

ADVENTRX PHARMACEUTICALS INC

Form 10-Q

November 07, 2008

**Table of Contents**

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

**(Mark One)**

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

**For the quarterly period ended September 30, 2008**

**OR**

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

**For the transition period from to**

**Commission File Number 001-32157**

**ADVENTRX Pharmaceuticals, Inc.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of incorporation or organization)*

**84-1318182**

*(I.R.S. Employer Identification No.)*

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

*(Address of principal executive offices)*

**92121**

*(Zip Code)*

**(858) 552-0866**

*(Registrant's telephone number, including area code)*

N/A

*(Former name, former address and former fiscal year, if changed since last report)*

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No   
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

(Do not check if a smaller reporting company)

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

The number of shares outstanding of the registrant's common stock, \$0.001 par value, as of November 7, 2008 was 90,252,572.

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<b><u>Item 1. Financial Statements (Unaudited)</u></b>	
<b><u>a. Condensed Consolidated Balance Sheets as of September 30, 2008 and December 31, 2007</u></b>	3
<b><u>b. Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2008 and 2007 and for the period from inception (June 12, 1996) through September 30, 2008</u></b>	4
<b><u>c. Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2008 and 2007 and for the period from inception (June 12, 1996) through September 30, 2008</u></b>	5
<b><u>d. Notes to Condensed Consolidated Financial Statements</u></b>	6
<b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	11
<b><u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u></b>	19
<b><u>Item 4. Controls and Procedures</u></b>	19
<b><u>PART II OTHER INFORMATION</u></b>	
<b><u>Item 1. Legal Proceedings</u></b>	20
<b><u>Item 1A. Risk Factors</u></b>	20
<b><u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	20
<b><u>Item 3. Defaults Upon Senior Securities</u></b>	20
<b><u>Item 4. Submission of Matters to a Vote of Security Holders</u></b>	20
<b><u>Item 5. Other Information</u></b>	20
<b><u>Item 6. Exhibits</u></b>	20
<b><u>SIGNATURES</u></b>	21
<b><u>EX-31.1</u></b>	
<b><u>EX-31.2</u></b>	
<b><u>EX-32.1</u></b>	

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Financial Statements****ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**

(A Development Stage Enterprise)

**Condensed Consolidated Balance Sheets**

	<b>September 30, 2008</b>	<b>December 31, 2007</b>
	(Unaudited)	(Note)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 15,306,476	\$ 14,780,739
Short-term investments		18,682,417
Other receivables	53,904	72,029
Prepaid expenses	1,576,574	615,691
Total current assets	16,936,954	34,150,876
Property and equipment, net	266,701	332,444
Other assets	61,496	58,305
Total assets	\$ 17,265,151	\$ 34,541,625
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 207,873	\$ 552,143
Accrued liabilities	2,960,773	2,317,910
Accrued compensation and payroll taxes	838,226	622,762
Total current liabilities	4,006,872	3,492,815
Long-term liabilities		14,270
Total liabilities	4,006,872	3,507,085
Commitments and contingencies		
Stockholders equity:		
Common stock, \$0.001 par value; 200,000,000 shares authorized; 90,252,572 shares issued and outstanding at September 30, 2008 and December 31, 2007	90,254	90,254
Additional paid-in capital	131,502,455	130,140,549
Deficit accumulated during the development stage	(118,334,430)	(99,198,965)
Accumulated other comprehensive income		2,702
Total stockholders equity	13,258,279	31,034,540
Total liabilities and stockholders equity	\$ 17,265,151	\$ 34,541,625

Note: The balance sheet at December 31, 2007 has been derived from audited financial statements at that date. It does not include, however, all of the information and notes required by U.S. generally accepted accounting principles for complete financial statements.

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

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

	<b>Three months ended</b>		<b>Nine months ended</b>		<b>Inception</b>
	<b>September 30,</b>		<b>September 30,</b>		<b>(June 12, 1996)</b>
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>	<b>through</b>
					<b>September 30,</b>
					<b>2008</b>
Revenues:					
Net sales	\$	\$	\$	\$	\$ 174,830
Cost of goods sold					51,094
Gross margin					123,736
Grant revenue					129,733
Licensing revenue			500,000	500,000	1,000,000
Total revenues			500,000	500,000	1,253,469
Operating expenses:					
Research and development	4,741,118	4,422,259	13,072,820	12,046,997	57,165,193
Selling, general and administrative	2,075,092	1,979,257	7,075,974	6,794,634	40,325,563
Depreciation and amortization	39,803	44,899	130,698	149,824	10,760,730
In-process research and development					10,422,130
Impairment loss write off of goodwill					5,702,130
Equity in loss of investee					178,936
Total operating expenses	6,856,013	6,446,415	20,279,492	18,991,455	124,554,682
Loss from operations	(6,856,013)	(6,446,415)	(19,779,492)	(18,491,455)	(123,301,213)
Interest and other income	79,150	532,291	644,027	1,730,689	4,676,091
Interest expense					(179,090)
Loss before cumulative effect of change in accounting	(6,776,863)	(5,914,124)	(19,135,465)	(16,760,766)	(118,804,212)

principle

Cumulative effect of change in accounting principle					(25,821)
---	--	--	--	--	----------

Net loss	(6,776,863)	(5,914,124)	(19,135,465)	(16,760,766)	(118,830,033)
----------	-------------	-------------	--------------	--------------	---------------

Preferred stock dividends					(621,240)
---------------------------	--	--	--	--	-----------

Net loss applicable to common stock	\$ (6,776,863)	\$ (5,914,124)	\$ (19,135,465)	\$ (16,760,766)	\$ (119,451,273)
-------------------------------------	----------------	----------------	-----------------	-----------------	------------------

Net loss per common share basic and diluted	\$ (0.08)	\$ (0.07)	\$ (0.21)	\$ (0.19)	
---	-----------	-----------	-----------	-----------	--

Weighted average shares basic and diluted	90,252,572	90,007,509	90,252,572	89,798,207	
---	------------	------------	------------	------------	--

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

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

	Nine months ended September 30,		Inception (June 12, 1996) through September 30, 2008
	2008	2007	
Cash flows from operating activities:			
Net loss	\$ (19,135,465)	\$ (16,760,766)	\$ (118,830,033)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	130,698	149,824	10,310,730
In-process research and development			10,422,130
Share-based compensation for employee awards	1,356,393	1,853,839	7,799,721
Expense related to stock options issued to non-employees	5,513	43,513	205,196
Expenses paid by issuance of common stock		58,750	1,144,697
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	(208,103)	(838,563)	(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
Write-off of license agreement			152,866
Write-off of assets available-for-sale			108,000
Cumulative effect of change in accounting principle			25,821
Changes in assets and liabilities, net of effect of acquisitions:			
Increase in prepaid expenses and other assets	(945,949)	(298,893)	(1,939,343)
Increase in accounts payable and accrued liabilities	517,882	1,488,893	4,187,404
Decrease in other long-term liabilities	(14,270)	(16,053)	
Net cash used in operating activities	(18,293,301)	(14,319,456)	(80,328,345)
Cash flows from investing activities:			
Purchases of short-term investments	(14,355,784)	(35,556,914)	(111,183,884)
Proceeds from sales and maturities of short-term investments	33,243,602	42,840,000	112,788,378
Purchases of property and equipment	(68,780)	(99,374)	(1,034,178)
Purchase of certificate of deposit			(1,016,330)
Maturity of certificate of deposit			1,016,330
Payment on obligation under license agreement			(106,250)



Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-Q

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 investing activities	18,819,038	7,183,712	987,504
Cash flows from financing activities:			
Proceeds from sale of preferred stock			4,200,993
Proceeds from sale of common stock			84,151,342
Proceeds from exercise of stock options		441,616	712,367
Proceeds from sale or exercise of warrants			11,382,894
Repurchase of warrants			(55,279)
Payment of financing and offering costs			(6,483,809)
Payments of notes payable and long-term debt			(605,909)
Proceeds from issuance of notes payable and detachable warrants			1,344,718
Net cash provided by financing activities		441,616	94,647,317
Net increase (decrease) in cash and cash equivalents	525,737	(6,694,128)	15,306,476
Cash and cash equivalents at beginning of period	14,780,739	25,974,041	
Cash and cash equivalents at end of period	\$ 15,306,476	\$ 19,279,913	\$ 15,306,476

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc. and Subsidiaries**

(A Development Stage Enterprise)

**Notes to Condensed Consolidated Financial Statements (Unaudited)**

**1. Basis of Presentation**

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation ( ADVENTRX, we or the Company ), prepared the unaudited interim condensed consolidated financial statements 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, 2007 included in our Annual Report on Form 10-K filed with the SEC on March 17, 2008 ( 2007 Annual Report ). The condensed consolidated balance sheet as of December 31, 2007 has been derived from the audited consolidated financial statements included in the 2007 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.

Since our inception, we have reported accumulated net losses of approximately \$118.8 million and recurring negative cash flows from operations. In order to maintain sufficient cash and investments to fund future operations, and to develop our existing product candidates at the levels we believe optimize their value, we will need to raise additional capital in the short-term and beyond through collaborations, licensing arrangements or other strategic transactions, public or private sales of our equity securities, and/or debt financings. The balance of securities available-for-sale under our existing shelf registration was approximately \$60.0 million as of September 30, 2008, but we may be subject to limitations with respect to the number of securities we can sell under this shelf registration. In October 2008, we implemented a restructuring plan designed to reduce operating costs, which included an approximately 27% reduction of our workforce and our discontinuation of work on all product candidates other than ANX-530 and ANX-514. With respect to ANX-530 and ANX-514, until we have secured additional funding, we anticipate focusing primarily on those activities relating to submitting new drug applications ( NDAs) for ANX-530 and ANX-514 and will delay or significantly reduce spending on other work, which may include delays or reductions with respect to scale-up manufacturing and product launch activities. If we are unable to raise capital as needed to fund future operations, then we may further defer or abandon our current development and commercialization plans for ANX-530 or ANX-514 and may also need to take additional cost-cutting measures which could have a material and adverse effect on our ability to achieve our business objectives. Our ability to raise capital has been materially and adversely affected by current credit conditions and the downturn in the financial markets and overall economy. Failure to obtain adequate financing would adversely affect our ability to operate as a going concern.

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

**2. Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

**3. Fair Value**

Effective January 1, 2008, we adopted Statement of Financial Accounting Standards ( FAS ) No. 157, Fair Value Measurements ( FAS 157 ). In February 2008, the Financial Accounting Standards Board ( FASB ) issued FASB Staff Position ( FSP ) No. FAS 157-2, Effective Date of FASB Statement No. 157, which provides a one year deferral of the effective date of FAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. As a result, we only partially adopted FAS 157 as it relates to our financial assets and liabilities until we are required to apply this pronouncement to our non-financial assets and liabilities beginning with fiscal year 2009. The adoption of FAS 157 did not have a material impact on our consolidated results of operations or financial condition.

**Table of Contents**

In October 2008, the FASB issued FSP No. FAS 157-3 *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* ( FSP FAS 157-3 ). FSP FAS 157-3 clarifies the application of FAS No. 157, in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP FAS 157-3 is effective upon issuance, including prior periods for which financial statements have not been issued. The adoption of FSP FAS 157-3 had no impact on our consolidated results of operations, financial position or cash flows.

FAS 157 defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. Fair value is defined under FAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under FAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. FAS 157 describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table represents our fair value hierarchy for our financial assets (which consisted solely of cash equivalents) measured at fair value on a recurring basis as of September 30, 2008:

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Money market funds	\$ 15,306,476	\$	\$	\$ 15,306,476
Total	\$ 15,306,476	\$	\$	\$ 15,306,476

Effective January 1, 2008, we adopted FAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( FAS 159 ). FAS 159 allows an entity the irrevocable option to elect to measure specified financial assets and liabilities in their entirety at fair value on a contract-by-contract basis. If an entity elects the fair value option for an eligible item, changes in the item's fair value must be reported as unrealized gains and losses in earnings at each subsequent reporting date. In adopting FAS 159, we did not elect the fair value option for any of our financial assets or financial liabilities.

**4. Share-Based Payments**

Estimated share-based compensation expense related to equity awards granted to employees for the three and nine months ended September 30, 2008 and 2007 was as follows:

<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
<b>September 30,</b>		<b>September 30,</b>	
<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>

Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-Q

Selling, general and administrative expense	\$ 163,853	\$ 374,434	\$ 712,627	\$ 1,060,096
Research and development expense	198,282	290,343	643,766	793,743
Share-based compensation expense before taxes	362,135	664,777	1,356,393	1,853,839
Related income tax benefits				
Share-based compensation expense	\$ 362,135	\$ 664,777	\$ 1,356,393	\$ 1,853,839
Net share-based compensation expense per common share basic and diluted	\$ 0.00	\$ 0.01	\$ 0.02	\$ 0.02

7

---

**Table of Contents**

Since we have a net operating loss carryforward as of September 30, 2008, no excess tax benefits for the tax deductions related to share-based awards were recognized in the condensed consolidated statement of operations. There were no employee stock options exercised in the nine months ended September 30, 2008. For the nine month period ended September 30, 2007, employees exercised stock options to purchase 575,833 shares of common stock for aggregate proceeds of \$442,000.

At September 30, 2008, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was \$2.7 million, which is expected to be recognized over a weighted-average period of 2.9 years. During the three and nine months ended September 30, 2008, we granted 228,000 and 2,880,500 stock options, respectively, to our employees and non-employee directors with an estimated weighted-average grant-date fair value of \$0.18 and \$0.46 per share, respectively. During the three and nine months ended September 30, 2007, we granted 44,400 and 1,155,733 stock options, respectively, to our employees and non-employee directors with the estimated weighted-average grant-date fair value of \$2.10 and \$2.40 per share, respectively.

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Weighted expected volatility	149.0%	137.0%	146.2%	138.0%
Average expected term (in years)	6.4	6.1	6.2	6.1
Average risk-free interest rate	3.3%	4.6%	3.1%	4.7%
Dividend yield	0	0	0	0

Estimated share-based compensation expense related to equity awards granted to non-employee consultants was \$0 and \$24,000 for the three months ended September 30, 2008 and 2007, respectively, and \$6,000 and \$102,000 for the nine months ended September 30, 2008 and 2007, respectively.

**5. Net Loss Per Common Share**

We calculate basic and diluted net loss per common share in accordance with the FAS No. 128, Earnings Per Share. Basic net loss per common share was calculated by dividing the net loss for the period by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per common share when their effect is dilutive. Because of the net loss, all of the options and warrants were excluded from the calculation.

We have excluded the following options and warrants from the calculation of diluted net loss per common share for the three and nine months ended September 30, 2008 and 2007 because they are anti-dilutive, due to the net loss:

	<b>2008</b>	<b>2007</b>
Warrants	13,373,549	13,408,549
Options	6,089,149	4,055,733
	19,462,698	17,464,282

**6. 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 short-term investments. Our components of comprehensive loss consist of net loss and unrealized gains or losses on short-term investments in securities. For the three months ended September 30, 2008 and 2007, comprehensive loss was \$6.8 million and \$5.9 million, respectively. For the nine months ended September 30, 2008 and 2007 and the period from inception (June 12, 1996) through September 30, 2008, comprehensive loss was \$19.1 million, \$16.8 million and \$118.8 million, respectively.

## 7. Recent Accounting Pronouncements

In May 2008, the FASB issued FAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( FAS 162 ). FAS 162 is intended to improve financial reporting by identifying a consistent hierarchy for selecting accounting principles to be used in preparing financial statements that are prepared in conformance with U.S. GAAP. Unlike Statement on Auditing Standards (SAS) No. 69, *The Meaning of Present Fairly in Conformity With GAAP*, FAS 162 is directed to the entity rather than the

**Table of Contents**

auditor. FAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board (PCAOB) amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with GAAP*, and is not expected to have any impact on the Company's consolidated results of operations, financial condition or liquidity.

In March 2008, the FASB issued FAS No. 161, *Disclosures About Derivative Instruments and Hedging Activities* an amendment of FASB Statement No. 133 ( FAS 161 ). FAS 161 expands quarterly disclosure requirements in FAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, about an entity's derivative instruments and hedging activities. FAS 161 is effective for fiscal years beginning after November 15, 2008. We do not expect the adoption of FAS 161 to have a material impact on our consolidated results of operations or financial position.

In December 2007, the FASB issued FAS No. 141 (revised 2007) ( FAS 141R ), *Business Combinations*, which replaces FAS No. 141. FAS 141R retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. FAS 141R is effective for financial statements issued for fiscal year 2009 and will apply prospectively to business combinations completed on or after January 1, 2009. We are currently evaluating the impact of implementing FAS 141R on our consolidated financial position, results of operations and liquidity.

**8. Licensing Revenue**

In October 2006, we entered into a license agreement with Theragenex, LLC ( Theragenex ). Under the agreement, we granted Theragenex exclusive rights to develop and commercialize ANX-211 in the U.S. in exchange for a licensing fee of \$1.0 million (\$0.5 million of which we received in January 2007 and \$0.5 million of which was due in June 2007), milestone payments and royalties. In May 2007, we received a letter from TRx Pharma, a subsidiary of Theragenex, that we believe was intended to constitute notice of termination of the agreement with Theragenex, though the letter did not explicitly state that it constituted notice of termination. In its letter, TRx Pharma requested a refund of the initial \$0.5 million payment and, in subsequent discussions, indicated that it did not intend to pay the remaining \$0.5 million. On July 3, 2007, we notified Theragenex that, among other things, its failure to make the final \$0.5 million payment constituted a material breach of the agreement. On August 9, 2007, we delivered a letter to Theragenex confirming our termination of the agreement as a result of Theragenex's breach, pursuant to the terms of the agreement.

In May 2008, we settled our dispute with Theragenex. In consideration of and conditioned upon Theragenex paying us an additional \$0.6 million, we and Theragenex agreed to jointly move to dismiss the underlying arbitration action, and in connection with dismissing the arbitration, we and Theragenex agreed to release each other from any and all claims related to our past relationship, including Theragenex's rights under the license agreement.

For the nine months ended September 30, 2007, we recognized \$0.5 million in licensing revenue, which we received from Theragenex in January 2007, because our performance obligations were complete, collectability was reasonably assured and we had no continuing obligations for performance under the agreement. For the nine months ended September 30, 2008, we recognized \$0.5 million in licensing revenue, which represents a portion of the \$0.6 million Theragenex settlement payment, because we met the criteria for revenue recognition. The additional \$0.1 million was recognized as other income. Since January 2007, we received a total of \$1.1 million from Theragenex.



**9. Supplementary Cash Flow Information**

	<b>Nine months ended September 30,</b>		<b>Inception (June 12, 1996)</b>
	<b>2008</b>	<b>2007</b>	<b>through September 30, 2008</b>
Supplemental disclosures of cash flow information:			
Interest paid	\$	\$	\$ 179,090
Income taxes paid			

9

---

**Table of Contents**

Noncash investing and financing transactions excluded from the condensed consolidated statements of cash flows for the nine months ended September 30, 2008 and 2007 and for the period from inception (June 12, 1996) through September 30, 2008 are as follows:

	Nine months ended September 30,		Inception (June 12, 1996) through September 30, 2008
	2008	2007	
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			2,705
Acquisitions			24,781,555
Payment of dividends			213,000
Financial advisor services in connection with private placement			1,137,456
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
Purchases of equipment, which are included in accounts payable	3,825	20,000	3,825
Unrealized (gain) loss on short-term investments	2,702	(7,553)	

**10. Commitments and Contingencies**

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.

In May 2008, we settled our dispute with Theragenex. See Note 8 *Licensing Revenue* for additional information.

**11. Subsequent Events**

On October 14, 2008, as part of a restructuring to reduce operating costs, we completed a work force reduction of nine employees. As a result of the reduction in force, we estimate that we will record severance-related charges of approximately \$422,000, of which approximately \$402,000 will be recorded in research and development and the remainder in selling, general and administrative expenses. Approximately \$387,000 of the severance-related charges relates to severance payments and related employer taxes, and approximately \$35,000 relates to health benefit allowance payments, which the eligible former employees may use, at their discretion, to pay the premiums required to continue their group health care coverage under COBRA or any other health care related

expenses. Approximately \$298,000 of the severance-related charges is expected to be recorded in the fourth quarter of 2008 and the remainder will be recorded in the first quarter of 2009. The severance-related charges that we expect to incur in connection with the reduction in force are subject to a number of assumptions and actual results may differ. We may also incur other charges not currently contemplated due to events that may occur as a result of, or associated with, the restructuring.

Effective as of October 17, 2008, Evan M. Levine resigned from all of his positions with the Company, its subsidiaries and affiliated companies, other than as a member of the Company's Board of Directors. Mr. Levine previously served as the Company's Chief Executive Officer and President.

The Company's Board of Directors appointed Mark E. Erwin to serve as Senior Vice President, Operations of the Company, effective as of October 20, 2008. Mr. Erwin previously served as Vice President, Commercialization of the Company since October 2007.

**Table of Contents**

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and related notes appearing elsewhere in this report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under Item 1A of Part I, Risk Factors, in our annual report on Form 10-K for the year ended December 31, 2007.*

**Overview**

We are a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates primarily for the treatment of cancer. We seek to improve the performance and commercial potential of existing treatments by addressing limitations associated with these treatment regimens. Currently, we are focused on advancing ANX-530 and ANX-514, which are novel emulsion formulations of currently marketed chemotherapy drugs. In October 2008, we discontinued active work on ANX-510, or CoFactor®, and all other product candidates other than ANX-530 and ANX-514. With respect to ANX-530 and ANX-514, until we have secured additional funding, we anticipate focusing primarily on those activities relating to submitting new drug applications ( NDAs ) for ANX-530 and ANX-514 and will delay or significantly reduce spending on other work, which may include delays or reductions with respect to scale-up manufacturing and product launch activities. We are a development stage company and have incurred annual net losses since inception. We have devoted substantially all of our resources to research and development ( R&D ), activities related to regulatory approvals and future commercialization and acquisition of our product candidates. We have not yet marketed any products or generated any significant revenue from licensing our products or technology. As of September 30, 2008, our accumulated net losses amounted to \$118.8 million. We expect that our R&D, selling, general and administrative ( SG&A ) and other operating costs will continue to exceed revenues for the foreseeable future. In order to maintain sufficient cash and investments to fund future operations, and to continue developing ANX-530 and ANX-514, we will need to raise additional capital in the short-term and beyond through collaborations, licensing arrangements or other strategic transactions, public or private sales of our equity securities, and/or debt financings. In October 2008, we implemented a restructuring plan designed to reduce operating costs while allowing us to continue development of ANX-530 and ANX-514. As part of the restructuring, we terminated a total of nine employees, consisting of four in research and development, two in clinical, two in selling, general and administrative and one in regulation/quality assurance. After adjusting to reflect anticipated severance costs, we expect this approximately 27% reduction of our workforce will reduce our compensation expenses in 2009 by approximately \$1.5 million (fully burdened). Until we raise additional capital, we anticipate focusing primarily on those activities relating to submitting NDAs to obtain the approval of the United States Food and Drug Administration ( FDA ) for marketing ANX-530 and ANX-514, and we will delay or significantly reduce spending on other work related to these product candidates, which may include delays or reductions with respect to certain scale-up manufacturing and product launch activities. The Company anticipates the submission of its NDA for ANX-530 will take place in the second quarter of 2009 and the submission of its NDA for ANX-514 will take place in the third quarter of 2009. If we are unable to raise capital as needed to fund future operations, then we may defer or abandon our current development and commercialization plans for ANX-530 and/or ANX-514 and may also need to take additional cost-cutting measures which could have a material and adverse effect on our ability to achieve our business objectives. As of September 30, 2008, we had cash and cash equivalents of approximately \$15.3 million, which in light of the restructuring we implemented in October 2008, we believe will be sufficient to sustain our operations through the second quarter of 2009. We cannot be sure that additional financing will be available when needed, or that, if available, financing will be obtained on terms favorable to us or our stockholders. Our ability to raise capital has been materially and adversely affected by current credit conditions and the downturn in the financial markets and overall economy. Having insufficient funds may require us to further delay, scale-back or eliminate some or all of our programs, relinquish some or even all rights to product candidates, or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing would adversely affect our ability to operate as a going concern.

We intend to commercialize ANX-530 and ANX-514 ourselves in the U.S. We also remain receptive to partnering these product candidates in the U.S. if presented with terms that are sufficiently attractive. In the event of commercialization, we will likely incur substantial costs undertaking the activities associated with preparing for commercial launch of a product, including establishing commercial-scale manufacturing capabilities and hiring sales personnel and creating and maintaining a sales and distribution

**Table of Contents**

organization and associated regulatory compliance infrastructure. Subject to our ability to raise additional capital, substantial costs may be incurred in advance of the FDA's decisions regarding marketing approvals of ANX-530 and ANX-514.

In October 2008, Evan M. Levine, our former Chief Executive Officer and President, resigned to pursue other opportunities. He continues to serve on our Board of Directors. We have informally begun a search for a new Chief Executive Officer. In the interim, consistent with our CEO succession planning, we are being led by a committee of executive officers. Mr. Bagnall has been appointed to serve as principal executive officer in addition to continuing in his other capacities.

Our Board of Directors appointed Mark E. Erwin to serve as Senior Vice President, Operations of the Company, effective as of October 20, 2008. Mr. Erwin had served as Vice President, Commercialization of the Company since October 2007.

**Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations is based upon consolidated financial statements that we have prepared in accordance with U.S. GAAP. 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 our consolidated financial statements and accompanying notes. On an on-going basis, we evaluate these estimates and assumptions, including those related to recognition of expenses in service contracts, license agreements, share-based compensation and registration payment arrangements. 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.

**Fair Value.** Effective January 1, 2008, we adopted FAS 157, Fair Value Measurements. In February 2008, the FASB issued FSP No. 157-2, Effective Date of FASB Statement No. 157, which provides a one year deferral of the effective date of FAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. As a result, we only partially adopted FAS 157 as it relates to our financial assets and liabilities until we are required to apply this pronouncement to our non-financial assets and liabilities beginning with fiscal year 2009.

In October 2008, the FASB issued FSP No. FAS 157-3 Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active. FSP FAS 157-3 clarifies the application of FAS No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP FAS 157-3 is effective upon issuance, including prior periods for which financial statements have not been issued. The adoption of FSP FAS 157-3 had no impact on our consolidated results of operations, financial position or cash flows.

FAS 157 defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. Fair value is defined under FAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under FAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. FAS 157 describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3

Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The adoption of FAS 157 did not have a material impact on our consolidated results of operations or financial condition.

Effective January 1, 2008, we adopted FAS 159, The Fair Value Option for Financial Assets and Financial Liabilities . FAS 159 allows an entity the irrevocable option to elect to measure specified financial assets and liabilities in their entirety at fair value on a contract-by-contract basis. If an entity elects the fair value option for an eligible item, changes in the item s fair value must be reported

**Table of Contents**

as unrealized gains and losses in earnings at each subsequent reporting date. In adopting FAS 159, we did not elect the fair value option for any of our financial assets or financial liabilities.

**Revenue Recognition.** We recognize revenue in accordance with Topic 13, Revenue Recognition, and Emerging Issues Task Force Issue ( EITF ) No. 00-21, Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). 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 license 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 revenue recognition criteria under Topic 13 and EITF 00-21 are met and the license term commences. 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, clinical trials, research-related manufacturing services, contract services and other outside expenses. R&D expenses are charged to operations as they are incurred. 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 or product candidates are approved for marketing by the FDA or when other significant risk factors are abated. For expense accounting purposes, management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain.

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

**Purchased In-Process Research and Development.** In accordance with FAS No. 141, Business Combinations, we immediately charge the costs associated with purchased in-process research and development ( IPR&D ) to 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 receiving future economic benefits from the purchased IPR&D. We determine the future economic benefits from the purchased IPR&D to be uncertain until such technology is approved by the FDA or when other significant risk factors are abated.

**Share-based Compensation Expenses.** Effective January 1, 2006, we accounted for share-based compensation awards granted to employees in accordance with the revised FAS No. 123, Share-Based Payment ( FAS 123R ) including the provisions of Staff

## **Table of Contents**

Accounting Bulletins No. 107, Share-Based Payment and No. 110. Share-based compensation cost 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. We have no awards with market or performance conditions. As share-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. FAS 123R 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 (Black-Scholes Model). The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock 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 in accordance with EITF No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services (EITF 96-18). Under EITF 96-18, we determine 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 stock price and other measurement assumptions as of the earlier of either 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.

The above listing 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 U.S. GAAP.

## **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 drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit an NDA, which includes complete reports of pre-clinical, clinical and laboratory studies and extensive manufacturing information to prove such product's safety and effectiveness. The NDA process generally requires, before the submission of the NDA, filing of an investigational new drug application, pursuant to which permission is sought to begin clinical testing of the new drug product. 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 (FDCA). Development of new formulations of pharmaceutical products under Section 505(b)(2) of the FDCA may have shorter timelines than those associated with developing new chemical entities.

Generally, with respect to any drug product 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 R&D programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, our ongoing assessment of its market potential and our available resources.

Our expenditures on R&D programs are subject to many uncertainties, including whether we develop our product candidates with a partner or independently. At this time, due to such uncertainties and the risks inherent in the clinical

and 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 we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of our R&D programs, in particular those associated with clinical trials, vary significantly among programs or within a particular program as a result of a variety of factors, including:

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

**Table of Contents**

the number of patients who participate in the trials;

the number of sites included in the trials and rates of site approval for the trials;

the rates of patient recruitment and enrollment;

the duration of patient treatment and follow-up;

the costs of manufacturing our product candidates; and

the costs, requirements, timing of, and the ability to secure regulatory approvals.

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

While substantially all of our R&D expenses are transacted in U.S. dollars, certain of our 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. We include realized gains and losses from foreign currency transactions in operations as incurred.

**Comparison of Three Months Ended September 30, 2008 and 2007**

**Revenue.** No revenue was recognized for the three months ended September 30, 2008 or 2007.

**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 of the uncertainties described above, as well as because we out-source a substantial portion of our work and our R&D personnel 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 the three months ended September 30, 2008 compared to the same period in 2007:

	Three months ended September 30,			% Variance
	2008	2007	\$ Variance	
External clinical study fees and expenses	\$ 737,644	\$ 1,936,308	\$ (1,198,664)	(62%)
External non-clinical study fees and expenses				
(1)	3,105,617	1,417,001	1,688,616	119%
Personnel costs	699,575	778,608	(79,033)	(10%)
Share-based compensation expense	198,282	290,342	(92,060)	(32%)
Total	\$ 4,741,118	\$ 4,422,259	\$ 318,859	7%

(1) External non-clinical study fees and expenses include preclinical, research-related manufacturing,

quality  
assurance and  
regulatory  
expenses.

R&D expenses increased by \$0.3 million, or 7%, to \$4.7 million for the three months ended September 30, 2008, compared to \$4.4 million for the comparable period in 2007. The increase in R&D expenses was primarily due to a \$1.7 million increase in external research-related manufacturing and regulatory expenses for ANX-530 and ANX-514, offset by a \$1.2 million decrease in external clinical trial expenses related to ANX-530 and CoFactor, a \$0.1 million decrease in personnel costs and a \$0.1 million decrease in share-based compensation expense.

***Selling, General and Administrative Expenses.*** SG&A expenses increased by \$0.1 million, or 5%, to \$2.1 million for the three months ended September 30, 2008, compared to \$2.0 million for the comparable period in 2007. The increase was primarily due to an increase in consulting expenses for market research for ANX-530.

**Table of Contents**

**Interest and Other Income.** Interest and other income decreased by \$0.4 million, or 85%, to \$0.1 million for the three months ended September 30, 2008, compared to \$0.5 million for the comparable period in 2007. The decrease was primarily attributable to lower interest income based on lower invested balances.

**Net Loss.** Net loss was \$6.8 million, or \$0.08 per share, for the three months ended September 30, 2008, compared to a net loss of \$5.9 million, or \$0.07 per share, for the comparable period in 2007.

**Comparison of Nine Months Ended September 30, 2008 and 2007**

**Revenue.** Revenue for the nine months ended September 30, 2008 and 2007 amounted to \$0.5 million. For the nine months ended September 30, 2008, we recognized \$0.5 million in licensing revenue, which represents a portion of the \$0.6 million Theragenex settlement payment, because we met the criteria for revenue recognition. The remainder of the payment was recorded as other income. Revenue for the nine months ended September 30, 2007 represents the \$0.5 million license fee paid by Theragenex in January 2007 under our license agreement with Theragenex. We recognized that nonrefundable license fee as revenue in the period when the criteria for revenue recognition were met. 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 that we have obtained approval from a regulatory agency to sell one of our product candidates, which we cannot predict will occur.

**R&D Expenses.**

The following table summarizes our consolidated R&D expenses by type for the nine months ended September 30, 2008 compared to the same period in 2007, and since January 1, 2005:

	Nine months ended September 30,				January 1, 2005 through September 30, 2008
	2008	2007	\$ Variance	% Variance	
External clinical study fees and expenses	\$ 2,711,909	\$ 5,612,856	\$ (2,900,947)	(52%)	\$ 22,537,526
External non-clinical study fees and expenses (1)	7,176,135	3,242,496	3,933,639	121%	15,535,910
Personnel costs	2,541,010	2,397,902	143,108	6%	8,815,041
Share-based compensation expense	643,766	793,743	(149,977)	(19%)	2,802,462
Total	\$ 13,072,820	\$ 12,046,997	\$ 1,025,823	9%	\$ 49,690,939

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

R&D expenses increased by \$1.0 million, or 9%, to \$13.1 million for the nine months ended September 30, 2008, compared to \$12.1 million for the comparable period in 2007. The increase in R&D expenses was primarily due to a \$3.9 million increase in external research-related manufacturing and regulatory expenses for ANX-530 and ANX-514

and an increase of \$0.1 million in personnel and related costs, offset by a \$2.9 million decrease in external clinical trial expenses related to ANX-530 and CoFactor and a \$0.1 million decrease in share-based compensation expense.

***Selling, General and Administrative Expenses.*** SG&A expenses increased by \$0.3 million, or 4%, to \$7.1 million for the nine months ended September 30, 2008, compared to \$6.8 million for the comparable period in 2007. The increase was primarily due to a \$0.2 million increase in severance expense related to the departure of our former chief financial officer and an increase in consulting expenses for market research for ANX-530.

***Interest and Other Income.*** Interest and other income for the nine months ended September 30, 2008 was \$0.6 million compared to \$1.7 million for the comparable period in 2007. The decrease was primarily attributable to lower interest income based on lower invested balances. The decrease was partially offset by \$0.1 million received as part of the Theragenex settlement which was recorded as other income.

**Table of Contents**

**Net Loss.** Net loss was \$19.1 million, or \$0.21 per share, for the nine months ended September 30, 2008, compared to a net loss of \$16.8 million, or \$0.19 per share, for the comparable period in 2007.

**Liquidity and Capital Resources**

Since our inception we have funded our operations primarily through sales of our equity securities. As of September 30, 2008, we had cash and cash equivalents and short-term investments in securities totaling \$15.3 million, compared to \$33.5 million as of December 31, 2007. The decrease in cash and investments in securities was attributed to cash used for operations. As of September 30, 2008, we had all of our cash in cash and cash equivalents and nothing in short-term investments in securities. To reduce risk, we purchased U.S. Treasury securities in the three months ended September 30, 2008, which now comprise all of our cash equivalents. As a result, future interest income may be less than we earned in the past.

**Operating Activities.** Net cash used in operating activities was \$18.3 million for the nine months ended September 30, 2008, compared to \$14.3 million for the comparable period in 2007. The increase in net cash used in operating activities was primarily due to: 1) a \$2.4 million increase in net loss primarily due to an increase in R&D expenses and a decrease in interest income, and 2) a \$1.6 million net decrease in operating assets and liabilities primarily due to increases in accounts payable and accrued liabilities.

**Investing Activities.** Net cash provided by investing activities was \$18.8 million for the nine months ended September 30, 2008, compared to net cash used in investing activities of \$7.2 million for the comparable period in 2007. Net cash provided by investing activities in the nine months ended September 30, 2008 was primarily attributable to proceeds from sales and maturities of short-term investments in securities, net of purchases of short-term investments in securities.

**Financing Activities.** There were no financing activities in the nine months ended September 30, 2008. Net cash provided by financing activities was \$0.4 million in the nine months ended September 30, 2007 from the exercise of employees' stock options.

**Accrued Compensation and Payroll Taxes.** Accrued compensation and payroll taxes were \$0.8 million at September 30, 2008, compared to \$0.6 million at December 31, 2007, an increase of \$0.2 million, or 35%. The increase was primarily due to an increase in the bonus accrual.

**Management Outlook**

As a result of the restructuring we implemented in October 2008, we believe that our cash and cash equivalents of approximately \$15.3 million at September 30, 2008 should be sufficient to sustain our operations through the second quarter of 2009. As part of our restructuring, we have discontinued active work on all of our product candidates other than ANX-530 and ANX-514, and, with respect to ANX-530 and ANX-514, until we have secured additional funding, we anticipate focusing primarily on activities relating to submitting NDAs for ANX-530 and ANX-514 and will delay or significantly reduce spending on other work, which may include delays or reductions with respect to certain scale-up manufacturing and activities related to product launch. In order to maintain sufficient cash and investments to fund operations beyond the second quarter of 2009 and to develop ANX-530, ANX-514 and our other existing product candidates at the levels we believe optimize their value, we will need to raise additional capital in the short-term and beyond through collaborations, licensing arrangements or other strategic transactions, public or private sales of our equity securities, and/or debt financings. The balance of securities available-for-sale under our existing shelf registration was approximately \$60.0 million as of September 30, 2008, but we may be subject to limitations with respect to the number of securities we can sell under this shelf registration. If we are unable to raise capital as needed to fund future operations, then we may further defer or abandon one or more of our R&D programs and/or our current commercialization plans for ANX-530 and/or ANX-514 and may also need to take additional cost-cutting measures, which could have a material and adverse effect on our ability to achieve our business objectives. Our ability to raise capital has been materially and adversely affected by current credit conditions and the downturn in the financial markets and overall economy. In addition, our ability to timely raise capital on commercially reasonable terms may be limited by requirements, rules and regulations of the Securities and Exchange Commission and the American Stock Exchange. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. In addition, depending upon the market price of our common stock at the time of any such transaction, we may be required to sell a significant percentage of common stock, potentially requiring a



stockholder vote pursuant to American Stock Exchange rules, which could lead to a significant delay and closing uncertainty. If we raise additional funds by incurring debt, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

## **Table of Contents**

We cannot be sure that additional financing will be available when needed, or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to further delay, scale-back or eliminate some or all of our programs, relinquish some or even all rights to product candidates, or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing would adversely affect our ability to operate as a going concern.

We have held discussions with, and intend to continue to seek, potential partners regarding certain of our product candidates, though some of our product candidates could take several more years of development before they reach the stage of being partnerable with other companies on terms that we believe are appropriate. If we successfully consummate a partnering transaction, we may be entitled to upfront or license fees and milestone payments; however, any such fees and payments will depend on successfully consummating a transaction and achieving milestones under such arrangements.

For information regarding the risks associated with our need to raise capital to fund our ongoing and planned operations and limitations on our ability to do so, see Item 1A of Part I, Risk Factors, in our annual report on Form 10-K for the year ended December 31, 2007.

### **Recent Accounting Pronouncements**

See Note 7, 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 on Form 10-Q, particularly in 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, but not limited to, statements regarding business strategy, expectations and plans, our objectives for future operations, including product development, and our future financial position. When used in this report, the words believe, may, could, will, estimate, continue, anticipate, intend, expect, indicate and similar expressions are used to identify forward-looking statements.*

*We have based these forward-looking statements largely on our current expectations and projections about future events and financial 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. These forward-looking statements are subject to certain risks and uncertainties that could cause our actual results to differ materially from those expressed or implied in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, the risk that we will be unable to raise sufficient capital to fund the projects necessary to meet our goals, including funding the continued development and commercialization of ANX-530 or ANX-514; the risk that our restructuring costs may be greater than anticipated and our October 2008 workforce reduction and any future workforce and expense reductions may have an adverse impact on our business; the risk the FDA will determine that ANX-530 and Navelbine® are not bioequivalent, including as a result of performing pharmacokinetic equivalence analysis based on a patient population other than the population on which we based our analysis; the risk that the on-going clinical study of ANX-514 does not demonstrate pharmacokinetic equivalence or bioequivalence; the risk of investigator bias in reporting adverse events as a result of the open-label nature of the ANX-530 bioequivalence clinical study, including bias that increased the reporting of adverse events associated with Navelbine and/or that decreased the reporting of adverse events associated with ANX-530; difficulties or delays in manufacturing, obtaining regulatory approval for and marketing ANX-530 and ANX-514, including validating commercial manufacturers and suppliers and the potential for automatic injunctions regarding FDA approval of ANX-514; the potential for regulatory authorities to require additional preclinical work or other clinical requirements to support regulatory filings, including prior to the submission or the approval of an NDA for ANX-530 and ANX-514; the risk that the resignation of our former Chief Executive Officer and President and/or our leadership by a committee of executive officers will negatively impact our ability to execute our business plan or to maintain effective disclosure controls and procedures or internal control over financial reporting; the risk that the performance of third parties on whom we rely to conduct our studies or evaluate the data, including clinical investigators, expert data monitoring*

*committees, contract laboratories and contract research organizations, may be substandard, or they may fail to perform as expected; and other risks and uncertainties more fully discussed in Item 1A of Part I, Risk Factors, in our annual report on Form 10-K for the year ended December 31, 2007, and those discussed in other documents we file with the Securities and Exchange Commission. Except as required by law, we do not intend to update these forward-looking statements 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.*

**Table of Contents**

*In light of these risks, uncertainties and 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, readers are cautioned not to place undue reliance on such forward-looking statements.*

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not required.

**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 are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

***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 Rule 13a-15(d) and 15d-15(d) of 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.

**Table of Contents**

**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**

Not required.

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Submission of Matters to a Vote of Security Holders**

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

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

**Table of Contents**

**Signatures**

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

ADVENTRX Pharmaceuticals, Inc.

Date: November 7, 2008

By: /s/ Mark N.K. Bagnall  
Mark N.K. Bagnall  
Executive Vice President and Chief Financial  
Officer  
(Principal Executive Officer, Principal Financial  
Officer,  
Principal Accounting Officer and Duly Authorized  
Officer)

**Table of Contents**

**Exhibit Index**

<b>Exhibit</b>	<b>Description</b>
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2	Certification of principal financial officer pursuant to Rule 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

\* This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are 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.