ADVENTRX PHARMACEUTICALS INC Form 10-Q November 08, 2011

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
 For the quarterly period ended September 30, 2011

OR

O 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 þ No o 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 þ No o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer o Smaller reporting company b

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

The number of shares outstanding of the registrant s common stock, \$0.001 par value per share, as of November 3, 2011 was 26,465,709.

TABLE OF CONTENTS

	Page
PART I FINANCIAL INFORMATION	1
Item 1. Financial Statements (Unaudited)	1
a. Condensed Consolidated Balance Sheets as of September 30, 2011 and December 31, 2010	1
b. Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2011 and 2010 and for the period from inception (June 12, 1996) through September 30, 2011	2
c. Condensed Consolidated Statements of Cash Flows for the three and nine months ended September 30, 2011 and 2010 and for the period from inception (June 12, 1996) through September 30, 2011	3
d. Notes to Condensed Consolidated Financial Statements (Unaudited)	5
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3. Quantitative and Qualitative Disclosures About Market Risk	22
Item 4. Controls and Procedures	23
PART II OTHER INFORMATION	23
Item 1. Legal Proceedings	23
Item 1A. Risk Factors	23
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	23
Item 3. Defaults Upon Senior Securities	23
Item 4. (Removed and Reserved)	23
Item 5. Other Information	23
Item 6. Exhibits	23
<u>SIGNATURES</u>	24
Exhibit 10.2 Exhibit 31.1 Exhibit 31.2 Exhibit 32.1 EX-101 INSTANCE DOCUMENT EX-101 SCHEMA DOCUMENT	

EX-101 CALCULATION LINKBASE DOCUMENT EX-101 LABELS LINKBASE DOCUMENT EX-101 PRESENTATION LINKBASE DOCUMENT

(i)

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets

(Unaudited)

	Se	eptember 30, 2011	D	ecember 31, 2010 (1)
Assets				
Current assets:				
Cash and cash equivalents	\$	32,768,888	\$	27,978,823
Short-term investments		5,522,955		
Interest and other receivables		6,869		1,980
Contingent asset		178,366		
Prepaid expenses		560,802		428,276
Total current assets		39,037,880		28,409,079
Property and equipment, net		235,527		44,254
In-process research and development		6,549,000		
Goodwill		403,795		
Other assets		48,311		33,484
Total assets	\$	46,274,513	\$	28,486,817
Liabilities and Stockholders Equity				
Current liabilities:				
Accounts payable	\$	489,200	\$	479,780
Accrued liabilities		1,312,882		864,857
Accrued compensation and payroll taxes		675,715		456,839
Contingent liability		644,000		
Total current liabilities		3,121,797		1,801,476
Stockholders equity: Common stock, \$0.001 par value; 500,000,000 shares authorized; 26,465,709 and 15,480,302 shares issued and outstanding at September 30, 2011 and				
December 31, 2010, respectively		26,466		15,480
Additional paid-in capital		210,166,429		182,798,982
Accumulated other comprehensive loss		(23,103)		
Deficit accumulated during the development stage		(167,017,076)	((156,129,121)

Total stockholders equity 43,152,716 26,685,341

Total liabilities and stockholders equity \$ 46,274,513 \$ 28,486,817

(1) The balance sheet at December 31, 2010 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.

(1)

Table of Contents

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

Inception

8

		Three months ended September 30,		<u> </u>			(June 12, 1996)
	2011	2010	2011	2010	September 30, 2011		
Licensing revenue Net sales Grant revenue	\$	\$	\$	\$	\$ 1,300,000 174,830 618,692		
Total net revenue					2,093,522		
Cost of sales					51,094		
Gross margin					2,042,428		
Operating expenses: Research and development	2,050,314	918,309	4,004,180	2,791,404	76,215,147		
Selling, general and administrative	1,981,869	944,950	5,379,723	3,422,843	58,336,937		
Transaction-related expenses	(487,836)		1,541,087		1,871,456		
Depreciation and amortization	8,498	4,879	28,735	16,526	10,926,353		
In-process research and development Impairment loss Equity in loss of investee					10,422,130 5,702,130 178,936		
Total operating expenses	3,552,845	1,868,138	10,953,725	6,230,773	163,653,089		
Loss from operations Loss on fair value of	(3,552,845)	(1,868,138)	(10,953,725)	(6,230,773)	(161,610,661)		
warrants Interest income Interest expense Other income (expense)	7,343 (272) 6,448	26,258 (2,019)	51,212 (272) 14,830	68,006 (1,629) (2,019)	(12,239,688) 4,733,273 (180,991) 78,205		
Loss before cumulative effect of change in accounting principle	(3,539,326)	(1,843,899)	(10,887,955)	(6,166,415)	(169,219,862)		

Cumulative effect of change in accounting

principle (25,821)

Net loss (3,539,326) (1,843,899) (10,887,955) (6,166,415) (169,245,683)

Preferred stock dividends (621,240)

Deemed dividends on

preferred stock (5,639,796) (10,506,683)

Net loss applicable to

common stock \$ (3,539,326) \$ (1,843,899) \$ (10,887,955) \$ (11,806,211) \$ (180,373,606)

Net loss per common

share basic and diluted \$ (0.13) \$ (0.13) \$ (0.43) \$ (0.94)

Weighted average shares

basic and diluted 26,465,709 14,701,216 25,170,734 12,593,971

See accompanying notes to unaudited condensed consolidated financial statements.

(2)

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

	Nine months end	led Sentember	Inception (June 12, 1996)
	30	through	
	2011	2010	September 30, 2011
Cash flows from operating activities:			
Net loss	\$ (10,887,955)	\$ (6,166,415)	\$ (169,245,683)
Adjustments to reconcile net loss to net cash used in	+ (,,	+ (*,-**,*-*)	+ (,,
operating activities:			
Depreciation and amortization	28,735	16,526	10,476,355
(Gain) loss on disposals of fixed assets	(2,973)	2,019	56,812
Loss on fair value of warrants			12,239,688
Gain on change in fair value of contingent			
consideration	(318,785)		(318,785)
Expenses related to share-based compensation	533,704	604,772	9,757,646
Expense related to stock 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
Accretion of discount on investments in securities			(1,604,494)
Amortization of debt discount			450,000
Forgiveness of employee receivable			30,036
Impairment loss write-off of goodwill			5,702,130
Equity in loss of investee			178,936
In-process research and development			10,422,130
Write-off of license agreement			152,866
Write-off of assets available-for-sale			108,000
Cumulative effect of change in accounting principle			25,821
Changes in assets and liabilities, net of effect of			
acquisitions:			
Increase in prepaid expenses and other assets	(154,146)	(186,929)	(865,256)
Increase (decrease) in accounts payable and accrued			
liabilities	374,755	(1,277,316)	2,352,939
Net cash used in operating activities	(10,426,665)	(7,007,343)	(117,206,965)
Cash flows from investing activities:			
Purchases of short-term investments			(111,183,884)

Proceeds from sales and maturities of short-term			
investments			112,788,378
Purchases of property and equipment	(208,982)	(6,780)	(1,267,849)
Proceeds from sale of property and equipment	12,635	1,700	66,920
Purchase of certificate of deposits	(5,523,201)		(6,539,531)
Maturity of certificate of deposits			1,016,330
Payment on obligation under license agreement			(106,250)
Cash acquired from acquisitions, net of cash paid			32,395
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 provided by (used in) investing activities	(5,719,548)	(5,080)	(4,702,448)

(3)

Table of Contents

Condensed Consolidated Statements of Cash Flows

				(J	Inception une 12, 1996)
	Nine months ended September 30,				through
	2011		2010	50	2011
Cash flows from financing activities: Proceeds from sale of preferred stock Proceeds of restricted cash for preferred stock		3	30,453,227		44,474,720
dividends			633,008		633,008
Proceeds from sale of common stock	22,507,529				106,658,871
Proceeds from exercise of stock options					712,367
Proceeds from sale or exercise of warrants			317,444		14,714,258
Payment to escrow for preferred stock dividends			(622.000)		(622,000)
obligation Property of the second se			(633,008)		(633,008)
Repurchase of warrants	(1.549.122)		(2.002.722)		(55,279)
Payments for financing and offering costs Payments on notes payable and long-term debt	(1,548,123)) ((3,093,733)		(12,542,171) (605,909)
Proceeds from issuance of notes payable and					(003,909)
detachable warrants					1,344,718
Cash paid in lieu of fractional shares for reverse stock					1,5 1 1,7 10
split			(146)		(146)
Net cash provided by financing activities	20,959,406	2	27,676,792		154,701,429
Effect of exchange rate changes on cash	(23,128))			(23,128)
Net increase in cash and cash equivalents Cash and cash equivalents at beginning of period	4,790,065 27,978,823		20,664,369 8,667,404		32,768,888
Cash and cash equivalents at end of period	\$ 32,768,888	\$ 2	29,331,773	\$	32,768,888

See accompanying notes to unaudited condensed consolidated financial statements.

(4)

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, our or the Company), prepared unaudited interim condensed consolidated financial statements included in this report in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and with the instructions of the Securities and Exchange Commission (SEC). 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, 2010 included in our Annual Report on Form 10-K filed with the SEC on March 10, 2011 (2010 Annual Report). The condensed consolidated balance sheet as of December 31, 2010 included in this report has been derived from the audited consolidated financial statements included in the 2010 Annual Report. In the opinion of management, these condensed consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation 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 results expected for the full year.

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

On April 23, 2010, the Company effected a 1-for-25 reverse split of its common stock, which was authorized by its stockholders at a special meeting held in August 2009.

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 the condensed consolidated financial statements and accompanying notes. Actual results could differ from those 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., 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 ADVENTRX s common stock, in the aggregate, as follows:

- (i) 862,078 shares (the Fully Vested Shares) of ADVENTRX s common stock, which shares were issued on April 8, 2011 and represent 1,000,000 shares, less 137,922 shares that were deducted as a result of certain expenses of SynthRx, and 200,000 of which were deposited into escrow (the Closing Escrow Amount) to indemnify ADVENTRX against breaches of representations and warranties;
- (ii) up to 1,938,773 shares of ADVENTRX s common stock, which shares were issued and outstanding on April 8, 2011 (the Subject to Vesting Shares, and together with the 862,078 Fully Vested Shares issued to the former stockholders of SynthRx and the escrow agent, the Closing Shares), which Subject to Vesting Shares are subject to various repurchase rights by ADVENTRX and fully vest, subject to reduction upon certain events, upon achievement of the First Milestone (defined below);
- (iii) up to 1,000,000 shares of ADVENTRX s common stock (the First Milestone Shares), which shares will be issued, if at all, upon achievement of the First Milestone (the First Milestone Payment); provided, however, that in the event the First Milestone is achieved prior to the first anniversary of the closing of the merger, 20% of the First Milestone Payment shall be deposited into escrow (the First Milestone Escrow Amount, and together with the Closing Escrow Amount, the Escrow Amount). The First Milestone means the dosing of the first patient in a phase 3 clinical study

carried out pursuant to a protocol that is mutually agreed to by SynthRx and ADVENTRX; provided, however, that the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint shall not exceed 250 (unless otherwise

(5)

Table of Contents

mutually agreed) (the First Protocol). In the event that the 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 ANX-188 for the treatment of sickle cell crisis in children (the ANX-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 ANX-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 ADVENTRX s common stock (the Second Milestone Shares), which shares will be issued, if at all, upon achievement of the Second Milestone (the Second Milestone Payment). The Second Milestone means the acceptance for review of the ANX-188 NDA by the FDA; and
- (v) 8,638,650 shares of ADVENTRX s common stock (the Third Milestone Shares, and together with the First Milestone Shares and the Second Milestone Shares, the Milestone Shares), which shares will be issued, if at all, upon achievement of the Third Milestone (the Third Milestone Payment, and together with the First Milestone Payment and the Second Milestone Payment, the Milestone Payments). The Third Milestone means the approval by the FDA of the ANX-188 NDA.

The Subject to Vesting Shares were issued on April 8, 2011 and classified as equity. However, ADVENTRX may repurchase up to 75% of the Subject to Vesting Shares, or 1,454,079 shares, 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 of the clinical trial associated with achievement of the First Milestone exceeds 250 patients, unless otherwise agreed. The fair value related to the number of such shares that may be repurchased was accounted for as a contingent asset. The fair value of the contingent asset will be remeasured at each reporting date until the arrangement is settled.

The Milestone Payments constitute contingent consideration because our obligation to make the Milestone Payments is contingent on future events. In order to determine the classification of the contingent consideration as a liability or equity, ADVENTRX reviewed Accounting Standards Codification (ASC) 815-40 Derivatives and Hedging Contracts in Entity s Own Equity. ASC 815-40 requires that contingent consideration arrangements that include potential net cash settlements or variable provisions should be classified as a liability. Classification as a liability requires fair value measurement initially and subsequently at each reporting date. Changes in the fair value of contingent consideration 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 fair value of the contingent consideration for the First Milestone was recorded as a liability as there is variability with respect to the number of shares that ultimately may be issued 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 of the clinical trial associated with achievement of the First Milestone exceeds 250 patients. The fair value of the contingent consideration for the First Milestone will be remeasured at each reporting date until the arrangement is settled. The fair values of the contingent consideration for the Second Milestone and the Third Milestone 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 remeasurement of the fair values for the contingent asset and liability at September 30, 2011 resulted in a net \$0.5 million reduction to transaction-related expenses for the quarter ended September 30, 2011.

Based on the fair value of the Closing Shares and the Milestone Payments (which is 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 estimated market price of a share of common stock of ADVENTRX on the estimated date of achievement for each milestone), the total preliminary estimated purchase price was approximately \$6.7 million.

Table of Contents

The elements of the total preliminary estimated purchase price of the acquisition were as follows:

Event	Shares Issued / To Be Issued	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
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

Under the acquisition method of accounting, we recorded the net tangible and intangible assets and liabilities acquired based on their estimated fair values on April 8, 2011, the date we completed the acquisition of SynthRx. The following table summarizes the net tangible and intangible assets and liabilities acquired:

Net tangible assets acquired	\$ 18,513
Net tangible liabilities assumed	(301,566)
Acquired intangibles:	
In-process research and development	6,549,000
Goodwill	403,795

Total preliminary estimated purchase price

\$ 6,669,742

A value of \$0.4 million, representing the difference between the total preliminary estimated purchase price and the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed, was recorded as goodwill. ADVENTRX acquired SynthRx to expand its 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.

The following unaudited pro forma information 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	2010	
Revenues	\$	\$	
Loss from operations	(10,222,478	(7,413,324)	
Net loss applicable to common stock	(10,156,682	(12,988,626)	

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

	Nine months ended 30,	l September
	2011	2010
Transaction-related expenses	(1,071,090)	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.

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.

(7)

4. Investments

We account for and report our investments in accordance with ASC 320, Accounting for Certain Investments in Debt and Equity Securities. Short-term investments are marketable securities with maturities of less than one year from the balance sheet date. All of our short-term investments are under the custodianship of a major financial institution and comprised of marketable securities consisting primarily of FDIC-insured certificates of deposit. Our policy is to protect the principal value of our investment portfolio.

Our marketable securities are classified as available-for-sale and stated at fair value, with net unrealized gains or losses recorded as a component of accumulated other comprehensive income (expense). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity with all amortization and accretion included in interest income. Realized gains and losses on available-for-sale securities are included in other income (loss). The cost basis of securities sold is based on the specific identification method. Interest on securities classified as available-for-sale is included in interest income. Marketable securities are evaluated periodically for impairment. If it is determined that a decline of any investment is other than temporary, then the investment basis would be written down to fair value and the write-down would be included in earnings as a loss.

At September 30, 2011, the fair value of our short-term investments was \$5,522,955. The cost basis of such investments was \$5,523,201 and unrealized gains were \$25.

5. Fair Value of Financial Instruments

Cash and cash equivalents, accounts payable and accrued liabilities are presented in the financial statements at their carrying amounts, which are reasonable estimates of fair value due to their short maturities.

The fair value of financial assets and liabilities is measured under a framework that establishes levels which are defined as follows: Level 1 fair value is determined from observable, quoted prices in active markets for identical assets or liabilities. 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. 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, 2011 of our short-term investments and our contingent asset and contingent liability related to the SynthRx acquisition are summarized in the following table:

	September 30, 2011				
	Total Fair Fair Value Determined			rmined Under:	
	Value	(Level 1)	(Level 2)	(Level 3)	
Short-term investments	\$ 5,522,955	\$ 5,522,955	\$	\$	
Contingent asset	\$ 178,366	\$	\$	\$ 178,366	
Contingent liability	\$ (644,000)	\$	\$	\$ (644,000)	

A reconciliation of the contingent asset and 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, 2011 is as follows:

	Nine months ended S Contingent		d September 30, 2011 Contingent	
	Asset		Liability	
Beginning balance	\$	\$		
Net purchases, issuances, sales and settlements	300.	,481	(1,084,900)	
Total net unrealized gains (losses) included in earnings	(122,	,115)	440,900	
Total net unrealized gains (losses) included in other comprehensive				
income				
Transfers into level 3 (gross)				
Transfers out of level 3 (gross)				

Ending balance \$ 178,366 \$ (644,000)

(8)

6. Accrued Liabilities

Accrued liabilities at September 30, 2011 and December 31, 2010 were as follows:

	September 30, 2011	D	December 31, 2010		
Accrued contracts and study expenses	\$ 860,525	\$	381,309		
Accrued acquisition costs	225,667				
Other accrued liabilities	226,690		483,548		
Total accrued liabilities	\$ 1,312,882	\$	864,857		

7. Share-Based Compensation Expense

Estimated share-based compensation expense related to equity awards granted to our employees and non-employee directors for the three and nine months ended September 30, 2011 and 2010 was as follows:

	Three months ended September 30,			Nine months ended September 30,				
	2011		2010		2011		2010	
Selling, general and administrative expense Research and development expense	\$	307,842 17,219	\$	154,041 (1,243)	\$	578,087 (44,383)	\$	610,329 (5,557)
Share-based compensation expense before taxes Related income tax benefits		325,061		152,798		533,704		604,772
Share-based compensation expense	\$	325,061	\$	152,798	\$	533,704	\$	604,772
Net share-based compensation expense per common share basic and diluted	\$	0.01	\$	0.01	\$	0.02	\$	0.05

There were no employee or non-employee director stock options exercised during the three and nine months ended September 30, 2011 and 2010. During the three and nine months ended September 30, 2011, we granted stock options to acquire an aggregate of 767,500 and 1,180,959 shares, respectively, of our common stock to our employees and non-employee directors with an estimated weighted-average grant date fair value of \$3.21 and \$2.88 per share, respectively. During the three and nine months ended September 30, 2010, we granted stock options to acquire an aggregate of 0 and 203,381 shares, respectively, of our common stock to our employees and non-employee directors with an estimated weighted-average grant date fair value of \$0 and \$6.91 per share, respectively. At September 30, 2011, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was \$3.2 million, which is expected to be recognized over a weighted-average period of 3.21 years.

8. Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, including foreign currency translation adjustments and unrealized gains and losses on marketable securities. For the three and nine months ended September 30, 2011 and 2010, comprehensive loss was as follows:

Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-Q

	Three months ended September 30,				Nine months ended September 30,				
		2011		2010		2011		2010	
Net loss	\$	(3,539,326)	\$	(1,843,899)	\$	(10,887,955)	\$	(11,806,211)	
Unrealized gains on marketable securities Foreign currency translation	25				25				
adjustments		(30,594)				(23,128)			
Comprehensive loss	\$	(3,569,895)	\$	(1,843,899)	\$	(10,911,058)	\$	(11,806,211)	
		(9)							

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 period by the weighted-average number of common shares outstanding during the period, without consideration for our outstanding common stock equivalents because their effect would have been anti-dilutive. Common stock equivalents are included in the calculation of diluted earnings per common share only if their effect is dilutive. At September 30, 2011 and 2010, our outstanding common stock equivalents consisted of options, warrants and convertible preferred stock as follows:

	Septem	September 30,		
	2011	2010		
Options	1,553,692	421,737		
Warrants	7,777,988	4,055,030		
Convertible preferred stock		779,092		
	9,331,680	5,255,859		

10. Recent Accounting Pronouncements

In December 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2010-29 Business Combinations (Topic 805): Disclosure of Supplementary Pro Forma Information for Business Combinations (ASU 2010-29). ASU 2010-29 specifies that if a public entity presents comparative financial statements, the entity should disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. The amendments in ASU 2010-29 also expand the supplemental pro forma disclosures under Topic 805 to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. The amended guidance is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. We have accounted for our acquisition of SynthRx in April 2011 in accordance with this guidance.

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

In June 2011, the FASB issued ASU No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05). The issuance of ASU 2011-05 is intended to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items reported in other comprehensive income. The guidance in ASU 2011-05 supersedes the presentation options in ASC Topic 220 and facilitates convergence of U.S. GAAP and IFRS 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. ASU 2011-05 is effective for interim periods and years beginning after December 15, 2011. We do not believe our adoption of the new guidance in the first quarter of 2012 will have an impact on our consolidated financial position, results of operations or cash flows.

In September 2011, the FASB issued ASU No. 2011-08, Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment (ASU 2011-08). ASU 2011-08 is intended to reduce cost and complexity of the annual

goodwill impairment test by providing companies the option of performing a qualitative assessment to determine whether further impairment testing is necessary. Under the amendments in ASU 2011-08, 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 a reporting unit is less than its carrying amount. An entity is required to perform step one of the two-step annual goodwill impairment test only if it determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. The amendments in ASU 2011-08 are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. 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. 2011-08 and have utilized this revised standard for our annual goodwill impairment test performed as of September 30, 2011. No impairment was noted.

(10)

11. Grant Revenue

In November 2010, the Internal Revenue Service notified us that an aggregate amount of \$488,959 in grants had been awarded to us under the qualifying therapeutic discovery project program established under Section 48D of the Internal Revenue Code as a result of the Patient Protection and Affordable Care Act of 2010. We submitted applications in July 2010 for qualified investments we made, or expected to make, in 2009 and 2010 in our Exelbine and ANX-514 programs, and a grant in the amount of \$244,479 was approved for each of those programs. These grants are not taxable for federal income tax purposes. We received full payment of the grants in November 2010, all of which we recognized as revenue in the three month period ended December 31, 2010 because the criteria under our revenue recognition policy were met in that period.

12. 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, 2011 and 2010 and for the period from inception (June 12, 1996) through September 30, 2011 are as follows:

			Inception (June 12, 1996)	
	Nine months er 3	through		
	2011	2010	September 30, 2011	
Supplemental disclosures of cash flow information				
Interest paid	\$	\$ 1,629	\$ 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		54,260	13,674	
Acquisitions	5,885,323		30,666,878	
Payment of dividends			213,000	
Financial advisor services in connection with private				
placements	1,061,910	724,286	3,615,464	
Acquisition of treasury stock in settlement of a claim			34,747	
Cancellation of treasury stock			(34,747)	
Assumptions of liabilities in acquisitions	301,566		1,537,473	
Fair value of contingent liabilities, net of contingent				
assets, recorded due to acquisition	784,419		784,419	
Acquisition of license agreement for long-term debt			161,180	
Unrealized (gain)/loss on short-term investments	(25)		(25)	
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		7,140,389	13,502,403	
13. Stockholders Equity				

Common Stock 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. We may receive up to \$11.3 million of additional proceeds from the exercise of the warrants issued in this financing. Those warrants have an exercise price of \$2.75 per share. The 5-year warrants are exercisable any time on or before January 11, 2016 and the 1-year warrants are exercisable any time on or before January 19, 2012, subject to certain beneficial ownership limitations.

(11)

Table of Contents

Warrants

During January 2011, we issued warrants to the investors in our registered direct equity financing and to the placement agent for that financing. See details of the equity financing above.

At September 30, 2011, outstanding warrants to purchase shares of common stock are as follows:

Warrants	Exe	rcise Price	Expiration Date
432,429	\$	56.5000	July 2012
36,071	\$	3.7500	June 2014
19,007	\$	4.4750	July 2014
14,183	\$	4.0625	August 2014
216,000	\$	3.6700	October 2014
144,000	\$	5.8750	October 2014
498,488	\$	8.7475	July 2012
99,696	\$	11.9125	June 2014
1,816,608	\$	3.6500	May 2015
2,046,139	\$	2.7500	January 2012
2,046,139	\$	2.7500	January 2016
409,228	\$	3.4400	April 2015
7,777,988			
		(12)	

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 under the section entitled Risk Factors, in Item 1A of Part I of our annual report on Form 10-K for the year ended December 31, 2010.

Overview and Recent Developments

We are a specialty pharmaceutical company focused on developing proprietary product candidates. Our current lead product candidates are ANX-188, a novel, purified, rheologic and antithrombotic compound, which we initially are developing as a first-in-class treatment for pediatric patients with sickle cell disease in acute crisis, and ANX-514, a novel, detergent-free formulation of the chemotherapy drug docetaxel.

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 have incurred significant losses since inception. We had a loss from operations of \$11.0 million for the nine months ended September 30, 2011 and cash, cash equivalents and short-term investments of approximately \$38.3 million at September 30, 2011.

ANX-188. We acquired ANX-188 (purified poloxamer 188) in April 2011 as part of our acquisition of SynthRx, Inc. We believe ANX-188 is a late-stage product candidate that restores hydration lattices and minimizes the cascade of adhesive, inflammatory and coagulation responses that cause adhesion of cells, impaired blood flow and tissue ischemia. ANX-188 may have numerous applications as a cytoprotective, rheologic, antithrombotic and anti-inflamatory agent. Initially, we are developing ANX-188 as a first-in-class treatment for pediatric patients with sickle cell disease in acute crisis. We plan to meet with the U.S. Food and Drug Administration, or FDA, in the fourth quarter of 2011 with the goal of reaching agreement on key aspects of our planned phase 3 pediatric study of ANX-188 in sickle cell crisis and to discuss our overall development plan for ANX-188 in that indication. In addition, we plan to meet with the FDA in the first quarter of 2012 to discuss the manufacture of ANX-188 for clinical trial material in connection with our planned phase 3 study and for commercial product.

ANX-514. In October 2011, we met with the FDA to discuss our clinical development plans for ANX-514 (docetaxel for injectable emulsion), a detergent-free reformulation of Taxotere® (docetaxel), and the FDA agreed that the clinical trial we proposed, which we refer to as Study 514-02, would generate sufficient clinical data to support approval of ANX-514 without requiring corticosteroid premedication. Study 514-02 will be a randomized, open-label, multicenter, non-inferiority study comparing ANX-514, administered without corticosteroid premedication, and Taxotere, administered with corticosteroid premedication in accordance with its label, in the treatment of non-small cell lung cancer after failure of prior platinum-based therapy. Approximately 400 patients will be enrolled and treated until evidence of progressive disease, unacceptable toxicity, withdrawal of consent, or other withdrawal criteria are met. The primary objective of Study 514-02 will be to compare the incidence of fluid retention between study arms. The secondary objectives will be to compare ANX-514 and Taxotere in terms of overall safety profile, objective response rate, duration of response, progression-free survival and overall survival. We believe that elimination of the high-dose corticosteroid premedication required for treatment with Taxotere would represent a significant benefit to cancer patients, particularly those who have diabetes or a predisposition to hyperglycemia, who we estimate constitute one-third of the patients who receive Taxotere. Corticosteroids expose cancer patients to otherwise unnecessary and costly complications, such as hyperglycemia, immunosuppression and insomnia. We believe ANX-514 has the potential to improve the tolerability and safety of docetaxel treatment while eliminating toxicities associated with the presence of the polysorbate 80 detergent in Taxotere and complications associated with the Taxotere premedication regimen. We plan to initiate Study 514-02 in 2012.

Exelbine . Until recently, we were also pursuing FDA approval of Exelbine, our novel emulsion formulation of the chemotherapy drug vinorelbine. In November 2010, we submitted a NDA for Exelbine to the FDA and in August 2011, we received a complete response letter from the FDA stating that it could not approve the Exelbine

NDA in its present form. In particular, the letter stated that, based on inspections at clinical sites, the authenticity of the drug products used in the pivotal bioequivalence trial, which we refer to as Study 530-01, could not be verified and that the bioequivalence trial would need to be repeated to address this deficiency. During a meeting with the FDA in September 2011, FDA staff indicated that the failure of the Study 530-01 clinical sites to randomly select and retain reserve samples of the test article (Exelbine) and reference standard (Navelbine®) could not be overcome by alternative methods of verifying authenticity and reiterated that the bioequivalence study would need to be repeated. We have discontinued making significant additional capital investments into the Exelbine program and are seeking a partner or outside investor for the program.

(13)

Table of Contents

We anticipate that our cash as of September 30, 2011 will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, we may seek to raise substantial additional capital in the near-term to support development of ANX-188 and ANX-514, including our planned phase 3 clinical trials. We may pursue development activities for our product candidates, at levels or on timelines, or we may incur unexpected expenses, that shorten the period through which our operating funds will sustain us. In addition, we may acquire new technologies and/or product candidates and the cost to acquire and develop such new technologies and/or product candidates may shorten the period through which our operating funds will sustain us. We may not be able to obtain additional financing on a timely basis or on acceptable terms, if at all.

All trademarks, service marks or trade names appearing in this report, including but not limited to Navelbine® and Taxotere®, are the property of their respective owners. Use or display by us of other parties trademarks, service marks, trade names, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark, trade name, trade dress or product owners.

Critical Accounting Policies 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 accounting principles generally accepted in the U.S. The preparation of these consolidated financial statements requires management to make a number of assumptions and estimates 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 on-going basis, we evaluate these estimates and assumptions, including those related to recognition of expenses in service contracts, license agreements and share-based compensation. Management bases its estimates on historical information 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.

Revenue Recognition. We may enter into revenue arrangements that contain multiple deliverables. In these cases, revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed and determinable; and (4) collectability is reasonably assured.

Revenue from licensing agreements is recognized based on the performance requirements of the agreement. Revenue is deferred for fees received before earned. Nonrefundable upfront fees that are not contingent on any future performance by us are recognized as revenue when the license term commences and the revenue recognition criteria are met. Nonrefundable upfront fees, where we have ongoing involvement or performance obligations, are recorded as deferred revenue and recognized as revenue over the life of the contract, the period of the performance obligation or the development period, whichever is appropriate in light of the circumstances.

Payments related to substantive, performance-based milestones in an agreement are recognized as revenue upon the achievement of the milestones as specified in the underlying agreement when they represent the culmination of the earnings process. Royalty revenue from licensed products will be recognized when earned in accordance with the terms of the applicable license agreements.

We recognize revenues from federal government research grants during the period in which we receive the grant funds, or their collection is reasonably assured, and we incur the qualified expenditures.

R&D Expenses. R&D expenses consist of expenses incurred in performing R&D activities, including salaries and benefits, facilities and other overhead expenses, clinical trials, research-related manufacturing services, contract services and other outside expenses. R&D expenses are charged to operations as the underlying work is performed. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future R&D activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

(14)

Table of Contents

Milestone payments that we make in connection with in-licensed technology or product candidates are expensed as incurred when there is uncertainty in receiving future economic benefits from the licensed technology or product candidates. We consider the future economic benefits from the licensed technology or product candidates to be uncertain until such licensed technology is incorporated into products that, or such product candidates, are approved for marketing by the FDA or when other significant risk factors are abated. For accounting purposes, management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain.

Payments in connection with our clinical trials are often made under contracts with multiple contract research organizations that conduct and manage these trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price or on a time-and-material basis. Payments under these contracts depend on factors such as the successful enrollment or treatment of patients or the completion of other milestones. Expenses related to clinical trials are accrued based on our estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies, and trial progress. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we modify our accruals accordingly on a prospective basis. Revisions in scope of contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. Because of the uncertainty of possible future changes to the scope of work in clinical trials contracts, we are unable to quantify an estimate of the reasonably likely effect of any such changes on our consolidated results of operations or financial position. Historically, we have had no material changes in our clinical trial expense accruals that would have had a material impact on our consolidated results of operations or financial position.

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. We remeasure the fair value of this contingent consideration as of the end of each fiscal quarter. The fair value of the contingent consideration is based on our stock price at the end of the each fiscal quarter and significant estimates and assumptions of management, including the probability that the First Milestone will be achieved and the estimated number shares expected to vest and become issuable upon achievement of the First Milestone.

Goodwill. Goodwill is the excess of purchase price of an acquired business over the assets acquired and liabilities assumed in a business combination. In accordance with U.S. GAAP, goodwill is not amortized. Goodwill is tested for impairment annually or whenever an event occurs or circumstances change that would indicate the carrying amount may be impaired. We perform our annual goodwill impairment test as of September 30 of each year. We elected to early adopt ASU No. 2011-08, Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment, and utilized this guidance for our September 30, 2011 testing. No impairment was noted.

Intangible Assets. Intangible assets include in-process research and development, or IPR&D, related to the acquisition of SynthRx and ANX-188. Under the guidance of Accounting Standards Codification, or ASC, 805, Business Combinations, the fair value of IPR&D is capitalized on the balance sheet until the project is either abandoned and written off or successfully commercialized, at which time the company begins amortizing the fair value over the estimated useful life.

In accordance with previous accounting guidance effective through December 31, 2008, we accounted for the costs associated with any purchased IPR&D as an expense on the statement of operations upon acquisition. These amounts represented an estimate of the fair value of purchased IPR&D for projects that, as of the acquisition date, had not yet reached technological feasibility, had no alternative future use, and had uncertainty in generating future economic benefits. We determined the future economic benefits from the purchased IPR&D to be uncertain until such technology is incorporated into products approved for marketing by the FDA or when other significant risk factors are abated.

Share-based Compensation Expenses. We account for share-based compensation awards granted to employees and non-employee members of our board of directors in accordance with ASC 718, Compensation Stock Compensation. Share-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the individual s requisite service period. As share-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience. Our estimated forfeiture rates may differ from actual forfeiture rates which would affect the amount of expense recognized during the period. Estimated forfeiture rates are adjusted to actual amounts as they become known.

(15)

Table of Contents

We estimate the fair value of stock option awards on the date of grant using the Black-Scholes option-pricing model, or Black-Scholes model. The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by the price of our common stock as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected share price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, a risk-free interest rate and expected dividends. Our future volatility may differ from our estimated volatility at the grant date.

We account for share-based compensation awards granted to non-employees by determining the fair value of the share-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured using the share price and other measurement assumptions as of the earlier of (1) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached or (2) the date at which the counterparty s performance is complete.

Income Taxes. We account for income taxes and the related accounts under the liability method in accordance with ASC 740, Income Taxes. Deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts and the income tax bases of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The tax effects from an uncertain tax position can be recognized in our consolidated financial statements only if the position is more likely than not of being sustained upon an examination by tax authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The foregoing is not intended to be a comprehensive list of all of our accounting policies. In most cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the U.S.

Results of Operations

A general understanding of the drug development process is critical to understanding our results of operations. 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 an NDA that includes complete reports of pre-clinical, clinical and laboratory studies and extensive manufacturing information to demonstrate the product safety and effectiveness. The NDA process generally requires, before the submission of the NDA, filing of an investigational new drug application, or IND, pursuant to which permission is sought to begin clinical testing of the new product candidate. An NDA based on published safety and effectiveness studies conducted by others, or previous findings of safety and effectiveness by the FDA, may be submitted under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or the FDCA.

Generally, with respect to any product candidate with active ingredients not previously approved by the FDA, an NDA must be supported by data from at least phase 1, phase 2 and phase 3 clinical trials. Phase 1 clinical trials can be expected to last from 6 to 18 months, phase 2 clinical trials can be expected to last from 12 to 24 months and phase 3 clinical trials can be expected to last from 18 to 36 months. However, clinical development timelines vary widely, as do the total costs of clinical trials and the likelihood of success. 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.

Future expenditures on R&D programs are subject to many uncertainties, including whether we will further develop our product candidates with a partner or independently. At this time, due to such uncertainties and the risks inherent in drug 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 trials and research-related manufacturing, can vary significantly among

programs as a result of a variety of factors, including:

the number of trials necessary to demonstrate the safety and efficacy of a product candidate;

the number of patients who participate in the trials;

the number and location of sites included in trials and the rate of site approval for the trial;

the rates of patient recruitment and enrollment;

(16)

Table of Contents

the ratio of randomized to evaluable patients;

the time and cost of process development activities related to our product candidates;

the costs of manufacturing our product candidates;

with respect to bioequivalence or comparative trials, 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 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, in particular any containing new chemical entities, 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 cannot be certain when, if ever, we will generate revenues from sales of any of our product candidates.

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

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

Comparison of Three Months Ended September 30, 2011 and 2010

Revenue. We recognized no revenue for the three months ended September 30, 2011 and 2010.

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.

R&D Expenses. We maintain and evaluate our R&D expenses by the type of cost incurred rather than by project. We maintain and evaluate R&D expenses by type 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. The following table summarizes our consolidated R&D expenses by type for each of the periods listed:

Innuary 1

					•	2005		
						through		
	\mathbf{T}	hree months e	nded Se	ptember				
	30,					September 30,		
		2011	2010)		2011		
External clinical trial fees and expenses	\$	126,477	\$	(61,074)	\$	24,467,631		
External nonclinical trial fees and expenses (1)		1,600,282		920,232		30,325,966		
Personnel costs		306,336		60,394		11,071,696		

Share-based compensation expense	17,219	(1,243)	2,875,601
Total	\$ 2.050.314	\$ 918 309	\$ 68 740 894

(1) External nonclinical trial fees and expenses include preclinical, research-related manufacturing, quality assurance and regulatory expenses.

R&D expenses increased by \$1.2 million, or approximately 123.3%, to \$2.1 million for the three months ended September 30, 2011, compared to \$0.9 million for the same period in 2010. The increase in R&D expenses for the three months ended September 30, 2011 compared to the same period in 2010 was due primarily to a \$0.7 million increase in external nonclinical trial fees and expenses, a \$0.2 million increase in external clinical trial fees and expenses and a \$0.3 million increase in personnel costs. The increase in external nonclinical trial fees and expenses was primarily related to increased research-related manufacturing expenses of \$0.5 million for Exelbine and \$0.2 million for ANX-188. The increase in external clinical trial fees and expenses was primarily related to increased clinical consulting expenses of \$0.1 million for ANX-188 and \$0.1 million for ANX-514.

(17)

Table of Contents

We expect R&D expenses to increase in 2012 relative to 2011 to support development of ANX-188 and ANX-514, including in connection with initiating and conducting clinical trial activities for these product candidates.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses increased by \$1.1 million, or approximately 109.7%, to \$2.0 million for the three months ended September 30, 2011, compared to \$0.9 million for the same period in 2010. This increase resulted primarily from a \$0.5 million increase in personnel costs, mainly due to additional staff hired in 2011 and an accrual for estimated bonus expense related to 2011 performance, a \$0.4 million increase in commercial-readiness activities for Exelbine, and a \$0.2 million increase in stock-based compensation.

We expect SG&A expenses to be flat in 2012 relative to 2011 as a result of our decision to discontinue any significant additional capital investments into our Exelbine program.

Transaction-Related Expenses. Transaction-related expenses were (\$0.5) million for the three months ended September 30, 2011, compared to \$0 for the same period in 2010. Our remeasurement at September 30, 2011 of the fair values for the contingent asset and contingent liability related to our consideration for the SynthRx acquisition resulted in a net \$0.5 million reduction to transaction-related expenses for the three months ended September 30, 2011. The reduction in fair value was primarily due to the decrease in our stock price at September 30, 2011 relative to June 30, 2011.

Interest Income. Interest income amounted to \$7,343 for the three months ended September 30, 2011, compared to \$26,258 for the same period in 2010. The decrease in interest income for the three months ended September 30, 2011 was attributable primarily to lower interest rates on invested balances in 2011 as compared to 2010. We expect that interest income will continue to be low due to negligible interest rates.

Net Loss Applicable to Common Stock. Net loss applicable to common stock was \$3.5 million, or \$0.13 per share, for the three months ended September 30, 2011, compared to net loss applicable to common stock of \$1.8 million, or \$0.13 per share, for the same period in 2010.

Comparison of Nine Months Ended September 30, 2011 and 2010

Revenue. We recognized no revenue for the nine months ended September 30, 2011 and 2010.

R&D Expenses. The following table summarizes our consolidated R&D expenses by type for each of the periods listed:

	Nine months ended September 30,			
		2011		2010
External clinical trial fees and expenses	\$	449,569	\$	(14,963)
External nonclinical trial fees and expenses (1)		3,071,295		2,660,492
Personnel costs		527,700		151,432
Share-based compensation expense		(44,384)		(5,557)
Total	\$	4,004,180	\$	2,791,404

(1) External nonclinical trial fees and expenses include preclinical, research-related manufacturing, quality assurance and regulatory expenses.

R&D expenses increased by \$1.2 million, or approximately 43.5%, to \$4.0 million for the nine months ended September 30, 2011, compared to \$2.8 million for the same period in 2010. The increase in R&D expenses for the nine months ended September 30, 2011 compared to the same period in 2010 was due primarily to a \$0.4 million increase in external clinical trial fees and expenses, a \$0.4 million increase in external nonclinical trial fees and expenses and a \$0.4 million increase in personnel costs. The increase in external clinical trial fees and expenses is primarily related to increased clinical consulting expenses of \$0.2 million for ANX-188 and \$0.1 million for ANX-514, as well as a \$0.1 million increase for consulting expenses related to Study 530-01 clinical site inspections.

The increase in external nonclinical trial fees and expenses is primarily related to increased research-related manufacturing expenses of \$0.8 million for Exelbine and \$0.3 million for ANX-188, offset by a \$0.7 million decrease in regulatory and research-related manufacturing expenses for ANX-514.

(18)

Table of Contents

Selling, General and Administrative Expenses. SG&A expenses increased by \$2.0 million, or approximately 57.2%, to \$5.4 million for the nine months ended September 30, 2011, compared to \$3.4 million for the same period in 2010. This increase resulted primarily from a \$0.9 million increase in personnel costs, mainly due to additional staff hired in 2011 and an accrual for estimated bonus expense related to 2011 performance, a \$0.7 million increase in commercial-readiness activities for Exelbine, a \$0.3 million increase in accounting, investor relations and business development professional fees and consulting services and a \$0.1 million increase in the cost of our facilities lease.

Transaction-Related Expenses. Transaction-related expenses were \$1.5 million for the nine months ended September 30, 2011, compared to \$0 for the same period in 2010. 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 the execution of our acquisition of SynthRx, offset by a \$0.3 million reduction related to changes in the fair value of the contingent asset and contingent liability related to our consideration for the SynthRx acquisition. The reduction in fair value was primarily due to the decrease in our stock price at September 30, 2011 relative to April 8, 2011, the date we completed our acquisition of SynthRx.

Interest Income. Interest income amounted to \$51,212 for the nine months ended September 30, 2011, compared to \$68,006 for the same period in 2010. The decrease in interest income for the nine months ended September 30, 2011 was attributable primarily to lower interest rates on invested balances in 2011 as compared to 2010.

Net Loss Applicable to Common Stock. Net loss applicable to common stock was \$10.9 million, or \$0.43 per share, for the nine months ended September 30, 2011, compared to net loss applicable to common stock of \$11.8 million, or \$0.94 per share, for the same period in 2010. Included in net loss applicable to common stock for the nine months ended September 30, 2010 was non-cash deemed dividend expense of \$5.6 million related to our January and May 2010 registered direct equity financings.

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 \$11.0 million for the nine months ended September 30, 2011 and cash, cash equivalents and short-term investments of approximately \$38.3 million as of September 30, 2011.

In January 2011, we completed a registered direct equity financing involving the issuance of units consisting of shares of our common stock and common stock purchase warrants. This financing resulted in \$22.5 million in gross proceeds, and we received \$21.0 million in net proceeds after deducting the fees and expenses of our placement agent and our other offering expenses.

We may receive up to \$0.8 million, \$4.4 million, \$9.5 million and \$11.3 million of additional net proceeds from the exercise of warrants issued in the registered direct equity financings we completed in October 2009, January and May 2010 and January 2011, respectively; however, the exercise of these warrants is subject to certain beneficial ownership limitations. Further, \$5.6 million of these potential net proceeds relate to warrants with an exercise price of \$2.75 per share that expire in January 2012. We may receive up to \$3.7 million of additional net proceeds from the exercise of warrants issued to our placement agent as additional consideration for services in connection with certain of our registered direct equity financings.

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

Operating activities. Net cash used in operating activities was \$10.4 million for the nine months ended September 30, 2011 compared to \$7.0 million for the same period in 2010. The increase in cash used in operating activities was primarily due to a higher net loss in 2011 as compared to 2010 (\$4.7 million), a gain on the change in fair value of contingent consideration related to our SynthRx acquisition (\$0.3 million), lower share-based compensation expense (\$0.1 million), offset by changes in assets and liabilities (\$1.7 million), primarily due to increases in accounts payable and accrued liabilities.

Investing activities. Net cash used in investing activities was \$5.7 million for the nine months ended September 30, 2011 compared to \$5,080 for the same period in 2010. The difference was primarily due to an increase of \$5.5 million in purchases of certificates of deposit and \$0.2 million in purchases of property and equipment.

Financing activities. Net cash provided by financing activities was \$21.0 million for the nine months ended September 30, 2011 compared to \$27.7 million for the same period in 2010. 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. The cash provided by financing activities for the nine months ended September 30, 2010 reflects adjusted net proceeds of \$27.4 million from our January and May 2010 registered direct equity financings and proceeds of \$0.3 million from the exercise of warrants issued in our June 2009 registered direct equity financing.

(19)

Table of Contents

Management Outlook

We anticipate that our cash as of September 30, 2011 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 trials, including clinical trials that we currently plan to conduct and any additional clinical trials recommended by the FDA in the future; the extent to which we acquire new technologies, product candidates, products or businesses; the extent to which we partner or collaborate with third parties to develop, seek regulatory approval of and commercialize our product candidates or products, or sell or license our product candidates or products to others; and whether any of our product candidates for which we receive regulatory approval, if any, achieve broad market acceptance. In addition, we have a small workforce and rely on third parties to perform many essential services for us, including the manufacture of clinical trial material, the conduct of clinical trials and regulatory submissions related to product approval. The timing and extent to which we increase our workforce is difficult to predict as it will be influenced by the rate of progress of development and regulatory approval of our product candidates and whether we partner them, as well as the extent to which we acquire and develop new technologies, product candidates, products or businesses. Increases in the size of our workforce would impact the period through which our operating funds will sustain us.

In April 2011, we completed our acquisition of SynthRx, Inc. and it became a wholly owned subsidiary of ours. As part of the acquisition, we acquired ANX-188 and, initially, we are developing it as a first-in-class treatment for pediatric patients with sickle cell disease in acute crisis. If we are able to reach agreement with the FDA on a study protocol on a timely basis, we may initiate a phase 3 clinical trial of ANX-188 for that indication in 2012. We plan to meet with the FDA in the fourth quarter of 2011 with the goal of reaching agreement on key aspects of the phase 3 study and to discuss our overall development plan for ANX-188 in pediatric sickle cell crisis. In parallel, we expect to prepare to initiate the phase 3 clinical trial, including conducting manufacturing process development activities and manufacturing clinical trial material, which could enable us to initiate it in 2012. We have and may continue to increase our workforce in connection with our development of ANX-188. We cannot forecast with any degree of certainty the costs that would be associated with our development of ANX-188, particularly in advance of meeting with the FDA. However, our preliminary estimate of third party costs related to this development program through submission of an NDA is approximately \$15 million to \$25 million.

In connection with the completion of the SynthRx acquisition, we issued 2,800,851 shares of our common stock to the former SynthRx stockholders, 1,454,079 of which are subject to repurchase by us in the event development of ANX-188 does not achieve the First Milestone, as described below, and 200,000 of which are subject to escrow to indemnify us against breaches of representations and warranties in the merger agreement, and we assumed \$0.3 million of SynthRx s transaction expenses. We could issue up to an aggregate of 13,478,050 additional shares of our common stock to the former SynthRx stockholders if the development of ANX-188 achieves certain milestones, as described below. Of the shares issuable in connection with achievement of milestones, up to 1,000,000 shares would be issuable upon 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 ANX-188 for the treatment of sickle cell crisis in children, or the ANX-188 NDA, which we refer to as the First Milestone; 3,839,400 shares would be issuable upon acceptance for review of the ANX-188 NDA by the FDA, which we refer to as the Second Milestone; and 8,638,650 shares would be issuable upon approval by the FDA of the ANX-188 NDA, which we refer to as the Third Milestone. The amounts of the 1,454,079 shares and the 1,000,000 shares that potentially vest or become issuable, as applicable, upon achievement of the First Milestone are subject to reduction 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.

With respect to ANX-514, following our October 2011 meeting with the FDA at which we proposed Study 514-02 and the FDA agreed that it would generate sufficient clinical data to support approval of ANX-514 without requiring

corticosteroid premedication, we are focused on conducting activities that would enable us to initiate Study 514-02 in 2012. We have incurred and expect to continue to incur significant R&D expenses in connection with initiating and conducting the 400-patient Study 514-02, including costs related to developing the protocol for the study, conducting manufacturing process development activities, manufacturing the clinical trial material, engaging a contract research organization, or CRO, to manage the trial and conducting the trial.

We believe ANX-514 has the potential to improve the tolerability and safety of docetaxel treatment while eliminating toxicities associated with the presence of the polysorbate 80 detergent in Taxotere and complications associated with the high-dose corticosteroid premedication required for treatment with Taxotere. Based on data from IMS Health, in 2010, before it went off-patent, sales of Taxotere were \$1.2 billion in the U.S. and \$2.9 billion worldwide. We currently estimate that peak annual sales of ANX-514 in the U.S. will be in excess of \$100 million. In parallel with our development of ANX-514, we also expect to continue to pursue partnering and other strategic opportunities for ANX-514, including its sale or exclusive license to a third party. However, partnering and other strategic options may not be available on acceptable terms, if at all.

(20)

Table of Contents

With respect to Exelbine, following our receipt of a complete response letter from the FDA in August 2011 and our September 2011 meeting with the FDA to discuss the complete response letter, we determined to discontinue any significant additional capital investments into the Exelbine program and we are seeking a partner or outside investor for the program.

During 2010 and the first half of 2011, our business strategy involved a particular focus on expanding our product pipeline through one or more in-license, asset acquisition or merger transactions. Although, currently, we are focused on developing ANX-188 and ANX-514, from time to time we evaluate additional pipeline expansion opportunities that we believe may increase the value of our company. We believe that, due to the continued challenging capital-raising environment, many drug development programs with substantial potential may be available at attractive valuations. The process of identifying and evaluating various opportunities can be lengthy and complex and divert management s attention from our current development programs, and we may not be able to acquire or acquire rights to additional technologies, product candidates and/or products on acceptable terms, or at all. We have limited resources to identify, evaluate and negotiate the acquisition of new technologies, product candidates and/or products or rights thereto and to integrate them into our current infrastructure. 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.

We may seek to raise substantial additional capital in the near-term through public or private sales of our equity securities or debt financings to support development of ANX-188 and ANX-514, including our planned phase 3 clinical trials of those product candidates. However, we may not be able to obtain additional financing on a timely basis or on acceptable terms, if at all.

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 announcements and their effect, if any, on us.

Forward Looking Statements

This quarterly 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, indicate and similar expressions. Examples of forward-looking statements in continue. anticipate. intend. expect. but are not limited to, statements we make regarding activities, timing and costs related to developing and seeking regulatory approval for our product candidates, estimated peak annual sales for our product candidates, seeking to partner or collaborate with third parties with respect to the development and commercialization of our product candidates, seeking to partner or find an outside investor for our Exelbine program, 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 to obtain additional funding to develop our current product candidates and any product candidates or products we may acquire in the future, on a timely basis or on acceptable terms, or at all;

our ability to establish and maintain relationships with third-party manufacturers and component suppliers for our product candidates, and the ability of such manufacturers and suppliers, which may be single source manufacturers and suppliers, to successfully manufacture and supply clinical trial material;

(21)

Table of Contents

delays in the commencement or completion of nonclinical testing and/or clinical trials of or manufacturing activities related to our product candidates;

the success of future clinical trials:

undesirable side effects that our product candidates may cause, including as a result of eliminating corticosteroid premedication with ANX-514;

the satisfactory performance of third parties on whom we rely significantly to conduct our nonclinical testing and clinical trials and other aspects of our development programs;

healthcare reform measures and reimbursement policies that, if not favorable to our product candidates, could hinder or prevent our ability to raise capital and, ultimately, the commercial success of our products;

our ability, or that of a future partner, to successfully develop and obtain regulatory approval for our product candidates and, if approved, to successfully commercialize them in the U.S. and/or elsewhere;

the extent to which we acquire new technologies, product candidates, products or businesses and our ability to integrate them, including the assets we acquired from SynthRx, Inc., successfully into our operations;

the potential that we may enter into one or more commercial partnerships or other strategic transactions relating to our product candidates, and the terms of any such transactions;

whether any of our product candidates for which we receive regulatory approval, if any, achieve broad market acceptance;

our ability to maintain compliance with NYSE Amex continued listing standards and maintain the listing of our common stock on the NYSE Amex equities market or another national securities exchange;

the extent to which we rebuild our workforce and our ability to attract and retain qualified personnel and manage growth;

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; and

the other factors that are described in the section entitled Risk Factors, in Item 1A of Part I of our annual report on Form 10-K for the year ended December 31, 2010.

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 the rules and regulations of the U.S. Securities and Exchange Commission, or SEC, as a smaller reporting company we are not required to provide the information required by this item.

(22)

Table of Contents

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2011.

Changes in Internal Control over Financial Reporting

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

PART II OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Under the rules and regulations of 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. (Removed and Reserved)

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.

(23)

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 8, 2011 By: /s/ Brian M. Culley

Brian M. Culley

Chief Executive Officer (Principal Executive Officer)

By: /s/ Patrick L. Keran Patrick L. Keran

President and Chief Operating Officer

(Principal Financial Officer)

(24)

Table of Contents

EXHIBIT INDEX

Exhibit	Description
10.1(1)#	2011 Mid-Year Executive Incentive Plan
10.2#	Form of Incentive Stock Option Grant Agreement (for the registrant's Chief Executive Officer and President and Chief Operating Officer) 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.
- (1) Filed with the registrant s Current Report on Form 8-K on July 8, 2011 (SEC file number 001-32157-11959481).

(25)