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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2012

OR

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

For the transition period from to

Commission File Number 001-32157

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

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
12390 El Camino Real, Suite 150, San Diego, CA	**92130**
(Address of principal executive offices)	**(Zip Code)**

(858) 552-0866
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐

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

The number of shares outstanding of the registrant's common stock, $0.001 par value per share, as of May 1, 2012 was 47,715,709.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Enterprise)
Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2012	December 31, 2011 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 35,051,277	$ 43,569,947
Short-term investments	10,995,127	7,133,697
Interest and other receivables	14,943	17,245
Contingent asset	953,149	815,011
Prepaid expenses	292,691	256,311
Total current assets	47,307,187	51,792,211
Property and equipment, net	603,054	464,465
In-process research and development	6,549,000	6,549,000
Goodwill	3,006,883	3,006,883
Other assets	43,912	43,912
Total assets	$ 57,510,036	$ 61,856,471
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 316,712	$ 451,705
Accrued liabilities	986,093	1,120,416
Accrued compensation and payroll taxes	478,519	756,773
Contingent liability	163,875	140,125
Total current liabilities	1,945,199	2,469,019
Deferred income tax liability	2,608,755	2,608,755
Total liabilities	4,553,954	5,077,774
Stockholders' equity:		
Common stock, $0.001 par value; 500,000,000 shares authorized; 47,715,709 shares issued and outstanding at both March 31, 2012 and December 31, 2011	47,716	47,716
Additional paid-in capital	226,452,094	226,122,331
Accumulated other comprehensive loss	(2,159)	(2,298)
Deficit accumulated during the development stage	(173,541,569)	(169,389,052)
Total stockholders' equity	52,956,082	56,778,697
Total liabilities and stockholders' equity	$ 57,510,036	$ 61,856,471

(1) The balance sheet at December 31, 2011 has been derived from audited financial statements at that date. It does not include, however, all of the information and notes required by accounting principles generally accepted in the United States of America for complete financial statements.

See accompanying notes to unaudited condensed consolidated financial statements.

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Enterprise)
Condensed Consolidated Statements of Operations and Comprehensive Income/(Loss)
(Unaudited)

	Three months ended March 31,		Inception (June 12, 1996) Through
	2012	2011	March 31, 2012
Revenues:			
Net sales	$ —	$ —	$ 174,830
Licensing revenue	—	—	1,300,000
Grant revenue	—	—	618,692
Total net revenues	—	—	2,093,522
Cost of goods sold	—	—	51,094
Gross margin	—	—	2,042,428
Operating expenses:			
Research and development	2,210,454	611,293	80,179,758
Selling, general and administrative	2,045,238	1,573,746	62,192,545
Transaction-related expenses	(114,388)	799,505	626,866
Depreciation and amortization	30,192	9,871	10,965,380
Write-off of in-process research and development	—	—	10,422,130
Goodwill impairment	—	—	5,702,130
Equity in loss of investee	—	—	178,936
Total operating expenses	4,171,496	2,994,415	170,267,745
Loss from operations	(4,171,496)	(2,994,415)	(168,225,317)
Reduction of fair value of warrants	—	—	(12,239,688)
Interest income	29,378	32,871	4,788,026
Interest expense	(10,710)	—	(202,439)
Other income	311	5,105	135,063
Loss before cumulative effect of change in accounting principle	(4,152,517)	(2,956,439)	(175,744,355)
Cumulative effect of change in accounting principle	—	—	(25,821)
Net loss	(4,152,517)	(2,956,439)	(175,770,176)
Preferred stock dividends	—	—	(621,240)
Deemed dividends on preferred stock	—	—	(10,506,683)
Net loss applicable to common stock	$ (4,152,517)	$ (2,956,439)	$(186,898,099)
Net loss per common share – basic and diluted	$ (0.09)	$ (0.13)	
Weighted average shares – basic and diluted	47,715,709	22,755,463	
Statement of Comprehensive Income/Loss:			
Net loss applicable to common stock	$ (4,152,517)	$ (2,956,439)	$(186,898,099)
Comprehensive gains (losses)	139	—	(3)
Comprehensive net loss applicable to common stock	$ (4,152,378)	$ (2,956,439)	$(186,898,102)

See accompanying notes to unaudited condensed consolidated financial statements.

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Enterprise)
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three months ended March 31, 2012	Three months ended March 31, 2011	Inception (June 12, 1996) through March 31, 2012
Cash flows from operating activities:			
Net loss	$(4,152,517)	$(2,956,439)	$(175,770,176)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	30,192	9,871	10,515,382
(Gain) loss on disposals of fixed assets	4,503	(2,973)	61,315
Loss on fair value of warrants	—	—	12,239,688
Gain on change in fair value of contingent consideration	(114,388)	—	(1,573,693)
Amortization of debt discount	—	—	450,000
Forgiveness of employee receivable	—	—	30,036
Impairment loss – write-off of goodwill	—	—	5,702,130
Share-based compensation expense related to employee stock options and restricted stock issued	377,505	135,318	10,467,499
Expense related to options issued to non-employees	—	—	204,664
Expenses paid by issuance of common stock	—	—	1,341,372
Expenses paid by issuance of warrants	—	—	573,357
Expenses paid by issuance of preferred stock	—	—	142,501
Expenses related to stock warrants issued	—	—	612,000
Equity in loss of investee	—	—	178,936
In-process research and development	—	—	10,422,130
Write-off of license agreement	—	—	152,866
Write-off of assets available-for-sale	—	—	108,000
Cumulative effect of change in accounting principle	—	—	25,821
Amortization of premium / (accretion of discount) on investments in securities	10,710	—	(1,582,632)
Changes in assets and liabilities, net of effect of acquisitions:			
Increase (decrease) in prepaid expenses and other assets	(34,078)	98,324	(601,233)
Increase (decrease) in accounts payable and accrued liabilities	(533,492)	332,061	1,641,218
Net cash used in operating activities	(4,411,565)	(2,383,838)	(124,658,819)
Cash flows from investing activities:			
Purchases of certificates of deposit	(5,312,000)	—	(13,473,179)
Maturity of certificates of deposit	1,440,000	—	2,456,330
Purchases of other short-term investments	—	—	(111,183,884)
Proceeds from sales and maturities of other short-term investments	—	—	112,788,378
Purchases of property and equipment	(187,363)	(14,858)	(1,657,992)
Proceeds from sale of property and equipment	—	12,635	66,920
Cash paid for acquisitions, net of cash acquired	—	—	32,395
Payment on obligation under license agreement	—	—	(106,250)
Issuance of note receivable – related party	—	—	(35,000)
Payments on note receivable	—	—	405,993
Advance to investee	—	—	(90,475)
Cash transferred in rescission of acquisition	—	—	(19,475)
Cash received in rescission of acquisition	—	—	230,000
Net cash used in investing activities	(4,059,363)	(2,223)	(10,586,239)

Cash flows from financing activities:			
Proceeds from sale of common stock	—	22,507,529	123,658,871
Proceeds from exercise of stock options	—	—	712,367
Proceeds from sale or exercise of warrants	—	—	14,714,258
Proceeds from sale of preferred stock	—	—	44,474,720
Repurchase of warrants	—	—	(55,279)
Payments for financing and offering costs	(47,742)	(1,548,123)	(13,945,109)
Payments on notes payable and long-term debt	—	—	(605,909)
Proceeds from issuance of notes payable and detachable warrants	—	—	1,344,718
Cash paid in lieu of fractional shares for reverse stock split	—	—	(146)
Net cash provided by (used in) financing activities	(47,742)	20,959,406	170,298,491
Effect of exchange rate changes on cash	—	—	(2,156)
Net (decrease)/increase in cash and cash equivalents	(8,518,670)	18,573,345	35,051,277
Cash and cash equivalents at beginning of period	43,569,947	27,978,823	—
Cash and cash equivalents at end of period	$35,051,277	$46,552,168	$ 35,051,277

See accompanying notes to unaudited condensed consolidated financial statements.

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Enterprise)
Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Basis of Presentation

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation ("ADVENTRX," "we" or "our company"), prepared the unaudited interim condensed consolidated financial statements included in this report in accordance with United States generally accepted accounting principles ("U.S. GAAP") for interim financial information and the rules and regulations of the Securities and Exchange Commission ("SEC") related to a quarterly report on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for annual audited financial statements and should be read in conjunction with our audited consolidated financial statements and related notes for the year ended December 31, 2011 included in our Annual Report on Form 10-K filed with the SEC on March 8, 2012 ("2011 Annual Report"). The condensed consolidated balance sheet as of December 31, 2011 included in this report has been derived from the audited consolidated financial statements included in the 2011 Annual Report. In the opinion of management, these condensed consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented. The results of operations for the interim periods shown in this report are not necessarily indicative of the results that may be expected for any future period, including the full year.

The condensed consolidated financial statements included in this report include the accounts of ADVENTRX and its wholly-owned subsidiaries, SD Pharmaceuticals, Inc. and SynthRx, Inc. All intercompany accounts and transactions have been eliminated in consolidation.

2. Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates, including estimates related to contingent consideration, research and development expenses and share-based compensation expenses. We base our estimates on historical experience and various other relevant assumptions we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

3. Acquisition of SynthRx

On February 12, 2011, we entered into an agreement and plan of merger (the "Merger Agreement") to acquire SynthRx, Inc. ("SynthRx"), a privately-held Delaware corporation, in exchange for shares of our common stock as described below. The transaction was completed on April 8, 2011 and SynthRx became a wholly owned subsidiary of ADVENTRX. The acquisition is accounted for as a business combination.

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

(i) 862,078 shares of our common stock, which were issued on April 8, 2011 (the "Fully Vested Shares") and represent 1,000,000 shares less 137,922 shares that were deducted as a result of certain expenses of SynthRx. Of the Fully Vested Shares, 200,000 were deposited into escrow to indemnify us against breaches of representations and warranties;

(ii) up to 1,938,773 shares of our common stock, which were issued on April 8, 2011 (the "Subject to Vesting Shares," and together with the Fully Vested Shares, the "Closing Shares"). The Subject to Vesting Shares are subject to various repurchase rights by us and fully vest, subject to reduction under certain circumstances, upon achievement of the First Milestone (defined below) as follows. Up to approximately 75% of the Subject to Vesting Shares, or 1,454,079 shares, are subject to repurchase by us for $0.001 per share based on whether the First Milestone is achieved, the timing of its achievement and whether and the extent to which the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint exceeds 250 patients, unless otherwise agreed;

(iii) up to 1,000,000 shares of our common stock (the "First Milestone Shares"), which will be issued, if at all, upon achievement of the First Milestone. The "First Milestone" means the dosing of the first patient in a phase 3 clinical study carried out pursuant to a protocol that is mutually agreed to by SynthRx and ADVENTRX; provided, however, that the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint shall not exceed 250 (unless otherwise mutually agreed) (the "First Protocol"). If the U.S. Food and Drug Administration ("FDA") indicates that a single phase 3 clinical study will not be adequate to support approval of a new drug application covering the use of purified P188 for the treatment of sickle cell crisis in children (the "188 NDA"), "First Milestone" shall mean the dosing of the first patient in a phase 3 clinical study carried out pursuant to a protocol that (a) is mutually agreed to by SynthRx and ADVENTRX as such and (b) describes a phase 3 clinical study that the FDA has indicated may be sufficient, with the phase 3 clinical study described in the First Protocol, to support approval of the 188 NDA. The amount of shares that becomes issuable upon achievement of the First Milestone may be reduced by up to 75%, or 750,000 shares, based on the timing of achievement of the First Milestone and whether and the extent to which the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint exceeds 250 patients, unless otherwise agreed;

(iv) 3,839,400 shares of our common stock (the "Second Milestone Shares"), which will be issued, if at all, upon achievement of the Second Milestone. The "Second Milestone" means the FDA's acceptance for review of the 188 NDA (the "Second Milestone"); and

(v) 8,638,650 shares of our common stock (the "Third Milestone Shares," and together with the First Milestone Shares and the Second Milestone Shares, the "Milestone Shares"), which will be issued, if at all, upon achievement of the Third Milestone. The "Third Milestone" means FDA approval of the 188 NDA.

Based on the estimated fair value as of April 8, 2011, the acquisition date, of the Closing Shares and the Milestone Shares (which was based upon the number of shares to be issued at the time of achievement of each milestone, the probability of achievement for each milestone, the estimated date of achievement for each milestone and the market price of a share of our common stock), the total purchase price was approximately $6.7 million. The elements of the total purchase price were as follows:

Event	Shares Issued / Issuable	Probability Weighted Fair Value
Initial consideration (Fully Vested Shares)	862,078	$2,017,263
Initial consideration (Subject to Vesting Shares)	1,938,773	2,103,375(1)
First Milestone – dosing of first patient	1,000,000	1,084,900
Second Milestone – NDA acceptance	3,839,400	733,403
Third Milestone – FDA approval	8,638,650	730,801
Total	16,278,901	$6,669,742

(1) This amount is net of the probability-weighted fair value of the Subject to Vesting Shares that we estimated, as of the acquisition date, ultimately may be repurchased by us ($300,481).

The allocation of the purchase price is based on our estimates of the fair values of tangible and intangible assets acquired, including in-process research and development ("IPR&D"), and liabilities assumed as of the acquisition date. Our purchase price allocation has been finalized. The following table summarizes the estimated fair values of net tangible and intangible assets acquired and liabilities assumed:

Net tangible assets acquired	$ 18,513
Net tangible liabilities assumed	(295,899)
Acquired intangibles:	
In-process research and development	6,549,000
Goodwill	3,006,883
Deferred income tax liability	(2,608,755)
Total purchase price	$ 6,669,742

Acquired In-Process Research and Development

Our acquired IPR&D is the estimated fair value of SynthRx's lead product candidate, ANX-188, as of the acquisition date. We determined that the estimated fair value of the ANX-188 program was $6.5 million as of the acquisition date using the Multi-Period Excess Earnings Method, or MPEEM, which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset's incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life.

To calculate fair value of the ANX-188 program under the MPEEM, we used probability-weighted cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by development-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to the program and then reduced by a contributory charge on requisite assets employed. Contributory assets included debt-free working capital, net fixed assets and assembled workforce. Rates of return on the contributory assets were based on rates used for comparable market participants. Cash flows were assumed to extend through the market exclusivity period estimated to be provided by orphan drug designation. The resultant cash flows were then discounted to present value using a weighted-average cost of equity capital for companies with profiles substantially similar to that of SynthRx, which we believe represents the rate that market participants would use to value the assets. We compensated for the phase of development of this program by probability-adjusting our estimation of the expected future cash flows. The projected cash flows were based on significant assumptions, such as the time and resources needed to complete the development and approval of ANX-188, estimates of revenue and operating profit related to the program considering its stage of development, the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in drug development, such as obtaining marketing approval from the FDA and other regulatory agencies, and risks related to the viability of and potential alternative treatments in any future target markets.

Goodwill

We recorded $3.0 million as goodwill, representing the difference between the total purchase price of approximately $6.7 million and the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed. We acquired SynthRx to expand our product pipeline, enter into new therapeutic areas and address unmet market needs. These are among the factors that contributed to a purchase price for the SynthRx acquisition that resulted in the recognition of goodwill.

Deferred Income Tax Liability

We recorded $2.6 million for deferred income tax liability resulting from the acquisition, which reflects the tax impact of the difference between the book basis and tax basis of acquired IPR&D. Such deferred income tax liability cannot be used to offset deferred tax assets when analyzing our end of year valuation allowance as the acquired IPR&D is considered to have an indefinite life until we complete or abandon development of ANX-188.

Contingent Asset and Contingent Liability

The number of Subject to Vesting Shares subject to repurchase by us (1,454,079 shares) and the Milestone Shares constitute contingent consideration because our repurchase rights with respect to those Subject to Vesting Shares and our obligation to issue the Milestone Shares are contingent on future events. In order to determine the classification of the fair value of the Milestone Shares as a liability or equity, we reviewed ASC Topic 815-40, *Derivatives and Hedging – Contracts in Entity's Own Equity* ("ASC 815-40"). ASC 815-40 requires that contingent consideration arrangements that include potential net cash settlements or variable provisions should be classified as a liability. Classification as a liability requires fair value measurement initially and subsequently at each reporting date. Changes in the fair value of contingent consideration classified as a liability are recognized in earnings until the contingent consideration arrangement is settled. Classification as equity requires fair value measurement initially and there are no subsequent re-measurements. Settlement of equity-classified contingent consideration is accounted for within equity.

The probability-weighted fair values of the Second Milestone Shares and the Third Milestone Shares were recorded as equity as there is no net cash settlement provision and the number of shares that ultimately may be issued upon achievement of each of those milestones is fixed.

The probability-weighted fair value of the First Milestone Shares was recorded as a liability as there is variability with respect to the number of shares that ultimately may be issued (from 250,000 to 1,000,000 shares) based on the circumstances of achievement of the First Milestone, as described above. This contingent liability is remeasured at each reporting date until the arrangement is settled. Upon achievement of the First Milestone, the contingent liability will be remeasured and any change in its fair value as of the date of achievement will be recognized in earnings as a transaction-related expense, and the contingent liability will be eliminated. The fair value of the issued First Milestone Shares will be recorded as equity.

As with the First Milestone Shares, there is variability with respect to the number of Subject to Vesting Shares that we ultimately may repurchase based on whether the First Milestone is achieved and the circumstances of its achievement, as described above. Accordingly, we recorded as a contingent asset the probability-weighted fair value of the Subject to Vesting Shares that we estimated may be repurchased by us. This contingent asset is remeasured at each reporting date until the arrangement is settled. At settlement, the contingent asset will be remeasured and any change in its fair value as of the date of settlement will be recognized in earnings as a transaction-related expense and the contingent asset will be reduced by the fair value of the repurchased Subject to Vesting Shares. The fair value of the repurchased Subject to Vesting Shares will be recorded as equity.

The remeasurement of the contingent asset and contingent liability as of March 31, 2012 resulted in a net $0.1 million reduction to transaction-related expenses for the three months ended March 31, 2012.

Pro Forma Information

The operations of SynthRx were fully integrated as of April 8, 2011, the acquisition date, and, accordingly, included in our results of operations for the three months ended March 31, 2012. The following unaudited pro forma information for the three months ended March 31, 2011 presents the condensed consolidated results of operations of ADVENTRX and SynthRx as if the acquisition had occurred on January 1, 2010:

	Three months ended March 31, 2011
Revenues	$ —
Loss from operations	(2,670,523)
Net loss applicable to common stock	(2,632,521)

The pro forma condensed consolidated financial information includes the following adjustment directly attributable to the acquisition:

	Three months ended March 31, 2011
Transaction-related expenses	$ (663,735)

The pro forma information is not necessarily indicative of what the results of operations actually would have been had the acquisition been completed on the date indicated. In addition, it does not purport to project the future operating results of the combined entity. The pro forma condensed consolidated financial information is presented for illustrative purposes only.

As previously discussed, the operations of SynthRx were fully integrated into our operations as of the closing of the acquisition. Accordingly, we do not present SynthRx's expenses separately.

4. Short-Term Investments

We consider income-yielding securities that can be readily converted to cash and have original maturities of more than three months and one year or less at the date of purchase to be short-term investments. All of our short-term investments are marketable securities under the custodianship of a major financial institution and consist primarily of FDIC-insured certificates of deposit.

We account for and report our short-term investments in accordance with ASC 320, *Accounting for Certain Investments in Debt and Equity Securities*. Our short-term investments are classified as "available-for-sale" securities and carried at fair value based on quoted market prices, with net unrealized gains or losses included in accumulated other comprehensive income (loss), which is a separate component of stockholders' equity. Realized gains and realized losses are included in other income (expense), while amortization of premiums and discounts are included in interest expense. Interest and dividends on available-for-sale securities are included in interest income. Marketable securities are evaluated periodically for impairment. If we determine that a decline in market value of any investment is other than temporary, then the investment basis would be written down to fair value and charged to earnings.

At March 31, 2012, the fair value of our short-term investments was $10,995,127. The cost basis of such investments was $10,994,988 and unrealized gains were $139.

5. Fair Value of Financial Instruments

Our short-term investments and our asset and liability for contingent consideration related to our acquisition of SynthRx are carried at fair value. The fair value of financial assets and liabilities is measured under a framework that establishes "levels" which are defined as follows: (i) Level 1 fair value is determined from observable, quoted prices in active markets for identical assets or liabilities; (ii) Level 2 fair value is determined from quoted prices for similar items in active markets or quoted prices for identical or similar items in markets that are not active; and (iii) Level 3 fair value is determined using the entity's own assumptions about the inputs that market participants would use in pricing an asset or liability.

The fair values at March 31, 2012 of our short-term investments and our contingent asset and contingent liability are summarized in the following table:

	March 31, 2012			
	Total Fair Value	Fair Value Determined Under:		
		(Level 1)	(Level 2)	(Level 3)
Short-term investments	$10,995,127	$10,995,127	$ —	$ —
Contingent asset	$ 953,149	$ —	$ —	$ 953,149
Contingent liability	$ (163,875)	$ —	$ —	$(163,875)

A reconciliation of the contingent asset and contingent liability that are measured and recorded at fair value on a recurring basis using significant unobservable inputs (Level 3) in the three months ended March 31, 2012 is as follows:

	Three months ended March 31, 2012	
	Contingent Asset	Contingent Liability
Beginning balance	$ 815,011	$ (140,125)
Net purchases, issuances, sales and settlements	—	—
Total net unrealized gains (losses) included in earnings	138,138	(23,750)
Total net unrealized gains (losses) included in other comprehensive income	—	—
Transfers into level 3 (gross)	—	—
Transfers out of level 3 (gross)	—	—
Ending balance	$ 953,149	$ (163,875)

The fair values of the contingent asset and contingent liability are based on significant estimates and assumptions of management. The fair values of the contingent asset and contingent liability at each remeasurement date are equal to our estimates of the fair value of the Subject to Vesting Shares that may be repurchased by us and the fair value of First Milestone Shares that may be issued by us, respectively. The fair value of these shares is based on our estimates of the probability of achievement of the First Milestone and assumptions regarding the circumstances under which it is achieved and the market price of our common stock. As discussed in Note 3, we may repurchase up to 75% of the Subject to Vesting Shares, or 1,454,079 shares, for $0.001 per share and the number of First Milestone Shares issuable upon achievement of the First Milestone may be reduced by up to 75%, or from 1,000,000 to 250,000 shares. The changes in fair values of the contingent asset and contingent liability were primarily due to the increase in our stock price at March 31, 2012 relative to December 31, 2011.

6. Accrued Liabilities

Accrued liabilities at March 31, 2012 and December 31, 2011 were as follows:

	March 31, 2012	December 31, 2011
Accrued contracts and study expenses	$772,249	$ 880,608
Other accrued liabilities	213,844	239,808
Total accrued liabilities	$986,093	$1,120,416

7. Share-Based Compensation Expense

Estimated share-based compensation expense related to equity awards granted to our employees and non-employee directors for the three months ended March 31, 2012 and 2011 was as follows:

	Three months ended March 31, 2012	2011
Selling, general and administrative expense	$ 351,804	$ 137,176
Research and development expense	25,701	(1,858)
Share-based compensation expense	$ 377,505	$ 135,318

There were no employee or non-employee director stock options exercised during the three months ended March 31, 2012 or 2011. During the three months ended March 31, 2012, we granted no stock options to our employees or non-employee directors. During the three months ended March 31, 2011, we granted stock options to acquire an aggregate of 244,654 shares of our common stock to our employees and non-employee directors with an estimated weighted-average grant date fair value of $2.04 per share. At March 31, 2012, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was $3.4 million, which is expected to be recognized over a weighted-average period of 3.30 years.

8. Net Loss Per Common Share

Basic and diluted net loss per common share was calculated by dividing the net loss applicable to common stock for the period by the weighted-average number of common shares outstanding during the period, without consideration for our outstanding common stock equivalents because their effect would have been anti-dilutive. Common stock equivalents are included in the calculation of diluted earnings per common share only if their effect is dilutive. At March 31, 2012 and 2011, our outstanding common stock equivalents consisted of options and warrants to acquire the number of shares of our common stock set forth in the table below:

	March 31, 2012	2011
Options	2,892,132	648,391
Warrants	17,419,349	8,556,536
	20,311,481	9,204,927

9. Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards* ("ASU 2011-04"). ASU 2011-04 represents the converged guidance of the FASB and the International Accounting Standards Board on fair value measurement. The guidance clarifies how a principal market is determined, addresses the fair value measurement of instruments with offsetting market or counterparty credit risks, addresses the concept of valuation premise and highest and best use, extends the prohibition on blockage factors to all three levels of the fair value hierarchy and requires additional disclosures. ASU 2011-04 is effective for interim and annual periods beginning after December 15, 2011 and is applied prospectively. We adopted this guidance in the first quarter of 2012 and it did not have a material impact on our financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* ("ASU 2011-05"). The issuance of ASU 2011-05 is intended to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items reported in other comprehensive income. The guidance in ASU 2011-05 supersedes the presentation options in ASC Topic 220 and facilitates convergence of U.S. GAAP and International Financial Reporting Standards by eliminating the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity and requiring that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In December 2011, the FASB issued ASU No. 2011-12, *Comprehensive Income (Topic 820): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU No. 2011-05*, which defers the ASU 2011-05 requirement to present reclassification adjustments for each component of accumulated other comprehensive income in both net income and other comprehensive income on the face of the financial statements. ASU 2011-05 is effective for interim periods and years beginning after December 15, 2011. We adopted ASU 2011-05, as modified by ASU 2011-12, in the first quarter of 2012 by presenting a single continuous statement of operations and comprehensive income/(loss).

10. Supplementary Cash Flow Information

Non-cash investing and financing transactions presented separately from the condensed consolidated statements of cash flows for the three months ended March 31, 2012 and 2011 and for the period from inception (June 12, 1996) through March 31, 2012 are as follows:

	Three months ended March 31,		Inception (June 12, 1996) through
	2012	2011	March 31, 2012
Supplemental disclosures of cash flow information:			
Interest paid	$ —	$ —	$ 180,719
Supplemental disclosures of non-cash investing and financing activities:			
Issuance of warrants, common stock and preferred stock for:			
Conversion of notes payable and accrued interest	—	—	1,213,988
Prepaid services to consultants	—	—	1,482,781
Conversion of preferred stock	—	—	13,674
Acquisitions	—	—	30,666,878
Issuance of common stock to pay dividends	—	—	213,000
Financial advisor services in conjunction with financings	—	1,061,910	3,477,571
Underwriter commissions in conjunction with financings	—	—	766,784
Acquisition of treasury stock in settlement of a claim	—	—	34,737
Cancellation of treasury stock	—	—	(34,737)
Assumptions of liabilities in acquisitions	—	—	1,531,806
Fair value of contingent liabilities, net of contingent assets, recorded at acquisition date	—	—	784,419
Acquisition of license agreement for long-term debt	—	—	161,180
Unrealized (gain)/loss on short-term investments	(139)	—	3
Cashless exercise of warrants	—	—	4,312
Dividends accrued	—	—	621,040
Trade asset converted to available-for-sale asset	—	—	108,000
Dividends extinguished	—	—	408,240
Trade payable converted to note payable	—	—	83,948
Issuance of warrants for return of common stock	—	—	50,852
Detachable warrants issued with notes payable	—	—	450,000
Cumulative preferred stock dividends	—	—	13,502,403

11. Stockholders' Equity

Common Stock and Warrant Registered Direct Equity Financing

In January 2011, we completed a registered direct equity financing involving the issuance of units consisting of 8,184,556 shares of our common stock, 5-year warrants to purchase up to an aggregate of 2,046,139 shares of our common stock and 1-year warrants to purchase up to an aggregate of 2,046,139 shares of our common stock. The gross proceeds of this financing were $22.5 million, and we received $21.0 million in net proceeds after deducting the fees and expenses of our placement agent and our other offering expenses. The 1-year warrants expired unexercised in January 2012. We may receive up to $5.6 million of additional proceeds from the exercise of the 5-year warrants. The exercise price of the warrants is $2.75 per share. Subject to certain beneficial ownership limitations, the 5-year warrants are exercisable any time on or before January 11, 2016.

Common Stock and Warrant Underwritten Public Offering

In November 2011, we completed an underwritten public offering of 21,250,000 shares of our common stock and warrants to purchase up to 10,625,000 additional shares of our common stock. These securities were offered and sold to the public in multiples of a fixed combination consisting of one share of our common stock and a warrant to purchase up to 0.5 of a share of our common stock. The gross proceeds from this financing were $17.0 million, and we received $15.6 million in net proceeds after deducting the underwriting commissions and our other offering expenses. We may receive up to $11.7 million of additional proceeds from the exercise of the warrants issued to investors in this financing. The exercise price of the warrants is $1.10 per share. Subject to certain beneficial ownership limitations, the warrants are exercisable at any time on or before November 16, 2016.

We also issued warrants to purchase up to 1,062,500 shares of our common stock at an exercise price of $1.00 per share to the underwriter of the offering and its designees as additional underwriting compensation. These compensation warrants are exercisable at any time on or before April 1, 2015.

Warrants

At March 31, 2012, outstanding warrants to purchase shares of common stock are as follows:

Warrants		Exercise Price	Expiration Date
432,429	$	56.5000	July 2012
99,696	$	11.9125	June 2014
498,488	$	8.7475	July 2012
144,000	$	5.8750	October 2014
19,007	$	4.4750	July 2014
14,183	$	4.0625	August 2014
36,071	$	3.7500	June 2014
216,000	$	3.6700	October 2014
1,816,608	$	3.6500	May 2015
409,228	$	3.4400	April 2015
2,046,139	$	2.7500	January 2016
1,062,500	$	1.0000	April 2015
10,625,000	$	1.1000	November 2016
17,419,349			

12. Income Taxes

Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, limit our ability to use net operating loss carry forwards and R&D tax credit carry forwards ("tax attribute carry forwards") to offset future taxable income if we experience a cumulative change in ownership of more than 50% within a three-year testing period. During the first quarter of 2012, we completed a formal study and determined ownership changes within the meaning of IRC Section 382 had occurred during 2010 and 2011, with the most recent as a result of our November 2011 common stock and warrant financing. As a result of these ownership changes, upon application of limitations prescribed by IRC Section 382, we may be ineligible to utilize any of the tax attribute carry forwards we had accumulated as of November 11, 2011 to offset future taxable income, and we have adjusted our tax attribute carry forwards accordingly. Through further analysis in the future we may determine that a small amount of these tax attribute carry forwards can be utilized. As the tax attribute carry forwards accumulated as of November 11, 2011 were fully offset by a valuation allowance, a corresponding reduction in the Company's valuation allowance has also been recorded, resulting in no income tax impact.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and related notes appearing elsewhere in this report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those identified under "Forward Looking Statements" below and those discussed in Item 1A (Risk Factors) of Part II of this report. All trademarks, service marks or trade names appearing in this report 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.

Overview

We are a biopharmaceutical company focused on developing proprietary product candidates. Our lead product candidate is ANX-188, a rheologic, antithrombotic and cytoprotective agent that improves microvascular blood flow and has potential application in treating a wide range of diseases and conditions, such as complications arising from sickle cell disease.

We have devoted substantially all of our resources to research and development, or R&D, and to acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue and we have incurred significant losses since inception. We incurred a loss from operations of $4.2 million for the three months ended March 31, 2012. Our cash, cash equivalents and short-term investments were $46.0 million at March 31, 2012.

We acquired ANX-188 (purified poloxamer 188) in April 2011 as part of our acquisition of SynthRx, Inc. and are focusing our resources primarily on its development. We believe ANX-188 is a late-stage product candidate that may have numerous applications for the treatment of diseases and conditions resulting from microvascular-flow abnormalities. Initially, we are developing ANX-188 to treat patients suffering from complications arising from sickle cell disease, and we plan to initiate a phase 3 clinical study of ANX-188 in patients with sickle cell disease in 2012. In addition, we plan to conduct a number of smaller-scale clinical studies to further assess the efficacy, safety and tolerability of ANX-188 in sickle cell disease and other indications, and expect these studies to overlap the planned phase 3 study.

With respect to ANX-514 (docetaxel for injectable emulsion), our detergent-free reformulation of Taxotere® (docetaxel), we are conducting manufacturing development activities to support production of clinical trial material. However, we currently do not plan to initiate any clinical studies of ANX-514 during 2012.

We anticipate that our cash, cash equivalents and short-term investments as of March 31, 2012 will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, we may pursue development activities for our product candidates, at levels or on timelines, or we may incur unexpected expenses, that shorten the period through which our operating funds will sustain us. We expect to incur significant and increasing losses for the next several years as we advance our product candidates through clinical studies and other development activities and seek regulatory approval to commercialize such product candidates. We will need additional financing to support our planned operating activities. In addition, we may seek to expand our product pipeline through acquisition of additional product candidates and/or technologies. For the foreseeable future, we plan to seek to fund our operations through public or private equity and/or debt financings. We may also seek to raise funds through strategic relationships and/or licensing transactions. Adequate additional financing may not be available to us on acceptable terms or on a timely basis, or at all. Our failure to raise capital as and when needed would have a material and adverse effect on our financial condition and ability to pursue our business strategy.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon consolidated financial statements and condensed consolidated financial statements that we have prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make a number of estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses in the condensed consolidated financial statements and accompanying notes included in this report. On an ongoing basis, we evaluate these estimates and assumptions, including those related to determination of the fair value of contingent consideration, goodwill and acquired in-process research and development, or IPR&D, and recognition of expenses for clinical study accruals and share-based compensation. We base our estimates on historical information, when available, and assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policies to be critical to the estimates used in the preparation of our financial statements. The following is not intended to be a comprehensive discussion of all of our significant accounting policies. See the note accompanying our consolidated financial statements appearing in our most recent annual report on Form 10-K for a summary of all of our significant accounting policies and other disclosures required by U.S. GAAP.

Accrued Research and Development Expenses. As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. Many of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The majority of our accrued expenses relate to R&D services and related expenses. Examples of estimated accrued R&D expenses include:

- fees paid to contract manufacturing organizations, or CMOs, in connection with process development activities and production of nonclinical and clinical trial material;
- fees paid to vendors in connection with nonclinical development activities;
- fees paid to consultants for regulatory-related advisory services;
- fees paid to contract research organizations, or CROs, in connection with clinical studies; and
- fees paid to investigative sites and investigators in connection with clinical studies.

We base our expenses related to CMOs and CROs on our estimates of the services received and efforts expended pursuant to purchase orders or contracts with multiple service providers that we engage to manufacture our clinical trial material or conduct and manage clinical studies on our behalf. The financial terms of our arrangements with our CMOs and CROs are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful completion of specified process development activities or the successful enrollment of patients and the completion of clinical study milestones. In accruing these service fees, we estimate, as applicable, the time period over which services will be performed (e.g., enrollment of patients, activation of clinical sites, etc.). If the actual timing varies from our estimate, we adjust the accrual accordingly. In addition, there may be instances in which payments made to service providers will exceed the level of services provided and result in a prepayment of R&D expense, which we report as an asset. The actual costs and timing of clinical studies and research-related manufacturing are uncertain and subject to change depending on a number of factors. Differences between actual costs of these services and the estimated costs that we have accrued in a prior period are recorded in the subsequent period in which the actual costs become known to us. Historically, these differences have not resulted in material adjustments, but such differences may occur in the future and have a material impact on our consolidated results of operations or financial position.

Business Combinations. We accounted for the acquisition of SynthRx in accordance with Accounting Standards Codification, or ASC, Topic 805, *Business Combinations*, which requires the purchase price to be measured at fair value. The purchase price consists entirely of shares of our common stock and includes contingent consideration, which becomes vested or issuable, as applicable, upon achievement of development and regulatory milestones related to ANX-188. We calculated the total purchase price by determining the probability-weighted fair value of the shares of our common stock issued, issued subject to repurchase and issuable to the former SynthRx stockholders as of April 8, 2011, the acquisition date. The probability and timing inputs related to the vesting and issuance events were based on estimates and assumptions regarding development of ANX-188, which are highly judgmental due to the inherent unpredictability of drug development, particularly by development-stage companies such as ours. We then allocated the total purchase price to the tangible assets and intangible assets acquired, including IPR&D, and liabilities assumed based on our estimates of their respective fair values as of the acquisition date. We recognized goodwill equal to the excess of the purchase price over the fair values of the tangible and IPR&D assets acquired and liabilities assumed.

The determination and allocation of the purchase price requires us to make significant estimates and assumptions, particularly with respect to the fair values of the contingent consideration and acquired IPR&D. We believe the fair values assigned to the contingent consideration and acquired IPR&D are based on reasonable estimates and assumptions given the available facts and circumstances as of the acquisition date. However, these calculations are highly judgmental and it is possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range of alternative estimated amounts. For instance, we used a discounted cash flow model to determine the fair value of contingent consideration, though other methodologies could have been used. Discounted cash flow models require the use of significant estimates and assumptions, including, but not limited to: the probability of clinical and regulatory success for a product candidate considering its stage of development; the time and resources needed to complete the development and approval of a product candidate, including the inherent difficulties and uncertainties in developing a product candidate, such as obtaining approvals from the U.S. Food and Drug Administration, or FDA, and other regulatory agencies; estimated cash flows projected following the approval of a product candidate in development; the commercial life of the potential approved product and associated risks; and risk associated with uncertainty regarding achievement of the milestone events and, with respect to the First Milestone (defined below), the circumstances under which it is achieved. We estimated the time needed to complete the development and approval of ANX-188 based on assumptions regarding its stage of development as of the acquisition date and resources needed to complete its development and approval, taking into account the inherent difficulties and uncertainties in developing product candidates in general and ANX-188 in particular. Changes to any of these estimates and assumptions could significantly impact the fair values recorded for the assets acquired and liabilities assumed in our acquisition of SynthRx, resulting in significant charges to our operations. In addition, unanticipated events and circumstances may occur which may affect the accuracy or validity of such assumptions, estimates or actual results. The “First Milestone” refers to the dosing of the first patient in a phase 3 clinical study that the FDA has indicated may be sufficient to support approval of a new drug application covering the use of purified poloxamer 188 for the treatment of sickle cell crisis in children, as described in more detail in Note 3, “Acquisition of SynthRx,” of the Notes to the Condensed Consolidated Financial Statements (Unaudited) included in this report.

Asset and Liability for Contingent Consideration. Our contingent asset and contingent liability are related to our acquisition of SynthRx and the amount of the purchase price, payable in shares of our common stock, that is subject to repurchase and issuance, respectively, contingent upon achievement of the First Milestone and the circumstances under which it is achieved. We remeasure the fair value of this contingent consideration as of the end of each fiscal quarter. Our determination of fair value is highly judgmental in that the number of shares that we may repurchase (up to 1,454,079 shares) and the number of shares we may be required to issue (from 250,000 to 1,000,000 shares) reflect our estimates based on assumptions regarding the probability and circumstances of achievement of the First Milestone and these estimates have changed since the acquisition date and may be different in the future. We believe our estimates and assumptions are reasonable based on available facts and circumstances as of each measurement date. The fair value of this contingent consideration is also based on the market price of our common stock. As a proxy, we use the last reported sale price of our common stock on the NYSE Amex equities market on the measurement date (i.e., the last trading day of each quarter), which, given the historic and expected future volatility of our stock price, likely will be different and may vary considerably from one measurement date to the next. Changes in the fair value of this contingent consideration are recognized in earnings, as transaction-related expenses, until the contingent consideration arrangement is settled.

Goodwill and Acquired IPR&D. In accordance with ASC Topic 350, *Intangibles – Goodwill and Other*, our goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment annually and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying amount may be impaired. We perform our annual impairment testing on September 30 of each year. Pursuant to Accounting Standards Update No. 2011-08, *Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment*, or ASU No. 2011-08, we first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more likely than not (that is, a likelihood of more than 50%) that goodwill is impaired, and, unless we determine that it is more likely than not goodwill is impaired, we do not perform the two-step quantitative impairment test otherwise required under ASC Topic 350. ASU No. 2011-08 does not apply to acquired IPR&D testing. Our determinations as to whether, and, if so, the extent to which, goodwill and acquired IPR&D become impaired are highly judgmental and based on assumptions regarding our projected future operating results, changes in the manner of our use of the acquired assets or our overall business strategy and regulatory, market and economic environment and trends.

Share-based Compensation Expenses. We account for share-based compensation awards granted to employees, including non-employee members of our board of directors, in accordance with ASC 718, *Compensation — Stock Compensation*. Compensation expense for all share-based awards is based on the estimated fair value of the award on its date of grant and recognized on a straight-line basis over its vesting period. As share-based compensation expense is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. We estimate forfeitures at the time of grant based on historical experience and revise our estimates in subsequent periods if actual forfeitures differ from those estimates. Although share-based compensation expense can be significant to our consolidated financial statements, it is not related to the payment of any cash by us.

We estimate the grant date fair value of a stock option award using the Black-Scholes option-pricing model, or Black-Scholes model. In determining the grant date fair value of a stock option award under the Black-Scholes model, we must make a number of assumptions, including the term of the award, the volatility of the price of our common stock over the term of the award, the risk-free interest rate and estimated forfeiture rate. Changes in these or other assumptions could have a material impact on the compensation expense we recognize.

Results of Operations – Overview

We operate our business and evaluate our company on the basis of a single reportable segment, which is the business of developing proprietary product candidates.

Revenue

We have not generated any revenue from product sales to date, and we do not expect to generate revenue from product sales until such time, if any, that we have obtained approval from a regulatory agency to sell one or more of our product candidates, which we cannot predict with certainty will occur.

Operating Expenses

Research and Development Expenses. We maintain and evaluate our R&D expenses by the type of cost incurred rather than by project. We do this primarily because we outsource a substantial portion of our work and our R&D personnel and consultants work across multiple programs rather than dedicating their time to one particular program. We began maintaining such expenses by type on January 1, 2005. We categorize our R&D expenses as external clinical study fees and expenses, external nonclinical study fees and expenses, personnel costs and share-based compensation expense. The major components of our external clinical study fees and expenses are fees and expenses related to CROs and clinical study investigative sites and investigators. The major components of our external nonclinical study fees and expenses are fees and expenses related to preclinical studies and other nonclinical testing, research-related manufacturing, including process development activities, quality assurance and regulatory affairs services. Research-related manufacturing expenses include costs associated with purchasing active pharmaceutical ingredient (API), conducting process development activities, producing clinical trial material, producing material for stability testing to support regulatory filings, related labeling, testing and release, packaging and storing services and related consulting fees. Personnel costs relate to employee salaries, benefits and related costs.

A general understanding of drug development is critical to understanding our results of operations and, particularly, our R&D expenses. Drug development in the U.S. and most countries throughout the world is a process that includes several steps defined by the FDA and similar regulatory authorities in foreign countries. The FDA approval processes relating to new drug products differ depending on the nature of the particular product candidate for which approval is sought. With respect to any product candidate with active ingredients not previously approved by the FDA, a prospective drug product manufacturer is required to submit a new drug application, or NDA, that includes complete reports of pre-clinical, clinical and laboratory studies and extensive manufacturing information to demonstrate the product candidate's safety and effectiveness. Generally, an NDA must be supported by at least phase 1, 2 and 3 clinical studies, with each study typically more expensive and lengthy than the previous study.

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

- the number of studies necessary to demonstrate the safety and efficacy of a product candidate;
- the number of patients who participate in the clinical studies;
- the number and location of sites included in clinical studies and the rate of site approval for in each study;
- the rates of patient recruitment and enrollment;
- the ratio of randomized to evaluable patients;
- with respect to bioequivalence or comparative studies, the availability and cost of reference or control product in the jurisdiction of each site;
- the duration of patient treatment and follow-up;
- the time and cost of process development activities related to the manufacture of our product candidates and key components thereof;
- the costs of manufacturing our product candidates;
- the time and cost of stability studies, including the need to identify critical parameters, methods to evaluate and test these parameters and validation of such methods and tests; and
- the costs, requirements, timing of and the ability to secure regulatory approvals.

The difficult process of seeking regulatory approvals for our product candidates and compliance with applicable regulations requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our R&D expenditures to increase and, in turn, have a material and unfavorable effect on our results of operations. We anticipate that we will make determinations as to which of our R&D programs to pursue and how much funding to direct to each R&D program on an ongoing basis in response to the scientific, nonclinical and clinical success of the underlying product candidate, our ongoing assessment of its market potential and our available resources.

While many of our R&D expenses are transacted in U.S. dollars, certain significant expenses are required to be paid in foreign currencies and expose us to transaction gains and losses that could result from changes in foreign currency exchange rates. In particular, we may be obligated to pay in foreign currencies for the services of third-party manufacturers of and component suppliers for our product candidates. Our exposure to currency risk may increase in connection with the manufacture of clinical trial material and, if and as applicable, product for commercial sale. We include realized gains and losses from foreign currency transactions in operations as incurred.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses consist primarily of salaries, benefits and related costs for personnel in executive, finance and accounting, legal and market research functions, professional and consulting fees for accounting, legal, investor relations, business development, market research, human resources and information technology services. Other SG&A expenses include facility lease and insurance costs.

Transaction-Related Expenses. Transaction-related expenses consist of legal, accounting, financial and business development advisory fees associated with the evaluation of potential acquisition targets and execution of acquisition transactions, including our acquisition of SynthRx. Transaction-related expenses also include any changes in the fair value of the contingent asset and contingent liability related to our acquisition of SynthRx, which we remeasure as of the end of each quarter.

Interest and Other Income/(Expense). Interest and other income/(expense) includes interest income, interest expense, unrealized gains and losses due to changes in the exchange rates on assets and liabilities denominated in foreign currencies, realized gains and losses from foreign currency transactions and other non-operating gains and losses.

Comparison of Three Months Ended March 31, 2012 and 2011

Revenue. We recognized no revenue for the three months ended March 31, 2012 or 2011.

R&D Expenses. Our R&D expenses for the three months ended March 31, 2012 consisted primarily of costs associated with external nonclinical study activities, which largely consisted of research-related manufacturing costs for ANX-188 and ANX-514. The following table summarizes our consolidated R&D expenses by type for each of the periods presented:

	Three months ended March 31,		January 1, 2005 through March 31,
	2012	2011	2012
External clinical study fees and expenses	$ 251,050	$ 90,233	$25,020,348
External nonclinical study fees and expenses	1,547,895	453,609	33,015,162
Personnel costs	385,808	69,309	11,746,849
Share-based compensation expense	25,701	(1,858)	2,923,146
Total	$ 2,210,454	$ 611,293	$72,705,505

R&D expenses increased by $1.6 million, or approximately 261.6%, to $2.2 million for the three months ended March 31, 2012, compared to $0.6 million for the same period in 2011. This increase was due to a $1.1 million increase in external nonclinical study fees and expenses, a $0.3 million increase in personnel costs and a $0.2 million increase in external clinical study fees and expenses. The increase in external nonclinical study fees and expenses was primarily related to increased research-related manufacturing expenses of $0.9 million for ANX-188 and $0.5 million for ANX-514, offset by a $0.3 million decrease in research-related manufacturing expenses related to Exelbine™. The increase in personnel costs was primarily related to increased headcount. The increase in external clinical study fees and expenses was primarily related to increased clinical consulting expenses of $0.2 million for ANX-188.

Selling, General and Administrative Expenses. SG&A expenses increased by $0.4 million, or approximately 30.0%, to $2.0 million for the three months ended March 31, 2012, compared to $1.6 million for the same period in 2011. This increase resulted from a $0.2 million increase in personnel costs, mainly due to increased headcount, and a $0.2 million increase in share-based compensation expense.

Transaction-Related Expenses. Transaction-related expenses were negative $0.1 million for the three months ended March 31, 2012, compared to $0.8 million for the same period in 2011. We recognized negative transaction-related expenses for the three months ended March 31, 2012 due to changes in the fair values of the contingent asset and contingent liability related to our consideration for the SynthRx acquisition at March 31, 2012 relative to December 31, 2011. The net $0.1 million reduction to transaction-related expenses was primarily due to the increase in our stock price at March 31, 2012 relative to December 31, 2011. Transaction-related expenses for the three months ended March 31, 2011 consisted of $0.8 million related to legal, accounting, financial and business development advisory fees associated with the evaluation of potential acquisition targets, including SynthRx.

Interest Income. Interest income amounted to $29,378 for the three months ended March 31, 2012, compared to $32,871 for the same period in 2011. The small decrease in interest income for the three months ended March 31, 2012 was attributable primarily to lower interest rates on invested balances in 2012 as compared to 2011.

Net Loss. Net loss applicable to common stock was $4.2 million, or $0.09 per share, for the three months ended March 31, 2012, compared to net loss applicable to common stock of $3.0 million, or $0.13 per share, for the same period in 2011.

Liquidity and Capital Resources

We have a history of annual losses from operations and we have funded our operations primarily through sales of our equity securities. We had a loss from operations of $4.2 million for the three months ended March 31, 2012 and cash, cash equivalents and short-term investments of approximately $46.0 million as of March 31, 2012. Our short-term investments at March 31, 2012 consisted entirely of FDIC-insured certificates of deposit.

We may receive up to $0.8 million, $4.4 million, $6.6 million, $5.6 million and $11.7 million of additional net proceeds from the exercise of warrants issued in the registered direct equity financings we completed in October 2009, January and May 2010 and January 2011 and the underwritten public offering we completed in November 2011, respectively; however, the exercise of these warrants is subject to certain beneficial ownership limitations. We may receive up to $4.8 million of additional net proceeds from the exercise of warrants issued to our placement agent and underwriter, and its designees, as additional consideration for services in connection with certain of our equity financings. See Note 11, “Stockholders’ Equity – Warrants,” of the Notes to the Condensed Consolidated Financial Statements (Unaudited) in this report for a list of shares of our common stock underlying warrants outstanding as of March 31, 2012 and their associated exercise prices and expiration dates.

For a discussion of our liquidity and capital resources outlook, see “Management Outlook” below.

Operating activities. Net cash used in operating activities was $4.4 million for the three months ended March 31, 2012 compared to $2.4 million for the same period in 2011. The increase in cash used in operating activities was primarily due to a higher net loss for the three months ended March 31, 2012 compared to the same period in 2011 ($1.1 million), changes in assets and liabilities ($1.0 million) primarily due to a decrease in accounts payable and accrued liabilities related to the timing of payments made and expenses incurred for evaluation of potential acquisition targets, Exelbine commercial-readiness activities and research-related manufacturing expenses for ANX-188 and ANX-514, and a gain on the change in fair value of contingent consideration related to our SynthRx acquisition ($0.1 million), offset by increased share-based compensation expense ($0.2 million).

Investing activities. Net cash used in investing activities was $4.1 million for the three months ended March 31, 2012 compared to $2,223 for the same period in 2011. The difference was primarily due to an increase of $5.3 million in purchases of certificates of deposit and $0.2 million in purchases of property and equipment, offset by $1.4 million in maturities of certificates of deposits.

Financing activities. Net cash of $47,742 was used in financing activities during the three months ended March 31, 2012 compared to net cash of $21.0 million provided by financing activities for the same period in 2011. The net cash used in financing activities for the three months ended March 31, 2012 resulted from expenses associated with filing a shelf registration statement. The cash provided by financing activities for the three months ended March 31, 2011 reflects net proceeds of $21.0 million from our January 2011 registered direct equity financing.

Management Outlook

We anticipate that our cash, cash equivalents and short-term investments as of March 31, 2012 will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, our future capital uses and requirements will be affected by numerous forward-looking factors that, depending on their actual outcome, could shorten or extend the period through which our operating funds will sustain us. These factors include, but are not limited to: the scope, prioritization and number of development programs we pursue; the rate of progress and costs of development and regulatory approval activities associated with our product candidates, including conducting manufacturing process development activities, manufacturing clinical trial material and initiating and conducting clinical studies; the extent to which we acquire new product candidates and/or technologies; the extent to which we partner or collaborate with third parties to develop, seek regulatory approval of and commercialize our product candidates, or sell or license our product candidates to others; and whether any of our product candidates for which we receive regulatory approval, if any, achieve broad market acceptance. In addition, we have a small workforce and rely on third parties to perform many essential services for us, including the manufacture of clinical trial material, the conduct of clinical studies and regulatory submissions related to product approval. The timing and extent to which we increase our workforce is difficult to predict as it will be influenced by the rate of progress of development and regulatory approval of our product candidates and whether we partner them, as well as the extent to which we acquire and develop new product candidates and/or technologies. Increases in the size of our workforce would impact the period through which our operating funds will sustain us.

We are focusing our resources primarily on the development of ANX-188 and plan to initiate a phase 3 clinical study of ANX-188 in 2012 for the treatment of patients suffering from complications associated with sickle cell disease. Currently, we are focused on finalizing the trial design and, in parallel, working with third-party manufacturers on process development and production of clinical trial material. In addition, we plan to conduct a number of smaller-scale clinical studies to further assess the efficacy, safety and tolerability of ANX-188 in sickle cell disease and other indications, and expect these studies to overlap the planned phase 3 study. We have and may continue to increase our workforce in connection with our development of ANX-188. We plan to pursue partnering and other strategic opportunities for development of ANX-188 outside of the U.S. and for additional indications in the U.S.

With respect to ANX-514, we are conducting manufacturing development activities to support production of clinical trial material. However, we currently do not plan to initiate any clinical studies of ANX-514 during 2012. As we investigate the optimal development path for ANX-514, if we determine the anticipated capital requirements associated with it are not financially justifiable, we may determine to discontinue this program. We are continuing to pursue partnering and other strategic opportunities for ANX-514, including its sale or exclusive license to a third party.

Although our current focus is on the development of ANX-188, from time to time, we may evaluate pipeline expansion opportunities that we believe will increase the long-term value of our company. The process of identifying and evaluating various opportunities can be lengthy and complex and divert management's attention from our current development programs. We have limited resources to identify, evaluate and negotiate potential transactions, and supplementing our current resources to complete one or more transactions may be costly. We expect that our capital requirements would increase in future periods if we were to expand our product pipeline.

Although we anticipate that our cash, cash equivalents and short-term investments as of March 31, 2012 will be sufficient to fund our currently planned level of operations for at least the next 12 months, we expect to incur significant and increasing losses for the next several years as we advance our product candidates through clinical studies and other development activities and seek regulatory approval to commercialize such product candidates. We will need additional financing to support our operating activities. In addition, we may seek to expand our product pipeline through acquisition of additional product candidates and/or technologies. For the foreseeable future, we plan to seek to fund our operations through public or private equity and/or debt financings. We may also seek to raise funds through strategic relationships and/or licensing transactions. Even though we were able to raise significant funds in the recent past through equity financings, adequate additional financing may not be available to us in the future on acceptable terms or on a timely basis or at all. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and ability to pursue our business strategy.

Recent Accounting Pronouncements

See Note 9, "Recent Accounting Pronouncements," of the Notes to the Condensed Consolidated Financial Statements (Unaudited) in this report for a discussion of recent accounting announcements and their effect, if any, on us.

Forward Looking Statements

This report, particularly Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations," includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including statements we make regarding our business strategy, expectations and plans, our objectives for future operations and our future financial position. Forward-looking statements can be identified by words such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "expect," "indicate" and similar expressions. Examples of forward-looking statements include, but are not limited to, statements we make regarding activities, timing and costs related to developing and seeking regulatory approval for our product candidates, seeking to partner or collaborate with third parties with respect to the development and commercialization of our product candidates, the sale or exclusive license of one or more of our product candidate programs, raising additional capital, expanding our product pipeline and our belief that we have sufficient liquidity to fund our currently planned level of operations for at least the next 12 months. The foregoing is not an exclusive list of all forward-looking statements we make.

We have based the forward-looking statements we make on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. The forward-looking statements we make are subject to risks and uncertainties that could cause our actual results to differ materially from those reflected in such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to the following:

- our ability, or that of a future partner, to successfully develop and obtain regulatory approval for, and then successfully commercialize our product candidates in the U.S. and/or elsewhere;
- our ability to obtain additional funding to develop our product candidates on a timely basis or on acceptable terms, or at all;
- the potential for us to delay, reduce or discontinue current and/or planned development activities, partner our product candidates at inopportune times or pursue less expensive but higher-risk development paths if we are unable to raise sufficient additional capital as needed;
- delays in the commencement or completion of a clinical study or manufacturing and regulatory activities related to our product candidates;
- suspension or termination of clinical study;
- the ability of our product candidates to demonstrate acceptable safety and efficacy in clinical studies;
- our ability to maintain our relationships with the single-source third-party manufacturers and suppliers for our product candidates and certain of their component materials and the ability of such manufacturers and suppliers to successfully and consistently meet our manufacturing and supply requirements;
- the satisfactory performance of third parties, including CROs, on whom we rely significantly to conduct our nonclinical testing, clinical studies and other aspects of our development programs;
- the extent of market acceptance of any of our product candidates for which we receive regulatory approval;
- the extent to which we acquire new technologies and/or product candidates and our ability to integrate them successfully into our operations;
- the potential that we may enter into one or more development and/or commercial partnerships or other strategic transactions relating to our product candidates, and the terms of any such transactions;
- the extent to which we increase our workforce and our ability to attract and retain qualified personnel and manage growth;
- competition in the marketplace for our products, if any are approved;
- our ability to protect our intellectual rights with respect to our product candidates and proprietary technology;
- claims against us for infringing the proprietary rights of third parties;

- healthcare reform measures and reimbursement policies that, if not favorable to our product candidates, could hinder or prevent our products' commercial success;
- undesirable side effects that our product candidates may cause;
- potential product liability exposure and, if successful claims are brought against us, liability for a product or product candidate;
- our ability to maintain compliance with NYSE Amex continued listing standards and maintain the listing of our common stock on the NYSE Amex equities market or another national securities exchange; and
- the other factors that are described in Item 1A (Risk Factors) of Part II of this report.

Except as required by law, we do not intend to update the forward-looking statements discussed in this report publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

In light of these risks and uncertainties and our assumptions, the forward-looking events and circumstances discussed in this report and in the documents incorporated in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in such forward-looking statements. Accordingly, you are cautioned not to place undue reliance on such forward-looking statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Under rules and regulations promulgated by the Securities and Exchange Commission, or SEC, because the aggregate worldwide market value of our common stock held by non-affiliates was more than $75 million, but less than $700 million, as of June 30, 2011, the last business day of our most recently completed second fiscal quarter, we are considered to be an "accelerated filer." We were considered to be a "smaller reporting company" when we determined our filing status for purposes of our annual report on Form 10-K for our fiscal year ended December 31, 2010. SEC rules and regulations provide that a smaller reporting company transitioning to the larger reporting system, as we are doing this year, may finish reporting as a smaller reporting company for the rest of the fiscal year, including in its annual report on Form 10-K, and is not required to satisfy the larger reporting company disclosure requirements until the first quarterly report for the new fiscal year following the determination date. Accordingly, we were not required to and did not provide the quantitative and qualitative disclosures about market risk required by Item 305 of Regulation S-K in our annual report on Form 10-K for our fiscal year ended December 31, 2011. As a result, we are not required to provide the quantitative and qualitative disclosures about market risk required by Item 305 of Regulation S-K in this report.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2012. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of March 31, 2012 these disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

In the normal course of business, we may become subject to lawsuits and other claims and proceedings. Such matters are subject to uncertainty and outcomes are often not predictable with assurance.

Item 1A. Risk Factors

Our financial position, results of operations and cash flows are subject to various risks, many of which are not exclusively within our control, that may cause actual performance to differ materially from historical or projected future performance. We urge investors to consider carefully the risks described below, together with all of the information in this quarterly report and our other public filings, before making investment decisions regarding our common stock. Each of these risk factors, as well as additional risks not presently known to us or that we currently deem immaterial, could adversely affect our business, operating results, financial condition and the value of an investment in our common stock.

We have marked with an asterisk (*) the title of those risk factors below that reflect material changes from the risk factors included in our annual report on Form 10-K for the year ended December 31, 2011.

RISKS RELATED TO OUR BUSINESS

Risks Related to Our Capital Requirements, Finances and Operations

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

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

The success of our business currently is dependent primarily on the success of ANX-188 and this product candidate may not receive regulatory approval or be successfully commercialized.*

We currently have no products for sale and we are focusing our resources primarily on the development of ANX-188. Accordingly, the success of our business currently depends primarily on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize this product candidate and our efforts in this regard may prove unsuccessful. ANX-188 requires considerable additional development, including a phase 3 clinical study and significant manufacturing activities prior to commencing clinical studies, all of which require us to expend significant resources and with which we have limited experience. We also are developing ANX-514, which requires significant additional development as well. Our product candidates, including ANX-188, may not be successful in clinical studies or, even if successful in clinical studies, may not receive regulatory approval in a timely manner, or at all. If any of our product candidates is approved by the FDA or any foreign regulatory agency, our ability to generate revenues from these products will depend in substantial part on the extent to which they are accepted by the medical community and reimbursed by third-party payors as well as our ability to market and sell them and ensure that our third-party manufacturers produce sufficient quantities of the products to meet commercial demand, if any.

Our financial resources are limited, we will need to obtain additional funding to pursue our current business strategy and we may not be able to obtain such funding on a timely basis or on commercially reasonable terms, if at all.

We have experienced significant losses in acquiring and funding the development of our product candidates, accumulating net losses totaling approximately $175.8 million as of March 31, 2012, and we expect to continue to incur substantial operating losses for the foreseeable future, even if we or a future partner of ours is successful in advancing our product candidates to market. We do not expect to generate cash flows from sales of our products unless and until our products are approved for marketing, the occurrence and timing of which we cannot predict accurately.

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

- the costs of seeking regulatory approval for our product candidates, including the number and size of clinical studies necessary to demonstrate the safety and efficacy of a product candidate and the process development, scale-up and other manufacturing and stability activities, and other work required to achieve such approval, as well as the timing of such activities and approval;
- the scope, prioritization and number of development programs we pursue and the rate of progress and costs with respect to each such program;
- the extent to which we invest in or acquire new technologies, product candidates, products or businesses and the development requirements with respect to any acquired programs;
- the timing and terms of any collaborative, licensing and other strategic arrangements that we may establish;
- the costs related to developing, acquiring and/or contracting for sales, marketing and distribution capabilities and regulatory compliance capabilities, if we obtain regulatory approval for a product candidate and commercialize it without a partner;
- the extent to which we increase our workforce and the costs involved in recruiting, training and incentivizing new employees;
- the effect of competing technological and market developments; and
- the cost involved in establishing, enforcing or defending patent claims and other intellectual property rights.

We anticipate that our cash, cash equivalents and short-term investments, which were approximately $46.0 million as of March 31, 2012, will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, we may determine to grow our organization and/or pursue development activities for our product candidates at levels or on timelines, or we may incur unexpected expenses, that shorten the period through which our current operating funds will sustain us. We may also seek to expand our product pipeline through acquisition of additional product candidates and/or technologies and the cost to acquire and develop such new product candidates and/or technologies may shorten the period through which our current operating funds will sustain us. For the foreseeable future, we plan to fund our operations through public or private equity and debt financings. We may also seek to raise funds through collaborations, licensing arrangements or other strategic or partnering transactions. However, adequate additional funding may not be available on acceptable terms or on a timely basis, if at all. 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. We believe global economic conditions, including the continued volatility of U.S. and international equity markets, may adversely impact our ability to raise additional capital.

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

Historically, we have raised capital through the sale of our equity securities. Since June 2009, we have completed seven equity financings under “shelf” registration statements on Form S-3. Using a shelf registration statement on Form S-3 to raise additional capital is generally more timely and cost effective than other means, such as conducting an offering under a Form S-1 registration statement. However, in the future, our ability to raise capital using a shelf registration statement may be limited by, among other things, current SEC rules and regulations. Under current SEC rules and regulations, we must meet certain requirements to use a Form S-3 registration statement to raise capital without restriction as to the amount of the market value of securities sold thereunder. One such requirement is that the market value of our outstanding common stock held by non-affiliates, or public float, be at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3. If we do not meet that requirement, then the aggregate market value of securities sold by us or on our behalf under the Form S-3 during in any 12-month period is limited to an aggregate of one-third of our public float. Moreover, even if we meet the public float requirement at the time we file a Form S-3, SEC rules and regulations require that we periodically re-evaluate the value of our public float, and if, at a re-evaluation date, our public float is less than $75.0 million, we would become subject to the one-third of public float limitation described above.

In addition, under current SEC rules and regulations, in order to use a Form S-3 registration statement if (i) we seek to conduct a primary offering and our public float is not at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3 or (ii) we seek to register the resale of our securities by persons other than us (i.e., a resale offering), then our common stock must be listed and registered on a national securities exchange. While currently our common stock is listed on the NYSE Amex equities market, there can be no assurance that we will be able to maintain such listing. The NYSE Amex reviews the appropriateness of continued listing of any issuer that falls below the exchange's continued listing standards. Previously, including during part of 2010, we were not in compliance with certain NYSE Amex continued listing standards and were at risk of having our common stock delisted from the NYSE Amex equities market. For additional information regarding this risk, see the risk factor below titled "If we are unable to maintain compliance with NYSE Amex continued listing standards, our common stock may be delisted from the NYSE Amex equities market, which would likely cause the liquidity and market price of our common stock to decline."

Our ability to timely raise sufficient additional capital also may be limited by the NYSE Amex's stockholder approval requirements 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 then outstanding common stock, unless the transaction is considered a "public offering" by the NYSE Amex staff. Based on the number of shares of our outstanding common stock as of May 1, 2012 and on the closing price per share of our common stock on such date, which was $0.60, we could not raise more than approximately $5.7 million without obtaining 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. In addition, certain prior sales by us may be aggregated with any offering we may propose in the future, further limiting the amount we could raise in any future offering that is not considered a public offering by the NYSE Amex staff and involves the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. The NYSE Amex also requires that we obtain stockholder approval if the issuance or potential issuance of additional shares will be considered by the NYSE Amex staff to result in a change of control of us.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our current business strategy, and there is no guarantee our stockholders ultimately would approve a proposed transaction. A public offering under the NYSE Amex rules typically involves broadly announcing the proposed transaction, which often times has the effect of depressing the issuer's stock price. Accordingly, the price at which we could sell our securities in a public offering may be less, and the dilution existing stockholders experience may in turn be greater, than if we were able to raise capital through other means.

Our ability to raise capital may be limited by contractual restrictions.

In the past, in connection with raising capital through the sale and issuance of our equity securities, we have agreed to certain restrictions on our ability to raise additional capital through additional equity financing transactions. For example, in connection with an equity financing we completed in July 2005, we entered into a rights agreement with certain of the purchasers of our securities, including entities affiliated with Carl C. Icahn. Pursuant to the Rights Agreement, dated July 27, 2005, as amended, or the Rights Agreement, we agreed, among other things, to grant the investors that were party to the Rights Agreement, or the Rights Investors, the right to participate in sales of our securities for up to seven years (with certain enumerated exceptions as set forth in the Rights Agreement). Pursuant to the Rights Agreement, we must notify the Rights Investors of certain proposed transactions on the timeline specified in the Rights Agreement. In many of our prior financing transactions, we have requested and received waivers from the Rights Investors with respect to their participation rights, but if we are unable to obtain such waivers in a timely manner, or at all, with respect to future financing transactions, we may be unable to consummate a financing that otherwise may be available to us and in the best interest of our company and stockholders. In addition, in connection with our public offering in November 2011, we entered into an underwriting agreement in which we agreed not to engage for 12 months in variable rate transactions, which involve issuances our securities at prices set or reset at some future date.

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

If we are unable to raise sufficient additional capital as needed, we may be forced to delay, reduce or discontinue our current and/or planned development activities, partner our product candidates at inopportune times or pursue less expensive but higher-risk development paths.

Although we anticipate that our cash, cash equivalents and short-term investments as of March 31, 2012 will be sufficient to fund our operations at their current levels for at least the next 12 months, we expect to need to raise additional capital in order to execute our current business plan. If we are not able to raise sufficient additional capital, we may be required to delay, reduce or discontinue our development activities or attempt to continue them by entering into arrangements with partners or others that may not be available on favorable terms, or at all, and may require us to relinquish some or all of our rights to our product candidates or the financial benefits thereof. For example, if we do not have sufficient capital, we may determine not to investigate additional indications or other label changes for a product candidate or to conduct other studies or activities intended to expand the scale and scope of its clinical benefit and market potential. Any such development delays could impair our ability to realize the full clinical and market potential of a product candidate and have a material adverse effect on our business and financial condition.

We may determine that it is in the best interest of our company to partner, sell or exclusively license rights to develop and/or commercialize one or more of our product candidates to a third party rather than independently continue their development, but such a strategic option may not be available on acceptable terms, or at all.*

As we consider the optimal development paths for our product candidates and our limited resources, we may determine to prioritize a particular program or programs over others. As a result, we may decide to discontinue independent development of a product candidate and solely pursue partnering and other strategic options, including selling or exclusively licensing them to a third party. For example, in 2011 we elected to discontinue independent development of Exelbine and are seeking a partner or outside investor for the program to complete the necessary bioequivalence study. A strategic option may not be available on acceptable terms, or at all, and we may not realize value from our investment in any discontinued development program. In addition, discontinuation of a development program may be viewed negatively, which could adversely affect our stock price.

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

Our industry in general and our company in particular historically have experienced a high rate of turnover of management personnel. Our ability to execute on our business strategy and compete in the highly competitive pharmaceutical and biotechnology industries depends on our ability to attract and retain highly qualified personnel for key positions in our company. We are highly dependent on certain personnel, including our chief executive officer, our president and chief operating officer and our senior vice president, development. If we lose any of these key employees, our ability to successfully implement our current business strategy could be seriously harmed. Replacing these key employees may be a difficult, costly and protracted process, particularly due to the fact that we currently do not have other executive officers or personnel to assume all of the responsibilities of these key employees, competition is intense for qualified personnel among pharmaceutical, biotechnology and other businesses and many of the companies against which we compete for qualified personnel have greater financial and other resources than our company, which may make them more attractive employers. All of our employees, including our executive officers, may terminate their employment with us at any time with or without notice.

In addition, we may seek to increase the size of our organization as our development of our product candidates progresses. Currently, we have only a small number of employees and we rely on third parties to perform many essential services for us. The success of our business will depend, in part, on our ability to attract and retain highly qualified personnel and 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 among pharmaceutical and biotechnology companies, universities and other research organizations, particularly in the San Diego, California area. Recruiting and retaining employees, including senior-level personnel, with relevant product development and regulatory experience may be difficult and costly. Our ability to provide competitive compensation to our management and other employees may also be adversely affected by our capital resources and our highly volatile stock price. If we cannot attract and retain additional skilled personnel, we may not achieve our development and other goals. In addition, our outsourcing strategy, which has included engaging consultants that spend considerable time in our office to manage key functional areas, may subject us to scrutiny under labor laws and regulations, which may divert management time and attention and have an adverse effect on our business and financial condition.

If we determine to grow our business through the acquisition of new technologies and/or product candidates, our existing stockholders may experience substantial dilution, we may fail to realize the benefits of any future strategic acquisition or investment and we may incur unexpected costs and disruptions to our business.

Although we are focused on developing our current product candidates, from time to time, we may evaluate pipeline expansion opportunities that we believe will increase the long-term value of our company. The process of identifying, evaluating, negotiating and implementing the purchase or license of new assets is lengthy and complex and may disrupt other development programs and distract our personnel. We have limited experience and resources with respect to identifying, evaluating, negotiating and implementing the acquisition of new assets or rights thereto and integrating them into our current infrastructure. Supplementing our current resources to complete one or more of these transactions may be costly.

We may use cash, shares of our common stock, securities convertible into our common stock or a combination of cash and our securities to pay the purchase price or license fee for any future strategic transaction. The use of cash could negatively impact our financial position and ability to develop our product candidates. The use of shares of our common stock or securities convertible into shares of our common stock would dilute the holdings of our existing stockholders and, given our recent market capitalization, such dilution could be substantial. For example, as consideration for our acquisition of SynthRx, in addition to the 2,800,851 shares we issued to SynthRx's former stockholders in April 2011, we could issue up to an aggregate of 13,478,050 additional shares of our common stock to such persons upon achievement of milestones related to the development and regulatory approval of ANX-188 for the treatment of sickle cell crisis in children. If all milestones are achieved without reduction, the number of shares we issue in connection with the SynthRx acquisition would, in the aggregate, represent an approximately 27% ownership stake in our company (based on shares outstanding as of May 1, 2012 plus shares issued in connection with achievement of the milestones). The issuance of shares in connection with other future strategic transactions, if any, may result in the stockholders who own the majority of our voting securities prior to one or more of such transactions owning less than a majority after such transactions.

Further, strategic transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop and/or commercialize acquired technologies and/or products candidates;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers of any acquired business due to changes in management and ownership; and
- inability to retain key employees of any acquired business.

Our stockholders will be required to rely on the judgment of our management and board of directors as to which new product candidates and/or technologies we pursue and may have limited or no opportunity to evaluate potential new assets prior to completion of a transaction, including the terms of acquisition, the costs of their future development and their commercial potential. We may devote resources to potential acquisition or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Any technology and/or product candidate that we acquire or to which we acquire rights likely will require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are subject to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe or effective for approval by regulatory authorities and other risks described under the section titled "Risks Related to Drug Development and Commercialization."

Our ability to use net operating loss carry forwards and research and development tax credits to offset future taxable income or future tax will be limited and may be limited further in the future due to changes in ownership (within the meaning of IRC Section 382) that have occurred and may occur in the future.*

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and certain other tax assets to offset future taxable income, and an ownership change is generally defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three year period. We have identified several ownership changes within the meaning of IRC Section 382, with the most recent as a result of our November 2011 common stock and warrant financing. As a result of these ownership changes, we do not expect to be eligible to utilize the NOL carry forwards and research and development tax credits we had accumulated as of November 11, 2011. Further ownership changes may occur in the future, which could eliminate or restrict our ability to use NOL carry forwards and research and development tax credits generated after November 11, 2011. Limitations on our ability to use NOL carry forwards and research and development tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

We expend substantial resources to comply with laws and regulations relating to public companies, and any failure to maintain compliance could subject us to regulatory scrutiny and cause investors to lose confidence in our company, which could harm our business and have a material adverse effect on our stock price.

Laws and regulations affecting public companies, including provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the Sarbanes-Oxley Act of 2002, or SOX, and the related rules and regulations adopted by the SEC and by the NYSE Amex have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these rules and respond to their requirements. For example, compliance with Section 404 of SOX, including performing the system and process documentation and evaluation necessary to issue our annual report on the effectiveness of our internal control over financial reporting and obtain the required attestation report from our independent registered public accounting firm, requires us to incur substantial expense and expend significant management time. Further, we have in the past discovered, and may in the future discover, areas of internal controls that need improvement. If we identify deficiencies in our internal controls that are deemed to be material weaknesses, we could become subject to scrutiny by regulatory authorities and lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on our stock price. Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations, including the possibility of human error and circumvention by collusion or overriding of controls. Accordingly, even an effective internal control system may not prevent or detect material misstatements on a timely basis. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

In addition, new laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees, and as our executive officers. We cannot predict or estimate the total amount or timing of the costs we may incur to comply with these laws and regulations.

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

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

Risks Related to Drug Development and Commercialization

Further clinical testing of our product candidates is required and clinical studies typically involve a lengthy and expensive process with an uncertain outcome.

Clinical testing typically is expensive and can take years to complete, and its outcome is inherently uncertain. Planned clinical studies may not commence on time or be completed on schedule, if at all. The commencement and completion of clinical studies can be delayed for a variety of reasons, including difficulties and delays related to:

- obtaining regulatory approval to commence a clinical study;
- obtaining institutional review board, or IRB, approval to conduct a clinical study at a prospective site;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, for the conduct of our clinical studies and contract manufacturing organizations, or CMOs, for the production of our clinical trial material, the terms of which agreements 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;
- identifying appropriate study sites and reaching agreement on acceptable terms with prospective study sites and investigators, the terms of which can be subject to extensive negotiation and may vary significantly among study sites;
- identifying and hiring or engaging, as applicable, additional employees or consultants to assist us in managing CRO and/or CMO activities, managing a clinical study and analyzing the data resulting from a study;
- manufacturing sufficient quantities of clinical trial material due, among other things, to lack of availability of capacity at a CMO or of the component materials, including the active pharmaceutical ingredient, or API, or other materials necessary to manufacture our clinical trial material or for various other reasons;
- unforeseen results of from other clinical studies or nonclinical testing that require us to amend a study design;
- recruiting and enrolling patients to participate in a clinical study; and
- having patients complete a study and/or return for and complete post-treatment follow-up.

Patient enrollment, a significant factor in the time required to complete a clinical study, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including therapies being investigated by other companies. Further, completion of a clinical study and/or its results may be adversely affected by failure to retain patients who enroll in a study but withdraw due to adverse side effects, lack of efficacy, improvement in condition before treatment has been completed or for personal issues or who fail to return for or complete post-treatment follow-up.

In addition, a clinical study may be suspended or terminated by us, an IRB, a data safety monitoring board, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the study in accordance with regulatory requirements or the study's protocol;
- inspection of clinical study operations or sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues, including adverse side effects;
- changes in governmental regulations or administrative actions; or
- lack of adequate funding to continue the study.

Changes in governmental regulations and guidance relating to clinical studies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit protocols to IRBs for reexamination or renegotiate terms with CROs and study sites and investigators, all of which may impact the costs, timing or successful completion of a trial.

Although we are planning to initiate a phase 3 clinical study of ANX-188 in 2012, the study may not begin on time or be completed in the timeframe we anticipate for a variety of reasons, including one or more of those described above. There can be no assurance that any of our clinical studies will commence or be completed as planned. The length of time necessary to complete clinical studies varies significantly and is difficult to predict accurately. If we experience delays in the completion of a clinical study or if a clinical study is terminated, the commercial prospects for our product candidate may be harmed and our ability to generate product revenues will be delayed. In addition, any delays in completing our clinical studies likely will increase our development costs. Further, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same indications may have been introduced to the market in the interim and established a competitive advantage.

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

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through nonclinical testing and clinical studies that each product is safe and effective for use in each target indication. Success in nonclinical testing and prior clinical studies does not ensure that subsequent or larger-scale studies will be successful. For example, the positive results generated to date in clinical studies of ANX-188 by prior sponsors do not ensure that our clinical studies will demonstrate that ANX-188 is safe or effective for the indications we are pursuing. In addition, clinical study results frequently are susceptible to varying interpretations and regulatory authorities may disagree on what are appropriate methods for analyzing data, which may delay, limit or prevent regulatory approvals. For instance, despite positive nonclinical testing that indicated bioequivalence between ANX-514 and the reference product, Taxotere, our bioequivalence study of ANX-514 did not demonstrate bioequivalence between ANX-514 and Taxotere based on the FDA's benchmark regulatory standards and the FDA determined ANX-514 could not be approved based on the findings from that study. Further, we have licensed to a third party certain rights to ANX-514 in South Korea and have limited control over any nonclinical testing or clinical studies that may be conducted by such third party or a future third-party licensee. If data from investigations of ANX-514 sponsored by a third-party licensee identify a safety or efficacy concern with respect to ANX-514, or the lack of comparable pharmacokinetics between ANX-514 and Taxotere, such data could adversely affect the U.S. regulatory process for ANX-514.

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

We may not achieve our projected development goals in the time frames we announce. Further testing and validation of our product candidates and related manufacturing processes are required and regulatory approval may be delayed or denied, which would delay or prevent us from marketing our product candidates and substantially harm our business.*

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

To varying degrees based on the regulatory plan for each of our product candidates, the effect of government regulation and the need for FDA and other regulatory agency approval will delay commercialization of our product candidates, impose costly procedures upon our activities, and put us at a disadvantage relative to larger companies with which we compete. There can be no assurance that FDA or other regulatory approval for any product candidates developed by us, alone or with a future partner, will be granted on a timely basis, or at all.

We set goals for and make public statements regarding our estimates of the timing for accomplishing certain objectives material to successful development of our product candidates. The actual timing of these events can vary dramatically due to many factors, including delays or failures in our nonclinical testing, clinical studies and manufacturing and regulatory activities and the uncertainties inherent in the regulatory approval process. For example, although we reached agreement with the FDA on a pivotal clinical study of ANX-514 that would support approval of ANX-514 without a corticosteroid premedication regimen, we do not plan to initiate any clinical studies of ANX-514 during 2012. In addition, if the FDA determines that the authenticity of the study drugs used in our bioequivalence study of ANX-514 cannot be verified, including because of the manner in which reserve samples were selected and maintained, we may be required to repeat the bioequivalence study prior to regulatory approval of ANX-514, and the results of a repeat study may cause the FDA to require additional clinical studies, which may increase the time and cost of seeking regulatory approval for ANX-514. Further, the FDA may inquire regarding the manufacturing source, in-process and product release specifications and overall uniformity of reference product used in our bioequivalence study, particularly since it was conducted at sites in multiple countries, and we may be unable to provide documentation satisfactory to the FDA with respect to such reference product, which may result in the FDA requiring that we evaluate additional patients, re-perform the bioequivalence study, conduct clinical studies or take other remedial measures. Further, the form of API used in the manufacture of ANX-514 for our bioequivalence study will not be the same form of API used in the manufacture of ANX-514 for any future clinical studies of ANX-514 or for process validation batches or commercial supply. To ensure the comparability of the ANX-514 used in the bioequivalence study and the ANX-514 intended for use in any future clinical study and commercial sale, the FDA may require that we evaluate each form of ANX-514 in additional patients, conduct other clinical studies or take other remedial actions. We may have insufficient quantities of each form of ANX-514 and could incur substantial cost and delay in acquiring such quantities, in addition to the time and expense associated with conducting the evaluation, conducting other clinical studies or taking other remedial measures. In addition, even though the FDA has confirmed the appropriateness of a Section 505(b)(2) regulatory path for ANX-514, the FDA's views may change and the FDA may not allow us to rely on data regarding the safety and efficacy of Taxotere in its evaluation of an NDA for ANX-514 or the FDA may allow us to rely only on certain subsets of the efficacy data related to Taxotere, in which case we likely would need to conduct substantial, additional clinical and nonclinical work prior to regulatory approval. Furthermore, we may determine to conduct clinical studies with respect to ANX-514 to support uses in new indications or other label changes or for other reasons. With respect to ANX-188, the FDA may require nonclinical testing and/or clinical studies in addition to our planned phase 3 and other clinical studies to demonstrate that ANX-188 is a safe and effective treatment for patients with sickle cell disease. If the development plan for any of our product candidates becomes more extensive and costly than anticipated, we may determine that the associated time and cost are not financially justifiable and, as a result, discontinue the program. Discontinuation of a development program may be viewed negatively, which could adversely affect our stock price.

Even if we complete a planned clinical study with successful results, we may not achieve our projected development goals in the time frames we initially anticipate or announce. For example, in August 2011, we received a complete response letter from the FDA stating that it could not approve our NDA for Exelbine in its present form. In particular, the letter stated that, based on inspections at clinical sites, the authenticity of the drug products used in the pivotal bioequivalence trial could not be verified and that the bioequivalence trial would need to be repeated to address this deficiency. As a result, we elected to discontinue independent development of Exelbine.

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

Further, 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. We rely on CMOs for the manufacture of clinical, and future commercial, quantities of our product candidates. If future FDA or other regulatory authority inspections identify cGMP compliance issues at these third-party facilities, production of our clinical trial material or, in the future, commercial product, could be disrupted and require substantial resources to correct.

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

We do not have, and do not intend to establish, manufacturing capabilities and are dependent on third parties to conduct manufacturing process development activities and to provide us with clinical trial material and, if any of our products are approved, commercial product, and the loss of any of these manufacturers, or their failure to provide to us with an adequate supply of our product candidates in a timely manner and on commercially acceptable terms, or at all, could harm our business.*

We do not have any manufacturing capability. We have executed or are in late-stage negotiations with third parties to supply us with ANX-188 API and ANX-188 drug product for clinical use, but we do not have any agreements for the supply of such materials for commercial use. Despite our late-stage negotiations, we may not be able to establish a relationship with the ANX-188 drug product supplier in a timely manner or on commercially acceptable terms, or at all. We do not have any long-term development or supply agreements with any third party manufacturer or component supplier for ANX-514. If we fail to maintain relationships with our current and planned third-party manufacturers and suppliers, we may not be able to complete development of our product candidates or market our products, if approved, on a timely basis, or at all, which would have a material and adverse effect on our business. These manufacturers and suppliers may not perform as agreed or may terminate their agreements with us. For example, because these third parties provide manufacturing services to a number of other pharmaceutical companies, they may experience capacity constraints or choose to prioritize one or more of their other customers over us. Any significant problem that our manufacturers or suppliers experience could delay or interrupt the supply to us of clinical trial material or commercial product until the manufacturer or supplier cures the problem or until we locate, negotiate for and validate an alternative source of supply, if an alternative source is available.

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

Currently, we do not anticipate engaging alternative sources to backup our primary sources of clinical trial material or, as applicable in the future, commercial product. Therefore, if our primary sources become unable or unwilling to perform, we could experience protracted delays or interruptions in the supply of clinical trial material and, ultimately, for product commercial sale, which could materially and adversely affect our development programs and commercial activities and operations. For example, if we are unable to maintain our relationship with our existing ANX-188 API supplier, we may be unable to identify or establish a relationship with an alternate supplier that has the technical capabilities and desire to perform the development and supply services that we require for ANX-188 API on commercially reasonable terms, or at all. The ANX-188 API is a purified form of poloxamer 188, or P188, that is produced through a proprietary extraction process. This extraction process is complex and requires highly specialized equipment and there are a limited number of CMOs capable and willing to perform the process as we require, which makes identifying and establishing relationships with CMOs more difficult and may provide them with substantial leverage over us in any negotiations. In addition, although P188 (non-purified), which is the ANX-188 active ingredient starting material, is widely available, we do not have any long-term agreement for its supply to us and the third-party manufacturers of this material could make changes that cause the FDA to determine that it is not acceptable active ingredient starting material. As a result, we could experience significant disruption in our ability to manufacture ANX-188, which likely would add significant cost to the overall development and commercialization of ANX-188 and adversely affect our ability to develop ANX-188 on a timely basis.

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

Furthermore, the manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling-up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, and shortages of qualified personnel. None of our product candidates have been manufactured at the scales we believe will be necessary to maximize their commercial value and, accordingly, we may encounter difficulties in attempting to scale-up production and may not succeed in scaling-up production. In addition, the FDA or other regulatory authorities may impose additional requirements as we scale-up initial production capabilities, which may delay our scale-up activities or add expense.

If our manufacturers encounter any of these difficulties or otherwise fail to comply with their contractual obligations, we may have insufficient quantities of clinical trial material for our planned and any future clinical studies. In addition, any delay or interruption in the supply of supplies necessary or useful to manufacture our product candidates could delay the completion of our planned and any future clinical studies, increase the costs associated with maintaining our development programs and, depending upon the period of delay, require us to commence new clinical studies at significant additional expense or terminate the studies completely. We cannot ensure that manufacturing or quality control problems will not arise in connection with the manufacture of our clinical trial material or products, or that third-party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such clinical trial material or products. 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 clinical trial material and products may adversely affect our future costs and our ability to develop and commercialize our product candidates on a timely and competitive basis.

If any of our product candidates are approved by the FDA or another regulatory authority, any problems or delays experienced in their manufacturing processes may impair our ability to provide commercial quantities, which would limit our ability to sell the products and adversely affect our business. Redesigning our manufacturing processes or identifying alternative suppliers in response to problems we may encounter could take significant time, 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.

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 clinical studies, collect stability data and provide additional information concerning any new supplier, or change in a validated manufacturing process, including scaling-up production, before we could distribute products from that supplier or revised process. For example, if the FDA requires substantial stability or other data from the new manufacturer, which would take significant time and cost to generate, our ability to meet commercial demand, if any, could be impaired. In addition, obtaining the necessary FDA or other applicable regulatory approvals and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and require the new supplier to bear significant additional costs, which may be passed on to us.

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

We do not employ personnel or possess the facilities necessary to conduct many of the activities associated with our programs. We engage consultants, advisors, CROs, CMOs and others to design, conduct, analyze and interpret the results of nonclinical tests and clinical studies in connection with the research and development of our product candidates, and we expect to continue to outsource a significant amount of such activities. As a result, many important aspects of our product candidates' development are and will continue to be outside our direct control. For instance, we lacked the internal capabilities to fully analyze the data from our bioequivalence study of ANX-514 and relied on multiple third-party consultants to help us interpret and understand the data. Because of the impact different analyses of the data may have on the success of our business, an employee may have approached the data and analysis in a substantially more rigorous, thoughtful and creative manner than a consultant or contractor. There can be no assurance that such third parties will perform all of their obligations under arrangements with us or will perform those obligations satisfactorily.

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

If any of our CRO relationships were to terminate, we may not be able to enter into arrangements with alternative CROs on acceptable terms or in a timely manner, or at all. Switching CROs would involve additional cost and divert management time and attention. In addition, there likely would be a transition period when a new CRO commences work. These challenges could result in delays in the commencement or completion of our clinical studies, which could materially impact our ability to meet our desired development timelines and have a material adverse impact on our business and financial condition.

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 clinical studies 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. For example, in clinical studies of ANX-188 conducted by a prior sponsor, transient, generally mild to moderate elevations in liver function tests were associated with treatment with ANX-188. If in our clinical studies of ANX-188 we observe more pronounced increases in liver function tests, or we observe other previously unidentified adverse events, whether or not statistically significant, we may be required to conduct additional clinical studies of ANX-188 or ANX-188 may not receive regulatory approval. In addition, if in future clinical studies of ANX-514 we observe adverse events, including as a result of eliminating corticosteroid premedication, we may be required to conduct further studies of ANX-514 or ANX-514 may not receive regulatory approval.

If any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product or, if applicable, 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 studies 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.

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 manufacturing processes, labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information regarding the product. For instance, the FDA may require changes to approved drug labels, require post-approval clinical studies and impose distribution and use restrictions on certain drug products. In addition, approved products, manufacturers and manufacturers’ facilities are subject to continuing regulatory review and periodic inspections. If previously unknown problems with a product are discovered, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, the FDA may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we or a CMO of ours fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications;
- exclude our product from reimbursement under government healthcare programs, including Medicaid or Medicare;
- impose restrictions or affirmative obligations on our or our CMO’s operations, including costly new manufacturing requirements;
- close the facilities of a CMO; or
- seize or detain products or require a product recall.

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

We currently do not have sales, marketing or other commercialization personnel. To commercialize our products, we will have to acquire or develop marketing, distribution, sales and associated regulatory compliance capabilities, or rely on marketing partners or other third parties for the marketing, distribution and sale of our products. There is no guarantee that we will be able to establish marketing, distribution or sales capabilities or make arrangements with third parties to perform those activities on terms satisfactory to us, or at all, or that any internal capabilities or third-party arrangements will be cost-effective. The acquisition or development of commercialization and associated regulatory compliance capabilities likely will require substantial financial and other resources and divert the attention of our management and key personnel, and, if not completed on time, could delay the launch of a product candidate and otherwise negatively impact our product development and commercialization efforts.

To the extent we establish marketing, distribution or sales arrangements with third parties, those third parties may hold significant control over important aspects of the commercialization of our products, including market identification, marketing methods, pricing, composition of sales force and promotional activities. Even if we are successful in establishing and maintaining these arrangements, there can be no assurance that we will be able to control the amount and timing of resources that any third party may devote to our products or prevent any third party from pursuing alternative technologies or products that could result in the development of products that compete with, or the withdrawal of support for, our products. If we retain third-party service providers to perform functions related to the marketing, distribution and sale of our products, key aspects of those functions that may be out of our direct control could include warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management. In this event, we would place substantial reliance on third-party providers to perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, encounter natural or other disasters at their facilities or otherwise fail to perform in a satisfactory manner, or at all, our ability to deliver product to meet commercial demand could be significantly impaired. In addition, we may use third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions.

If any of our product candidates for which we receive regulatory approval fails to achieve significant market acceptance among the medical community, patients or third-party payors, the revenues we generate from its 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, if approved, are accepted by the medical community and patients and reimbursed by third-party payors, including government payors. The degree of market acceptance with respect to each of our approved products, if any, will depend upon a number of factors, including:

- the safety and efficacy of our product demonstrated in clinical studies;
- acceptance in the medical and patient communities of our product as a safe and effective treatment;
- the perceived advantages of our product over alternative treatments, including with respect to the incidence and severity of any adverse side effects and the cost of treatment;
- the indications for which our product is approved;
- 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 of our product relative to alternative treatments;
- availability of alternative treatments;
- the prevalence of off-label substitution of chemically equivalent products or alternative treatments; and
- the resources we devote to marketing our product and restrictions on promotional claims we can make with respect to the product;

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 to become or remain profitable. In addition, our efforts to educate the medical community and third-party payors regarding the benefits, if any, of our products may require significant resources and may never be successful.

In addition, if we, or a future partner or licensee, fail to obtain a unique Healthcare Common Procedure Coding System, or HCPCS, product code for any of our approved products, we, or our partner or licensee, may be unable to sell those products at a price that exceeds their respective manufacturing, marketing and distribution costs. Sales of pharmaceuticals that patients are restricted from self-administering, such as injectable chemotherapy drugs, are dependent in large part on the availability and rate of reimbursement from third-party payors to the healthcare providers that purchase the drugs and administer them to patients. The HCPCS was established to identify and provide unique codes for healthcare goods and procedures, and virtually all third-party payors, including Medicare and private insurance plans, use it in setting their reimbursement rates. In determining a specific reimbursement rate for a drug, the Centers for Medicare and Medicaid Services, or CMS, publishes an average sales price for the drug based on manufacturer-reported sales data for all drugs within the same HCPCS product code as well as a reimbursement rate, expressed as a percentage of the average sales price. Because generic equivalents of drugs are assigned the same HCPCS product code as the original drug, generic competition can be expected to decrease the level of reimbursement for all drugs with the same HCPCS product code until price equilibrium is reached. If our products are not assigned a unique HCPCS product code, they will not be reimbursed based on a sales price that we set but based on an average of prices of drugs with the same HCPCS product code, which could limit our ability to set an appropriate price for our product and have a material adverse effect on our results of operations.

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

There can be no assurance that, in the future, we will continue to develop or seek regulatory approval for our current product candidates as quickly as possible, or at all, if, among other factors, we determine a product candidate may not achieve adequate market acceptance. Additionally, in the future, we may reduce our expenditures on the development and/or the process of seeking regulatory approval of these product candidates while we evaluate whether and on what timeline to move the programs forward.

Even if we receive regulatory approval for one or more of our product candidates, our products may face competition from lower priced alternatives.

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

In addition, we may face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. Proposed federal legislative changes may expand consumers' ability to import lower priced versions of our and competing products from Canada. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, it is possible other states and local governments may 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 to market one or more of our product candidates in the U.S., we may never receive approval or commercialize our products outside of the U.S., which would limit our ability to realize the full commercial potential of our product candidates.

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

Risks Related to Our Intellectual Property

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

Our success will depend in part on our ability to:

- obtain and maintain patent and other exclusivity with respect to our products;
- prevent third parties from infringing upon our proprietary rights;
- maintain trade secrets;
- operate without infringing upon the patents and proprietary rights of others; and
- obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, both in the U.S. and in foreign countries.

The patent and intellectual property positions of biopharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims 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, any patents that are issued to us may be challenged, invalidated, infringed or circumvented, including by our competitors, and rights we have under issued patents may not provide competitive advantages to us.

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

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

With respect to ANX-188 for the treatment of sickle cell crisis, we acquired exclusive rights to a variety of issued patents that cover, among other things, P188, purified P188, methods of treating sickle cell anemia using P188 and methods of preparing purified P188. However, we expect many of the patents covering ANX-188 for the treatment of sickle cell crisis will expire prior to regulatory approval of ANX-188 for that indication. For exclusivity, we expect to rely primarily on the orphan drug designation that the FDA has granted for P188 for the treatment of sickle cell crisis. However, the orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. ANX-188 would not receive the seven-year orphan drug marketing exclusivity if it is not the first P188 drug product to obtain FDA marketing approval for the treatment of sickle cell crisis. In addition, orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. Furthermore, if the FDA later determines another drug or biologic for the treatment of sickle cell crisis to be clinically superior to or different from ANX-188, the FDA may approve such other product candidate for marketing during ANX-188's seven year exclusive marketing period.

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

Our emulsion-formulation product candidates consist of common excipients that emulsify the underlying chemical entity. We believe the specific combinations of excipients in our formulations are not obvious and that many of the properties that the resulting formulations exhibit are surprising. However, there is substantial prior art involving the emulsification of drugs and a patent examiner may combine numerous disparate references in order to reject our formulations for obviousness. A patent examiner could also determine that, even without combining references, the prior art taught the specific combination of excipients in our formulations or that, for other reasons, such combination was obvious. If our formulations are deemed obvious, the invention would not be patentable.

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

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

Our commercial success depends on our ability and the ability of our CMOs and component suppliers to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are or may be developing products. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we will be subject to claims that our products or product candidates, or their use, infringe the rights of others. Because patent applications can take many years to publish and issue, there currently may be pending applications, unknown to us, that may later result in issued patents that our products, product candidates or technologies infringe, or that the process of manufacturing our products or any of their respective component materials, or the component materials themselves, infringe, or that the use of our products, product candidates or technologies infringe.

We or our CMOs or component material suppliers may be exposed to, or threatened with, litigation by third parties alleging that our products, product candidates and/or technologies infringe their patents and/or other intellectual property rights, or that one or more of the processes for manufacturing our products or any of their respective component materials, or the component materials themselves, or the use of our products, product candidates or technologies, infringe their patents and/or other intellectual property rights. If a third-party patent or other intellectual property right is found to cover our products, product candidates, technologies or their uses, or any of the underlying manufacturing processes or components, we could be required to pay damages and could be unable to commercialize our products or use our technologies or methods unless we are able to obtain a license to the patent or intellectual property right. A license may not be available to us in a timely manner or on acceptable terms, or at all. In addition, during litigation, the third-party alleging infringement could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using or selling our products, technologies or methods.

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

- infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert our management's time and attention from our core business;
- substantial damages for infringement, including the potential for treble damages and attorneys' fees, which we may have to pay if a court decides that the product at issue infringes or violates the third party's rights;

- a court prohibiting us from selling or licensing the product unless the third party licenses its intellectual property 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 the third party ; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial expense and time.

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

In addition, it may be necessary for us to enforce patents under which we have rights, or to determine the scope, validity and unenforceability of other parties' proprietary rights, which may affect our rights. In litigation or administrative proceedings, we may not succeed in causing a court or administrative body to find that one or more of our patents are valid or that an alleged infringer has infringed one or more of our patents. The uncertainty resulting from the mere institution and continuation of any patent related litigation or interference proceeding could have a material and adverse effect on us.

RISKS RELATED TO OUR INDUSTRY

We expect intense competition in the marketplace for each of our products, if any of our product candidates are approved.

The industry in which we operate is highly competitive and rapidly changing. If successfully developed and approved, our products will likely compete with existing and new products and therapies and our competitors may succeed in commercializing products more rapidly or effectively than us, which would have a material and adverse effect on our ability to generate revenues from product sales. In addition, there are numerous companies with a focus in hematology or oncology or that are pursuing the development of pharmaceuticals that target the same diseases and conditions as are targeted by the products that we are developing. We anticipate that we will face intense and increasing competition in the future as new products enter the market and new technologies become available. Existing products or new products developed by competitors may be more effective, or more effectively marketed and sold, than those we may market and sell. Competitive products may render our products and product candidates obsolete or noncompetitive.

With respect to competition for ANX-188 for the treatment of sickle cell crisis, we are aware of numerous companies with product candidates in varying stages of development for the treatment of sickle cell crisis. In addition, we expect advances in the understanding of the signaling pathways associated with sickle cell disease to lead to further interest and development of treatment options. More broadly, ANX-188, if approved for the treatment of sickle cell crisis, would compete against agents designed to treat sickle cell disease, of which sickle cell crisis is a condition. Hydroxyurea, a form of chemotherapy used for myeloproliferative disease, is an approved product that has been shown to decrease the frequency of sickle cell crisis. Blood transfusions also are used to treat patients with sickle cell disease. Bone marrow and stem cell transplantation have also been shown to be effective to treat and, in some cases, cure sickle cell disease. In addition, there is increasing interest in developing drugs for "rare diseases," which may have the effect of increasing the development of agents to treat sickle cell disease generally or sickle cell crisis in particular. GlaxoSmithKline and Pfizer each have a unit focused on rare diseases. Legislative action, such as the potential to expand the priority review voucher system to rare pediatric diseases, may generate further interest. If an effective treatment or cure for sickle cell disease or sickle cell crisis receives regulatory approval, the commercial success of ANX-188, if approved, could be severely jeopardized.

ANX-514 and Exelbine, if approved, would compete against Taxotere and Navelbine®, respectively, as well as their generic equivalents and other formulations of docetaxel and vinorelbine. If our emulsion-formulation product candidates receive regulatory approval based on bioequivalence to their currently marketed reference products, our ability to differentiate them from competing products will be limited. Even if we believe they demonstrate clinical, pharmacoeconomic or other benefits relative to competing products, we may be unable to market or promote them based on these benefits. If ANX-514 and/or Exelbine receive regulatory approval, but such approval is for less than all of the indications for which Taxotere and Navelbine, respectively, are approved, the commercial success of those products could be significantly limited. If our products do not receive unique HCPCS product codes, we may be required to price our products at levels that do not cover our costs to manufacture, market and distribute the products or provide any profit, or to price our products at levels at which they are not competitive.

In addition, numerous companies are focused on reformulating currently approved chemotherapeutic agents. In particular, the taxanes, the class of drugs of which Taxotere is a member, have experienced substantial commercial success, in part as a result of their effectiveness in treating a wide variety of cancers, which has generated significant interest in reformulating Taxotere and other taxanes. For instance, in 2010, the FDA approved Jevtana® for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen. The active ingredient of Jevtana is cabazitaxel, an antineoplastic agent belonging to the taxane class. In addition to our approach of emulsifying docetaxel, other companies may be pursuing alternative delivery vehicles, including the use of albumin nanoparticles, prodrugs, polyglutamates, analogs, co-solvents, liposomes and microspheres. Many of these or similar approaches could be applied to vinorelbine. Relative to our formulations, formulations based on one or more of these other methods may result in greater efficacy or safety, provide better drug delivery to tumor sites or otherwise increase benefits to patients and healthcare providers.

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

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

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

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

- our ability to set an appropriate price for our products;
- our ability to generate revenues or achieve or maintain profitability;
- the future revenues and profitability of our potential customers, suppliers and collaborators; and
- our access to additional capital.

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

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

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

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

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

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

We expect that we would expand our insurance coverage to include the sale of commercial products if we obtain marketing approval of any of our product candidates, but we may be unable to obtain product liability insurance on commercially acceptable terms or may not be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect us against potential losses. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

RISKS RELATED TO OUR COMMON STOCK

If we are unable to maintain compliance with NYSE Amex continued listing standards, our common stock may be delisted from the NYSE Amex equities market, which would likely cause the liquidity and market price of our common stock to decline.

Our common stock currently is listed on the NYSE Amex equities market. The NYSE Amex will consider suspending dealings in, or delisting, securities of an issuer that does not meet its continued listing standards, including specified stockholders' equity levels. In addition, the NYSE Amex will consider suspending dealings in, or delisting, securities selling for a substantial period of time at a low price per share if the issuer fails to effect a reverse split of such stock within a reasonable time after being notified that the NYSE Amex deems such action to be appropriate under the circumstances.

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

In April 2010, we announced that we had resolved the stockholders' equity continued listing deficiencies and we implemented a 1-for-25 reverse split of our common stock, in part to address the NYSE Amex's requirement that we address our low stock price. However, there is no assurance that we will continue to maintain compliance with such standards. For example, we may determine to pursue development or other activities or grow our organization or product pipeline or at levels or on timelines that reduces our stockholders' equity below the level required to maintain compliance with NYSE Amex continued listing standards. In addition, the market price for our common stock historically has been highly volatile, as more fully described below under the risk titled "The market price of our common stock historically has been and likely will continue to be highly volatile," and recently has traded at under $1.00 per share. The NYSE Amex may again determine that the selling price per share of our common stock is low and require that we effect a reverse stock split of our common stock, which would require stockholder approval that we may be unable to obtain. Our failure to maintain compliance with NYSE Amex continued listing standards could result in the delisting of our common stock from the NYSE Amex.

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

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

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

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

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

- the level of our financial resources;
- announcements of entry into or consummation of a financing or strategic transaction;
- changes in the regulatory status of our product candidates, including results of any clinical studies and other research and development programs;
- FDA or international regulatory actions and regulatory developments in the U.S. and foreign countries;
- announcements of new products or technologies, commercial relationships or other events (including clinical study results and regulatory events and actions) by us or our competitors;
- market conditions in the pharmaceutical, biopharmaceutical, specialty pharmaceutical and biotechnology sectors;
- developments concerning intellectual property rights generally or those of us or our competitors;
- changes in securities analysts' estimates of our financial performance or deviations in our business and the trading price of our common stock from the estimates of securities analysts;
- events affecting any future collaborations, commercial agreements and grants;
- fluctuations in stock market prices and trading volumes of similar companies;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders or pursuant to shelf or resale registration statements that register shares of our common stock that may be sold by us or certain of our current or future stockholders;

- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- commencement of delisting proceedings by the NYSE Amex;
- additions or departures of key personnel; and
- changes in third-party payor reimbursement policies.

As evidenced by the August 10, 2011 decline, the realization of any of the foregoing could have a dramatic and adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced a substantial decline in market price. Moreover, regulatory entities often undertake investigations of investor transactions in securities that experience volatility following an announcement of a significant event or condition. Any such litigation brought against us or any such investigation involving our investors could result in substantial costs and a diversion of management's attention and resources, which could hurt our business, operating results and financial condition.

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

The market price of our common stock could decline as a result of sales by, or the perceived possibility of sales by, us or our existing stockholders of shares of our common stock. These sales by our existing stockholders might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate. Currently, we have effective primary registration statements on Form S-3 under which we may sell and issue more than $205 million of securities. We also have effective resale registration statements on Form S-3 and an effective registration statement on Form S-1 that register a significant number of shares of our common stock and securities convertible into our common stock that may be sold by us or certain of our stockholders, including an effective resale registration statement for up to 16,278,901 shares of our common stock that were issued or may be issued in the future to the selling stockholders named therein in connection with our acquisition of SynthRx. Collectively, these registration statements may increase the likelihood of sales by, or the perception of an increased likelihood of sales by, us or our existing stockholders of shares of our common stock.

We currently have voting control with respect to approximately 5% of our outstanding common stock and we may obtain voting control over a significant additional amount of our outstanding common stock if we issue the milestone-related shares to the former SynthRx stockholders, and we may determine to cause those shares to be voted in such a manner that does not necessarily coincide with the interests of individual stockholders or particular groups of stockholders.

Pursuant to the voting and transfer restriction agreement between us and each of the former principal stockholders of SynthRx, each stockholder party has agreed to vote all shares of our common stock beneficially owned by that party with respect to every action or approval by written consent of our stockholders in such manner as directed by us, except in limited circumstances, and has executed an irrevocable proxy appointing and authorizing us to vote such shares in such manner. If the development of ANX-188 achieves all of the milestones set forth in our merger agreement with SynthRx without reduction, we will issue an additional 13,478,050 shares of our common stock, representing, in the aggregate (and including the shares issued in connection with the closing of our acquisition of SynthRx) an approximately 27% ownership stake in our company (based on shares outstanding as of May 1, 2012 plus shares issued in connection with achievement of the milestones). As a result of such issuances and the voting and transfer restriction agreement, we currently have, and in the future may have even more, significant control over substantially all matters requiring approval by our stockholders, including the election of directors and the approval of certain mergers and other business combination transactions. Even if less than all potential milestone-related shares are issued, our ability to control a potentially significant block of stockholder votes pursuant to the voting and transfer restriction agreement may enable us to substantially affect the outcome of proposals brought before our stockholders. Although our board of directors acts in a manner it believes is in the best interest of our stockholders as a whole, the interests of our stockholders as a whole may not always coincide with the interests of individual stockholders or particular groups of stockholders.

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

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

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

An Exhibit Index has been attached as part of this report and is incorporated herein by reference.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ADVENTRX Pharmaceuticals, Inc.

Date: May 7, 2012

By: /s/ Brian M. Culley
Brian M. Culley
Chief Executive Officer and Director
(Principal Executive Officer)

By: /s/ Patrick L. Keran
Patrick L. Keran
President and Chief Operating Officer
(Principal Financial Officer)

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EXHIBIT INDEX

Exhibit	Description
10.1#(1)	2012 Executive Incentive Plan
31.1	Certification of principal executive officer pursuant to Rules 13a-14(a)/15d-14(a)
31.2	Certification of principal financial officer pursuant to Rules 13a-14(a)/15d-14(a)
32.1*	Certification of principal executive officer and principal financial officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

\# Indicates management contract or compensatory plan

* This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, and otherwise are not subject to liability under those sections.

(1) Filed with the registrant's Current Report on Form 8-K on February 27, 2012 (SEC file number 001-32157-12642097).

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15(d)-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian M. Culley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ADVENTRX Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 7, 2012

/s/ Brian M. Culley
Brian M. Culley
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15(d)-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Patrick L. Keran, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ADVENTRX Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 7, 2012

/s/ Patrick L. Keran
Patrick L. Keran
President and Chief Operating Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of ADVENTRX Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian M. Culley, principal executive officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 7, 2012

/s/ Brian M. Culley
Brian M. Culley
Chief Executive Officer
(Principal Executive Officer)

In connection with the Quarterly Report of ADVENTRX Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Patrick L. Keran, principal financial officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 7, 2012

/s/ Patrick L. Keran
Patrick L. Keran
President and Chief Operating Officer
(Principal Financial Officer)