ADVENTRX PHARMACEUTICALS INC Form 10-Q November 07, 2008

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

(Mark One)

DESCRIPTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2008

OR

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

For the transition period from to

Commission File Number 001-32157

ADVENTRX Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware 84-1318182

(State or other jurisdiction of incorporation or organization)

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

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 b 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. (Check one):

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

(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 o No þ

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

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

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets

	September 30, 2008 (Unaudited)		December 31, 2007 (Note)	
Assets				
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
		01,150		20,202
Total assets	\$	17,265,151	\$	34,541,625
Liabilities and Stockholders Equity				
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		4,000,872		14,270
Long-term naomities				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
Total Infolities and Stockholders equity	Ψ	17,200,101	Ψ	5-1,5-11,025

Note: The balance sheet at December 31,

December 31, 2007 has been derived from audited financial

audited illiancial

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.

3

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

	Three months ended September 30,		Nine months ended September 30,		Inception (June 12, 1996) through September 30,
_	2008	2007	2008 200'		2008
Revenues: Net sales Cost of goods sold	\$	\$	\$	\$	\$ 174,830 51,094
Gross margin Grant revenue Licensing revenue			500,000	500,000	123,736 129,733 1,000,000
Total revenues			500,000	500,000	1,253,469
Operating expenses: Research and					
development Selling, general and	4,741,118	4,422,259	13,072,820	12,046,997	57,165,193
administrative Depreciation and	2,075,092	1,979,257	7,075,974	6,794,634	40,325,563
amortization	39,803	44,899	130,698	149,824	10,760,730
In-process research and development Impairment loss					10,422,130
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 Interest expense	79,150	532,291	644,027	1,730,689	4,676,091 (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.

4

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

Inception

			(June 12, 1996) through
	Nine months en	C 4 1 20	
	2008	o, 2007	September 30, 2008
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	1 256 202	1 052 020	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	3,313	58,750	1,144,697
Expenses paid by issuance of warrants		30,730	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 Cumulative effect of change in accounting			108,000
principle			25,821
Changes in assets and liabilities, net of effect of			25,021
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)

Cash acquired from acquisitions, net of cash paid Issuance of note receivable related party Payments on note receivable Advance to investee Cash transferred in rescission of acquisition Cash received in rescission of acquisition					32,395 (35,000) 405,993 (90,475) (19,475) 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 Proceeds from sale of common stock Proceeds from exercise of stock options Proceeds from sale or exercise of warrants Repurchase of warrants Payment of financing and offering costs Payments of notes payable and long-term debt Proceeds from issuance of notes payable and detachable warrants				441,616	4,200,993 84,151,342 712,367 11,382,894 (55,279) (6,483,809) (605,909) 1,344,718
Net cash provided by financing activities				441,616	94,647,317
Net increase (decrease) in cash and cash equivalents Cash and cash equivalents at beginning of period		525,737 14,780,739		(6,694,128) 25,974,041	15,306,476
Cash and cash equivalents at end of period	\$	15,306,476	\$	19,279,913	\$ 15,306,476
See accompanying notes to unaudited condensed con	onsolic	lated financial s	tatem	ents.	

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.

6

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:

			Level		
	Level 1	2	3	Total	
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:

Three Mon	nths Ended	Nine Mon	ths Ended
Septem	ıber 30,	Septem	ber 30,
2008	2007	2008	2007

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

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.

	Three Months Ended September 30,		Nine Months End September 30,	
	2008	2007	2008	2007
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: