ADVENTRX PHARMACEUTICALS INC
Form S-1/A
September 25, 2009

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As filed with the Securities and Exchange Commission on September 25, 2009
Registration No. 333-160778

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 2
to
Form S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ADVENTRX Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**84-1318182**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification Number)*

6725 Mesa Ridge Road,
Suite 100,
San Diego, CA 92121
(858) 552-0866
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Brian M. Culley
Principal Executive Officer
ADVENTRX Pharmaceuticals, Inc.

6725 Mesa Ridge Road, Suite 100
San Diego, CA 92121
Telephone: (858) 552-0866
(Name, address, including zip code, and telephone number, including area code, of agent for service)

With a Copy to:

Michael S. Kagnoff, Esq. **DLA Piper LLP (US)** **4365 Executive Drive, Suite 1100** **San Diego, CA 92121** **Telephone: (858) 677-1400** **Facsimile: (858) 677-1401**	**Patrick L. Keran, Esq.** **Principal Financial and Accounting Officer and General Counsel** **ADVENTRX Pharmaceuticals, Inc.** **6725 Mesa Ridge Road, Suite 100** **San Diego, CA 92121** **Telephone: (858) 552-0866**	**Robert F. Charron, Esq.** **Weinstein Smith LLP** **420 Lexington Ave** **New York, NY 10170** **Telephone: (212) 616-3007** **Facsimile: (212) 869-2249**	**Harvey J. Kesher, Esq.** **Sichenzia Ross Friedman Ference LLP** **61 Broadway, Suite 3200** **New York, NY 10006** **Telephone: (212) 930-9700** **Facsimile: (212) 930-9725**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective statement for the same offering o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company þ

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered(1)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(2)
Convertible Preferred Stock, par value $0.001 per share(3)		
Shares of Common Stock, par value $0.001 per share, underlying Convertible Preferred Stock		
Warrants(3)		
Shares of Common Stock, par value $0.001 per share, underlying Warrants		
Total	$ 10,000,000	$ 557(4)

(1) Any securities registered hereunder may be sold separately or together with other securities registered hereunder.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the Securities Act), the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends, anti-dilution provisions, or similar transactions. No additional registration fee is being paid for these shares.

(3) Pursuant to Rule 457(g) under the Securities Act, no separate registration fee is required for the convertible preferred stock or the warrants because the Registrant is registering these securities in the same Registration Statement as the underlying common stock to be offered pursuant thereto.

(4) Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS SUBJECT TO COMPLETION September 25, 2009

shares of 4% Series D Convertible Preferred Stock
Warrants to Purchase up to shares of Common Stock
shares of Common Stock Underlying the Convertible Preferred Stock and the Warrants

We are offering up to $10,000,000 of our 4% Series D Convertible Preferred Stock, or shares based on a stated value of $1,000 per share, and warrants to purchase up to shares of our common stock. We are also offering 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 up to approximately shares of our 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 $ per share and will accrue a 4% dividend for ten years from the date of issuance. The warrants are exercisable at any time after and on or before the anniversary of their initial exercise date at an exercise price of $ per share of common stock. In the event the convertible preferred stock is converted at any time prior to the date that is ten years after the date of issuance, 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. 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 an aggregate of %, or approximately $, 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 under the symbol ANX. The last reported sale price of our common stock on the NYSE Amex on September 21, 2009 was $0.16 per share. We do not intend to list the convertible preferred stock or warrants on any securities exchange.

Investing in our securities involves a high degree of risk. Before buying any of our securities, you should read the discussion of material risks of investing in our securities stock in Risk Factors beginning on page 6.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Unit	Maximum Total
Public offering price	$	$

Placement agent s fees	$	$
Proceeds, before expenses, to us[1]	$	$

(1) We estimate the total expenses of this offering, excluding the placement agent s fees, will be approximately $250,000.

We have retained Rodman & Renshaw, LLC as our exclusive placement agent to use its reasonable best efforts to solicit offers to purchase our units in this offering. See Plan of Distribution for more information regarding these arrangements.

The placement agent is not purchasing or selling any units pursuant to this prospectus, nor are we requiring any minimum purchase or sale of any specific number of units. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual public offering price, placement agent s fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above.

Delivery of the shares will be made on or about , 2009.

Rodman & Renshaw, LLC

You should rely only on the information contained in this prospectus and any free writing prospectus prepared by us or on our behalf. We have not authorized anyone to provide you with different or additional information. If anyone provides you with different or additional information, you should not rely on it. We are not making offers to sell, or seeking offers to buy, these securities in any state or other jurisdiction where the offers and sales are not permitted. The information contained in this prospectus is accurate only as of the date hereof, regardless of the time of delivery of this prospectus or of any sale of the securities offered hereby. Our business, financial condition, results of operations and prospects may have changed since the date of this prospectus.

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Our trademark CoFactor® is registered in the United States Patent and Trademark Office (in the Supplemental Register) under Registration No. 2,946,934, for use in connection with chemotherapy modulators derived from folic acid. We are developing commercial names for our other product candidates. All other trademarks, service marks or trade names appearing in this prospectus, including but not limited to Navelbine® and Taxotere®, are the property of their respective owners. Use or display by us of other parties trademarks, service marks, trade names, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark, trade name, trade dress or product owners. As indicated in this prospectus, we have included market data and industry forecasts that were obtained from industry publications.

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PROSPECTUS SUMMARY

This summary highlights selected information about us and this offering contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements contained elsewhere in this prospectus. It may not contain all of the information that is important to you. You should carefully read this entire prospectus, including the risks and uncertainties discussed under the heading Risk Factors below, our consolidated financial statements and the notes related thereto, our condensed consolidated financial statements and the notes related thereto, and the other documents included in or to which this prospectus refers, before making an investment decision. When used in this prospectus, the terms ADVENTRX, we, our, us and the Company refer to ADVENTR Pharmaceuticals, Inc. and its 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.

Our lead product candidates, ANX-530 (vinorelbine emulsion) and ANX-514 (docetaxel emulsion), are novel emulsion formulations of currently marketed chemotherapy drugs. We believe ANX-530 and ANX-514 may improve the safety of the currently marketed reference products, Navelbine (vinorelbine tartrate) and Taxotere (docetaxel), respectively, by:

- Reducing the incidence and severity of adverse effects; and
- Improving their pharmacoeconomics and convenience to healthcare practitioners and patients.

Following the registered direct equity financing that we completed in June 2009, we re-started certain development activities that we had suspended in March 2009 to conserve cash while we evaluated strategic options, pursued financing alternatives and considered other alternatives. Specifically, we re-started the final manufacturing activities related to submitting a New Drug Application, or NDA, for ANX-530 to seek approval of the United States Food and Drug Administration, or FDA, to market ANX-530 in the United States.

In August 2009, we announced that, while we continue to evaluate our ANX-530 bioequivalence and preclinical data, we plan to submit an NDA for ANX-530 before the end of 2009. Assuming we submit an ANX-530 NDA in December 2009, and the FDA does not request and we do not otherwise provide additional information or clarification with respect to our submission, we expect a response from the FDA to our submission in the fourth quarter of 2010.

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 Strategy

Our goal is to be a leading specialty pharmaceutical company focused on developing and commercializing proprietary product candidates that improve the performance of currently approved products. Our near-term strategy is to obtain marketing approval of our lead product candidates and either partner with leading organizations or establish an infrastructure to support marketing, distributing and selling these products in the U.S. and abroad, should they be

approved. Longer term, we intend to acquire additional product candidates that fit our areas of expertise. Specifically, we intend to:

Seek marketing approval for ANX-530 and ANX-514 in the U.S. We are applying our operational experience to complete and seek approval of NDAs for ANX-530 and ANX-514 that we intend to submit to the FDA. In August 2009, we announced that, while we continue to evaluate the bioequivalence and preclinical data, we plan to submit an NDA for ANX-530 before the end of 2009. In addition, we are continuing to evaluate the data from our recently-completed bioequivalence study of ANX-514 and plan to seek a meeting with the FDA to discuss the results.

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Establish sales and marketing capabilities for ANX-530 and ANX-514 in the U.S. We intend to gain access to a substantial portion of the U.S. markets for ANX-530 and ANX-514 through a small, specialized sales force targeting distributors, provider networks and group purchasing organizations. For the near-term, we intend to maintain our current cost-efficient and flexible infrastructure by limiting the number of our full-time employees, engaging consultants on a project basis and outsourcing substantially all of our development activities to specialized vendors and contract development organizations. As we near regulatory approval of our product candidates, we plan to establish the infrastructure and relationships necessary to access what we believe will be concentrated markets for ANX-530 and ANX-514. However, we also remain receptive to partnering these product candidates in the U.S. if presented with terms that are sufficiently attractive.

Partner with leading organizations to develop and market ANX-530 and ANX-514 outside the U.S. or globally. We plan to draw on the development, regulatory and commercial expertise of other companies in instances where we believe our product candidates would benefit from such expertise. For markets in which a large sales force is required to gain access, and for markets outside the U.S. and possibly within the U.S., we plan to commercialize products for which we obtain regulatory approval through a variety of licensing, collaboration and distribution arrangements with other pharmaceutical and biotechnology companies. In March 2009, we entered into a license agreement with Shin Poong Pharmaceutical Co., Ltd. pursuant to which we granted Shin Poong an exclusive license to make use and sell ANX-514 in South Korea.

Pursue additional indications and commercial opportunities for ANX-530 and ANX-514 independently and through collaborations. We may increase the value of our product candidates by seeking approval for label changes and pursuing other commercial opportunities. For example, we or a future partner may conduct clinical and non-clinical studies that seek to differentiate ANX-530 and ANX-514 from Navelbine and Taxotere, respectively.

Acquire and develop new and improved formulations of currently marketed products. We may pursue other currently approved products that we believe can be improved, the U.S. markets for which are concentrated and to which we can apply our operational experience.

Net Loss and Recent Financing Activity

We have devoted substantially all of our resources to research and development activities or to acquisition of our product candidates and have experienced annual net losses since inception, accumulating net losses totaling approximately $144.3 million as of June 30, 2009, and we expect to incur substantial losses for the foreseeable future. As of June 30, 2009, we had approximately $5.4 million in cash and cash equivalents and $2.2 million in working capital, which working capital amount reflects a liability of $1.4 million that was eliminated on July 6, 2009 following the closing of a registered direct equity financing that we completed on July 6, 2009. We do not expect to generate positive net cash flows for the foreseeable future. Historically, we have funded our operations primarily through sales of our equity securities. 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. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On June 12, 2009, July 6, 2009 and August 10, 2009, we completed registered direct equity financings involving, respectively, shares of our 0% Series A Convertible Preferred Stock, 5% Series B Convertible Preferred Stock and 5% Series C Convertible Preferred Stock, which financings resulted in a total of $4.3 million in gross proceeds and $3.7 million in net proceeds, after deducting the fees of our placement agent in those financings and our estimated offering expenses, but before deducting our dividend and related payment obligations. All of these shares of

Convertible Preferred Stock subsequently have been converted into shares of our common stock and, pursuant to the terms of our 5% Series B Convertible Preferred Stock and our 5% Series C Convertible Preferred Stock, we paid an aggregate of $455,500 to the holders of such Convertible Preferred Stock in connection with such conversions. We may receive up to $1.2 million of additional proceeds from the exercise of warrants issued in our June 2009 financing; however, those warrants are not exercisable until December 13, 2009 and their exercise is subject to certain ownership limitations.

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Increase in Authorized Shares of Common Stock

At a special meeting of our stockholders on August 25, 2009 called by our board of directors, our stockholders approved increasing the total number of authorized shares of our common stock from 200 million shares to 500 million shares. Prior to the closing of the offering described in this prospectus, we will increase the number of authorized shares of our common stock to 500 million, with a corresponding increase in the total number of authorized shares of our capital stock.

Risk Factors

We face numerous risks and uncertainties that could materially and adversely affect our business, results of operations and financial condition, including the risk that we may not be able to raise sufficient capital to continue our business operations, which could result in our inability to continue as a going concern, and the risk that we may be unable to regain compliance with the continued listing requirements of the NYSE Amex, the securities exchange on which our common stock is listed, and our common stock may be delisted from that exchange. For additional discussion of the risk and uncertainties we face, see Risk Factors below.

Corporate Information

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. Information on our website does not constitute part of this prospectus.

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The Offering

Securities offered:	Up to shares of convertible preferred stock; Up to shares of common stock issuable upon conversion of the convertible preferred stock; Warrants to purchase up to shares of common stock; and Up to shares of common stock issuable upon exercise of the warrants.
Common stock to be outstanding after this offering:	124,885,267 shares of common stock, or 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 , 2019, we will pay to the holder an amount equal to $ 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 , as escrow agent, to be held for a period of 120 months from the date of closing. 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 our operations during the FDA review period of an ANX-530 NDA and to continue development of ANX-514, and for general corporate purposes. Please see Use of Proceeds below.
NYSE Amex symbol:	ANX
Risk factors:	Investing in our securities involves a high degree of risk and purchasers of our securities may lose their entire investment. See Risk Factors below and the other information included elsewhere in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

The number of shares of our common stock to be outstanding immediately after this offering is based on 124,885,267 shares of our common stock outstanding as of September 21, 2009. This number does not include, as of September 21, 2009:

- 5,925,406 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 $0.81 per share;

13,767,250 shares of common stock available for future issuance under our 2008 Omnibus Incentive Plan;

20,658,733 shares of common stock issuable upon the exercise of outstanding warrants issued prior to this offering, at a weighted average exercise price of $1.26 per share;

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 $ per share; and

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, at an exercise price of $ per share (125% of the public offering price, which is the effective acquisition price of the common stock underlying the convertible preferred stock sold in this offering).

Except as otherwise indicated, all information in this prospectus assumes the convertible preferred stock offered hereby converts 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 $ per share.

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Summary Financial Data

The following tables set forth our summary statement of operations data for the fiscal years ended December 31, 2008 and 2007, for the three months ended June 30, 2009 and 2008, and our summary balance sheet as of June 30, 2009. Our statement of operations data for the fiscal years ended December 31, 2008 and 2007 were derived from our audited consolidated financial statements included elsewhere in this prospectus. Our statement of operations data for the three months ended June 30, 2009 and 2008 and our balance sheet data as of June 30, 2009 were derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. In the opinion of management the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of our operating results and financial position for those periods and as of such dates. The results for any interim period are not necessarily indicative of the results that may be expected for a full year.

The results indicated below and elsewhere in this prospectus are not necessarily indicative of our future performance. You should read this information together with Capitalization, Management s Discussion and Analysis of Financial Condition and Results of Operations, our consolidated financial statements and related notes and our unaudited condensed consolidated financial statements and related notes included elsewhere in this prospectus.

Statement of Operations Data

	Year Ended December 31, 2007	Year Ended December 31, 2008	Three Months Ended June 30, 2008	Three Months Ended June 30, 2009
Revenue	$ 500,000	$ 500,000	$ 500,000	$
Operating Expenses:				
Research and development	15,934,409	17,922,183	4,511,395	1,454,896
Selling, general and administrative	8,678,853	9,719,613	2,635,688	1,071,754
Depreciation and amortization	197,783	168,039	44,116	25,835
Total operating expenses	24,811,045	27,809,835	7,191,199	2,552,485
Loss from operations	(24,311,045)	(27,309,835)	(6,691,199)	(2,552,485)
Interest and other income (expense)	2,169,005	662,342	265,669	(43,056)
Net loss	(22,142,040)	(26,647,493)	(6,425,530)	(2,595,541)
Deemed dividends on preferred stock				(1,232,415)
Net loss applicable to common stock	$ (22,142,040)	$ (26,647,493)	$ (6,425,530)	$ (3,827,956)
Net loss per share basic and diluted	$ (0.25)	$ (0.30)	$ (0.07)	$ (0.04)
Weighted average shares outstanding basic and diluted	89,912,732	90,252,572	90,252,572	93,389,302

Balance Sheet Data

	As of June 30, 2009
Cash and cash equivalents	$ 5,419,227
Total current assets	$ 6,024,057
Total current liabilities	$ 3,870,811
Deficit accumulated during the development stage	$ (132,831,425)
Total stockholders equity	$ 2,295,819

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RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risk factors discussed below, together with all the other information contained in this prospectus before deciding whether to purchase any of our securities. 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 operations and pursue our business strategy, and, if we are unable to raise sufficient additional capital, we may cease operating as a going concern and seek protection under the U.S. Bankruptcy Code or liquidate our assets.

We have experienced significant operating losses in funding the development of our product candidates, accumulating net losses totaling approximately $144.3 million as of June 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 June 30, 2009, we had approximately $5.4 million in cash and cash equivalents and $2.2 million in working capital, which working capital amount reflects a liability of $1.4 million that was eliminated on July 6, 2009 following the closing of a registered direct equity financing that we completed on July 6, 2009. 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. Following the equity financing we completed in June 2009, we re-started the final manufacturing activities related to submitting a New Drug Application, or NDA, for ANX-530 to seek approval of the FDA to market ANX-530 in the United States, or U.S., and intend to continue to evaluate the data from our recently-completed bioequivalence study of ANX-514. We expect to incur substantial costs in connection with activities relating to submitting an NDA for ANX-530 and advancing ANX-530 toward commercialization in the U.S. We may also incur substantial costs in connection with evaluating, negotiating and consummating capital-raising and/or strategic or partnering 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 or partnering transactions, our efforts may not prove successful. Excluding the potentially significant costs associated with evaluating, negotiating and consummating capital-raising and/or strategic or partnering transactions or seeking protection under the provisions of the U.S. Bankruptcy Code or liquidating our assets and winding-up our operations, we anticipate that our cash and cash equivalents as of June 30, 2009, together

with the net proceeds from the equity financings we completed on July 6, 2009 and August 10, 2009, will be sufficient to permit us to conduct our business through December 31, 2009. We will need to raise substantial additional capital to continue our business after this period.

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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, we will need substantial additional capital in order to commercialize ANX-530 and to continue to develop ANX-514. 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 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.

If we sell the maximum amount of convertible preferred stock and warrants offered by this prospectus, we estimate that we will have funds to support our operations through 2010. However, we may need or seek additional funding sooner. 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 on Form S-3 that allows us to raise up to $25 million from the sale of common stock, preferred stock, debt securities, warrants and units, 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

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$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. 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. As of September 21, 2009, our public float was approximately 121 million shares. Based on a market value of $0.20 per share, which was the closing price of our common stock on August 13, 2009, a date within 60 days prior to the date hereof, the aggregate market value of our public float was approximately $24.1 million. The value of one-third of that public float was approximately $8.0 million; however, the market value of all securities sold by us under our Form S-3 registration statement in the past 12 months (including the 653,812 shares of our common stock underlying the 0% Series A Convertible Preferred Stock and the warrants that we issued on June 12, 2009, the 237,605 shares of our common stock underlying the 5% Series B Convertible Preferred Stock that we issued on July 6, 2009 and the 177,308 shares of our common stock underlying the 5% Series C Convertible Preferred Stock that we issued on August 10, 2009) will be subtracted from that amount to determine any future amount we can raise using our Form S-3 registration statement. 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.

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 September 21, 2009 and a closing price of $0.16, which was the closing price of our common stock on September 21, 2009, we could not raise more than approximately $4.0 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.

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Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to 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 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, we will need substantial additional capital in order to commercialize ANX-530 and to continue to develop ANX-514. 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.

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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 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.

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 principal executive officer and our General Counsel, Secretary and Vice President, Legal currently is acting as our 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, 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.

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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, 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.

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.

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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. 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

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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 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.

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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:

- 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 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, 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,

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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;
- 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.

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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 short- or long-term relationships with willing manufacturers more difficult and provide them with substantial leverage over us in any negotiations. Furthermore, certain of the component materials of 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 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.

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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 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.

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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.

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.

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

Many of the currently marketed and anticipated products against which our product candidates may compete are, or we anticipate will be, available as generics. For instance, 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.

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 s 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;

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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 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.

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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

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that our products and product candidates may give rise to claims that our products or product candidates 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.