, if any, from exercise of the warrants issued in this offering, will be approximately \$17.6 million, if we sell the maximum number of units available for such increase. Because there is no minimum offering amount required as a condition to closing in this offering, we may sell less than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us.

We currently intend to use the majority of the net proceeds from this offering to fund activities relating to the commercial launch of ANX-530, including acquiring or developing sales, marketing and distribution capabilities and the associated regulatory compliance infrastructure, and to continue the development of ANX-514 in the United States, and for general corporate purposes. At this time we cannot estimate the allocation of the net proceeds of this offering among these anticipated uses. The amounts and timing of the expenditures may vary significantly depending on numerous factors, including the net proceeds to us from the sales of the securities offered under this prospectus supplement and our need for and ability to raise additional capital to launch ANX-530 in the U.S., should it be approved, and continue the development of ANX-514. We reserve the right to change the use of proceeds as a result of certain contingencies, such as those discussed above and any future opportunities to evaluate, negotiate and complete one or more strategic or partnering transactions. Accordingly, our management will have broad discretion in the application of the net proceeds of this offering. Pending use of the net proceeds, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities.

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock and do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. Our 5% Series B Convertible Preferred Stock would have accrued cumulative dividends at a rate of 5% per annum until July 6, 2014, payable on a quarterly basis beginning on October 1, 2009, our 5% Series C Convertible Preferred Stock would have accrued cumulative dividends at a rate of 5% per annum until February 10, 2012, payable on a quarterly basis beginning on October 1, 2009 and our 4.25660% Series D Convertible Preferred Stock would have accrued cumulative dividends at a rate of 4.25660% per annum until October 9, 2020, payable on a quarterly basis beginning January 1, 2010. However, all of the shares of the 5% Series B Convertible Preferred Stock, the 5% Series C Convertible Preferred Stock and the 4.25660% Series D Convertible Preferred Stock were converted into common stock prior to the initial dividend payment date. Pursuant to the terms of the 5% Series B Convertible Preferred Stock, the 5% Series C Convertible Preferred Stock and the 4.25660% Series D Convertible Preferred Stock, in connection with these conversions, we paid an amount equal to \$250 per \$1,000 stated value of such converted shares of 5% Series B Convertible Preferred Stock, or an aggregate of \$340,250, we paid an amount equal to \$125 per \$1,000 stated value of such converted shares of the 5% Series C Convertible Preferred Stock, or an aggregate of \$115,250, and we paid an amount equal to \$468.23 per \$1,000 stated value of such converted shares of 4,25660% Series D Convertible Preferred Stock, or an aggregate of \$5,283,000, in each case in lieu of our dividend obligations. Such payments may be deemed dividends under the DGCL. Except for dividends, or amounts that may be deemed dividends, payable on our 3.73344597664961% Series E convertible Preferred stock offered hereby, we expect to retain all available funds and any future earnings to support operations and fund the development and growth of our business. Our board of directors will determine whether we pay and the amount of future dividends (including cash dividends), if any.

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DILUTION

If you invest in the units being offered by this prospectus supplement, you will suffer immediate and substantial dilution in the net tangible book value per share of common stock. Our net tangible book value as of September 30, 2009 was approximately \$1.6 million, or approximately \$0.01 per share of common stock. Net tangible book value per share is determined by dividing our net tangible book value, which consists of our total tangible assets less total liabilities, by the number of shares of our common stock outstanding on that date.

Dilution in net tangible book value per share represents the difference between the amount per share of common stock underlying the convertible preferred stock paid by purchasers in this offering and the net tangible book value per share of our common stock immediately after this offering. Without taking into account any other changes in the net tangible book value after September 30, 2009 other than to give effect to:

our receipt of the proceeds from the sale of 11,283 shares of units, or 60,000,000 shares of common stock issuable upon conversion of the convertible preferred stock comprising the units at an effective acquisition price of \$0.18805 per share of common stock, in our financing that closed on October 9, 2009, less the placement agent s fees and our estimated offering expenses, but before deducting our dividend and related payment obligations, and

our receipt of the estimated proceeds from the sale of 15,676 units in this offering at an offering price of \$1,000 per unit, or 41,128,165 shares of common stock issuable upon conversion of the convertible preferred stock comprising the units at an effective acquisition price of \$0.38115 per share of common stock, less the estimated placement agent s fees and our estimated offering expenses, but before deducting our dividend and related payment obligations,

our net tangible book value as of September 30, 2009, after giving effect to the items above, would have been approximately \$26.5 million, or approximately \$0.12 per share of common stock. This represents an immediate increase of approximately \$0.11 in net tangible book value per share to our existing stockholders and an immediate dilution of approximately \$0.26 per share to purchasers of units in this offering. The following table illustrates this per share dilution.

| Public offering price per share of common stock underlying convertible preferred stock | | \$ 0.3 | 88115 |
|--|--------|--------|-------|
| Net tangible book value per share as of September 30, 2009 | \$0.01 | | |
| Increase in net tangible book value per share attributable to offering closed October 9, 2009 | \$0.06 | | |
| Increase in net tangible book value per share attributable to this offering | \$0.05 | | |
| Pro forma net tangible book value per share as of September 30, 2009, after giving effect to the offering closed October 9, 2009 | | \$ | 0.07 |
| Pro forma net tangible book value per share as of September 30, 2009, after giving effect to this offering | | \$ | 0.12 |

Dilution in net tangible book value per share to new investors in this offering

\$(0.26115)

We may increase the dollar value of securities we offer under the registration statement(s) of which this prospectus supplement and the accompanying prospectus form a part by up to \$3,901,311. After giving effect to our receipt of the estimated proceeds from the sale of 19,000 units, which reflects the maximum number of units we could sell under the registration statement(s) of which this prospectus supplement and the accompanying prospectus form a part after such increase, at an offering price of \$1,000 per unit, or 49,849,141 shares of common stock issuable upon conversion of the convertible preferred stock comprising the units at an effective acquisition price of \$0.38115 per share of common

stock, less the estimated placement agent s fees and our estimated offering expenses, but before deducting our dividend and related payment obligations, our net tangible book value as of September 30, 2009, after giving effect to the items above, would have been approximately \$29.7 million, or approximately \$0.13 per share of common stock. This represents an immediate increase of approximately \$0.12 in net tangible book value per share to our existing stockholders and an immediate dilution of approximately \$0.25 per share to purchasers of units in this offering.

The above is based on 124,885,267 shares of our common stock outstanding as of September 30, 2009 (as adjusted for 60,000,000 shares of common stock issued upon conversion of the convertible preferred stock issued in our offering that closed on October 9, 2009 and 41,128,165 shares (or 49,849,141 shares if we effect the increase) of common stock to be issued upon conversion of the convertible preferred stock to be issued in this offering), and excludes, as of that date:

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5,859,000 shares of common stock issuable upon the exercise of outstanding stock options issued under our equity incentive plans prior to this offering, at a weighted average exercise price of \$0.80 per share; 14,383,656 shares of common stock available for future issuance under our 2008 Omnibus Incentive Plan;

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20,658,33 shares of common stock issuable upon the exercise of outstanding warrants, at a weighted average exercise price of \$1.26 per share;

19,800,000 shares of common stock issued or issuable upon the exercise of outstanding warrants issued to the purchasers in the offering the closed October 9, 2009, at an exercise price of \$0.1468;

3,600,000 shares of common stock issuable upon the exercise of outstanding warrants issued to the placement agent in connection with the offering that closed October 9, 2009, at an exercise price of \$0.235 per share

12,462,285 shares of common stock issuable upon the exercise of the warrants to be issued to the purchasers in this offering, at an exercise price of \$0.3499 per share, which amount assumes we increase the dollar value of securities in this offering by a total of \$3,901,311; and

2,492,457 shares of common stock issuable upon exercise of warrants to be issued to the placement agent in connection with this offering, which are not covered by this prospectus supplement, at an exercise price of \$0.4765 per share, which amount assumes we increase the dollar value of securities in this offering by a total of \$3.901.311.

To the extent that any options or warrants are exercised, new options or other equity awards are issued under our 2008 Omnibus Incentive Plan, or we otherwise issue additional shares of common stock in the future, there will be further dilution to new investors.

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DESCRIPTION OF SECURITIES WE ARE OFFERING

The convertible preferred stock and the warrants being offered in this offering will be issued pursuant to a securities purchase agreement between each of the investors and us. We urge you to review the securities purchase agreement, the certificate of designation authorizing the convertible preferred stock and the form of warrant, which we will file as exhibits to a Current Report on Form 8-K filed with the SEC in connection with this offering, for a complete description of the terms and conditions applicable to the convertible preferred stock and the warrants. The following brief summary of the material terms and provisions of the convertible preferred stock and the warrants is subject to, and qualified in its entirety by, the certificate of designation authorizing the convertible preferred stock and the form of warrant. This prospectus supplement also relates to the offering of the shares of our common stock upon the conversion or exercise, if any, of the convertible preferred stock or the warrants issued to the investors in this offering. The warrants we are issuing to the placement agent in connection with this offering to purchase up to an aggregate of 2,492,457 shares of our common stock are not covered by this prospectus supplement, which amount assumes we increase the dollar value of securities in this offering by a total of \$3,901,311.

Convertible Preferred Stock

We will authorize the convertible preferred stock by filing a certificate of designation with the Secretary of State of the State of Delaware. The certificate of designation may be authorized by our board of directors without approval by our stockholders.

The convertible preferred stock will be convertible at the option of the holder at any time into shares of our common stock at a conversion ratio determined by dividing the stated value of the convertible preferred stock, or \$1,000, by a conversion price of \$0.38115 per share. The conversion price of the convertible preferred stock will be subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The convertible preferred stock will be subject to automatic conversion into shares of common stock upon the occurrence of a change in control of our company and we may become obligated to redeem the convertible preferred stock upon the occurrence of certain triggering events, including the material breach by us of certain contractual obligations to the holders of the convertible preferred stock, the occurrence of a change in control of our company, the occurrence of certain insolvency events relating to our company or the failure of our common stock to continue to be listed or quoted for trading on one or more specified United States securities exchanges. Subject to limited exceptions, a holder of the convertible preferred stock will not have the right to convert any portion of its convertible preferred stock if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to its conversion.

The convertible preferred stock is entitled to receive cumulative dividends at the rate per share (as a percentage of the stated value of \$1,000 per share) of 3.73344597664961% per annum until January 7, 2015, payable quarterly beginning April 1, 2010. If the convertible preferred stock is converted any time prior to January 7, 2015, we will pay the holder of the converted shares an amount equal to \$186.67 per \$1,000 in stated value (subject to adjustment) of the shares of convertible preferred stock converted, less dividends paid with respect to such converted preferred shares before the relevant conversion date.

Except as required by law, holders of the convertible preferred stock are not entitled to voting rights, except that the affirmative vote of the holders of a majority of the outstanding shares of convertible preferred stock is required to take certain actions that may adversely affect the rights or preferences of the holders of convertible preferred stock.

The securities purchase agreement pursuant to which the convertible preferred stock will be issued and the certificate of designation authorizing the preferred stock includes certain agreements and covenants for the benefit of the holders of convertible preferred stock, including restrictions on our ability to amend our certificate of incorporation or bylaws, pay cash dividends or distributions with respect to our common stock or other junior securities, repurchase shares of common stock or other junior securities, issue additional equity securities for a period of 90-days after the closing of the offering and incur indebtedness.

Warrants

The warrants will provide for an exercise price of \$0.3499 per share and will be exercisable at the option of the holder at any time after the date of issuance, which will be the closing date of this offering, through and including the date that is the 30-month anniversary of the initial exercise date. Subject to limited exceptions, a warrant holder will

not have the right to exercise any portion of the warrant if the holder, together with its affiliates, would beneficially own in excess of 4.9% of the number of shares of our common stock outstanding immediately after the exercise. The exercise price of the warrants, and in some cases the number of shares issuable upon exercise of the warrants, will be subject to adjustment in the event of stock splits, stock dividends, combinations and similar events affecting our common stock. In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common stock is converted or exchanged for securities, cash or other property, or we sell, lease, license or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding common stock, then following such event, the holders of the warrants will be entitled to receive upon exercise of the warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations

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under the warrants.

The warrant holders must surrender payment in cash of the aggregate exercise price of the shares being acquired upon exercise of the warrants. If, however, we are unable to offer and sell the shares underlying these warrants pursuant to this prospectus supplement due to the ineffectiveness of the registration statement of which this prospectus supplement is a part, then the warrants may only be exercised on a net or cashless basis. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

We do not intend to list the convertible preferred stock or the warrants on any securities exchange or automated quotation system.

PLAN OF DISTRIBUTION

We have entered into an engagement letter agreement, dated January 3, 2010, with Rodman & Renshaw, LLC. Subject to the terms and conditions set forth in the agreement, Rodman & Renshaw has agreed to act as our placement agent in connection with this offering. The placement agent is not purchasing or selling any securities being offered by this prospectus supplement or the accompanying prospectus, nor is it required to arrange for the purchase or sale of any specific number or dollar amount of the units, but has agreed to use its reasonable best efforts to arrange for the sale of all of the units in this offering.

There is no requirement that any minimum number of units or dollar amount of units be sold in this offering and there can be no assurance that we will sell all or any of the units being offered.

Our agreement with the placement agent provides that the obligations of the placement agent and the investors are subject to certain conditions precedent, including, among other things, the absence of any material change in our business and receipt of a customary written legal opinion.

We currently anticipate that the closing of this offering will take place on or about January 7, 2010. On the scheduled closing date, the following will occur:

we will receive funds in the amount of the aggregate purchase price;

the placement agent will receive the placement agent fees and compensation warrants to purchase shares of our common stock in accordance with the terms of the engagement letter agreement; and we will deliver the units to the investors.

We have agreed to pay the placement agent an aggregate fee equal to 7.0% of the gross proceeds of the sale of the units in this offering. We have also agreed to grant compensation warrants to the placement agent to purchase that number of our shares of common stock equal to 5.0% of the number of shares of common stock underlying the convertible preferred stock sold by us in this offering, or up to an aggregate of 2,492,457 shares (which amount assumes we increase the dollar value of securities in this offering by a total of \$3,901,311), at an exercise price of \$0.4765 per share. In compliance with the guidelines of FINRA, under no circumstances will the fee, commission or discount received by the placement agent or any other FINRA member or independent broker-dealer exceed 8.0% of the gross proceeds to us in this offering or any other offering in the United States pursuant the accompanying prospectus.

The compensation warrants will be substantially on the same terms as the warrants offered hereby, except that they will comply with FINRA Rule 5110(g) in that for a period of six months after their date of issuance (which shall not be earlier than the closing date of this offering), neither the compensation warrants nor any shares issued upon exercise of the compensation warrants shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person, except the transfer of any security:

by operation of law or by reason of reorganization of us;

to any FINRA member firm participating in this offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction described above for the remainder of the time period; if the aggregate amount of our securities held by Rodman & Renshaw or related persons do not exceed 1% of the securities being offered;

that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in

the aggregate do not own more than 10% of the equity in the fund; or S-29

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the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

The following table shows the per unit and total fees we will pay to the placement agent in connection with the sale of the units offered pursuant to this prospectus supplement and the accompanying prospectus, assuming the purchase of all of the units being offered hereby. Because there is no minimum offering amount required as a condition to closing in this offering, the actual total offering fees, if any, are not presently determinable and may be substantially less than the maximum amount set forth below.

Per unit placement agent fees \$ 70 Maximum offering total \$1,097,320

Maximum offering total (following increase to dollar value of securities we may offer under the registration statement(s) of which this prospectus supplement and the accompanying prospectus form a part)

\$1,330,000

The placement agent proposes to arrange for the sale to one or more purchasers of the units offered pursuant to this prospectus supplement and the accompanying prospectus directly through a securities purchase agreement between the purchasers and us.

The purchase price per unit and the exercise price for the warrants were determined based on negotiations with the purchasers and discussions with the placement agent.

We have agreed to indemnify the placement agent and its affiliates against certain liabilities relating to or arising out of its activities under the engagement letter agreement. We have also agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

A copy of the engagement letter agreement will be included as an exhibit to a Current Report on Form 8-K filed with the SEC in connection with this offering.

The placement agent has informed us that it will not engage in over-allotment, stabilizing transactions or syndicate covering transactions in connection with this offering.

The transfer agent for our common stock is American Stock Transfer & Trust Company. We will act as transfer agent for the shares of convertible preferred stock and the warrants being offered hereby.

Our common stock is traded on the NYSE Amex under the symbol ANX. Neither the convertible preferred stock nor the warrants being offered hereby are expected to be eligible for trading on any market.

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LEGAL MATTERS

The validity of the issuance of the securities being offered hereby will be passed upon for us by DLA Piper LLP (US), San Diego, California.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and current reports, proxy statements and other information electronically with the SEC. You may read and copy these reports, proxy statements and other information at the SEC s public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. You can request copies of these documents by writing to the SEC and paying a fee for the copying costs. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us. The SEC s Internet site can be found at http://www.sec.gov. In addition, we make available on or through our Internet site copies of these reports as soon as reasonably practicable after we electronically file or furnish them to the SEC. Our Internet site can be found at http://www.adventrx.com.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

We are allowed to incorporate by reference information contained in documents that we file with the SEC. This means that we can disclose important information to you by referring you to those documents and that the information in this prospectus supplement and the accompanying prospectus is not complete. You should read the information incorporated by reference for more detail. We incorporate by reference in two ways. First, we list below certain documents that we have already filed with the SEC. The information in these documents is considered part of this prospectus supplement. Second, the information in documents that we file in the future will update and supersede the current information in, and be incorporated by reference in, this prospectus supplement.

We incorporate by reference the documents listed below and any filings we make with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement until the termination of this offering (in each case, except for the information furnished under Item 2.02 or Item 7.01 in any current report on Form 8-K and Form 8-K/A):

our annual report on Form 10-K for the year ended December 31, 2008 filed with the SEC on March 27, 2009 (File No. 001-32157- 09708145);

the information specifically incorporated by reference into our annual report on Form 10-K for the year ended December 31, 2008 from our definitive proxy statement on Schedule 14A filed with the SEC on April 30, 2009 (File No. 001-32157-09781242);

our quarterly report on Form 10-Q for the quarterly period ended March 31, 2009 filed with the SEC on May 15, 2009 (File No. 001-32157-09829059);

our quarterly report on Form 10-Q for the quarterly period ended June 30, 2009 filed with the SEC on August 12, 2009 (File No. 001-32157-091007525):

our quarterly report on Form 10-Q for the quarterly period ended September 30, 2009 filed with the SEC on November 10, 2009 (File No. 001-32157-091172685);

our current reports on Form 8-K filed with the SEC on January 2, 2009 (File No. 001-32157-09501628); January 5, 2009 (File No. 001-32157-09505346); January 8, 2009 (File No. 001-32157-09516181);

February 2, 2009 (File No. 001-32157-09561715); February 5, 2009 (File No. 001-32157-09573163);

February 10, 2009 (File No. 001-32157-09583495); March 20, 2009 (File No. 001-32157-09696365);

March 25, 2009 (File No. 001-32157-09702853); March 25, 2009 (File No. 001-32157-09702857); May 7,

2009 (File No. 001-32157-09806033); June 2, 2009 (File No. 001-32157-09868487); June 8, 2009 (File No.

001-32157-09878961); June 29, 2009 (File No. 001-32157-09914471); June 30, 2009 (File

No. 001-32157-09917820); July 22, 2009 (File No. 001-32157-09957353); July 24, 2009 (File

No. 001-32157- 09962569); August 4, 2009 (File No. 001-32157-09983616); August 5, 2009 (File

No. 001-32157-09989205); August 20, 2009 (File No. 001-32157-091025631); August 28, 2009 (File

No. 001-32157-091043396); September 1, 2009 (File No. 001-32157-091049161); October 13, 2009 (File

No. 001-32157-091115090); October 19, 2009 (File No. 001-32157-091126027); and December 24, 2009

(File No. 001-32157-091260100); and

the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on April 27, 2004 (File No. 001-32157-041020580).

We will provide each person, including any beneficial owner, to whom this prospectus supplement and the accompanying prospectus is delivered, a copy of any or all of the documents incorporated by reference in this prospectus supplement and the

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accompanying prospectus but not delivered with this prospectus supplement and the accompanying prospectus upon written or oral request at no cost to the requester. Requests should be directed to: ADVENTRX Pharmaceuticals, Inc., 6725 Mesa Ridge Road, Suite 100, San Diego, California 92121, Attn: Investor Relations, telephone: (858) 552-0866.

This prospectus supplement is part of a registration statement on Form S-3 that we have filed and/or will file with the SEC. That registration statement(s) contains more information than this prospectus supplement 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.

You should rely only on the information in and incorporated by reference into this prospectus supplement and the accompanying prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus supplement or the accompanying prospectus is accurate as of any date other than the date on the front cover of these documents.

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PROSPECTUS \$25,000,000 Common Stock Preferred Stock Debt Securities Warrants Units

ADVENTRX PHARMACEUTICALS, INC.

We may, from time to time in one or more offerings, offer and sell up to \$25,000,000 in the aggregate of common stock, preferred stock, debt securities, warrants to purchase common stock, preferred stock or debt securities, or any combination of the foregoing, either individually or as units comprised of one or more of the other securities.

This prospectus provides a general description of the securities we may offer. We will provide the specific terms of the securities offered in one or more supplements to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. You should read carefully this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as any documents incorporated by reference before you invest in any of our securities. **This prospectus may not be used to offer or sell any securities unless accompanied by the applicable prospectus supplement**

Our common stock is listed on the NYSE Amex (formerly, the American Stock Exchange) under the symbol ANX. As of May 20, 2009, the aggregate market value of our outstanding common stock held by non-affiliates was approximately \$10,689,066, based on 90,252,572 shares of outstanding common stock, of which 8,656,648 shares are held by affiliates, and a price of \$0.1310 per share, which was the last reported sale price of our common stock on the NYSE Amex on May 20, 2009. As of the date of this prospectus, we have not offered any securities pursuant to General Instruction I.B.6. of Form S-3 during the prior 12 calendar month period that ends on, and includes, the date of this prospectus.

Investing in our securities involves risk. You should carefully review the risks and uncertainties described under the heading Risk Factors beginning on page 4 of this prospectus and contained in the applicable prospectus supplement and any related free writing prospectus.

We will sell these securities directly to investors, through agents designated from time to time or to or through underwriters or dealers. For additional information on the methods of sale, you should refer to the section entitled Plan of Distribution in this prospectus. If any underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a 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 is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is June 4, 2009.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. Under this shelf registration process, we may from time to time sell common stock, preferred stock, debt securities or warrants to purchase common stock, preferred stock or debt securities, or any combination of the foregoing, either individually or as units comprised of one or more of the other securities, in one or more offerings up to a total dollar amount of \$25,000,000. We have provided to you in this prospectus a general description of the securities we may offer. Each time we sell securities under this shelf registration, we will, to the extent required by law, provide a prospectus supplement that will contain specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change information contained in this prospectus or in any documents that we have incorporated by reference into this prospectus. To the extent there is a conflict between the information contained in this prospectus and the prospectus supplement or any related free writing prospectus, you should rely on the information in the prospectus supplement or the related free writing prospectus; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in this prospectus or any prospectus supplement or any related free writing prospectus the statement in the document having the later date modifies or supersedes the earlier statement.

We have not authorized any dealer, agent or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and any accompanying prospectus supplement. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or an accompanying prospectus supplement. This prospectus and the accompanying prospectus supplement, if any, do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and the accompanying prospectus supplement constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference (as our business, financial condition, results of operations and prospects may have changed since that date), even though this prospectus, any applicable prospectus supplement or any related free writing prospectus is delivered or securities are sold on a later date.

As permitted by the rules and regulations of the SEC, the registration statement, of which this prospectus forms a part, includes additional information not contained in this prospectus. You may read the registration statement and the other reports we file with the SEC at the SEC s web site or at the SEC s offices described below under the heading Where You Can Find Additional Information.

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SUMMARY

This summary highlights selected information from this prospectus and does not contain all of the information that you need to consider in making your investment decision. You should carefully read the entire prospectus, including the risks of investing discussed under Risk Factors beginning on page 4, the information incorporated by reference, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part. When used in this prospectus, the terms ADVENTRX, we, our, us or the Company refer to ADVENTRX Pharmaceuticals, Inc. and its consolidated subsidiaries, unless otherwise indicated or as the context otherwise requires.

About ADVENTRX Pharmaceuticals, Inc.

We are a development-stage biopharmaceutical company whose fundamental business is focused on in-licensing, developing and commercializing proprietary product candidates for the treatment of cancer. We seek to improve the performance and commercial potential of existing treatments by addressing limitations associated principally with their safety and use. 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. Our lead product candidates, ANX-530 and ANX-514, are novel emulsion formulations of currently marketed chemotherapy drugs. However, due to our immediate need to raise additional capital to continue our business, we have discontinued substantially all of our development activities and fundamental business operations to conserve cash while we pursue financing alternatives, evaluate strategic options, including the sale or exclusive license of one or more of our product candidate programs, a strategic business merger and other similar transactions, and consider whether to liquidate our assets, wind-up our operations and distribute any remaining cash to our stockholders.

Our business was incorporated in Delaware in December 1995. In October 2000, we merged our wholly-owned subsidiary, Biokeys Acquisition Corp., with and into Biokeys, Inc. and changed our name to Biokeys Pharmaceuticals, Inc. In May 2003, we merged Biokeys, Inc., our wholly-owned subsidiary, with and into us and changed our name to ADVENTRX Pharmaceuticals, Inc. In July 2004, we formed a wholly-owned subsidiary, ADVENTRX (Europe) Ltd., in the United Kingdom primarily to facilitate conducting clinical trials in the European Union and to obtain favorable pricing for discussions with the European Medicines Agency. In April 2006, we acquired SD Pharmaceuticals, Inc. as a wholly-owned subsidiary. Our executive offices are located at 6725 Mesa Ridge Road, Suite 100, San Diego, California 92121, 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 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. Information on our website does not constitute part of this prospectus or any prospectus supplement.

The Securities We May Offer

We may offer shares of our common stock and preferred stock, various series of debt securities and warrants to purchase any of such securities, either individually or in units, with a total value of up to \$25,000,000 from time to time under this prospectus, together with any applicable prospectus supplement and related free writing prospectus, at prices and on terms to be determined by market conditions at the time of offering. If we issue any debt securities at a discount from their original stated principal amount, then, for purposes of calculating the total dollar amount of all securities issued under this prospectus, we will treat the initial offering price of the debt securities as the total original principal amount of the debt securities. Each time we offer securities under this prospectus, we will provide offerees with a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities being offered, including, to the extent applicable:

designation or classification;

aggregate principal amount or aggregate offering price;

maturity, if applicable;

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original issue discount, if any;

rates and times of payment of interest or dividends, if any;

redemption, conversion, exchange or sinking fund terms, if any;

conversion or exchange prices or rates, if any, and, if applicable, any provisions for changes to or adjustments in the conversion or exchange prices or rates and in the securities or other property receivable upon conversion or exchange;

ranking;

restrictive covenants, if any;

voting or other rights, if any; and

important United States federal income tax considerations.

A prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change information contained in this prospectus or in documents we have incorporated by reference. However, no prospectus supplement or free writing prospectus will offer a security that is not registered and described in this prospectus at the time of the effectiveness of the registration statement of which this prospectus is a part.

We may sell the securities to or through underwriters, dealers or agents or directly to purchasers. We, as well as any agents acting on our behalf, reserve the sole right to accept and to reject in whole or in part any proposed purchase of securities. Each prospectus supplement will set forth the names of any underwriters, dealers or agents involved in the sale of securities described in that prospectus supplement and any applicable fee, commission or discount arrangements with them, details regarding any over-allotment option granted to them, and net proceeds to us. The following is a summary of the securities we may offer with this prospectus.

Common Stock

We currently have authorized 200,000,000 shares of common stock, par value \$0.001 per share. We may offer shares of our common stock either alone or underlying other registered securities convertible into or exercisable for our common stock. Holders of our common stock are entitled to such dividends as our board of directors may declare from time to time out of legally available funds, subject to the preferential rights of the holders of any shares of our preferred stock that are outstanding or that we may issue in the future. Currently, we do not pay any dividends. Each holder of our common stock is entitled to one vote per share. In this prospectus, we provide a general description of, among other things, the rights and restrictions that apply to holders of our common stock.

Preferred Stock

We currently have authorized 1,000,000 shares of preferred stock, par value \$0.001 per share, none of which are outstanding. Under our certificate of incorporation, our board of directors has the authority to issue shares of our preferred stock in one or more series and to fix or alter the rights, preferences, privileges and restrictions granted to or imposed upon any series of preferred stock. The particular terms of each class or series of preferred stock, including redemption privileges, liquidation preferences, voting rights, dividend rights and/or conversion rights, will be more fully described in the applicable prospectus supplement relating to the preferred stock offered thereby.

The rights, preferences, privileges and restrictions granted to or imposed upon any series of preferred stock that we offer and sell under this prospectus and applicable prospectus supplements will be set forth in a certificate of designation relating to the series. We will incorporate by reference into the registration statement of which this prospectus is a part the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of shares of that series of preferred stock. You should read to read any

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prospectus supplement and any free writing prospectus that we may authorize to be provided to you related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

Debt Securities

We may offer general debt obligations, which may be secured or unsecured, senior or subordinated and convertible into shares of our common stock. In this prospectus, we refer to the senior debt securities and the subordinated debt securities together as the debt securities. We may issue debt securities under a note purchase agreement or under an indenture to be entered between us and a trustee; a form of the indenture is included as an exhibit to the registration statement of which this prospectus is a part. The indenture does not limit the amount of securities that may be issued under it and provides that debt securities may be issued in one or more series. The senior debt securities will have the same rank as all of our other indebtedness that is not subordinated. The subordinated debt securities will be subordinated to our senior debt on terms set forth in the applicable prospectus supplement. In addition, the subordinated debt securities will be effectively subordinated to creditors and preferred stockholders of our subsidiaries. Our board of directors will determine the terms of each series of debt securities being offered. This prospectus contains only general terms and provisions of the debt securities. The applicable prospectus supplement will describe the particular terms of the debt securities offered thereby. You should read any prospectus supplement and any free writing prospectus that we may authorize to be provided to you related to the series of debt securities being offered, as well as the complete note agreements and/or indentures that contain the terms of the debt securities. Forms of indentures have been filed as exhibits to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of debt securities being offered will be incorporated by reference into the registration statement of which this prospectus is a part from reports we file with the SEC.

Warrants

We may offer warrants for the purchase of shares of our common stock or preferred stock or of debt securities. We may issue the warrants by themselves or together with preferred stock, common stock or debt securities, and the warrants may be attached to or separate from any offered securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and the investors or a warrant agent. Our board of directors will determine the terms of the warrants. This prospectus contains only general terms and provisions of the warrants. The applicable prospectus supplement will describe the particular terms of the warrants being offered thereby. You should read any prospectus supplement and any free writing prospectus that we may authorize to be provided to you related to the series of warrants being offered, as well as the complete warrant agreements that contain the terms of the warrants. Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference into the registration statement of which this prospectus is a part from reports we file with the SEC.

Units

We may offer units consisting of our common stock or preferred stock, debt securities and/or warrants to purchase any of these securities in one or more series. We may evidence each series of units by unit certificates that we will issue under a separate agreement. We may enter into unit agreements with a unit agent. Each unit agent will be a bank or trust company that we select. We will indicate the name and address of the unit agent in the applicable prospectus supplement relating to a particular series of units. This prospectus contains only a summary of certain general features of the units. The applicable prospectus supplement will describe the particular features of the units being offered thereby. You should read any prospectus supplement and any free writing prospectus that we may authorize to be provided to you related to the series of units being offered, as well as the complete unit agreements that contain the terms of the units. Specific unit agreements will contain additional important terms and provisions and will be incorporated by reference into the registration statement of which this prospectus is a part from reports we file with the SEC.

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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 or incorporated by reference in this prospectus, as may be updated by our subsequent filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the risk factors and other information contained in any applicable prospectus supplement and in any related free writing prospectus in connection with a specific offering, and in the documents incorporated herein or therein before deciding whether to purchase any of the securities being registered pursuant to the registration statement of which this prospectus is a part. 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 Financial Performance, Operations and Ability to Continue as a Going Concern 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 developing a new generation of therapeutic products, but such products cannot be marketed until the regulatory process is completed and governmental approvals have been obtained. Accordingly, there is no current source of revenues from operations, much less profits, to sustain our present activities, and no revenues from operations will likely be available until, and unless, our product candidates are approved by the U.S. Food and Drug Administration, or FDA, or other regulatory agencies and successfully marketed, either by us or a partner, an outcome which we are not able to guarantee.

Our financial resources are limited, we will require substantial additional funding to continue our business, and, if we are unable to raise sufficient additional capital, we may cease operating as a going concern and liquidate our assets.

We have experienced significant operating losses in funding the development of our product candidates, accumulating operating losses totaling approximately \$141.7 million as of March 31, 2009, and we expect to continue to incur substantial operating losses for the foreseeable future, even if we or a future partner of ours is successful in advancing our product candidates to market. As of March 31, 2009, we had approximately \$5.3 million in cash and cash equivalents and \$2.8 million in working capital and we do not expect to generate positive net cash flows for the foreseeable future. While we have discontinued substantially all of our development activities and fundamental business operations, we expect to incur substantial costs in connection with evaluating, negotiating and consummating capital-raising and/or strategic transactions or liquidating our assets and winding-up our operations. We cannot currently predict the extent of these costs. Even if we incur costs in pursuing, evaluating and negotiating particular capital-raising and/or strategic transactions, our efforts may not prove successful. Accordingly, we do not believe we can provide a reasonable estimate of the rate of utilization of our cash resources in the near term. However, excluding the potentially significant costs associated with evaluating, negotiating and consummating capital-raising and/or strategic transactions or liquidating our assets and winding-up our operations, we anticipate that our cash and cash equivalents as of March 31, 2009 will be sufficient to permit us to conduct our business through at least September 30, 2009. We will need to raise substantial additional capital to continue our business after this period. Our independent auditor s report for the year ended December 31, 2008 includes an explanatory paragraph stating that

our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain additional financing or consummate a strategic transaction on commercially reasonable terms, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements. Based on our current working capital and estimated costs of implementing an orderly liquidation of our assets, we do not expect that there will be material cash available for distribution to our stockholders.

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We have been evaluating and continue to evaluate strategic options, including the sale or exclusive license of one or more of our product candidate programs, a strategic business merger and similar transactions. However, discussions with potential strategic transaction partners have been unsuccessful, protracted or on terms that we determined were unacceptable. We intend to seek funding during the second quarter of 2009 in order to continue our business and resume certain of our development activities and fundamental business operations, including activities related to submitting a new drug application, or NDA, to obtain approval of the FDA for marketing ANX-530 in the United States, or U.S. Our future expenditures on our programs are subject to many uncertainties, including whether our product candidates will be developed with a partner or independently. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

the costs of seeking regulatory approval for our lead product candidates, ANX-530 and ANX-514, including any bioequivalence or clinical studies, process development, scale-up and other manufacturing activities, or other work required to achieve such approval, as well as the timing of such activities and approval;

the timing and terms of any collaborative, licensing and other strategic arrangements that we may establish;

the cost related to establishing or contracting for sales and marketing capabilities and other commercial capabilities;

the scope, prioritization and number of development and/or commercialization programs we pursue and the rate of progress and costs with respect to such programs;

the extent to which we will need to rebuild our workforce, which currently consists of three full-time employees, and the cost involved in hiring, training and incentivizing new employees;

the extent to which we invest in or acquire new technologies, products or businesses;

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 intend to seek additional funding through public or private sales of our equity securities, debt financings, collaborations, licensing arrangements or other strategic 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 credit crisis, have adversely impacted our ability to raise additional capital and may continue to do so.

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

Under current SEC regulations, we will not be eligible to use a registration statement on Form S-3 for primary offerings of our common stock or securities convertible into our common stock unless our common stock is listed and registered on a national securities exchange. The NYSE Amex will review the appropriateness of continued listing of any issuer that falls below the exchange s continued listing standards and may, in its discretion, at any time, and without notice, suspend dealings in, or may remove any security from, listing privileges. The NYSE Amex will normally consider suspending dealings in, or removing from the list, securities of an issuer which has stockholders equity of less than \$6.0 million if such issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. As of March 31, 2009, we do not meet this continued listing standard. As of May 20, 2009, we have not received any notice from the NYSE Amex of its intention to suspend dealings in, or remove from listing, our common stock. However, we may receive such notice at any time. If our common stock were delisted from the NYSE Amex, our ability to raise capital on terms and conditions we deem acceptable, if at all, may be materially impaired. Currently, we do not anticipate being eligible to register and list our common stock on any other national securities exchange.

In addition, even if we maintain our listing with the NYSE Amex, under current SEC regulations, at any time during

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which 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 can raise through primary offerings of our securities in any twelve-month period using a registration statement on Form S-3 will be limited to an aggregate of one-third of our public float. As of May 20, 2009, our public float was approximately \$1.6 million shares, the value of which was approximately \$10.7 million based upon the closing price of our common stock of \$0.1310 on such date. As of May 20, 2009, the value of one-third of our public float calculated on the same basis was approximately \$3.6 million. 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.

Even if we maintain our listing with the NYSE Amex, our ability to timely raise sufficient capital may be limited by the exchange 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 deemed a public offering by the NYSE Amex staff. Based on our outstanding common stock and closing price as of May 20, 2009, we could not raise more than approximately \$2.4 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.

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 continue as a going concern, and there is no guarantee our stockholders would ultimately approve a proposed transaction. A public offering under 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.

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

We may raise additional capital at any time and may do so through one or more financing alternatives, including public or private sales of our equity securities, debt financings, collaborations, licensing arrangements or other strategic transactions. Each of these financing alternatives carries certain risks. Raising capital through the issuance of common stock may depress the market price of our stock and may substantially dilute our existing stockholders. If we instead seek to raise capital through strategic transactions, such as licensing arrangements or sales of one or more of our technologies or product candidates, we may be required to relinquish valuable rights. For example, any licensing arrangement would likely require us to share a significant portion of any revenues generated by our licensed technologies with our licensees. Additionally, the development of any product candidates licensed or sold to third parties will no longer be in our control and thus we may not realize the full value of any such 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. As we continue to use our cash and cash equivalents to fund our operations, it will likely become increasingly difficult to raise additional capital on commercially reasonable terms, or at all.

If we are unable to raise sufficient additional capital, we may be not be able to resume our development programs or we may be forced to partner product candidates at inopportune times or pursue less-expensive but higher-risk development paths.

Currently, we have suspended substantially all of our development activities and fundamental business operations and we have reduced our workforce to three full-time employees in order to provide additional time to consummate

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a strategic transaction or otherwise obtain financing. If we are not able to raise adequate funds to resume our development programs and operations at levels we believe would enable us to capitalize on our assets, we may have to abandon some or all of them altogether or attempt to continue our development and commercialization efforts by entering into arrangements with partners or others that, if available at all, may not be on favorable terms and may require us to relinquish some or all of our rights to our product candidates or the financial benefits thereof or we may determine to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements.

To conserve funds, we may pursue less expensive but higher-risk development paths. For instance, we may limit our process development activities to the minimum we feel is sufficient to support our development and commercialization goals, in particular, with respect to ANX-530. Process development helps define the various parameters and specifications for manufacturing products at commercial-scale. Without comprehensive process development activities, we may lack the information necessary to develop an accurate validation plan to support an NDA and may be unable to successfully manufacture at commercial scale. If we are unable to validate the manufacturing processes included in an NDA, we may be required to amend the NDA, which could result in substantial delays in commercializing the subject drug, as well as call into question our ability to ultimately obtain marketing approval for that drug. In addition, we would expect to spend significant funds undertaking the activities necessary to support an amendment to an NDA.

We may seek to merge with or be acquired by another company and that transaction may adversely affect our business and the value of our securities.

Because of our limited ability to raise funds, including for the reasons noted above, we may seek to merge with another company with a stronger cash position, complementary work force or product candidate portfolio or for other reasons. We believe the market price for our common stock may not accurately reflect the value of our business. While we will continue to seek to maximize the value of our business to our stockholders, the most attractive option for doing so may require us to consummate a transaction involving an exchange of our common stock with that of another company.

There are numerous risks associated with merging or being acquired. These risks include, among others, incorrectly assessing the quality of a prospective acquirer or merger-partner, encountering greater than anticipated costs in integrating businesses, facing resistance from employees and being unable to profitably deploy the assets of the new entity. The operations, financial condition, and prospects of the post-transaction entity depend in part on our and our acquirer/merger-partner s ability to successfully integrate the operations related to our product candidates, business and technologies. We may be unable to integrate operations successfully or to achieve expected cost savings and any cost savings which are realized may be offset by losses in revenues or other charges to operations. As a result, our stockholders may not realize the full value of their investment.

If we fail to maintain registration of the shares of common stock issued or issuable pursuant to the exercise of warrants we issued in our July 2005 private placement, we will be required to pay the holders of those securities liquidated damages, which could be material in amount.

The terms of the securities purchase agreement that we entered into in connection with our July 2005 private placement require us to pay liquidated damages to the purchasers of those securities in the event any shares issued or issuable pursuant to the exercise of warrants we issued in the private placement cannot be resold pursuant to our registration statement on Form S-3 (No. 333-127857) filed with and declared effective by the SEC on September 2, 2005. We refer to this as a maintenance failure. For each 30-day period or portion thereof during which a maintenance failure remains uncured, we are obligated to pay each purchaser an amount in cash equal to 1% of the purchaser s aggregate purchase price for any shares of common stock or shares of common stock issuable upon exercise of warrants then held by the purchaser (pro rated for any period less than a month), increasing by an additional 1% with regard to each additional 30-day period or portion thereof until the maintenance failure is cured. There is no cap with respect to the total amount of these liquidated damages. The aggregate gross proceeds from our July 2005 private placement were approximately \$20 million. We are required to maintain the registration statement until the earlier of the date (i) all of the securities issued in our July 2005 private placement have been resold and (ii) each purchaser can resell the securities pursuant to Rule 144 under the Securities Act of 1933, as amended, without regard to the adequate

current public information, volume, manner of sale or notice filing restrictions. The amount of these liquidated damages could be substantial and could have a material adverse effect on our financial condition.

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For additional information, see Note 11 of the Notes to Consolidated Financial Statements, Registration Payment Arrangement, of our annual report on Form 10-K for the year ended December 31, 2008.

We may be unable to retain the services of key personnel, and, even if we are successful in raising additional funds to continue our business and resume development and commercialization of our product candidates, we may not be successful in rebuilding our workforce to carry out those activities.

As of May 20, 2009, we had only three full-time employees and we depend on the services of certain of these employees to continue our business. We do not have a chief executive officer or chief financial officer. Our Chief Business Officer and Senior Vice President is currently acting as our interim principal executive officer and a member of our board of directors is currently acting as our interim principal financial and accounting officer. To the extent we are successful in raising additional funds to continue our business and resume our development and commercialization activities, we may need to expand our managerial, financial, regulatory, research and development, manufacturing, commercial, quality, compliance and other resources in order to manage our operations, submit applications to and respond to inquiries from the FDA and, if approved, commercialize our products. We do not expect that our current management and personnel, systems and facilities will be adequate to support these activities.

The success of our business will depend, in part, on our ability to attract and retain highly qualified management, scientific and other personnel, and on our ability to develop and maintain important relationships with respected service providers and industry-leading consultants and advisors. Competition for these types of personnel and relationships is intense from numerous pharmaceutical and biotechnology companies, universities and other research institutions, particularly in the San Diego, California area. In connection with the cost-cutting measures we implemented in October 2008, January 2009 and March 2009, we eliminated, among others, our scientific staff and our manufacturing and regulatory personnel, who had a deep background in our product candidates and our research and development programs. Recruiting and retaining employees, including senior-level personnel, with relevant product development experience in cancer and process development experience with emulsified cytotoxic drugs may be costly and time-consuming. We have historically provided incentive compensation to our officers and employees in part through grants of stock options and, more recently, restricted stock units under our equity compensation plans. Decreases in the trading price of our common stock, however, have substantially reduced the value of equity compensation awards made to our officers and employees in prior years and such awards may not provide adequate compensation to retain such individuals. Our ability to provide competitive compensation to our officers and employees may also be adversely affected by our limited capital resources and anticipated need to raise substantial additional capital to continue our business. We cannot ensure that we will be able to retain existing employees or attract and retain additional skilled personnel on acceptable terms as a result of these factors and, accordingly, we may not achieve our development and commercialization goals.

We have significant incentive and may, under certain circumstances, have significant severance and other obligations under agreements with certain of our current officers.

In January 2009, we entered into incentive and retention agreements with each of our current officers that, except in the event of a termination for cause, effectively guarantee their respective salaries through specified dates (either June 30, 2009 or September 30, 2009). Our aggregate contractual obligation under these agreements, determined as of May 20, 2009, was approximately \$225,000. We believe these agreements were necessary to incentivize and retain these key employees and reinforce their dedication to us during a period when they would otherwise likely seek alternative employment. In addition, we may determine to enter into new incentive and retention and/or severance agreements with our current officers under which we may agree to effectively guarantee their respective salaries through specified extended dates and/or provide for cash severance payments and/or the continuation of health insurance and other benefits upon termination by us without cause or involuntary termination by the officer for good reason, which may or may not be conditioned upon a change in control. Our contractual responsibility for our current and any future incentive and/or severance obligations may cause us to cease or curtail our operations at an earlier date than would otherwise be the case if we were not required to satisfy these obligations. In addition, part or all of the proceeds from a future capital raising transaction may be used to satisfy these obligations.

The use of our net operating loss carryforwards may be limited.

Net operating loss carryforwards may expire and not be used. As of December 31, 2008, we had generated federal

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net operating loss carryforwards of approximately \$90.4 million and state net operating loss carryforwards of approximately \$41.4 million. Federal net operating loss carryforwards have a 20-year carryforward period and begin to expire in 2020. State net operating loss carryforwards have a ten year carry forward period and begin to expire in 2012.

Pursuant to Section 382 of the Internal Revenue Code, annual use of our net operating loss carryforwards may be limited in the event a cumulative change in ownership of more than 50 percent occurs within a three-year period. We determined that, as of January 1, 2009, no such ownership change had occurred. However, future financing events may cause changes in ownership under Section 382, which could cause our net operating loss carryforwards to be subject to limitations and restrictions. If a change in ownership were to occur, our net operating loss carryforwards could be eliminated or restricted.

If we fail to maintain an effective system of internal control over financial reporting, 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. In addition, under current SEC rules, we will be required to obtain an attestation from our independent registered public accounting firm as to our internal control over financial reporting for our annual report on Form 10-K for our fiscal year ending December 31, 2009. Performing the system and process documentation and evaluation needed to comply with Section 404 is both costly and challenging. 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 as they related 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 additional material weaknesses are identified in our internal control over financial reporting, neither our management nor our independent registered public accounting firm will be able to assert that our internal control over financial reporting and/or our disclosure controls and procedures are effective, and we could be required to further implement expensive and time-consuming remedial measures. We cannot be certain that any measures we take will ensure that we implement and maintain adequate internal control over financial reporting and that we will remediate the material weakness. As a result of recent reductions in our workforce and other personnel departures, we have experienced substantial turnover in our personnel responsible for performing activities related to our internal control over financial reporting. We have used third-party contractors to maintain effective internal control over financial reporting during this turn-over. However, if we fail to maintain effective internal control over financial reporting and/or disclosure controls and procedures we could lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on our stock price.

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

Our corporate headquarters are located at a single business park in San Diego, California. Important documents and records, including copies of our laboratory books and records for our product candidates, are located at our facilities and we depend on our facilities for the continued operation of our business. Natural disasters and other catastrophic events, such as wildfires and other fires, earthquakes and extended power interruptions, which have impacted San Diego businesses in the past, and terrorist attacks, drought or flood, could significantly disrupt our operations and result in additional, unplanned expense. As a small company, we have limited capability to establish and maintain a

comprehensive disaster recovery program and, accordingly, we do not have a formal business continuity or disaster recovery plan, and any natural disaster or catastrophic event could delay our development and commercialization

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efforts. Even though we believe we carry commercially reasonable insurance, we might suffer losses that exceed the coverage available under these insurance policies. In addition, we are not insured against terrorist attacks or earthquakes.

Risks Related to Drug Development and Commercialization

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

To varying degrees based on the regulatory plan for each product candidate, the effect of government regulation and the need for FDA and other regulatory agency approval will delay commercialization of our product candidates, impose costly procedures upon our activities, and put us at a disadvantage relative to larger companies with which we compete. There can be no assurance that FDA or other regulatory approval for any product candidates developed by us will be granted on a timely basis, or at all. Even though the FDA has confirmed the appropriateness of a Section 505(b)(2) regulatory path for ANX-530 and ANX-514, the FDA s views may change. If the FDA requires the longer-term regulatory approval pathway associated with traditional drug development for ANX-530 and ANX-514, we may determine that the associated time and cost is not financially justifiable and, as a result, discontinue those programs. If we discontinue the development of one or both of these product candidates, our business and stock price may suffer.

In connection with any NDA that we file under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, we may be required to notify third parties that we have certified to the FDA that any patents listed for the approved drug in the FDA s Orange Book publication are invalid or will not be infringed by the manufacture, use or sale of our drug. If the third-party files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our Section 505(b)(2) NDA until, subject to certain adjustments, the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to us. Accordingly, we may invest significant time and expense in the development of our product candidates, including ANX-530 and ANX-514, only to be subject to significant delay and patent litigation before our products may be commercialized.

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

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

We conduct pre/non-clinical 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 pre/non-clinical activities could occur for a number of reasons, including:

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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;

changes in regulatory requirements or other standards or guidance relating to preclinical testing, including testing of pharmaceutical products in animals;

a lack of availability of animals that are suitable for the types of studies we plan to conduct;

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 preclinical or nonclinical testing that require us to amend study or test designs or delay future testing or bioequivalence or clinical trials and related regulatory filings.

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

obtaining regulatory approval to commence a trial;

identifying appropriate trial sites and reaching agreement on acceptable terms with prospective CROs, trial sites and investigators, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and investigators;

manufacturing sufficient quantities of a product candidate;

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 or personal issues, or who are lost to further follow-up.

For example, in October 2007, we announced results of our phase 2b clinical trial of ANX-510, or CoFactor, for the first-line treatment of metastatic colorectal cancer, which demonstrated that the CoFactor/5-FU arm did not demonstrate statistically significant improved safety in the trial s primary endpoint. In November 2007, we announced that we would discontinue enrolling patients in our phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer and, in October 2008, we announced that we had discontinued active work on all product candidates other than ANX-530 and ANX-514, including CoFactor. In addition, in May 2009, we announced that we did not meet the primary endpoint in our bioequivalence study of ANX-514, resulting in additional uncertainty around the cost and timeline to obtaining FDA approval for that product candidate.

In addition, a trial may be suspended or terminated by us, 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;

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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 clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards, or IRBs, for reexamination or renegotiate terms with CROs, trial sites and clinical investigators, all of which may impact the costs, timing or successful completion of a clinical trial. There can be no assurance that our preclinical and nonclinical testing and bioequivalence and/or clinical trials will commence or be completed, that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our current schedule for the development or commercialization of any of our product candidates. If we experience delays in completion of, or if we terminate, our bioequivalence or clinical trials or preclinical and nonclinical testing, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of bioequivalence or clinical trials or preclinical and 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 and established a competitive advantage.

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

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through preclinical testing and bioequivalence or clinical trials that each product is safe and effective for use in each target indication. Success in preclinical 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, any of which may delay, limit or prevent regulatory approvals. For instance, with respect to our bioequivalence trial of ANX-530, the FDA may perform its pharmacokinetic equivalence analysis based a patient population other than the population on which we based our analysis, which may result in the FDA determining that ANX-530 and Navelbine® are not bioequivalent, requiring that we evaluate additional patients, re-perform the study or take other remedial action. In addition, the FDA may inquire regarding the manufacturing source, in-process and product release specifications and overall uniformity of reference product used in the bioequivalence trial of ANX-530, particularly since it was conducted at sites in multiple countries, and we may be unable to provide documentation satisfactory to the FDA with respect to such reference product, which may result in the FDA requiring that we evaluate additional patients, re-perform the study or take other remedial measures. Further, the ANX-530 bioequivalence trial was open-label, meaning physician-investigators, as well as patients, may have been aware of which drug was being administered. There is a risk of investigator bias in reporting adverse events as a result of the study s open-label nature, including bias that increased the reporting of adverse events associated with Navelbine and/or that decreased the reporting of adverse events associated with ANX-530. With respect to ANX-514, despite positive preclinical testing that indicated pharmacokinetic equivalence between ANX-514 and the reference product, our bioequivalence trial of ANX-514 did not demonstrate pharmacokinetic equivalence between ANX-514 and the reference product based on benchmark regulatory standards.

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 may be difficult to predict. In addition, delays or rejections may be encountered based upon changes in FDA policy for drug approval during the period of product development and FDA regulatory review of each submitted NDA. There is a significant risk that any of our product candidates could fail to show satisfactory results in human trials, as was the case in our bioequivalence study of ANX-514, or manufacturing development, and, as a result, we may not continue their development. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope

requested will delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

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

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

our product s perceived advantages over existing treatment methods (including relative convenience and ease of administration and prevalence and severity of any adverse side effects);

claims or other information (including limitations or warnings) in our product s approved labeling;

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, or GPOs (including distributors and other network providers), to sell our products to their constituencies;

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

availability of alternative treatments; and

the prevalence of off-label substitution of chemically equivalent products.

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 of our products may require significant resources and may never be successful.

Under our Section 505(b)(2) regulatory strategy for ANX-530 and ANX-514, because we anticipate submitting Section 505(b)(2) NDAs based on pharmacokinetic data, our ability to differentiate our products from competitor products will be limited unless the FDA allows us to include certain data in our products labels. Even if our products demonstrate clinical or pharmacoeconomic benefits, we may be unable to market our products based on these benefits. If we fail to obtain a unique Healthcare Common Procedure Coding System, or HCPCS, product code for ANX-530, it is unlikely we will be able to sell that product at a price that exceeds its manufacturing, marketing and distribution costs. Even if we obtain separate HCPCS codes for our products, if our products are perceived to provide little or no advantage relative to competitive products or for other reasons, we may be required to price our products at levels that do not cover our costs to manufacture, market and distribute the products or provide any profit, or to price our products at levels at which they are not competitive.

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

We do not have any manufacturing capability. We rely on third-party manufacturers and component materials suppliers for the manufacture of our product candidates for bioequivalence or clinical trial purposes and we

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

For instance, ANX-530 is an emulsified cytotoxic product that must be aseptically-filled. There are a limited number of CMOs capable and willing to manufacture this type of product at the commercial scale at which we anticipate requiring in accordance with our marketing plans for ANX-530, which will make identifying and establishing shortor long-term relationships with willing manufacturers more difficult and provide them with substantial leverage over us in any negotiations. Furthermore, certain of the component materials of ANX-530 are available only from a particular supplier, and currently we do not have any short- or long-term agreements for the supply of those materials. Even if we successfully establish a long-term relationship with our current CMO for ANX-530 on commercially acceptable terms, our CMO may be unable to successfully and consistently manufacture ANX-530 at commercial scale. We and this manufacturer have limited experience manufacturing ANX-530, and the experience we and this manufacturer do have is limited to manufacturing a single engineering batch. Because data from a single bioequivalence trial of ANX-530 may be sufficient to support a Section 505(b)(2) NDA, our and our current contract manufacturer s ability to gain experience manufacturing ANX-530, in particular at various scales, has been limited. If our current CMO is unable to manufacture ANX-530 successfully and consistently at commercial scale and within established parameters, we may be unable to validate our manufacturing process, even if the FDA other would approve our NDA, and therefore unable to sell ANX-530. Our current CMO has similarly limited experience with ANX-514.

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

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

If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their contractual obligations, our ability to provide product candidates to patients in our bioequivalence or clinical trials may be jeopardized. Any delay or interruption in the supply of supplies could delay the completion of our 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

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and approvals to continue manufacturing such products or product candidates. Any of the above factors could cause us to delay or suspend anticipated or on-going trials, regulatory submissions, required approvals or commercialization of our product candidates, entail higher costs or result in our being unable to effectively commercialize our products. Our dependence upon third parties for the manufacture of our products and product candidates may adversely affect our future costs and our ability to develop and commercialize our products and product candidates on a timely and competitive basis.

If any of our product candidates should be approved, any problems or delays experienced in their manufacturing processes may impair our ability to provide commercial quantities of the products, which would limit our ability to sell the products and would adversely affect our business. It could take significant time to redesign our manufacturing processes or identify alternative suppliers in response to problems we may encounter as we manufacture our products, if such alternative processes and suppliers are available at all. Even if we are able to identify alternative suppliers, they may be unwilling to manufacture our products on commercially reasonable terms. Neither ANX-530 nor ANX-514 have been manufactured at the scales we believe will be necessary to maximize their commercial value to us and, accordingly, we may encounter difficulties in production while scaling-up initial production and may not be successful at all 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. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new supplier to bear significant additional costs which may be passed on to us. For instance, with respect to ANX-530, the form of API used in the manufacture of ANX-530 for purposes of our bioequivalence study of ANX-530 will not be the same form of API used in the manufacture of ANX-530 for purposes of process validation batches or commercial supply. To ensure the comparability of the ANX-530 used in the bioequivalence study and the ANX-530 intended for commercial sale, FDA may require that we evaluate both forms of ANX-530 in additional patients, re-perform the bioequivalence study or take other remedial actions. We may have insufficient quantities of both forms of ANX-530 and could incur substantial cost and delay in acquiring such quantities, in addition to the time and expense associated with conducting the evaluation, re-performing the study or taking other remedial measures.

We rely in part on third parties to conduct our preclinical and 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 the activities associated with our programs, particularly since we implemented severe cost-cutting measures in late 2008 and early 2009. We engage consultants, advisors, CROs, CMOs and others to design and conduct preclinical and nonclinical tests and bioequivalence and clinical studies in connection with the research and development of our product candidates. As a result, many important aspects of our product candidates—development are outside our direct control. There can be no assurance that such third parties will perform all of their obligations under arrangements with us or will perform those obligations satisfactorily.

The CROs with which we contract for execution of our bioequivalence and clinical studies play a significant role in the conduct of the studies and subsequent collection and analysis of data, and we will likely depend on these and other CROs and clinical investigators to conduct our future bioequivalence or clinical or studies or assist with our on-going bioequivalence studies. Individuals working at the CROs with which we contract, as well as investigators at the sites at which our studies are conducted, are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If these CROs fail to devote sufficient time and resources to our studies, or if their performance is substandard, it will delay the approval of our applications to regulatory agencies and the introduction of our products. Failure of these CROs to meet their obligations could adversely affect development of our product

candidates. Moreover, these CROs may have relationships with other commercial entities, some of which may compete with us. If they assist our competitors at our expense, it could harm our competitive position.

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

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

We currently do not have sales, marketing or commercialization personnel. We have limited business development personnel. To commercialize our products, including ANX-530, we will have to acquire or develop sales, marketing and distribution capabilities, or rely on marketing partners or other arrangements with third parties for the marketing, distribution and sale of our products. There is no guarantee that we will be able to establish marketing, distribution or sales capabilities or make arrangements with third parties to perform those activities on terms satisfactory to us, or that any internal capabilities or third party arrangements will be cost-effective. The acquisition or development of a sales and distribution and associated regulatory compliance infrastructure will require substantial resources, which may divert the attention of our management and key personnel and negatively impact our product development efforts. In addition, any third parties with which we establish marketing, distribution or sales arrangements may have significant control over important aspects of the commercialization of our products, including market identification, marketing methods, pricing, composition of sales force and promotional activities. If we retain third-party service providers to perform functions related to the sale and distribution of our products, key aspects of those functions that would be out of our direct control could include warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management. In this event, we would place substantial reliance on third-party providers to perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter natural or other disasters at their facilitates, our ability to deliver product to meet commercial demand could be significantly impaired. In addition, we may use third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms, or at all. Even if we are successful in establishing and maintaining these arrangement, 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 receive regulatory approval for one or more of our product candidates, we may face competition from generic products, which could exert downward pressure on the pricing and market share of our products and limit our ability to generate revenues.

Many of the currently marketed and anticipated products against which our product candidates may compete are, or we anticipate will be, available as generics. For instance, ANX-530 will compete against Navelbine, for which generic equivalents are already available. ANX-514 will compete against Taxotere®. We anticipate that ANX-514 will also compete against other formulations of docetaxel and that generic Taxotere will enter the market in November 2013 or May 2014 (depending on whether a period of pediatric exclusivity is granted in the future). Even if we obtain unique HCPCS codes for our products, the existence of generic products could make it more difficult for our branded products, including ANX-530 and ANX-514, to gain or maintain market share and could cause prices for our products to drop, each of which could adversely affect our business.

We may also 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 16

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curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own products could negatively impact our business and prospects.

Even if we receive regulatory approval in the U.S. for ANX-530 and/or ANX-514, we will likely depend on a limited number of group purchasing organizations for retail distribution of these products, and if we subsequently lose any significant GPO relationship, our business could be harmed.

Our current U.S. commercialization strategy for our lead emulsion formulations initially involves marketing and selling these products through a limited number of GPOs. Even if we are successful in securing relationships with these entities, the subsequent loss of any one or more of these GPO accounts or a material reduction in their participation could harm our business, financial condition or results of operations. In addition, we may face pricing pressure from these GPOs.

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

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

issue warning letters or untitled letters;

impose civil or criminal penalties;

suspend or withdraw regulatory approval;

suspend or terminate any ongoing bioequivalence or clinical trials;

refuse to approve pending applications or supplements to approved applications;

impose restrictions or affirmative obligations on our or our CMO s operations, including costly new manufacturing requirements;

close the facilities of a CMO; or

seize or detain products or require a product recall.

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

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. In particular,

other countries may not have a comparable regulatory as is available under Section 505(b)(2) of FDCA. Even if a 17

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country did have a comparable procedure, that country may require a more robust data package than the pharmacokinetic data package that we intend to submit in support of NDAs for ANX-530 and ANX-514. 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.

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

regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication:

regulatory authorities may withdraw their approval of the product;

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; and

our reputation may suffer.

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

Risks Related to Our Intellectual Property

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

Our success will depend in part on our ability to:

obtain and maintain patent protection with respect to our products;

prevent third parties from infringing upon our proprietary rights;

maintain trade secrets;

operate without infringing upon the patents and proprietary rights of others; and

obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, both in the U.S. and in foreign countries.

The patent and intellectual property positions of biopharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims

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

Exclusivity for our emulsion-formulation product candidates may be limited because of the n