ADVENTRX PHARMACEUTICALS INC Form 10-Q November 08, 2010

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

(Mark One)

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

For the quarterly period ended September 30, 2010

OR

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES

For the transition period from ______ to _____

EXCHANGE ACT OF 1934

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

(Address of principal executive offices)

92121

(Zip Code)

(OFO)

(858) 552-0866

(Registrant s telephone number, including area code)

N/A

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

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

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

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

TABLE OF CONTENTS

	Page
PART I FINANCIAL INFORMATION	1
Item 1. Financial Statements (Unaudited)	1
a. Condensed Consolidated Balance Sheets as of September 30, 2010 and December 31, 2009	1
b. Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2010 and 2009 and for the period from inception (June 12, 1996) through September 30, 2010	2
c. Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2010 and 2009 and for the period from inception (June 12, 1996) through September 30, 2010	3
d. Notes to Condensed Consolidated Financial Statements (Unaudited)	4
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3. Quantitative and Qualitative Disclosures About Market Risk	21
Item 4. Controls and Procedures	21
PART II OTHER INFORMATION	21
Item 1. Legal Proceedings	21
Item 1A. Risk Factors	21
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	21
Item 3. Defaults Upon Senior Securities	22
Item 4. (Removed and Reserved)	22
Item 5. Other Information	22
Item 6. Exhibits	22
<u>SIGNATURES</u>	23
Exhibit 31.1 Exhibit 31.2 Exhibit 32.1	

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets

	September 30, 2010 (Unaudited)		December 31, 2009	
Assets				
Current assets: Cash Restricted cash	\$	29,331,773 623,513	\$	8,667,404
Interest and other receivables Prepaid expenses		12,634 487,677		14,841 290,249
Total current assets		30,455,597		8,972,494
Property and equipment, net Other assets		30,744 2,221		44,210 10,513
Total assets	\$	30,488,562	\$	9,027,217
Liabilities and Stockholders Equity				
Current liabilities:				
Accounts payable	\$	260,067	\$	385,358
Accrued liabilities		685,620		1,379,010
Preferred stock dividends obligation		623,513		5 00 21 0
Accrued compensation and payroll taxes		130,685		589,319
Total current liabilities		1,699,885		2,353,687
Stockholders equity: Convertible Preferred Stock, Series A through F, \$0.001 par value, 53,776.13 shares authorized; 2,884.57 (all Series F) and 0 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively (liquidation		2.472.161		
preference of \$3,508,083) Common stock, \$0.001 par value; 500,000,000 shares authorized; 14,701,216 and 8,211,410 shares issued and outstanding at September 30, 2010 and		2,472,161		
December 31, 2009, respectively		14,701		8,211
Additional paid-in capital		180,146,429	1	148,703,722
Deficit accumulated during the development stage		(153,844,614)	(1	142,038,403)

Total stockholders equity 28,788,677 6,673,530

\$ 30,488,562 \$ 9,027,217 Total liabilities and stockholders equity

Note: The balance

sheet at

December 31, 2009 has been derived from audited financial statements at that date. It does not include, however, all of the information

and notes

required by

accounting

principles

generally

accepted in the

United States of

America for

complete

financial

statements.

See accompanying notes to unaudited condensed consolidated financial statements.

(1)

Table of Contents

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

Inception

8

	- T-1		Nine months en		(June 12, 1996)
	Three mon Septem		through		
	2010	2009	2010	2009	September 30, 2010
Licensing revenue Net sales Grant revenue	\$	\$	\$	\$ 300,000	\$ 1,300,000 174,830 129,733
Total net revenue				300,000	1,604,563
Cost of sales					51,094
Gross margin				300,000	1,553,469
Operating expenses: Research and development	918,309	1,444,038	2,791,404	4,546,235	71,313,609
Selling, general and administrative Depreciation and	944,950	893,477	3,422,843	3,744,470	51,390,353
amortization In-process research and	4,879	12,350	16,526	70,431	10,894,324
development Impairment loss write					10,422,130
off of goodwill Equity in loss of					5,702,130
investee					178,936
Total operating expenses	1,868,138	2,349,865	6,230,773	8,361,136	149,901,482
Loss from operations Loss on fair value of	(1,868,138)	(2,349,865)	(6,230,773)	(8,061,136)	(148,348,013)
warrants Interest income	26,258	40	68,006	2,432	(12,239,688) 4,657,194
Interest expense Other income (expense)	(2,019)	(2,761)	(1,629) (2,019)	(46,434)	(180,719) 63,826
Loss before cumulative effect of change in	(1.042.000)	(2.252.505)	(6.166.415)	(0.105.120)	(15(0.15 400)
accounting principle	(1,843,899)	(2,352,586)	(6,166,415)	(8,105,138)	(156,047,400)

Cumulative effect of change in accounting

principle (25,821)

Net loss (1,843,899) (2,352,586) (6,166,415) (8,105,138) (156,073,221)

Preferred stock

dividends (621,240)

Deemed dividends on

preferred stock (376,089) (5,639,796) (1,608,504) (10,506,683)

Net loss applicable to

common stock \$ (1,843,899) \$ (2,728,675) \$ (11,806,211) \$ (9,713,642) \$ (167,201,144)

Net loss per common

share basic and diluted \$ (0.13) \$ (0.57) \$ (0.94) \$ (2.40)

Weighted average shares

basic and diluted 14,701,216 4,779,228 12,593,971 4,046,376

See accompanying notes to unaudited condensed consolidated financial statements.

(2)

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

	N	line months en	Inception (June 12, 1996)					
		30),		through			
		2010 2009		September 30, 2010				
Cash flows from operating activities:								
Net loss	\$	(6,166,415)	\$	(8,105,138)	\$	(156,073,221)		
Adjustments to reconcile net loss to net cash used in	_	(=,===,===)	7	(=,===,===)	_	(,-,-,,		
operating activities:								
Depreciation and amortization		16,526		70,431		10,444,325		
Loss on disposals of fixed assets		2,019		59,012		57,535		
Loss on fair value of warrants		_,-,-		,		12,239,688		
Expenses related to employee stock options and						,,		
restricted stock issued		604,772		454,827		9,042,771		
Expense related to stock options issued to		,,,,,		- ,-		- ,- ,- ,-		
non-employees						204,664		
Expenses paid by issuance of common stock						1,341,372		
Expenses paid by issuance of warrants						573,357		
Expenses paid by issuance of preferred stock						142,501		
Expenses related to stock warrants issued						612,000		
Accretion of discount on investments in securities						(1,604,494)		
Amortization of debt discount						450,000		
Forgiveness of employee receivable						30,036		
Impairment loss write-off of goodwill						5,702,130		
Equity in loss of investee						178,936		
In-process research and development						10,422,130		
Write-off of license agreement						152,866		
Write-off of assets available-for-sale						108,000		
Cumulative effect of change in accounting principle						25,821		
Changes in assets and liabilities, net of effect of						,		
acquisitions:								
(Increase) decrease in prepaid expenses and other								
assets		(186,929)		43,215		(749,901)		
Increase (decrease) in accounts payable and accrued		, , ,		,		, , ,		
liabilities		(1,277,316)		(2,508,501)		1,253,078		
Net cash used in operating activities		(7,007,343)		(9,986,154)		(105,446,406)		
Cash flows from investing activities:								
Purchases of short-term investments						(111,183,884)		

Proceeds from sales and maturities of short-term investments Purchases of property and equipment Proceeds from sale of property and equipment Purchase of certificate of deposit Maturity of certificate of deposit Payment on obligation under license agreement 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	(6,780) 1,700	16,000	112,788,378 (1,037,134) 51,606 (1,016,330) 1,016,330 (106,250) 32,395 (35,000) 405,993 (90,475) (19,475) 230,000
Net cash provided by (used in) investing activities	(5,080)	16,000	1,036,154
Cash flows from financing activities:			
Proceeds from sale of preferred stock	30,453,227	4,276,000	44,474,720
Proceeds of restricted cash for preferred stock dividends Proceeds from sale of common stock Proceeds from exercise of stock options	633,008	633,008 84,151,342 712,367	
Proceeds from sale or exercise of warrants	317,444		14,714,258
Payment to escrow for preferred stock dividends obligation Repurchase of warrants	(633,008)		(633,008) (55,279)
Payments for financing and offering costs Payments on notes payable and long-term debt	(3,093,733)	(996,140)	(10,994,046) (605,909)
Proceeds from issuance of notes payable and detachable warrants			1,344,718
Cash paid in lieu of fractional shares for reverse stock split	(146)		(146)
Net cash provided by financing activities	27,676,792	3,279,860	133,742,025
Net increase (decrease) in cash Cash at beginning of period	20,664,369 8,667,404	(6,690,294) 9,849,904	29,331,773
Cash at end of period	\$ 29,331,773	\$ 3,159,610	\$ 29,331,773

See accompanying notes to unaudited condensed consolidated financial statements.

(3)

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

1. Basis of Presentation

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation (ADVENTRX, we, our or the Company), prepared unaudited interim condensed consolidated financial statements included in this report in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and with the instructions of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for annual audited financial statements and should be read in conjunction with our audited consolidated financial statements and related notes for the year ended December 31, 2009 included in our Annual Report on Form 10-K filed with the SEC on March 18, 2010 (2009 Annual Report). The condensed consolidated balance sheet as of December 31, 2009 included in this report has been derived from the audited consolidated financial statements included in the 2009 Annual Report. In the opinion of management, these consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. The results of operations for the interim periods shown in this report are not necessarily indicative of results expected for the full year.

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, SD Pharmaceuticals, Inc. and ADVENTRX (Europe) Ltd. up until its dissolution. We dissolved ADVENTRX (Europe) Ltd. in December 2009. All intercompany accounts and transactions have been eliminated in consolidation.

On April 23, 2010, the Company effected a 1-for-25 reverse split of its common stock, which was authorized by its stockholders at a special meeting held in August 2009. All common stock share and per share information in the condensed consolidated financial statements and notes thereto included in this report have been restated to reflect retrospective application of the reverse stock split for all periods presented ending or as of a date prior to April 23, 2010, except for par value per share and the number of authorized shares, which were not affected by the reverse stock split.

2. Use of Estimates

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

3. Share-Based Compensation Expense

Estimated share-based compensation expense related to equity awards granted to our employees and non-employee directors for the three and nine months ended September 30, 2010 and 2009 was as follows:

	Three months ended September 30,			Nine months ended September 30,				
		2010		2009		2010		2009
Selling, general and administrative expense Research and development expense	\$	154,041 (1,243)	\$	135,343 14,305	\$	610,329 (5,557)	\$	424,095 30,731
Share-based compensation expense before taxes Related income tax benefits		152,798		149,648		604,772		454,826
Share-based compensation expense	\$	152,798	\$	149,648	\$	604,772	\$	454,826

Net share-based compensation expense per common share basic and diluted \$ 0.01 \$ 0.03 \$ 0.05 \$ 0.11

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

(4)

Table of Contents

There were no employee or non-employee director stock options exercised during the three and nine months ended September 30, 2010 and 2009. During the three and nine months ended September 30, 2010, we granted stock options to acquire an aggregate of 0 and 203,381 shares, respectively, of our common stock to our employees and non-employee directors with an estimated weighted-average grant date fair value of \$0 and \$6.91 per share, respectively. At September 30, 2010, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was \$1.0 million, which is expected to be recognized over a weighted-average period of 2.7 years. During the three months ended September 30, 2009, we granted stock options to acquire an aggregate of 135,998 shares of our common stock to our employees with an estimated weighted-average grant date fair value of \$3.18 per share. No stock options were granted to our employees during the first six months of 2009. No stock options, or any other equity-based awards, were granted to our non-employee directors during the nine months ended September 30, 2009.

4. Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, including foreign currency translation adjustments and unrealized gains and losses on marketable securities. Our components of comprehensive loss consist only of net loss. For the nine months ended September 30, 2010 and 2009, comprehensive loss was \$6.2 million and \$8.1 million, respectively.

5. Net Loss Per Common Share

Basic and diluted net loss per common share was calculated by dividing the net loss applicable to common stock for the period by the weighted-average number of common shares outstanding during the period, without consideration for our outstanding common stock equivalents because their effect would have been anti-dilutive. Common stock equivalents are included in the calculation of diluted earnings per common share only if their effect is dilutive. As of September 30, 2010 and 2009, our outstanding common stock equivalents consisted of options, warrants and convertible preferred stock as follows:

	Septemb	September 30,		
	2010	2009		
Options	421,737	234,356		
Warrants	4,055,030	826,344		
Convertible preferred stock	779,092			
	5,255,859	1.060.700		

6. Recent Accounting Pronouncements

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

7. Licensing Revenue

In June 2010, we announced that we had entered into a license agreement with respect to our know-how to develop, make, use and sell ANX-510, or CoFactor® (5,10-methylenetetrahydrofolate), with Theragence, Inc., a California corporation (Theragence). Pursuant to the agreement, we granted to Theragence an exclusive worldwide license, including the right to grant sublicenses under certain circumstances, to conduct research on and to develop, make,

have made, use, offer for sale, sell, have sold and import licensed products in any field or use. We are entitled to receive royalties on net sales of licensed products and commercial milestone payments of up to approximately \$30 million based on aggregate gross sales of licensed products in the United States, European Union and Japan. Theragence agreed to use commercially reasonable efforts to research, develop and commercialize at least one licensed product. We discontinued active work on our CoFactor program in October 2008.

(5)

Table of Contents

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

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

In September 2010, pursuant to the terms of the license agreement, we elected to make the \$0.1 million cash payment to Shin Poong in lieu of supplying product for