# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark	One)	)
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# **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.)

6725 Mesa Ridge Road, Suite 100, San Diego, CA

92121

(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  $\square$  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 o 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  $\square$ 

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

The number of shares outstanding of the registrant's common stock, \$0.001 par value per share, as of November 1, 2010 was 14,701,216.

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# PART I — FINANCIAL INFORMATION

#### **Item 1. Financial Statements**

# ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

# **Condensed Consolidated Balance Sheets**

	Se	September 30, 2010		ecember 31, 2009
	(	(Unaudited)		
Assets				
Current assets:				
Cash	\$	29,331,773	\$	8,667,404
Restricted cash		623,513		
Interest and other receivables		12,634		14,841
Prepaid expenses		487,677		290,249
Total current assets		30,455,597		8,972,494
Property and equipment, net		30,744		44,210
Other assets	_	2,221	_	10,513
Total assets	\$	30,488,562	\$	9,027,217
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	260,067	\$	385,358
Accrued liabilities		685,620		1,379,010
Preferred stock dividends obligation		623,513		_
Accrued compensation and payroll taxes	_	130,685	_	589,319
Total current liabilities		1,699,885	_	2,353,687
Stockholders' equity:				
Convertible Preferred Stock, Series A through F, \$0.001 par value, 53,776.13 shares authorized; 2,884.57 (all Series F) and 0 shares issued and outstanding at September 30,		2.452.464		
2010 and December 31, 2009, respectively (liquidation preference of \$3,508,083)  Common stock, \$0.001 par value; 500,000,000 shares authorized; 14,701,216 and 8,211,410 shares issued and outstanding at September 30, 2010 and December 31, 2009,		2,472,161		_
respectively		14,701		8,211
Additional paid-in capital		180,146,429		148,703,722
Deficit accumulated during the development stage	_	(153,844,614)	(	142,038,403)
Total stockholders' equity	_	28,788,677		6,673,530
Total liabilities and stockholders' equity	\$	30,488,562	\$	9,027,217

Note: The balance sheet at December 31, 2009 has been derived from audited financial statements at that date. It does not include, however, all of the information and notes required by accounting principles generally accepted in the United States of America for complete financial statements.

See accompanying notes to unaudited condensed consolidated financial statements.

#### **ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**

(A Development Stage Enterprise)

# **Condensed Consolidated Statements of Operations**

(Unaudited)

Inception

(June 12, 1996) Three months ended September 30, Nine months ended September 30, through 2009 September 30, 2010 2010 2010 2009 \$ 1,300,000 Licensing revenue \$ \$ \$ 300,000 \$ Net sales 174,830 Grant revenue 129,733 300,000 1,604,563 Total net revenue Cost of sales 51,094 300,000 1,553,469 Gross margin Operating expenses: Research and development 918,309 1,444,038 2,791,404 4,546,235 71,313,609 Selling, general and administrative 944,950 893,477 3,422,843 3,744,470 51,390,353 Depreciation and amortization 4,879 12,350 16,526 70,431 10,894,324 In-process research and 10,422,130 development Impairment loss — write off of goodwill 5,702,130 Equity in loss of investee 178,936 Total operating expenses 1,868,138 2,349,865 6,230,773 8,361,136 149,901,482 (2,349,865)(148, 348, 013)(1,868,138)(6,230,773)(8,061,136)Loss from operations Loss on fair value of warrants (12,239,688)40 68,006 Interest income 26,258 2,432 4,657,194 Interest expense (1,629)(180,719)(2,761)63,826 Other income (expense) (2,019)(2,019)(46,434)Loss before cumulative effect of change in accounting (156,047,400)principle (1,843,899)(2,352,586)(6,166,415)(8,105,138)Cumulative effect of change in accounting principle (25,821)(1,843,899)(2,352,586)(8,105,138)Net loss (6,166,415)(156,073,221)Preferred stock dividends (621,240)Deemed dividends on preferred stock (376,089)(5,639,796)(1,608,504)(10,506,683)Net loss applicable to common stock (1,843,899)(2,728,675)\$ (11,806,211) (9,713,642)(167,201,144)Net loss per common share (0.57) basic and diluted (0.94)(0.13)(2.40)Weighted average shares -12,593,971 4,046,376 basic and diluted 14,701,216 4,779,228

See accompanying notes to unaudited condensed consolidated financial statements.

# ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

# (A Development Stage Enterprise) Condensed Consolidated Statements of Cash Flows

(Unaudited)

Inception

	Nine months end	(June 12, 1996) through		
	2010	2009	September 30, 2010	
Cash flows from operating activities:				
Caon no no nom operating activates				
Net loss	\$ (6,166,415)	\$ (8,105,138)	\$ (156,073,221)	
Adjustments to reconcile net loss to net cash used in operating				
activities:	4.C. ED.C	<b>50.404</b>	40.444.225	
Depreciation and amortization	16,526	70,431	10,444,325	
Loss on disposals of fixed assets Loss on fair value of warrants	2,019	59,012	57,535 12,239,688	
Expenses related to employee stock options and restricted	<del>_</del>		12,239,000	
stock issued	604,772	454,827	9,042,771	
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:	(106 020)	42 21E	(740,001)	
(Increase) decrease in prepaid expenses and other assets	(186,929)	43,215	(749,901) 1,253,078	
Increase (decrease) in accounts payable and accrued liabilities	(1,277,316)	(2,508,501)		
Net cash used in operating activities	(7,007,343)	(9,986,154)	(105,446,406)	
Cash flows from investing activities:				
Purchases of short-term investments			(111,183,884)	
Proceeds from sales and maturities of short-term investments	<u> </u>	<u> </u>	112,788,378	
Purchases of property and equipment	(6,780)	_	(1,037,134)	
Proceeds from sale of property and equipment	1,700	16,000	51,606	
Purchase of certificate of deposit			(1,016,330)	
Maturity of certificate of deposit	_	_	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	(5,080)	16,000	1,036,154	
Cash flows from financing activities:				
Proceeds from sale of preferred stock	30,453,227	4,276,000	44,474,720	
Proceeds of restricted cash for preferred stock dividends	633,008	_	633,008	
Proceeds from sale of common stock	_	_	84,151,342	
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 obligation	(633,008)	_	(633,008)	
Repurchase of warrants	(2.002.502)	(000.1.10)	(55,279)	
Payments for financing and offering costs	(3,093,733)	(996,140)	(10,994,046)	
Payments on notes payable and long-term debt	_	_	(605,909)	
Proceeds from issuance of notes payable and detachable warrants	(1.46)	<del>-</del>	1,344,718	
Cash paid in lieu of fractional shares for reverse stock split	(146)		(146)	
Net cash provided by financing activities	27,676,792	3,279,860	133,742,025	
Matternation (Income)	20.004.200	(6,600,00.0	00.004.550	
Net increase (decrease) in cash	20,664,369	(6,690,294)	29,331,773	
Cash at beginning of period	8,667,404	9,849,904		

Cash at end of period <u>\$ 29,331,773</u> <u>\$ 3,159,610</u> <u>\$ 29,331,773</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

#### 1. Basis of Presentation

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation ("ADVENTRX," "we," "our" or the "Company"), prepared the 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, 2009 included in our Annual Report on Form 10-K filed with the SEC on March 18, 2010 ("2009 Annual Report"). The condensed consolidated balance sheet as of December 31, 2009 included in this report has been derived from the audited consolidated financial statements included in the 2009 Annual Report. In the opinion of management, these 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 ADVENTRX (Europe) Ltd. up until its dissolution. We dissolved ADVENTRX (Europe) Ltd. in December 2009. 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. All common stock share and per share information in the condensed consolidated financial statements and notes thereto included in this report have been restated to reflect retrospective application of the reverse stock split for all periods presented ending or as of a date prior to April 23, 2010, except for par value per share and the number of authorized shares, which were not affected by the reverse stock split.

#### 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. 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, 2010 and 2009 was as follows:

	Three months ended September 30,			Nine months ended September 30,				
		2010		2009		2010		2009
Selling, general and administrative expense	\$	154,041	\$	135,343	\$	610,329	\$	424,095
Research and development expense		(1,243)		14,305		(5,557)		30,731
Share-based compensation expense before taxes		152,798		149,648		604,772		454,826
Related income tax benefits		<u> </u>				<u> </u>		
Share-based compensation expense	\$	152,798	\$	149,648	\$	604,772	\$	454,826
Net share-based compensation expense per common share — basic and diluted	\$	0.01	\$	0.03	\$	0.05	\$	0.11

In January 2009, we granted restricted stock units under our 2008 Omnibus Incentive Plan to seven employees that represented the right to receive in the aggregate 148,000 shares of our common stock. These units were to vest immediately prior to a strategic transaction (as defined in the documentation evidencing the grant of the units). We would record share-based compensation expense in connection with these restricted stock units, if at all, only if a strategic transaction was consummated. All of the restricted stock units granted in January 2009 were subsequently canceled in the first, second and third quarters of 2009 as a result of employee terminations and resignations and in connection with certain compensation arrangements with our remaining employees. As of September 30, 2010 and 2009, no restricted stock units were outstanding.

There were no employee or non-employee director stock options exercised during the three and nine months ended September 30, 2010 and 2009. 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, 2010, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was \$1.0 million, which is expected to be recognized over a weighted-average period of 2.7 years. During the three months ended September 30, 2009, we granted stock options to acquire an aggregate of 135,998 shares of our common stock to our employees with an estimated weighted-average grant date fair value of \$3.18 per share. No stock options were granted to our employees during the first six months of 2009. No stock options, or any other equity-based awards, were granted to our non-employee directors during the nine months ended September 30, 2009.

#### 4. 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. Our components of comprehensive loss consist only of net loss. For the nine months ended September 30, 2010 and 2009, comprehensive loss was \$6.2 million and \$8.1 million, respectively.

#### 5. 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. As of September 30, 2010 and 2009, our outstanding common stock equivalents consisted of options, warrants and convertible preferred stock as follows:

	Septemb	oer 30,
	2010	2009
Options	421,737	234,356
Warrants	4,055,030	826,344
Convertible preferred stock	779,092	_
	5,255,859	1,060,700

#### 6. Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2009-13, Revenue Recognition (ASC 605) — Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force. The guidance modifies the fair value requirements of Accounting Standards Codification ("ASC") subtopic 605-25 Revenue Recognition — Multiple Element Arrangements by providing principles for allocation of consideration among its multiple elements, allowing more flexibility in identifying and accounting for separate deliverables under an arrangement. An estimated selling price method is introduced for valuing the elements of a bundled arrangement if vendor-specific objective evidence or third-party evidence of selling price is not available, and significantly expands related disclosure requirements. This guidance is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Currently, we have no multiple-deliverable revenue arrangements that would be affected by this guidance.

#### 7. Licensing Revenue

In June 2010, we announced that we had entered into a license agreement with respect to our know-how to develop, make, use and sell ANX-510, or CoFactor® (5,10-methylenetetrahydrofolate), with Theragence, Inc., a California corporation ("Theragence"). Pursuant to the agreement, we granted to Theragence an exclusive worldwide license, including the right to grant sublicenses under certain circumstances, to conduct research on and to develop, make, have made, use, offer for sale, sell, have sold and import licensed products in any field or use. We are entitled to receive royalties on net sales of licensed products and commercial milestone payments of up to approximately \$30 million based on aggregate gross sales of licensed products in the United States, European Union and Japan. Theragence agreed to use commercially reasonable efforts to research, develop and commercialize at least one licensed product. We discontinued active work on our CoFactor program in October 2008.

In March 2009, we announced that we and our wholly-owned subsidiary, SD Pharmaceuticals, Inc., had entered into a license agreement with respect to our product candidate ANX-514 (docetaxel lyophilized emulsion for injection) with Shin Poong Pharmaceutical Co., Ltd., a company organized under the laws of the Republic of Korea ("Shin Poong"), pursuant to which we granted to Shin Poong an exclusive license, including the right to sublicense, to research, develop, make, have made, use, offer for sale, sell and import licensed products, in each case solely for the treatment of cancer by intravenous administration of formulations of docetaxel as emulsified products and solely in South Korea. Under the terms of the agreement, we received an upfront licensing fee of \$0.3 million, and are entitled to receive a regulatory milestone payment of either \$0.2 million or \$0.4 million upon receipt of regulatory approval for marketing a licensed product in South Korea (the amount depends on whether the Korea Food and Drug Administration requires Shin Poong to conduct a bioequivalence or clinical study in human subjects prior to receipt of regulatory approval), one-time commercial milestone payments tied to annual net sales of licensed products in an aggregate amount of up to \$1.5 million and royalty payments on net sales of licensed products. Shin Poong is responsible for all development and commercial activities related to ANX-514 in South Korea. We agreed to pay Shin Poong \$0.1 million if the Korea Food and Drug Administration required Shin Poong to conduct a bioequivalence or clinical trial in human subjects prior to receipt of regulatory approval and we elect not to supply product to conduct such trial, which supply obligation is subject to limitations.

We received the \$0.3 million upfront licensing fee in April 2009. We recognized \$0.3 million in licensing revenue in the three-month period ended March 31, 2009 because the criteria under our revenue recognition policy were met in that period.

In September 2010, pursuant to the terms of the license agreement, we elected to make the \$0.1 million cash payment to Shin Poong in lieu of supplying product for the ANX-514 trial in human subjects required by the Korea Food and Drug Administration.

#### 8. Supplementary Cash Flow Information

Noncash investing and financing transactions presented separately from the condensed consolidated statements of cash flows for the nine months ended September 30, 2010 and 2009 and for the period from inception (June 12, 1996) through September 30, 2010 are as follows:

			 ember 30,	(June tl	ception e 12, 1996) nrough	
	201	0	 2009	September 30, 2010		
Supplemental disclosures of cash flow information						
Interest paid	\$	1,629	\$ 	\$	180,719	
Income taxes paid		—	_		_	
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	5	54,260	34,632		151,597	
Acquisitions		_	_		24,781,555	
Payment of dividends		_	_		213,000	
Financial advisor services in connection with private placements	72	24,286	240,012		2,553,554	
Acquisition of treasury stock in settlement of a claim		_	_		34,747	
Cancellation of treasury stock		—	_		(34,747)	
Assumptions of liabilities in acquisitions		—	_		1,235,907	
Acquisition of license agreement for long-term debt		_	_		161,180	
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	7,14	10,389	455,500		12,878,889	

#### 9. Severance Related Expenses

As part of restructuring to reduce operating costs, we completed workforce reductions of nine employees in the three months ended December 31, 2008 and fifteen employees in the six months ended June 30, 2009. As a result, we recorded severance-related charges of \$350,000 in the first quarter of 2009, of which \$237,000 was recorded in research and development and the balance was recorded in selling, general and administrative, and \$163,000 in the second quarter of 2009, of which \$121,000 was recorded in research and development and the balance was recorded in selling, general and administrative. As of June 30, 2009, all severance-related costs associated with these workforce reductions had been paid. No severance-related costs were recorded or paid during the three months ended September 30, 2009.

#### 10. Stockholders' Equity

#### Reverse Stock Split

At a special meeting of our stockholders held on August 25, 2009, our stockholders approved a proposal to authorize our board of directors, in its discretion, to effect a reverse split of our outstanding common stock without further action by our stockholders. In April 2010, our board of directors approved a 1-for-25 reverse split of our common stock and on April 23, 2010 at 4:01 p.m. Eastern time, the reverse stock split became effective. As a result of the reverse stock split, each 25 shares of our issued and outstanding common stock were automatically reclassified as and changed into one share of our common stock. The reverse stock split reduced the number of our issued and outstanding shares of common stock as of April 23, 2010 from approximately 257.3 million shares to approximately 10.3 million shares. No fractional shares were issued in connection with the reverse stock split. Stockholders who were entitled to fractional shares instead became entitled to receive a cash payment in lieu of receiving fractional shares (after taking into account and aggregating all shares of our common stock then held by such stockholder) equal to the fractional share interest multiplied by \$4.6275 (the per share closing price of our common stock (on a post-split basis) as determined by the NYSE Amex on April 23, 2010). The reverse stock split affected all of the holders of our common stock uniformly. Shares of our common stock underlying outstanding options and warrants were proportionately reduced and the exercise prices of outstanding options and warrants were proportionately increased in accordance with the terms of the agreements governing such securities. All common stock share and per share information in the condensed consolidated financial statements and notes thereto included in this report have been restated to reflect retrospective application of the reverse stock split for all periods presented ending or as of a date on or prior to April 23, 2010, except for par value per share and the number of authorized shares, which were not affected by the reverse stock split.

#### 0% Series A Convertible Preferred Stock

In June 2009, we completed a registered direct equity financing raising gross proceeds of approximately \$2.0 million involving the issuance of 1,993 shares of our 0% Series A Convertible Preferred Stock with a stated value of \$1,000 per share ("Series A Stock"), and 5-year warrants to purchase up to 324,651 shares of our common stock at an exercise price of \$3.75 per share. In the aggregate, the shares of Series A Stock we issued were convertible into 721,447 shares of our common stock. All of the shares of the Series A Stock have been converted into common stock and are no longer outstanding. We received approximately \$1.7 million in net proceeds from the financing, after deducting the placement agent's fees and expenses and other offering expenses. In December 2009, in connection with the exercise of warrants issued in the June 2009 financing, we issued 240,000 shares of our common stock and received net proceeds of \$0.9 million. In January 2010, in connection with the exercise of the remaining warrants issued in the June 2009 financing, we issued an additional \$4,651 shares of our common stock and received an additional \$0.3 million of net proceeds. All of the warrants we issued in the June 2009 financing have been exercised and are no longer outstanding.

The convertible feature of our Series A Stock and the terms of the warrants issued in connection with our Series A Stock provided for a rate of conversion or exercise that was below the market value of our common stock at issuance. The convertible feature of our Series A Stock is characterized as a beneficial conversion feature ("BCF"). The estimated relative fair values of the shares of our Series A Stock and the warrants issued in connection with such stock were calculated as approximately \$1.2 million and \$531,000, respectively. The value of the BCF was determined using the intrinsic value method and calculated as approximately \$1.2 million. Because our Series A Stock did not have a stated redemption date, the value of the BCF was fully realized at the time our Series A Stock was issued. The fair value of the warrants was determined using the Black-Scholes option-pricing model as of the date of issuance assuming a five-year term, stock volatility of 197.01%, and a risk-free interest rate of 2.81%. The value of the BCF was treated as a deemed dividend to the holders of our Series A Stock and, due to the potential immediate convertibility of our Series A Stock at issuance, was recorded as an increase to additional paid-in capital and accumulated deficit at the time of issuance.

We also issued warrants to purchase up to 36,071 shares of our common stock at an exercise price of \$3.75 per share to the placement agent in the June 2009 financing as additional consideration for its services in connection with the financing. These warrants had a fair value of approximately \$132,000 using the Black-Scholes option-pricing model as of the date of issuance assuming a five-year term, stock volatility of 196.5%, and a risk-free interest rate of 2.85%. The warrants became exercisable on December 13, 2009 and are exercisable at any time on or before June 12, 2014.

#### 5% Series B Convertible Preferred Stock

In July 2009, we completed a registered direct equity financing raising gross proceeds of approximately \$1.4 million involving the issuance of 1,361 shares of our 5% Series B Convertible Preferred Stock with a stated value of \$1,000 per share ("Series B Stock"). In the aggregate, the shares of Series B Stock we issued were convertible into 380,167 shares of our common stock. All of the shares of our Series B Stock have been converted into common stock and are no longer outstanding. Our Series B Stock would have accrued a cumulative annual dividend of 5% per share until July 6, 2014, and no dividend thereafter. In accordance with the terms of the Series B Stock, because the Series B Stock was converted prior to July 6, 2014, we paid the holders an amount equal to the total dividend that would have accrued in respect of the shares converted from the issuance date through July 6, 2014, or \$250 per \$1,000 of stated value of the shares converted. We received approximately \$0.8 million in net proceeds from the financing after deducting the \$340,250 we placed into an escrow account to pay the aggregate dividend payment in respect of our Series B Stock, placement agent's fees and expenses and other offering expenses.

The convertible feature of our Series B Stock and the value of the dividend in respect thereof provided for a rate of conversion that was below the market value of our common stock at issuance. The convertible feature of our Series B Stock is characterized as a BCF. The estimated relative fair value of the shares of our Series B Stock was calculated as approximately \$1.0 million. The value of the BCF was determined using the intrinsic value method and calculated as approximately \$215,000. Because our Series B Stock did not have a stated redemption date, the value of the BCF was fully realized at the time our Series B Stock was issued. The value of the BCF was treated as a deemed dividend to the holders of our Series B Stock and, due to the potential immediate convertibility of our Series B Stock at issuance, was recorded as an increase to additional paid-in capital and accumulated deficit at the time of issuance.

We also issued warrants to purchase up to 19,007 shares of our common stock at an exercise price of \$4.48 per share to the placement agent in the July 2009 financing as additional consideration for its services in connection with the financing. These warrants had a fair value of approximately \$60,000 using the Black-Scholes option-pricing model as of the date of issuance assuming a five-year term, stock volatility of 197.37%, and a risk-free interest rate of 2.4%. The warrants became exercisable on January 7, 2010 and are exercisable at any time on or before July 6, 2014.

#### 5% Series C Convertible Preferred Stock

In August 2009, we completed a registered direct equity financing raising gross proceeds of approximately \$0.9 million involving the issuance of 922 shares of our 5% Series C Convertible Preferred Stock with a stated value of \$1,000 per share ("Series C Stock"). In the aggregate, the shares of Series C Stock we issued were convertible into 283,692 shares of our common stock. All of the shares of our Series C Stock have been converted into common stock and are no longer outstanding. Our Series C Stock would have accrued a cumulative annual dividend of 5% per share until February 10, 2012, and no dividend thereafter. In accordance with the terms of the Series C Stock, because the Series C Stock was converted prior to February 10, 2012, we paid the holders an amount equal to the total dividend that would have accrued in respect of the shares converted from the issuance date through February 10, 2012, or \$125 per \$1,000 of stated value of the shares converted. We received approximately \$0.7 million in net proceeds from the financing after deducting the \$115,250 we placed into an escrow account to pay the aggregate dividend payment in respect of our Series C Stock, placement agent's fees and expenses and other offering expenses.

The convertible feature of our Series C Stock and the value of the dividend in respect thereof provided for a rate of conversion that was below the market value of our common stock at issuance. The convertible feature of our Series C Stock is characterized as a BCF. The estimated relative fair value of the shares of our Series C Stock was calculated as approximately \$807,000. The value of the BCF was determined using the intrinsic value method and calculated as approximately \$186,000. Because our Series C Stock did not have a stated redemption date, the value of the BCF was fully realized at the time our Series C Stock was issued. The value of the BCF was treated as a deemed dividend to the holders of our Series C Stock and, due to the potential immediate convertibility of our Series C Stock at issuance, was recorded as an increase to additional paid-in capital and accumulated deficit at the time of issuance.

We also issued warrants to purchase up to 14,183 shares of our common stock at an exercise price of \$4.06 per share to the placement agent in the August 2009 financing as additional consideration for its services in connection with the financing. These warrants had a fair value of approximately \$48,000 using the Black-Scholes option-pricing model as of the date of issuance assuming a five-year term, stock volatility of 198.94%, and a risk-free interest rate of 2.75%. The warrants became exercisable on February 10, 2010 and are exercisable at any time on or before August 10, 2014.

#### 4.25660% Series D Convertible Preferred Stock

In October 2009, we completed a registered direct equity financing raising gross proceeds of approximately \$11.3 million involving the issuance of 11,283 shares of our 4.25660% Series D Convertible Preferred Stock with a stated value of \$1,000 per share ("Series D Stock"), and 5-year warrants to purchase up to an aggregate of 792,000 shares of our common stock. In the aggregate, the shares of Series D Stock we issued were convertible into 2,400,000 shares of our common stock. All of the shares of our Series D Stock have been converted into common stock and are no longer outstanding. Our Series D Stock would have accrued a cumulative annual dividend of 4.25660% per share until October 9, 2020, and no dividend thereafter. In accordance with the terms of the Series D Stock, because the Series D Stock was converted prior to October 9, 2020, we paid the holders an amount equal to the total dividend that would have accrued in respect of the shares converted from the issuance date through October 9, 2020, or \$468.23 per \$1,000 of stated value of the shares converted. We received approximately \$5.1 million in net proceeds from the financing after deducting the approximately \$5.3 million we placed into an escrow account to pay the aggregate dividend payment in respect of our Series D Stock, placement agent's fees and expenses and other offering expenses. In December 2009, in connection with the exercise of warrants issued in the October 2009 financing, we issued 576,000 shares of our common stock and received net proceeds of \$2.1 million. We may receive an additional \$0.8 million of net proceeds from the exercise of the remaining warrants issued in the October 2009 financing. Those warrants, which have an exercise price of \$3.67 per share, are exercisable any time on or before October 9, 2014, subject to certain beneficial ownership limitations.

The convertible feature of our Series D Stock and the terms of the warrants issued in connection with our Series D Stock provide for a rate of conversion or exercise that was below the market value of our common stock at issuance. The convertible feature of our Series D Stock is characterized as BCF. The estimated relative fair values of the shares of our Series D Stock and the warrants issued in connection with such stock were calculated as approximately \$3.9 million and \$1.3 million, respectively. The value of the BCF was determined using the intrinsic value method and calculated as approximately \$3.3 million. Because our Series D Stock did not have a stated redemption date, the value of the BCF was fully realized at the time our Series D Stock was issued. The fair value of the warrants was determined using the Black-Scholes option-pricing model as of the date of issuance assuming a five-year term, stock volatility of 197.63%, and a risk-free interest rate of 2.36%. The value of the BCF was treated as a deemed dividend to the holders of our Series D Stock and, due to the potential immediate convertibility of our Series D Stock at issuance, was recorded as an increase to additional paid-in capital and accumulated deficit at the time of issuance.

We also issued warrants to purchase up to 144,000 shares of our common stock at an exercise price of \$5.88 per share to the placement agent in the October 2009 financing as additional consideration for its services in connection with the financing. These warrants had a fair value of approximately \$452,000 using the Black-Scholes option-pricing model as of the date of issuance assuming a five-year term, stock volatility of 197.63%, and a risk-free interest rate of 2.36%. The warrants are exercisable at any time on or after April 7, 2010 and on or before October 6, 2014.

#### 3.73344597664961% Series E Convertible Preferred Stock

In January 2010, we completed a registered direct equity financing raising gross proceeds of \$19.0 million involving the issuance of 19,000 shares of our 3.73344597664961% Series E Convertible Preferred Stock with a stated value of \$1,000 per share ("Series E Stock"), and 30-month warrants to purchase up to an aggregate of 498,488 shares of our common stock. In the aggregate, the shares of Series E Stock we issued were convertible into 1,993,965 shares of our common stock. All of the shares of our Series E Stock have been converted into common stock and are no longer outstanding. Our Series E Stock would have accrued a cumulative annual dividend of 3.73344597664961% per share until January 7, 2015, and no dividend thereafter. In accordance with the terms of the Series E Stock, because the Series E Stock was converted prior to January 7, 2015, we paid the holders an amount equal to the total dividend that would have accrued in respect of the shares converted from the issuance date through January 7, 2015, or \$186.67 per \$1,000 of stated value of the shares converted. We received approximately \$14.0 million in net proceeds from the financing after deducting the approximately \$3.5 million we placed into an escrow account to pay the aggregate dividend payment in respect of our Series E Stock, placement agent's fees and expenses and other offering expenses. We may receive up to approximately \$4.4 million of additional proceeds from the exercise of the warrants issued in the January 2010 financing. Those warrants, which have an exercise price of \$8.75 per share, are exercisable any time on or before July 6, 2012, subject to certain beneficial ownership limitations.

The convertible feature of our Series E Stock and the terms of the warrants issued in connection with our Series E Stock provide for a rate of conversion or exercise that was below the market value of our common stock at issuance. The convertible feature of our Series E Stock is characterized as BCF. The estimated relative fair values of the shares of our Series E Stock and the warrants issued in connection with such stock were calculated as approximately \$12.4 million and \$3.0 million, respectively. The value of the BCF was determined using the intrinsic value method and calculated as approximately \$2.5 million. Because our Series E Stock did not have a stated redemption date, the value of the BCF was fully realized at the time our Series E Stock was issued. The fair value of the warrants was determined using the Black-Scholes option-pricing model as of the date of issuance assuming a 30-month term, stock volatility of 275.79%, and a risk-free interest rate of 1.325%. The value of the BCF was treated as a deemed dividend to the holders of our Series E Stock and, due to the potential immediate convertibility of our Series E Stock at issuance, was recorded as an increase to additional paid-in capital and accumulated deficit at the time of issuance.

We also issued warrants to purchase up to 99,696 shares of our common stock at an exercise price of \$11.91 per share to the placement agent in the January 2010 financing as additional consideration for its services in connection with the financing. These warrants had a fair value of approximately \$724,000 using the Black-Scholes option-pricing model as of the date of issuance assuming a 4.5-year term, stock volatility of 209.46%, and a risk-free interest rate of 2.37%. The warrants are exercisable at any time on or after July 7, 2010 and on or before June 3, 2014.

#### 2.19446320054018% Series F Convertible Preferred Stock

In May 2010, we completed a registered direct equity financing raising gross proceeds of \$19.2 million involving the issuance of 19,217.13 shares of our 2.19446320054018% Series F Convertible Preferred Stock with a stated value of \$1,000 per share ("Series F Stock"), and 5-year and 1-year warrants to purchase up to an aggregate of 2,595,156 shares of our common stock. In the aggregate, the shares of Series F Stock we issued are convertible into 5,190,312 shares of our common stock. As of September 30, 2010, 2,884.57 shares of our Series F Stock were outstanding. All other shares of Series F Stock have been converted into an aggregate of 4,411,220 shares of our common stock. We received approximately \$13.3 million in net proceeds from the financing after deducting the approximately \$4.2 million we placed into an escrow account to pay the aggregate dividend payment in respect of our Series F Stock, placement agent and financial advisor fees and other offering expenses. We may receive up to approximately \$9.5 million of additional proceeds from the exercise of the warrants issued in the May 2010 financing. The exercise price of the warrants is \$3.65 per share. Subject to certain beneficial ownership limitations, the 5-year warrants are exercisable any time on or before May 20, 2011.

Our Series F Stock accrues a cumulative annual dividend of 2.19446320054018% per share until May 6, 2020, and no dividend thereafter. To the extent shares of our Series F Stock are converted at any time prior to May 6, 2020, we are obligated to pay the holder an amount equal to the total dividend that would have accrued in respect of the shares converted, or \$219.45 per \$1,000 of stated value of the shares converted, less the amount of any dividend paid on such shares before their conversion. The dividend on our Series F Stock is payable quarterly on January 1, April 1, July 1 and October 1. As of September 30, 2010, we have paid an aggregate of \$3.6 million out of the escrow account in connection with payments due upon conversion of shares of our Series F Stock and our quarterly dividend payments, and there was approximately \$0.6 million, which we classified as restricted cash, remaining in the escrow account for the benefit of the holders of outstanding shares of our Series F Stock. On October 1, 2010, we paid aggregate dividends of approximately \$15,800 out of the escrow account to the holders of outstanding shares of our Series F Stock in connection with our quarterly dividend payment obligations. Upon any liquidation, dissolution or windingup of our company, whether voluntary or involuntary, the holders of our outstanding Series F Stock are entitled to receive a liquidation preference in an amount equal to the stated value per share, which, as of September 30, 2010, was \$1,000 per share, plus any amount remaining in the escrow account for the benefit of such holders, plus any fees or liquidated damages then due and owing thereon. A merger, consolidation, disposition of all or substantially all of our assets or other change of control transaction will not be deemed a liquidation. As of September 30, 2010, the liquidation preference on the Series F Stock was \$1,216.15 per share, or \$3,508,083 in the aggregate.

The convertible feature of our Series F Stock and the terms of the warrants issued in connection with our Series F Stock provide for a rate of conversion or exercise that was below the market value of our common stock at issuance. The convertible feature of our Series F Stock is characterized as BCF. The estimated relative fair values of the shares of our Series F Stock and the warrants issued in connection with such stock were calculated as approximately \$10.1 million and \$4.9 million, respectively. The value of the BCF was determined using the intrinsic value method and calculated as approximately \$3.1 million. Because our Series F Stock did not have a stated redemption date, the value of the BCF was fully realized at the time our Series F Stock was issued. The fair value of the 5-year warrants was determined using the Black-Scholes option-pricing model as of the date of issuance assuming a 5-year term, stock volatility of 202%, and a risk-free interest rate of 2%. The fair value of the 1-year warrants was determined using the Black-Scholes option-pricing model as of the date of issuance assuming a 1-year term, stock volatility of 361%, and a risk-free interest rate of 0.4%. The value of the BCF was treated as a deemed dividend to the holders of our Series F Stock and, due to the potential immediate convertibility of our Series F Stock at issuance, was recorded as an increase to additional paid-in capital and accumulated deficit at the time of issuance.

#### Common Stock Issued for Warrants Exercised

As described above, in January 2010, we issued 84,651 shares of our common stock and received net proceeds of \$0.3 million in connection with the exercise of the remaining warrants issued in the June 2009 financing at an exercise price of \$3.75 per share.

#### 11. Subsequent Events

In November 2010, the Internal Revenue Service notified us that an aggregate amount of \$488,958 in grants has been awarded to us under the qualifying therapeutic discovery project ("QTDP") program established under Section 48D of the Internal Revenue Code as part 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 ANX-530, or 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 expect full payment of the grants to be made before the end of 2010.

# 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, 2009.

#### Overview

We are a development-stage specialty pharmaceutical company focused on acquiring, developing and commercializing proprietary product candidates for the treatment of cancer. We seek to improve the performance of existing drugs by addressing limitations associated principally with their safety and use. We have devoted substantially all of our resources to research and development, or R&D, or to acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue.

We have incurred annual net losses since inception, and, as of September 30, 2010, our accumulated net losses amounted to \$156.1 million. We had cash of approximately \$29.3 million at September 30, 2010.

Our lead product candidates, ANX-530 (vinorelbine injectable emulsion), or Exelbine™, and ANX-514 (docetaxel lyophilized emulsion for injection), are novel emulsion formulations of currently marketed chemotherapy drugs. In November 2010, we submitted a new drug application, or NDA, for Exelbine to the U.S. Food and Drug Administration, or FDA. In October 2010, we announced that we had received a Notice of Allowance from the U.S. Patent and Trademark Office for our patent application entitled "Compositions for Delivering Highly Water Soluble Drugs" (U.S. Patent Application No. 10/889,226). The patent claims are directed to formulations of vinorelbine bitartrate and, upon issuance, the patent (before taking into account patent term extension) will provide coverage for Exelbine until July 2024.

In addition to developing and seeking regulatory approval for Exelbine and ANX-514, we continue to pursue partnering and other strategic opportunities for these product candidates. We also remain focused on expanding our product pipeline and may do so through one or more in-license, asset acquisition or merger transactions. In August 2010, we announced that we have engaged the investment banking firm Canaccord Genuity Inc. to advise us in connection with expanding our product pipeline and that our board of directors has formed a special committee to assist it in evaluating potential opportunities. The special committee, which includes Drs. Michael Goldberg and Eric Rowinsky and is chaired by Dr. Odysseas Kostas, meets regularly with management and Canaccord Genuity to identify and evaluate opportunities and determine whether to recommend them to the full board of directors.

We continue to evaluate the data from our bioequivalence study of ANX-514 and expect to meet with the FDA to discuss the results. Based on discussions with clinicians and experts in taxane pharmacokinetics, we continue to believe that the differences between study drugs observed in the bioequivalence study are not clinically relevant and do not affect adversely the safety or efficacy of ANX-514 relative to Taxotere. However, given our limited resources and our management's recent focus on submitting the Exelbine NDA, pursuing partnering and other strategic opportunities for Exelbine and ANX-514 and expanding our product pipeline, we have not yet requested a meeting with the FDA to discuss the results of our bioequivalence study of ANX-514, though we expect to do so later this year.

In November 2010, the Internal Revenue Service notified us that an aggregate amount of \$488,958 in grants has been awarded to us under the qualifying therapeutic discovery project ("QTDP") program established under Section 48D of the Internal Revenue Code as part 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 expect full payment of the grants to be made before the end of 2010.

We anticipate that our cash as of September 30, 2010 will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, we may seek to raise additional capital to acquire new technologies and/or product candidates and support their development. In addition, we may pursue development activities for our current product development programs at levels or on timelines, or we may incur unexpected expenses, that shorten the period through which our operating funds will sustain us. We may also need to raise substantial additional capital to support activities that we believe will enhance the value of our current product development programs and increase stockholder value. We may not be able to obtain additional financing on a timely basis or on acceptable terms, if at all.

The FDA has accepted our proposed proprietary name, "Exelbine," for ANX-530. The FDA's acceptance of our Exelbine brand name is conditioned upon its review of an Exelbine NDA and its confirmation of the information in the NDA regarding the safety of interchanging Exelbine with other vinorelbine injectable products. We are developing commercial names for our other product candidates. All trademarks, service marks or trade names appearing in this report, including but not limited to Navelbine<sup>®</sup> and Taxotere<sup>®</sup>, 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.

**R&D** Expenses. R&D expenses consist of expenses incurred in performing R&D activities, including salaries and benefits, facilities and other overhead expenses, bioequivalence and 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.

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 bioequivalence and 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-materials 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 bioequivalence and 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 bioequivalence or 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 bioequivalence and 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 bioequivalence and clinical trial expense accruals that would have had a material impact on our consolidated results of operations or financial position.

**Purchased In-Process Research and Development.** We adopted the Financial Accounting Standards Board's, or FASB's, changes to Accounting Standards Codification, or ASC, 805, "Business Combinations," effective January 1, 2009. The adoption of the changes to ASC 805 did not have a material effect on our consolidated results of operations or financial position. In accordance with previous accounting guidance effective through December 31, 2008, we accounted for the costs associated with any purchased in-process research and development, or IPR&D, as an expense on the statement of operations upon acquisition. These amounts represent 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 determine 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. Effective January 1, 2006, we account for share-based compensation awards granted to employees, including non-employee members of our board of directors, in accordance with ASC 718, "Compensation — Stock Compensation." 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 employee'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 were estimated based on historical experience. Although estimates of share-based compensation expenses are significant to our consolidated financial statements, they are not related to the payment of any cash by us.

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 as of 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. We may elect to use different assumptions under the Black-Scholes model in the future, which could materially affect our net income or loss and net income or loss per share.

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, based on available evidence, it has less than a 50% likelihood of being sustained.

Costs Associated with Exit or Disposal Activities. As part of our efforts to reduce operating costs, we completed one workforce reduction in the fourth quarter of 2008 and two workforce reductions in the first six months of 2009, each of which was accounted for in accordance with ASC 420, "Exit or Disposal Cost Obligations." We recorded severance-related charges, including salary, payroll taxes and healthcare benefits, of \$757,000 in the aggregate over three consecutive quarters beginning in the fourth quarter of 2008. We recorded severance-related charges of \$350,000 in the first quarter of 2009, of which \$237,000 was recorded in research and development and the balance was recorded in selling, general and administrative, and \$163,000 in the second quarter of 2009, of which \$121,000 was recorded in research and development and the balance was recorded in selling, general and administrative. As of June 30, 2009, all severance-related costs associated with these workforce reductions had been paid. No severance-related costs were recorded or paid during the three months ended September 30, 2009.

Convertible Instruments. At issuance, we value separately embedded beneficial conversion features present in convertible securities. Embedded beneficial conversion features are recognized by allocating to additional paid-in capital and accumulated deficit that portion of the net proceeds from the sale of the convertible security equal to the intrinsic value of the beneficial conversion feature. Intrinsic value is calculated as the difference, as of the commitment date, between the conversion price of the convertible security and the fair value of the common stock underlying the convertible security, which for us is the closing price of a share of our common stock as determined by the NYSE Amex multiplied by the number of shares of our common stock into which the convertible security is convertible. If the intrinsic value of the beneficial conversion feature is greater than the net proceeds allocated to the convertible security, the amount of the discount assigned to the beneficial conversion feature is limited to the amount of the net proceeds. In our registered direct equity financings that closed in June, July, August and October 2009 and in January and May 2010, we issued convertible preferred stock securities with non-detachable conversion features that were in-the-money as of the commitment date, which we recognized as beneficial conversion features. Except for 2,884.57 shares of our Series F Stock that were outstanding as of September 30, 2010, all shares of the convertible preferred stock we issued in these financings have been converted into common stock at fixed conversion rates. The embedded beneficial conversion features were valued separately and recognized by allocating to additional paid-in capital and accumulated deficit a portion of the net proceeds equal to the intrinsic value of the beneficial conversion features.

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 preclinical, clinical and laboratory studies and extensive manufacturing information to demonstrate such product's 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 seek approval of product candidates under Section 505(b)(2) of the FDCA or seek approval of product candidates with active ingredients not previously approved by the FDA, and 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 bioequivalence or clinical trials and research-related manufacturing, can vary significantly among programs as a result of a variety of factors, including:

- 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;
- the ratio of randomized to evaluable patients;
- the availability and cost of reference product in the jurisdiction of each site;
- the time and cost of process development activities related to our product candidates;
- the costs of manufacturing our product candidates;
- the time and cost of stability studies, including the need to identify critical parameters, methods to evaluate and test these parameters and validation of such methods and tests; and
- the costs, requirements, timing of and the ability to secure regulatory approvals.

The difficult process of seeking regulatory approvals for our product candidates and compliance with applicable regulations requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our R&D expenditures to increase and, in turn, have a material and unfavorable effect on our results of operations. We cannot be certain when, if ever, we will generate revenues from sales of any of our products.

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, our current contract manufacturer, which is also our intended commercial manufacturer, for both Exelbine and ANX-514 is located outside the U.S. and generally we pay for its services, including technology transfer and process development and validation activities related to ANX-514, in Euros. As a result, our exposure to currency risk likely will increase as we move our products towards commercialization and increase the services we request from our current contract manufacturer. 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 for the treatment of cancer.

#### Comparison of Three Months Ended September 30, 2010 and 2009

*Revenue*. We recognized no revenue for the three months ended September 30, 2010 or 2009.

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 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 out-source 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:

	Thr	ee months end	led Se	ptember 30,		nuary 1, 2005 through ptember 30,
	2010		2009		2010	
External bioequivalence and clinical trial fees and expenses	\$	(61,074)	\$	28,583	\$	23,787,613
External nonclinical study fees and expenses (1)		920,232		1,372,543		26,689,440
Personnel costs		60,394		28,607		10,442,130
Stock-based compensation expense		(1,243)		14,305		2,920,173
Total	\$	918,309	\$	1,444,038	\$	63,839,356

<sup>(1)</sup> External nonclinical study fees and expenses include preclinical, research-related manufacturing, quality assurance and regulatory expenses.

R&D expenses decreased by \$0.5 million, or approximately 36%, to \$0.9 million for the three months ended September 30, 2010, compared to \$1.4 million for the same period in 2009. The decrease in R&D expenses for the three months ended September 30, 2010 compared to the same period in 2009 was due primarily to a \$0.5 million decrease in external nonclinical study fees and expenses. This decrease resulted largely from a \$1.0 million decrease in research-related manufacturing expenses for Exelbine, partially offset by a \$0.3 million increase in fees for consulting services related to Exelbine and ANX-514 and a \$0.2 million increase in toxicology study expenses related to Exelbine. The decrease in external bioequivalence and clinical trial fees and expenses for the three months ended September 30, 2010 compared to the same period in 2009 was attributable primarily to the release of residual accruals for expenses related to ANX-510 clinical trials that were completed in the fourth quarter of 2008 and the first quarter of 2009.

We expect R&D expenses to increase in 2011 relative to 2010 to support continued development of ANX-514 and if and to the extent we acquire and pursue development of new technologies or product candidates.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses were \$0.9 million for both the three months ended September 30, 2010 and 2009. In the three months ended September 30, 2010 compared to the same period in 2009, personnel costs increased by \$0.2 million, partially as a result of increased cost of benefits and an additional employee, and fees for third-party services related to identifying and evaluating strategic opportunities for our product candidates and pipeline expansion increased by \$0.1 million, but fees for professional legal and audit services decreased by \$0.2 million. We expect SG&A expenses to increase in 2011 relative to 2010 if and to the extent we acquire and pursue development of new technologies or product candidates.

*Interest and Other Income.* Interest income amounted to \$26,258 for the three months ended September 30, 2010, compared to \$40 for the same period in 2009. The increase in interest income for the three months ended September 30, 2010 was attributable primarily to overall larger invested balances in 2010 as compared to 2009. Even though we raised a substantial amount of additional capital through our registered direct equity financings in 2009 and in January and May 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 \$1.8 million, or \$0.13 per share, for the three months ended September 30, 2010, compared to net loss applicable to common stock of \$2.7 million, or \$0.57 per share, for the same period in 2009. Included in net loss applicable to common stock for the three months ended September 30, 2009 was non-cash deemed dividend expense of \$0.4 million related to our July and August 2009 registered direct equity financings.

#### Comparison of Nine Months Ended September 30, 2010 and 2009

**Revenue**. We recognized no revenue for the nine months ended September 30, 2010. We recognized revenue of \$0.3 million for the nine months ended September 30, 2009, which represents a nonrefundable license fee under our March 2009 license agreement with respect to ANX-514 with Shin Poong Pharmaceutical Co., Ltd.

**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				
		2010		2009	
External bioequivalence and clinical trial fees and expenses	\$	(14,963)	\$	563,433	
External nonclinical study fees and expenses (1)		2,660,492		3,168,153	
Personnel costs		151,432		783,918	
Stock-based compensation expense		(5,557)		30,731	
Total	\$	2,791,404	\$	4,546,235	

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

R&D expenses decreased by \$1.8 million, or approximately 39%, to \$2.8 million for the nine months ended September 30, 2010, compared to \$4.5 million for the same period in 2009. The decrease in R&D expenses for the nine months ended September 30, 2010 compared to the same period in 2009 was due primarily to a \$0.6 million decrease in external bioequivalence and clinical trial expenses largely as a result of the completion of patient enrollment in the ANX-514 bioequivalence study and the completion of ANX-510 studies in the first quarter of 2009, a \$0.6 million decrease in personnel costs attributable to lower headcount and the absence of severance costs in 2010, and a \$0.5 million decrease in external nonclinical study fees and expenses. The decrease in external nonclinical study fees and expenses was attributable primarily to a \$2.2 million decrease in research-related manufacturing expenses for Exelbine, partially offset by a \$1.2 million increase in fees for consulting services related to Exelbine and ANX-514, a \$0.3 million increase in toxicology study expenses related to Exelbine, and a \$0.2 million increase in research-related manufacturing expenses for ANX-514. The decrease in stock-based compensation expense resulted primarily from the forfeiture of stock option awards in connection with employee terminations in 2009 and 2008.

**Selling, General and Administrative Expenses.** SG&A expenses decreased by \$0.3 million, or approximately 9%, to \$3.4 million for the nine months ended September 30, 2010, compared to \$3.7 million for the same period in 2009. The decrease was due primarily to a \$0.4 million decrease in fees for professional legal, audit and tax services, a \$0.3 million decrease in personnel costs attributable to lower headcount and the absence of severance costs in 2010, and a \$0.1 million decrease in the cost of our facilities lease, partially offset by a \$0.3 million increase in director compensation and stock compensation expense and a \$0.2 million increase in fees for accounting, investor relations and commercialization consulting services.

*Interest and Other Income*. Interest income amounted to \$68,006 for the nine months ended September 30, 2010, compared to \$2,432 for the same period in 2009. The increase in interest income for the nine months ended September 30, 2010 was attributable primarily to overall larger invested balances in 2010 as compared to 2009.

**Net Loss Applicable to Common Stock.** Net loss applicable to common stock was \$11.8 million, or \$0.94 per share, for the nine months ended September 30, 2010, compared to net loss applicable to common stock of \$9.7 million, or \$2.40 per share, for the same period in 2009. Included in net loss applicable to common stock for the nine months ended September 30, 2010 and 2009 were non-cash deemed dividend expenses of \$5.6 million and \$1.6 million, respectively, related to our January and May 2010 and June, July and August 2009 registered direct equity financings. Included in both net loss and net loss applicable to common stock for 2009 were charges associated with our 2009 and 2008 workforce reductions.

### **Liquidity and Capital Resources**

We have a history of recurring losses from operations and we have funded our operations primarily through sales of our equity securities. We had a net loss of \$6.2 million for the nine months ended September 30, 2010 and cash of approximately \$29.3 million as of September 30, 2010.

In January and May 2010, we completed registered direct equity financings involving the issuance, respectively, of shares of our 3.73344597664961% Series E Convertible Preferred Stock and our 2.19446320054018% Series F Convertible Preferred Stock. These financings resulted in an aggregate of \$38.2 million in gross proceeds and an aggregate of \$27.4 million in adjusted net proceeds after deducting the fees and expenses of our placement agent and financial advisor in the financings, our offering expenses and the amounts deposited into an escrow account to fund our dividend and related payment obligations. As of September 30, 2010, all of the shares of preferred stock we issued in these financings had been converted into common stock, except for 2,884.57 shares of our Series F Stock. The dividend on our Series F Stock is payable quarterly on January 1, April 1, July 1 and October 1. On July 1 and October 1, 2010, we made payments of approximately \$9,500 and \$15,800, respectively, out of the escrow account to the holders of our outstanding Series F Stock in connection with our quarterly dividend payment obligations.

In January 2010, we received an aggregate of \$0.3 million of net proceeds and issued an aggregate of 84,651 shares of our common stock in connection with the exercise of warrants issued in our June 2009 registered direct equity financing.

We may receive up to \$0.8 million, \$4.4 million and \$9.5 million of additional net proceeds from the exercise of warrants issued in the registered direct equity financings we completed in October 2009 and January and May 2010, respectively; however, the exercise of these warrants is subject to certain beneficial ownership limitations. In addition, we may receive up to \$2.3 million of additional net proceeds from the exercise of warrants issued to our placement agent as additional consideration for services in connection with our June, July, August and October 2009 and January 2010 registered direct equity financings.

See Note 10, "Stockholders' Equity," in the Notes to Condensed Consolidated Financial Statements (Unaudited) in this report, for a more detailed discussion regarding these financings.

In November 2010, the Internal Revenue Service notified us that an aggregate amount of \$488,958 in grants has been awarded to us under the QTDP program. 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 expect full payment of the grants to be made before the end of 2010.

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

**Operating activities**. Net cash used in operating activities was \$7.0 million for the nine months ended September 30, 2010 compared to \$10.0 million for the same period in 2009. The decrease in cash used in operating activities was due primarily to the restructuring and cost-cutting initiatives we implemented beginning in October 2008 through April 2009, specifically our workforce reductions and our discontinuation of active work on all development programs, other than Exelbine and ANX-514, to which we have or had rights during that period.

*Investing activities*. Net cash used in investing activities was \$5,080 for the nine months ended September 30, 2010 compared to net cash provided by investing activities of \$16,000 for the same period in 2009. The difference was due to the purchase of property and equipment net of the receipt of proceeds from the sale of property and equipment in the nine months ended September 30, 2010 compared to the receipt of proceeds from the sale of property and equipment in the nine months ended September 30, 2009.

*Financing activities*. Net cash provided by financing activities was \$27.7 million for the nine months ended September 30, 2010 compared to \$3.3 million for the same period in 2009. The cash provided by financing activities in 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.

#### **Management Outlook**

We anticipate that our cash as of September 30, 2010 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 extent to which we acquire new technologies, product candidates, products or businesses; the scope, prioritization and number of development and/or commercialization programs we pursue; the rate of progress and costs of development and regulatory approval activities associated with our product candidates; the extent to which we partner or collaborate with third parties to develop, seek regulatory approval of and commercialize our product candidates, or sell or license our product candidates or proprietary technologies to others; the costs and timing of acquiring or developing sales, marketing and distribution capabilities and the regulatory compliance and administrative capabilities to commercialize Exelbine in the U.S., if Exelbine is ultimately approved by the FDA and we determine to commercialize it without a partner; the costs and timing of acquiring or developing similar commercialization capabilities for other of our product candidates, including ANX-514, if we determine to commercialize any of them without a partner; and whether any of our product candidates for which we receive regulatory approval, if any, achieve broad market acceptance. In addition, currently, we have only three full-time employees and one part-time employee and rely on third parties to perform many essential services for us. Increasing the size of our workforce will also impact the period through which our operating funds will sustain us, but the timing and extent to which we do so 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.

We continue to pursue partnering and other strategic opportunities for Exelbine and ANX-514, including the sale or exclusive license of one or both of them. However, partnering and other strategic options may not be available on acceptable terms, if at all. If we are unable to consummate partnering or other strategic transactions with regard to Exelbine and ANX-514, we may determine to commercialize these product candidates in the U.S. without a partner if they receive regulatory approval. The FDA has confirmed the appropriateness of a Section 505(b)(2) regulatory path for Exelbine and ANX-514; however, the FDA's view may change. If the FDA requires additional nonclinical testing or clinical studies beyond the bioequivalence studies we have conducted for each of Exelbine and ANX-514, we may determine the associated time and cost is not financially justifiable and, as a result, discontinue these programs.

We also continue to spend significant time and attention identifying and evaluating opportunities to expand our product pipeline and may do so through one or more in-license, asset acquisition or merger transactions. We believe that, due to a challenging capital raising environment, many drug development programs with substantial potential currently are available at attractive valuations. If we seek to expand our product pipeline through a merger or other business combination with one of these companies, given our recent market capitalization and our desire to preserve our cash for development activities, such a transaction may result in our stockholders owning less than a majority of the voting securities of the surviving entity. The process of identifying and evaluating various opportunities may 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 and/or product candidates on acceptable terms, or at all. We have limited resources to identify, evaluate, negotiate and implement the acquisition of new technologies and/or product candidates 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 anticipate that our capital requirements will increase in future periods if we are successful in expanding our product pipeline.

We may also seek to raise additional capital through public or private sales of our equity securities or debt financings. 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 6, "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," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "expect," "indicate" and similar expressions. Examples of forward-looking statements include, but are not limited to, statements we make regarding expanding our product pipeline, activities related to developing and seeking regulatory approval for Exelbine and ANX-514, the issuance of, and the protection provided by, a patent based on U.S. Patent Application No. 10/889,226, seeking to partner or collaborate with third parties with respect to the development and commercialization of Exelbine and ANX-514, the sale or exclusive license of one or both of these product candidate programs, raising additional capital, receipt of cash awards that have been allocated to us under the QTDP program, 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:

- the extent to which we acquire new technologies, product candidates, products or businesses and our ability to integrate them successfully into our operations;
- the potential that we may enter into a merger or other business combination whereby the stockholders who own the majority of our voting securities prior to the transaction own less than a majority after the transaction;
- our or a future partner's ability to obtain regulatory approval for our product candidates and, if approved, to successfully commercialize them in the U.S. and/or elsewhere;
- the potential that we may enter into one or more commercial partnerships or other strategic transactions relating to Exelbine and/or ANX-514, and the terms of any such transactions;
- our ability to obtain stockholder approval to complete a product pipeline expansion transaction, if necessary, on a timely basis, or at all;
- our ability to obtain additional funding on a timely basis or on acceptable terms, or at all;
- · the extent to which we rebuild our workforce and our ability to attract and retain qualified personnel and manage growth;
- delays in the commencement or completion of nonclinical testing, bioequivalence or clinical trials of or manufacturing, regulatory or launch activities related to our product candidates;
- the success of future bioequivalence or clinical trials;
- our ability to develop sales, marketing and distribution capabilities, if we determine to commercialize any of our product candidates for which we obtain regulatory approval without a partner;
- whether any of our product candidates for which we receive regulatory approval, if any, achieve broad market acceptance;
- our ability to maintain our relationships with the single source manufacturers and suppliers for certain of our product candidates and their component materials and the ability of such manufacturers and suppliers to successfully and consistently manufacture and supply, as applicable, our products and their component materials on a commercial scale, if we receive regulatory approval to commercialize our product candidates;
- the satisfactory performance of third parties on whom we rely significantly to conduct our nonclinical testing and bioequivalence and clinical studies and other aspects of our development programs;
- undesirable side effects that our product candidates may cause;
- 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;
- competition in the marketplace for our products, if any are approved;

- healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent our products' commercial success;
- potential product liability exposure and, if successful claims are brought against us, liability for a product or product candidate;
- our ability to maintain compliance with NYSE Amex continued listing standards and maintain the listing of our common stock on the NYSE Amex or another national securities exchange; 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, 2009.

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.

#### **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 (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, 2010.

#### 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.

### **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, 2010 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 and Accounting Officer)

(23)

# EXHIBIT INDEX

Exhibit	Description
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

<sup>\*</sup> 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.

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

#### I, Brian M. Culley, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of ADVENTRX Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 8, 2010

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

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

#### I, Patrick L. Keran, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of ADVENTRX Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 8, 2010

/s/ Patrick L. Keran

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

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

In connection with the Quarterly Report of ADVENTRX Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2010, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian M. Culley, principal executive officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 8, 2010

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

In connection with the Quarterly Report of ADVENTRX Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2010, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Patrick L. Keran, principal financial and accounting officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 8, 2010

/s/ Patrick L. Keran

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