ADVENTRX PHARMACEUTICALS INC
Form 10-Q
November 05, 2012
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 x 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 x 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 x

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

The number of shares outstanding of the registrant s common stock, $0.001 par value per share, as of November 1, 2012 was 47,719,365.

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I

PART II FINANCIAL INFORMATION

Item 1. Financial Statements

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2012	December 31, 2011 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 26,088,710	$ 43,569,947
Short-term investments	13,812,937	7,133,697
Interest and other receivables	10,172	17,245
Contingent asset	1,025,997	815,011
Prepaid expenses	700,650	256,311
Total current assets	41,638,466	51,792,211
Property and equipment, net	320,427	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	$ 51,558,688	$ 61,856,471
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 343,197	$ 451,705
Accrued liabilities	1,314,621	1,120,416
Accrued compensation and payroll taxes	825,800	756,773
Contingent liability	176,400	140,125
Total current liabilities	2,660,018	2,469,019
Deferred income tax liability	2,608,755	2,608,755
Total liabilities	5,268,773	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 September 30, 2012 and December 31, 2011	47,716	47,716
Additional paid-in capital	227,196,203	226,122,331
Accumulated other comprehensive loss	(2,219)	(2,298)
Deficit accumulated during the development stage	(180,951,785)	(169,389,052)
Total stockholders equity	46,289,915	56,778,697

Total liabilities and stockholders equity	$ 51,558,688	$ 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.

Table of Contents

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Condensed Consolidated Statements of Operations and Comprehensive Income/(Loss)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,		Inception (June 12, 1996) through
	2012	2011	2012	2011	September 30, 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	1,657,902	2,050,314	5,976,217	4,004,180	83,945,521
Selling, general and administrative	1,816,181	1,981,869	5,732,478	5,379,723	65,879,785
Transaction-related expenses	(266,222)	(487,836)	(174,711)	1,541,087	566,543
Depreciation and amortization	10,638	8,498	77,569	28,735	11,012,757
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	3,218,499	3,552,845	11,611,553	10,953,725	177,707,802
Loss from operations	(3,218,499)	(3,552,845)	(11,611,553)	(10,953,725)	(175,665,374)
Reduction of fair value of warrants					(12,239,688)
Interest income	18,347	7,343	56,300	51,212	4,814,948
Interest expense		(272)		(272)	(191,729)
Other income (expense)	1,099	6,448	(7,480)	14,830	127,272
Loss before cumulative effect of change in accounting principle	(3,199,053)	(3,539,326)	(11,562,733)	(10,887,955)	(183,154,571)
Cumulative effect of change in accounting principle					(25,821)
Net loss	(3,199,053)	(3,539,326)	(11,562,733)	(10,887,955)	(183,180,392)
Preferred stock dividends					(621,240)
Deemed dividends on preferred stock					(10,506,683)
Net loss applicable to common stock	$ (3,199,053)	$ (3,539,326)	$ (11,562,733)	$ (10,887,955)	$ (194,308,315)
Net loss per common share basic and diluted	$ (0.07)	$ (0.13)	$ (0.24)	$ (0.43)	

Weighted average shares	basic and diluted	47,715,709	26,465,709	47,715,709	25,170,734	
Comprehensive Income/(Loss):						
Net loss		$ (3,199,053)	$ (3,539,326)	$ (11,562,733)	$ (10,887,955)	$ (183,180,392)
Other comprehensive gains (losses)		76	25	79	25	(63)
Comprehensive net loss		$ (3,198,977)	$ (3,539,301)	$ (11,562,654)	$ (10,887,930)	$ (183,180,455)

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Nine months ended September 30,		Inception (June 12, 1996) through
	2012	2011	September 30, 2012
Cash flows from operating activities:			
Net loss	$ (11,562,733)	$ (10,887,955)	$ (183,180,392)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	77,569	28,735	10,562,759
(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	(174,711)	(318,785)	(1,634,016)
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	1,073,872	533,704	11,163,866
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 fixed assets	300,114		408,114
Cumulative effect of change in accounting principle			25,821
Amortization of premium / (accretion of discount) on investments in securities	21,840		(1,571,502)
Changes in assets and liabilities, net of effect of acquisitions:			
Decrease in prepaid expenses and other assets	(437,266)	(154,146)	(1,004,421)
Increase in accounts payable and accrued liabilities	127,484	351,627	2,302,194
Net cash used in operating activities	(10,569,328)	(10,449,793)	(130,816,582)
Cash flows from investing activities:			
Purchases of certificates of deposit	(13,581,000)	(5,523,201)	(21,742,179)
Proceeds from maturities and sales of certificates of deposit	6,880,000		7,896,330
Purchases of other short-term investments			(111,183,884)
Proceeds from maturities and sales of other short-term investments			112,788,378
Purchases of property and equipment	(210,909)	(208,982)	(1,681,538)
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	(6,911,909)	(5,719,548)	(13,438,785)

Table of Contents

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		(1,548,123)	(13,897,367)
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 financing activities		20,959,406	170,346,233
Effect of exchange rate changes on cash			(2,156)
Net (decrease)/increase in cash and cash equivalents	(17,481,237)	4,790,065	26,088,710
Cash and cash equivalents at beginning of period	43,569,947	27,978,823	
Cash and cash equivalents at end of period	$ 26,088,710	$ 32,768,888	$ 26,088,710

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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.

Certain prior year amounts have been reclassified in the condensed consolidated financial statements to conform to the current year presentation. These reclassifications were not material and had no effect on previously reported results of operations.

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;

(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

Table of Contents

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. 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

(6)

Table of Contents

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.

We test our acquired IPR&D 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) in accordance with Accounting Standards Codification (ASC) Topic 350, *Intangibles Goodwill and Other*, and Accounting Standards Update (ASU) No. 2012-02, *Intangibles Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*. We perform our annual indefinite-lived intangible assets impairment testing as of September 30 of each year. As of September 30, 2012, no impairment of our acquired IPR&D was noted.

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.

We test our goodwill 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) in accordance with ASC Topic 350, *Intangibles Goodwill and Other*, and ASU No. 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment*. We perform our annual goodwill impairment testing as of September 30 of each year. As of September 30, 2012, no impairment was noted.

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

(7)

Table of Contents

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 September 30, 2012 resulted in a net $0.3 million decrease and a net $0.2 million decrease to transaction-related expenses for the three and nine months ended September 30, 2012, respectively.

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 and nine months ended September 30, 2012. The following unaudited pro forma information for the nine months ended September 30, 2011 presents the condensed consolidated results of operations of ADVENTRX and SynthRx as if the acquisition had occurred on January 1, 2010:

	Nine months ended September 30, 2011
Revenue	$
Loss from operations	(10,222,478)
Net loss applicable to common stock	(10,156,682)
Net loss per share, basic and diluted	(0.39)

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

	Nine months ended September 30, 2011
Transaction-related expenses	$ (1,071,090)

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.

(8)

Table of Contents

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 Topic 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 accretion of discounts are included in interest income. 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 September 30, 2012, the fair value of our short-term investments was $13,812,937. The cost basis of such investments was $13,813,000. During the three months ended September 30, 2012 and 2011, we had unrealized gains on short-term investments of $76 and $25, respectively. During the nine months ended September 30, 2012 and 2011, we had unrealized gains on short-term investments of $79 and $25, respectively.

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 September 30, 2012 of our short-term investments and our contingent asset and contingent liability are summarized in the following table:

		September 30, 2012 Fair Value Determined Under:		
	Total Fair Value	(Level 1)	(Level 2)	(Level 3)
Short-term investments	$ 13,812,937	$ 13,812,937	$	$
Contingent asset	$ 1,025,997	$	$	$ 1,025,997
Contingent liability	$ (176,400)	$	$	$ (176,400)

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 nine months ended September 30, 2012 is as follows:

	Nine months ended September 30, 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	210,986	(36,275)
Total net unrealized gains (losses) included in other comprehensive income		
Transfers into level 3 (gross)		
Transfers out of level 3 (gross)		
Ending balance	$ 1,025,997	$ (176,400)

(9)

Table of Contents

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 September 30, 2012 relative to December 31, 2011.

6. Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, which is generally three to five years. Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter.

In connection with our determination in the three months ended June 30, 2012 to not make any further significant investment in manufacturing development activities for ANX-514, we assessed the classification and recoverability, as of June 30, 2012, of certain equipment held and used in research and development-related manufacturing of ANX-514. We determined, based on an independent appraisal, that the carrying amount of the equipment exceeded its estimated fair value and was not recoverable. Accordingly, we recorded an impairment loss of $0.3 million, which was the difference between the carrying amount and estimated fair value, as a research and development expense in our condensed consolidated statement of operations for the three months ended June 30, 2012. We reevaluated the classification and recoverability of this equipment as of September 30, 2012 and, based on the independent appraiser s assessment that the estimated fair value of the equipment had not changed since June 30, 2012, determined that no additional impairment adjustment was necessary. The equipment was not classified separately as held for sale because the criteria for that classification, as set forth in ASC Topic 360-10, *Property, Plant and Equipment Overall*, were not met as of September 30, 2012.

7. Accrued Liabilities

Accrued liabilities at September 30, 2012 and December 31, 2011 were as follows:

	September 30, 2012	December 31, 2011
Accrued contracts and study expenses	$ 1,238,774	$ 880,608
Other accrued liabilities	75,847	239,808
Total accrued liabilities	$ 1,314,621	$ 1,120,416

8. Share-Based Compensation Expense

Estimated share-based compensation expense related to equity awards granted to our employees and non-employee directors for the three and nine months ended September 30, 2012 and 2011 was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Selling, general and administrative expense	$ 338,447	$ 307,842	$ 1,036,373	$ 578,087
Research and development expense	21,096	17,219	37,499	(44,383)
Share-based compensation expense	$ 359,543	$ 325,061	$ 1,073,872	$ 533,704

There were no employee or non-employee director stock options exercised during the three and nine months ended September 30, 2012 or 2011. During the three months ended September 30, 2012 and 2011, we granted stock options to acquire an aggregate of 933,996 and 767,500 shares of our common stock, respectively, to our employees and non-employee directors, with an estimated weighted-average grant date fair value of $0.68 and $2.94 per share, respectively. During the nine months ended September 30, 2012 and 2011, we granted stock options to acquire an aggregate of 933,996 and 1,180,959 shares of our common stock,

Table of Contents

respectively, to our employees and non-employee directors, with an estimated weighted-average grant date fair value of $0.68 and $2.63 per share, respectively. At September 30, 2012, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was $3.0 million, which is expected to be recognized over a weighted-average period of 3.0 years.

9. 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 three and nine months ended September 30, 2012 and 2011 by the weighted-average number of common shares outstanding during those periods, respectively, without consideration for 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. For the periods presented, our outstanding common stock equivalents consisted of options and warrants to purchase shares of our common stock. The weighted-average number of those common stock equivalents outstanding for each of the periods presented is set forth in the table below:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Options	3,120,646	1,470,496	2,949,056	905,151
Warrants	16,652,811	7,777,988	17,296,389	8,025,990

10. Recent Accounting Pronouncements

In July 2012, the Financial Accounting Standards Board (FASB) issued ASU No. 2012-02, *Intangibles Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment* (ASU 2012-02). Similar to the approach to annual goodwill impairment testing set forth in ASU 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment*, which FASB issued in September 2011, ASU 2012-02 is intended to reduce the cost and complexity of annual indefinite-lived intangible assets impairment testing by providing companies the option of performing a qualitative assessment to determine whether further impairment testing is necessary. Under the amendments in ASU 2012-02, an entity may first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not (that is, a likelihood of more than 50%) that the fair value of an indefinite-lived intangible asset is less than its carrying amount. An entity is required to perform step one of the two-step annual indefinite-lived intangible assets impairment test only if it determines that it is more likely than not that the fair value of an indefinite-lived intangible asset is less than its carrying amount. The amendments in ASU 2012-02 are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. Early adoption is permitted if an entity s financial statements for the most recent annual or interim period have not yet been issued. We have elected to early adopt ASU No. 2012-02 and have utilized this revised standard for our annual impairment testing, which was performed as of September 30, 2012.

In June 2011, 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 was 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).

Table of Contents

11. Supplementary Cash Flow Information

Non-cash investing and financing transactions presented separately from the condensed consolidated statements of cash flows for the nine months ended September 30, 2012 and 2011 and for the period from inception (June 12, 1996) through September 30, 2012 are as follows:

	Nine months ended September 30,		Inception (June 12, 1996) through
	2012	2011	September 30, 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		5,885,323	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		301,566	1,531,806
Fair value of contingent liabilities, net of contingent assets, recorded at acquisition date		784,419	784,419
Acquisition of license agreement for long-term debt			161,180
Unrealized (gain)/loss on short-term investments	(79)	(25)	63
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

12. 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.

Table of Contents

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 September 30, 2012, outstanding warrants to purchase shares of common stock are as follows:

Warrants	Exercise Price	Expiration Date
99,696	$ 11.9125	June 2014
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
16,488,432		

13. 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.

Table of Contents

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 our quarterly report on Form 10-Q for the period ended March 31, 2012. 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 or trade names is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark or trade name owners.

Overview

We are a biopharmaceutical company developing proprietary product candidates to treat various diseases and conditions. Our lead product candidate, ANX-188, has potential to reduce ischemic tissue injury and end-organ damage by restoring microvascular function, which is compromised in a wide range of serious and life-threatening diseases and conditions. We initially are developing ANX-188 as a treatment for 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 $11.6 million for the nine months ended September 30, 2012. Our cash, cash equivalents and short-term investments were $39.9 million at September 30, 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 plan to initiate a phase 3 clinical study of ANX-188 in 2012. The study will be a 388-subject, randomized, double-blind, two-arm, placebo-controlled study. The primary objective will be to demonstrate that ANX-188 reduces the duration of vaso-occlusive crisis in patients with sickle cell disease. Secondary endpoints will compare the rate of re-hospitalization for vaso-occlusive crisis within 14 days of initial discharge from the hospital and the occurrence of acute chest syndrome within 120 hours of randomization. In addition to the phase 3 study, we plan to conduct a number of smaller-scale clinical studies to further assess the efficacy, safety and tolerability of ANX-188, and expect these studies to overlap with the phase 3 study.

With respect to ANX-514 (docetaxel for injectable emulsion), our detergent-free reformulation of Taxotere® (docetaxel), we are conducting animal studies to evaluate its potential to improve upon the efficacy of docetaxel treatment. Due to our focus on ANX-188, we do not plan to initiate any clinical studies of ANX-514 in the foreseeable future and we are not making any further significant investment in manufacturing development activities for ANX-514. If the results of the initial animal studies are encouraging, we likely will seek a third party to fund further development of ANX-514.

We anticipate that our cash, cash equivalents and short-term investments as of September 30, 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 or lengthen 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. In addition, we may seek to expand our product pipeline through acquisition of additional product candidates and/or technologies. We will need additional capital to support our planned operating activities. For the foreseeable future, we likely will seek to fund our operations through public or private equity and/or debt financings and/or strategic alliances, including 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

(14)

Table of Contents

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

Table of Contents

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 MKT equities market (formerly, the NYSE Amex) 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 as of September 30 of each year. Pursuant to Accounting Standards Update, or ASU, No. 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment*, and No. 2012-02, *Intangibles Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, 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 our goodwill or our acquired IPR&D is impaired, and, unless we determine that it is more likely than not goodwill or acquired IPR&D is impaired, we do not perform the two-step quantitative impairment test otherwise required under ASC Topic 350. 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.

Property and Equipment, Net. Property and equipment are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, which is generally three to five years. Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter. Repairs and maintenance are expensed as incurred.

In accordance with ASC Topic 360-10, *Property, Plant and Equipment Overall*, we test for recoverability of long-lived assets, including property and equipment, if events or changes in circumstances indicate that the carrying amount for the assets may not be recoverable. If our assessment indicates impairment, we measure the impairment loss as the amount by which the carrying amount exceeds fair value of the assets. Fair value determinations are based on an undiscounted cash flow model, or independent appraisals, as appropriate.

Table of Contents

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 Topic 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. Impairment losses on R&D-related manufacturing equipment are also considered research-related manufacturing expenses. 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;

Table of Contents

- the number and location of sites included in clinical studies and the rate of site approval 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 clinical trial material and key components thereof;
- the costs of manufacturing our clinical trial material;
- 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 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 product for commercial sale, if and as we obtain the regulatory approvals necessary to market our product candidates. 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, and 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 September 30, 2012 and 2011

Revenue. We recognized no revenue for the three months ended September 30, 2012 or 2011.

Table of Contents

R&D Expenses. Our R&D expenses for the three months ended September 30, 2012 consisted primarily of costs associated with external nonclinical study activities, which largely consisted of research-related manufacturing costs for ANX-188, and personnel costs. The following table summarizes our consolidated R&D expenses by type for each of the periods presented:

	Three months ended September 30, 2012	2011	January 1, 2005 through September 30, 2012
External clinical study fees and expenses	$ 277,430	$ 126,477	$ 25,476,198
External nonclinical study fees and expenses	753,213	1,600,282	35,206,090
Personnel costs	606,163	306,336	12,854,036
Share-based compensation expense	21,096	17,219	2,934,944
Total	$ 1,657,902	$ 2,050,314	$ 76,471,268

R&D expenses decreased by $0.4 million, or approximately 19.1%, to $1.7 million for the three months ended September 30, 2012, compared to $2.1 million for the same period in 2011. This decrease was primarily due to a $0.8 million decrease in external nonclinical study fees and expenses, which was offset by increases of $0.3 million in personnel costs and $0.1 million in external clinical study fees and expenses. The decrease in external nonclinical study fees and expenses resulted primarily from decreases in research-related manufacturing expenses of $1.1 million for Exelbine and $0.2 million for ANX-514, offset by a $0.5 million increase in research-related manufacturing expenses related to ANX-188. The increase in personnel costs was primarily related to increased headcount, including relocation and recruitment costs for our new Chief Medical Officer. The increase in external clinical study fees and expenses was primarily related to increased clinical consulting expenses related to ANX-188.

Selling, General and Administrative Expenses. SG&A expenses decreased by $0.2 million, or approximately 8.4%, to $1.8 million for the three months ended September 30, 2012, compared to $2.0 million for the same period in 2011. This decrease resulted primarily from a decrease in consulting fees and legal expenses due to cost-savings realized by discontinuation of commercial-readiness activities related to Exelbine.

Transaction-Related Expenses. Transaction-related expenses were ($0.3) million for the three months ended September 30, 2012, compared to ($0.5) million for the same period in 2011. We recognized transaction-related expenses for the three months ended September 30, 2012 and 2011 due to changes in the fair values at September 30, 2012 and 2011 relative to June 30, 2012 and 2011, respectively, of the contingent asset and contingent liability related to the consideration for our acquisition of SynthRx. The net $0.3 million reduction to transaction-related expenses was primarily due to the increase in our stock price at September 30, 2012 relative to June 30, 2012.

Interest Income. Interest income amounted to $18,347 for the three months ended September 30, 2012, compared to $7,343 for the same period in 2011. The increase in interest income for the three months ended September 30, 2012 was attributable primarily to higher interest rates on amounts invested in FDIC-insured certificates of deposit.

Net Loss. Net loss was $3.2 million, or $0.07 per share, for the three months ended September 30, 2012, compared to net loss of $3.5 million, or $0.13 per share, for the same period in 2011.

Comparison of Nine Months Ended September 30, 2012 and 2011

Revenue. We recognized no revenue for the nine months ended September 30, 2012 or 2011.

R&D Expenses. Our R&D expenses for the nine months ended September 30, 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:

	Nine months ended September 30, 2012	2011
External clinical study fees and expenses	$ 706,900	$ 449,569

External nonclinical study fees and expenses	3,738,823	3,071,295
Personnel costs	1,492,995	527,700
Share-based compensation expense	37,499	(44,384)
Total	$ 5,976,217	$ 4,004,180

R&D expenses increased by $2.0 million, or approximately 49.3%, to $6.0 million for the nine months ended September 30, 2012, compared to $4.0 million for the same period in 2011. This increase was primarily due to a $1.0 million increase in personnel costs, a $0.7 million increase in external nonclinical study fees and expenses and a $0.3 million increase in external clinical study fees and expenses. The increase in personnel costs was primarily related to increased headcount. The increase in external nonclinical study

Table of Contents

fees and expenses was primarily related to increases in research-related manufacturing expenses of $1.9 million for ANX-188 and $1.0 million for ANX-514, offset by a $2.2 million decrease in research-related manufacturing expenses related to Exelbine. The increase in external clinical study fees and expenses was primarily related to a $0.4 million increase in clinical consulting expenses for ANX-188, offset by a $0.1 million decrease in clinical consulting expenses for Exelbine.

Selling, General and Administrative Expenses. SG&A expenses increased by $0.3 million, or approximately 6.6%, to $5.7 million for the nine months ended September 30, 2012, compared to $5.4 million for the same period in 2011. This increase resulted primarily from a $0.6 million increase in personnel costs, mainly due to increased headcount, and a $0.5 million increase in share-based compensation expense, offset by a $0.8 million decrease in consulting fees and legal expenses.

Transaction-Related Expenses. Transaction-related expenses were ($0.2) million for the nine months ended September 30, 2012, compared to $1.5 million for the same period in 2011. We recognized transaction-related expenses for the nine months ended September 30, 2012 due to changes in the fair values at September 30, 2012 relative to December 31, 2011 of the contingent asset and contingent liability related to the consideration for our acquisition of SynthRx. The net $0.2 million reduction to transaction-related expenses was primarily due to the increase in our stock price at September 30, 2012 relative to December 31, 2011. Transaction-related expenses for the nine months ended September 30, 2011 consisted of $1.8 million related to legal, accounting, financial and business development advisory fees associated with the evaluation of potential acquisition targets, including SynthRx, and a $0.3 million reduction related to changes in the fair value of contingent consideration related to the SynthRx acquisition.

Interest Income. Interest income amounted to $56,300 for the nine months ended September 30, 2012, compared to $51,212 for the same period in 2011. The slight increase in interest income for the nine months ended September 30, 2012 was attributable primarily to higher interest rates on amounts invested in FDIC-insured certificates of deposit as compared to interest rates on invested balances for the same period in 2011.

Net Loss. Net loss was $11.6 million, or $0.24 per share, for the nine months ended September 30, 2012, compared to net loss of $10.9 million, or $0.43 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 $11.6 million for the nine months ended September 30, 2012 and cash, cash equivalents and short-term investments of approximately $39.9 million as of September 30, 2012. Our short-term investments at September 30, 2012 consisted entirely of FDIC-insured certificates of deposit.

We may receive up to $0.8 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, 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. See Note 12, Stockholders Equity, 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 September 30, 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 $10.6 million for the nine months ended September 30, 2012 compared to $10.4 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 nine months ended September 30, 2012 compared to the same period in 2011 ($0.7 million), an increase in prepaids and other assets ($0.3 million), a decrease in accounts payable and accrued liabilities ($0.2 million), offset by increased share-based compensation expense ($0.5 million), a write-off of manufacturing equipment related to the discontinuation of ANX-514 manufacturing activities ($0.3 million), a gain on the change in fair value of contingent consideration related to our acquisition of SynthRx ($0.1 million) and increased depreciation and amortization ($0.1 million).

Investing activities. Net cash used in investing activities was $6.9 million for the nine months ended September 30, 2012 compared to $5.7 million for the same period in 2011. The difference was primarily due to an increase of $8.1 million in purchases of certificates of deposit, offset by $6.9 million in sales and maturities of certificates of deposits.

Financing activities. There was no cash used in or provided by financing activities during the nine months ended September 30, 2012 compared to net cash of $21.0 million provided by financing activities for the same period in 2011. The cash provided by financing activities for the nine months ended September 30, 2011 reflects net proceeds of $21.0 million from our January 2011 registered direct equity financing.

(20)

Table of Contents

Management Outlook

We anticipate that our cash, cash equivalents and short-term investments as of September 30, 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 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 and the conduct of clinical studies. 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 principally on the development of ANX-188 and plan to initiate a 388-subject phase 3 clinical study of ANX-188 in sickle cell disease in 2012. We have engaged Pierre Fabre Médicament and Patheon Inc. to manufacture drug substance and finished drug product, respectively, for use in the study, and we have engaged Theradex Systems, Inc. to manage the study. The study will enroll subjects from approximately 40 medical centers, primarily in the United States. Although we cannot accurately predict the rate of enrollment before the study has been initiated, our target timeframe for full enrollment is 24 months after the first subject is dosed. Currently, we are focused on releasing clinical trial material for use in the study, qualifying prospective study sites and obtaining institutional review board approvals. We currently estimate that external clinical study fees and expenses for the planned phase 3 study will be approximately $15 to $18 million.

In connection with the phase 3 study, we plan to conduct a thorough QT/QTc study, or TQT study, of ANX-188 in approximately 60 healthy volunteers. We plan to initiate the TQT study during the first quarter of 2013 and estimate that external clinical study fees and expenses for the study will be approximately $2 million. Currently, we also plan to conduct additional, smaller-scale clinical studies to further assess the efficacy, safety and tolerability of ANX-188 in sickle cell disease, including a repeat-dose safety study and a study to measure the effect of ANX-188 on microvascular blood flow (mBF) and tissue oxygen saturation (StO_2), both in patients who are experiencing a vaso-occlusive crisis. We anticipate that each of these studies would enroll fewer than 50 subjects and begin in 2013. In addition, we continue to evaluate the benefits of developing ANX-188 in indications outside of sickle cell disease, and we currently expect to conduct nonclinical and/or clinical studies in one or more such indications that will overlap with the planned phase 3 study in sickle cell disease.

We have and may continue to increase our workforce in connection with our development of ANX-188; in particular, in September 2012, we hired a new Chief Medical Officer. However, we do not anticipate any significant increase in our workforce during the remainder of 2012. We also plan to continue to evaluate partnering and other strategic opportunities for development of ANX-188 within and outside of the United States.

With respect to ANX-514, we currently are limiting development activities to animal studies intended to evaluate its potential to improve upon the efficacy of docetaxel treatment. Due to our focus on ANX-188, we do not plan to initiate any clinical studies of ANX-514 in the foreseeable future and we are not making any further significant investment in manufacturing development activities for ANX-514. If the results of the initial animal studies are encouraging, we likely will seek a third party to fund further development of ANX-514. As we continue to 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.

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 September 30, 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

(21)

Table of Contents

approval to commercialize such product candidates. In addition, we may seek to expand our product pipeline through acquisition of additional product candidates and/or technologies. We will need additional capital to support our planned operating activities. For the foreseeable future, we likely will seek to fund our operations through public or private equity and/or debt financings and/or strategic alliances, including licensing transactions. Even though we were able to raise significant funds in the past through equity financings, the conditions of and our access to capital markets are highly variable and 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 10, Recent Accounting Pronouncements, of the Notes to the Condensed Consolidated Financial Statements (Unaudited) in this report for a discussion of recent accounting pronouncements 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, would, will, estimate, con anticipate, plan, 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, including the nature, timing and costs of clinical studies and nonclinical testing, 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 on a timely basis or on acceptable terms, or at all;
- delays in the commencement or completion of a clinical study or manufacturing and regulatory activities related to our product candidates;
- suspension or termination of a clinical study;
- our ability to successfully execute clinical studies and the ability of our product candidates to demonstrate acceptable safety and efficacy in clinical studies;

the potential for the FDA, or another regulatory agency, to require clinical studies of a product candidate in addition to our planned clinical studies prior to regulatory approval, even if our planned studies are successful;

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;

Table of Contents

- 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;

- 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 MKT continued listing standards and maintain the listing of our common stock on the NYSE MKT equities market or another national securities exchange; and

- the other factors that are described in Item 1A (Risk Factors) of Part II of our quarterly report on Form 10-Q for the period ended March 31, 2012.

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, as a smaller reporting company we are not required to provide the information required by this item.

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.

Table of Contents

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 September 30, 2012. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of September 30, 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 quarterly 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

Under rules and regulations promulgated by the SEC, as a smaller reporting company we are not required to provide the information required by this item.

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.

Table of Contents

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: November 5, 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)

Table of Contents

EXHIBIT INDEX

Exhibit	Description
10.1#	Offer letter, dated July 20, 2012, to Santosh Vetticaden
10.2#	Form of Incentive Stock Option Grant Agreement for grants to the registrant s Chief Medical Officer (beginning September 5, 2012) under the Amended and Restated 2008 Omnibus 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.