

ADVENTRX PHARMACEUTICALS INC

Form 10-Q

August 07, 2007

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 June 30, 2007

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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer Accelerated filer Non-accelerated filer

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, \$.001 par value, as of August 1, 2007 was 89,752,572.

Table of Contents

TABLE OF CONTENTS

	Page
<u>PART I</u>	
	<u>FINANCIAL INFORMATION</u>
<u>Item 1.</u>	<u>Financial Statements</u>
	<u>a. Condensed Consolidated Balance Sheets as of June 30, 2007 (Unaudited) and December 31, 2006</u>
	3
	<u>b. Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2007 and 2006 and for the period from inception (June 12, 1996) through June 30, 2007 (Unaudited)</u>
	4
	<u>c. Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2007 and 2006 and for the period from inception (June 12, 1996) through June 30, 2007 (Unaudited)</u>
	5
	<u>d. Notes to Condensed Consolidated Financial Statements (Unaudited)</u>
	6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
	11
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	18
<u>Item 4.</u>	<u>Controls and Procedures</u>
	19
<u>PART II</u>	
	<u>OTHER INFORMATION</u>
<u>Item 1.</u>	<u>Legal Proceedings</u>
	19
<u>Item 1A.</u>	<u>Risk Factors</u>
	19
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
	19
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>
	19
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>
	19
<u>Item 5.</u>	<u>Other Information</u>
	20
<u>Item 6.</u>	<u>Exhibits</u>
	20
	<u>SIGNATURES</u>
	21
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	

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

(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets

	June 30, 2007	December 31, 2006
	(unaudited)	(Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,751,763	\$ 25,974,041
Short-term investments	26,966,978	25,771,406
Interest receivable	91,649	80,338
Prepaid expenses	707,104	511,327
Total current assets	44,517,494	52,337,112
Property and equipment, net	369,646	402,968
Other assets	58,305	58,305
Total assets	\$ 44,945,445	\$ 52,798,385
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 876,834	\$ 480,402
Accrued liabilities	2,482,074	1,675,226
Accrued compensation and payroll taxes	804,917	292,896
Total current liabilities	4,163,825	2,448,524
Long-term liabilities	24,972	35,674
Total liabilities	4,188,797	2,484,198
Commitments and contingencies		
Stockholders equity:		
Preferred stock; 1,000,000 shares authorized; no shares issued or outstanding		
Common stock, \$0.001 par value; 200,000,000 shares authorized; 89,706,739 and 89,676,739 shares issued and outstanding at June 30, 2007 and December 31, 2006, respectively	89,708	89,678
Additional paid-in capital	128,572,496	127,283,524
Deficit accumulated during the development stage	(87,903,567)	(77,056,925)
Accumulated other comprehensive loss	(1,989)	(2,090)
Total stockholders equity	40,756,648	50,314,187

Total liabilities and stockholders' equity	\$ 44,945,445	\$ 52,798,385
--	---------------	---------------

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)

	Three months ended June		Six months ended June 30,		Inception
	2007	2006	2007	2006	(June 12,
		30,		30,	1996)
		(Note 1)		(Note 1)	through
					June 30, 2007
					(Note 1)
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
Total revenues			500,000		753,469
Operating expenses:					
Research and development	4,239,610	3,233,735	7,624,270	5,717,593	35,782,234
Selling, general and administrative	2,006,396	1,754,757	4,815,845	3,489,929	29,386,581
Depreciation and amortization	53,036	41,089	104,925	78,202	10,537,174
In-process research and development		10,422,130		10,422,130	10,422,130
Impairment loss write off of goodwill					5,702,130
Equity in loss of investee					178,936
Total operating expenses	6,299,042	15,451,711	12,545,040	19,707,854	92,009,185
Loss from operations	(6,299,042)	(15,451,711)	(12,045,040)	(19,707,854)	(91,255,716)
Interest income	576,214	252,114	1,198,398	488,641	3,061,457
Interest expense					(179,090)
Loss before cumulative effect of change in accounting principle	(5,722,828)	(15,199,597)	(10,846,642)	(19,219,213)	(88,373,349)
Cumulative effect of change in accounting principle					(25,821)

Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-Q

Net loss	(5,722,828)	(15,199,597)	(10,846,642)	(19,219,213)	(88,399,170)
Preferred stock dividends					(621,240)
Net loss applicable to common stock	\$ (5,722,828)	\$ (15,199,597)	\$ (10,846,642)	\$ (19,219,213)	\$ (89,020,410)
Net loss per common share basic and diluted	\$ (0.06)	\$ (0.21)	\$ (0.12)	\$ (0.28)	
Weighted average shares basic and diluted	89,706,739	71,214,523	89,691,822	69,604,383	

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)

	Six months ended June 30,		Inception
	2007	2006	(June 12,
		(Note 1)	1996)
			through
			June 30,
			2007
			(Note 1)
Cash flows from operating activities:			
Net loss	\$ (10,846,642)	\$ (19,219,213)	\$ (88,399,170)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	104,925	78,202	10,087,174
In-process research and development		10,422,130	10,422,130
Share-based compensation for employee equity awards	1,189,062	838,487	5,021,639
Share-based compensation for non-employee equity awards	38,740	38,261	236,514
Expenses paid by issuance of common stock	39,167	107,817	1,302,206
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	(576,462)	(96,722)	(931,103)
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	(246,255)	(426,928)	(1,065,261)
Increase in accounts payable and accrued liabilities	1,689,473	1,136,166	4,314,704
Increase (decrease) in other long-term liabilities	(10,702)	(10,702)	24,972
Net cash used in operating activities	(8,618,694)	(7,132,502)	(51,010,548)
Cash flows from investing activities:			
Purchases of short-term investments	(28,294,009)	(4,470,574)	(74,017,640)
Proceeds from sales and maturities of short-term investments	27,675,000	11,379,776	47,979,776
Cash paid for acquisitions, net of cash acquired		(258,178)	32,395
Purchases of property and equipment	(45,775)	(88,471)	(883,914)
Purchase of certificate of deposit			(1,016,330)
Maturity of certificate of deposit			1,016,330

Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-Q

Payment on obligation under license agreement			(106,250)
Issuance of note receivable related party			(35,000)
Payments on note receivable			405,993
Advance to investee			(90,475)
Cash transferred in rescission of acquisition			(19,475)
Cash received in rescission of acquisition			230,000
Net cash provided by (used in) investing activities	(664,784)	6,562,553	(26,504,590)
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	61,200	5,750	331,951
Proceeds from sale or exercise of warrants		3,595,130	11,382,894
Repurchase of warrants			(55,279)
Payment of financing and offering costs		(63,621)	(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	61,200	3,537,259	94,266,901
Net increase (decrease) in cash and cash equivalents	(9,222,278)	2,967,310	16,751,763
Cash and cash equivalents at beginning of period	25,974,041	14,634,618	
Cash and cash equivalents at end of period	\$ 16,751,763	\$ 17,601,928	\$ 16,751,763

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. Summary of Significant Accounting Policies**

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 the Company s audited consolidated financial statements and related notes for the year ended December 31, 2006 included in the Company s Annual Report on Form 10-K filed with the SEC on March 15, 2007 (2006 Annual Report). The condensed consolidated balance sheet as of December 31, 2006 has been derived from the audited consolidated financial statements included in the 2006 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. Certain amounts in the prior periods have been reclassified to conform to the current year presentation. Since our inception, we have reported accumulated net losses of approximately \$88.4 million and recurring negative cash flows from operations. In order to maintain sufficient cash and investments to fund future operations, we anticipate raising additional capital in the next 12 months through various financing alternatives including licensing or selling our technologies, issuing debt securities, or selling and issuing shares of our common stock or preferred stock or rights to purchase these securities. The balance of securities available for sale under our existing shelf registration was approximately \$60.0 million as of June 30, 2007. We believe our cash, cash equivalents and investments in securities of approximately \$43.7 million as of June 30, 2007 will be sufficient to sustain our planned level of operations for at least the next 12 months.

Principles of Consolidation. 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. Certain amounts in the prior year consolidated financial statements have been reclassified to conform to the current year presentation.

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

Change in Accounting Principle for Registration Payment Arrangements. In December 2006, the Financial Accounting Standards Board (FASB) issued FASB Staff Position on No. EITF 00-19-2, *Accounting for Registration Payment Arrangements* (FSP EITF 00-19-2). FSP EITF 00-19-2 provides that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement should be separately recognized and measured in accordance with Statement of Financial Accounting Standards (FAS) No. 5, *Accounting for Contingencies*, which provides that loss contingencies should be recognized as liabilities if they are probable and reasonably estimable. Subsequent to the adoption of FSP EITF 00-19-2, any changes in the carrying amount of the contingent liability will result in a gain or loss that will be recognized in the consolidated statement of operations in the period the changes occur. The guidance in FSP EITF 00-19-2 is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of FSP EITF 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of FSP EITF 00-19-2, this guidance is effective for our consolidated financial statements issued for the year beginning January 1, 2007, and interim periods within that year.

On January 1, 2007, we adopted the provisions of FSP EITF 00-19-2 to account for the registration payment arrangement associated with our July 2005 financing (the July 2005 Registration Payment Arrangement). As of June 30, 2007, management determined that it was not probable that we would have any payment obligation under the

July 2005 Registration Payment Arrangement; therefore, no accrual for contingent obligation is required under the provisions of FSP EITF 00-19-2. The comparative condensed consolidated financial statements of periods prior to January 1, 2007 have been adjusted to apply the new

Table of Contents

method retrospectively. The following financial statement line items for the three and six months ended June 30, 2006 and from inception through June 30, 2006 were affected by the change in accounting principle:

Consolidated Statements of Operations

	As Originally Reported	As Adjusted	Effect of Change
<i>Three Months Ended June 30, 2006</i>			
Loss from operations	\$(15,451,711)	\$(15,451,711)	\$
Gain on fair value warrants	17,963,311		(17,963,311)
Net income (loss)	2,763,714	(15,199,597)	(17,963,311)
Net income (loss) per share-basic	\$ 0.04	\$ (0.21)	\$ (0.25)
Net income (loss) per share-diluted	\$ 0.03	\$ (0.21)	\$ (0.25)
<i>Six Months Ended June 30, 2006</i>			
Loss from operations	\$(19,707,854)	\$(19,707,854)	\$
Gain on fair value warrants	936,246		(936,246)
Net loss	(18,282,967)	(19,219,213)	(936,246)
Net loss per share basic and diluted	\$ (0.26)	\$ (0.28)	\$ (0.02)
<i>Inception (June 12, 1996) Through June 30, 2006</i>			
Loss from operations	\$(69,082,063)	\$(69,082,063)	\$
Loss on fair value warrants	(10,643,414)		10,643,414
Net loss	(78,743,410)	(68,099,996)	10,643,414
Net loss applicable to common stock	(79,364,650)	(68,721,236)	10,643,414

Consolidated Statements of Cash Flows

	As Originally Reported	As Adjusted	Effect of Change
<i>Six Months Ended June 30, 2006</i>			
Net loss	\$(18,282,967)	\$(19,219,213)	\$ (936,246)
Gain on value of warrant liability	(936,246)		936,246
<i>Inception (June 12, 1996) through June 30, 2006</i>			
Net loss	\$(78,743,410)	\$(68,099,996)	\$ 10,643,414
Loss on value of warrant liability	10,643,414		(10,643,414)

Income Taxes. In July 2006, FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an Interpretation of FASB Statement 109* (FIN 48), which clarifies the accounting for uncertainty in tax positions. FIN 48 provides that the tax effects from an uncertain tax position can be recognized in our consolidated financial statements only if the position is more likely than not of being sustained upon an examination by tax authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The provisions of FIN 48 are effective for us as of January 1, 2007, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings in the year of adoption. We adopted FIN 48 on January 1, 2007, which did not have a material impact on our consolidated results of operations or financial position. See Note 4.

Computation of 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. Diluted net loss per common share was calculated by dividing the net

loss for the period by the weighted-average number of common stock equivalents outstanding during the period. For purposes of this calculation, 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.

Table of Contents

We have excluded the following options and warrants from the calculation of diluted net loss per common share for the three and six months ended June 30, 2007 and 2006 because their effect is anti-dilutive:

	2007	2006
Warrants	13,408,549	16,575,090
Options	4,686,540	3,455,500
	18,095,089	20,030,590

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 June 30, 2007 and 2006, comprehensive loss was \$5.7 million and \$15.2 million, respectively. For the six months ended June 30, 2007 and 2006 and the period from inception (June 12, 1996) through June 30, 2007, comprehensive loss was \$10.9 million, \$19.2 million and \$88.4 million, respectively.

Share-Based Payments. Estimated share-based compensation expense related to stock options granted to employees for the three and six months ended June 30, 2007 and 2006 was as follows:

	Three Months Ended June		Six Months Ended June	
	2007	2006	2007	2006
Selling, general and administrative expense	\$ 339,357	\$ 270,076	\$ 685,662	\$ 581,271
Research and development expense	249,696	123,756	503,400	257,216
Share-based compensation expense before taxes	589,053	393,832	1,189,062	838,487
Related income tax benefits				
Share-based compensation expense	\$ 589,053	\$ 393,832	\$ 1,189,062	\$ 838,487
Net share-based compensation expense per common share basic and diluted	\$ 0.01	\$ 0.01	\$ 0.01	\$ 0.01

Since we have a net operating loss carryforward as of June 30, 2007, no excess tax benefits for the tax deductions related to share-based awards were recognized in the condensed consolidated statement of operations. For the six-month periods ended June 30, 2007 and 2006, employees exercised stock options to purchase 30,000 and 2,500 shares of common stock, respectively, for aggregate proceeds of \$61,200 and \$5,750, respectively.

At June 30, 2007, total unrecognized estimated compensation cost related to non-vested employee share-based awards granted prior to that date was \$5.3 million, which is expected to be recognized over a weighted-average period of 2.9 years. During the six months ended June 30, 2007 and 2006, we granted 1,111,333 and 1,016,000 stock options, respectively, to our employees with the estimated weighted-average grant-date fair value of \$2.40 and \$3.25 per share, respectively.

Supplementary Cash Flow Information. Noncash investing and financing transactions excluded from the condensed consolidated statements of cash flows for the six months ended June 30, 2007 and 2006 and for the period from inception (June 12, 1996) through June 30, 2007 are as follows:

**Inception
(June 12, 1996)**

	Six months ended June 30,		through
	2007	2006	June 30, 2007
Supplemental disclosures of cash flow information:			
Interest paid	\$	\$	\$ 179,090
Income taxes paid			
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		10,163,952	24,781,555
Payment of dividends			213,000
Financial advisor services in conjunction with private placement			1,137,456

8

Table of Contents

	Six months ended June 30,		Inception (June 12, 1996) through June 30, 2007
	2007	2006	
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		13	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	25,828		25,828
Unrealized (gain) loss on short-term investments	(101)	2,871	1,989

2. Registration Payment Arrangement

On July 21, 2005, we entered into a securities purchase agreement (the *Agreement*) with certain accredited institutional investors (the *Purchasers*) for the sale of 10,810,809 shares of our common stock (the *Shares*) at a purchase price of \$1.85 per share for aggregate gross proceeds of \$19,999,997. In connection with this financing, we issued the Purchasers seven-year warrants to purchase 10,810,809 shares of our common stock (the *Warrant Shares*) at an exercise price of \$2.26 per share. We received net proceeds of \$18,116,751, after deducting commissions and offering fees and expenses, which included cash payments of \$1,600,000 to placement agents and \$283,246 in legal and accounting fees.

Pursuant to the terms of the *Agreement*, if (i) a registration statement covering (A) all of the *Shares* and the *Warrant Shares* and (B) any other shares of common stock issued or issuable in respect to the *Shares* and the *Warrant Shares* because of stock splits, stock dividends, reclassifications, recapitalizations or similar events (together, the *Registrable Shares*) required to be covered thereby and required to be filed by us is (A) not filed with the SEC on or before 45 days after the closing of such financing (a *Filing Failure*) or (B) if such registration statement is not declared effective by the SEC on or before 90 days after the closing of such financing (an *Effectiveness Failure*) or (ii) on any day after the effective date of the registration statement sales of all the *Registrable Shares* required to be included on such registration statement cannot be made (other than as permitted during a suspension pursuant to the *Agreement*) pursuant to such registration statement (including, without limitation, because of a failure to keep the registration statement effective, to disclose such information as is necessary for sales to be made pursuant to such registration statement or to register sufficient number of *Shares*) (a *Maintenance Failure*), then, we will be obligated, without limiting any other remedies of any *Purchaser*, to pay as liquidated damages (the *Liquidated Damages*) for such failure and not as a penalty to any *Purchaser* an amount in cash determined in accordance with the formula set forth below:

For each 30-day period that a *Filing Failure*, *Effectiveness Failure* or *Maintenance Failure* remains uncured, we will pay an amount equal to the purchase price paid to us for all *Shares* then held by such *Purchaser* multiplied by 1% for the first 30-day period or any portion thereof and increasing by an additional 1% with regard to each additional 30 day period until such *Filing Failure*, *Effectiveness Failure* or *Maintenance Failure* is cured.

Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-Q

For any partial 30-day period in which a Filing Failure, Effectiveness Failure or Maintenance Failure exists but is cured prior to the end of the 30-day period, we will pay the Purchasers a pro rata portion of the amount which would be due if the failure continued for the entire 30-day period. For example, if the purchase price paid for all Shares then held by a Purchaser is \$5,000,000, then, (a) at the end of the 30th day, the Liquidated Damages would be 1% or \$50,000, (b) at the end of the 60th day, the Liquidated Damages for the first 30-day period would have been 1% or \$50,000 and for the second 30-day period would be 2% or \$100,000, and (c) at the end of the 105th day, the Liquidated Damages for the first 30-day period would have been 1% or \$50,000, for the second 30-day period 2% or \$100,000, for the third 30-day period 3% or \$150,000, and for the final 15-day period, 4% applied pro rata to such 15 days, or \$100,000.

There is no cap to the amount of Liquidated Damages that we may be obligated to pay. Payments to be made pursuant to the July 2005 Registration Payment Arrangement will be due and payable to the Purchasers at the end of each calendar month during which Liquidated Damages will have accrued. No Liquidated Damages will be due or payable to a Purchaser in any event if as of the date of the Filing Failure, Effectiveness Failure or Maintenance Failure such Purchaser could sell all of the Registrable Shares such Purchaser then holds without registration by reason of Rule 144(k) of the Securities Act.

Table of Contents

The registration statement was filed and declared effective by the SEC on September 2, 2005, which was within the allowed time. As of August 3, 2007, we have not incurred nor paid any Liquidated Damages in connection with the July 2005 Registration Payment Arrangement.

Effective January 1, 2007, we accounted for the July 2005 Registration Payment Arrangement under the provisions of FSP EITF 00-19-2. See Note 1, *Significant Accounting Policies – Change in Accounting Principle for Registration Payment Arrangement*, for a detailed discussion. As of August 1, 2007, management determined that it is not probable that we will be obligated to pay any Liquidated Damages in connection with the July 2005 Registration Payment Arrangement. Accordingly, no accrual for contingent obligation is required at June 30, 2007.

3. License Fee Revenue

In October 2006, we entered into a license agreement with Theragenex, LLC. 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 (\$500,000 of which we received in January 2007 and \$500,000 of which was due in June 2007 but remains unpaid), 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 \$500,000 payment and, in subsequent discussions, has indicated that it does not intend to pay the remaining \$500,000. On July 3, 2007, we notified Theragenex that, among other things, its failure to make the final \$500,000 payment constituted a material breach of the agreement. Pursuant to the terms of the agreement, if Theragenex does not cure this breach within 30 days after receipt of this notice, we have the right to terminate the agreement, such termination to be effective upon expiration of the 30-day notice period.

In accordance with the provisions of the SEC's Staff Accounting Bulletin Topic 13, *Revenue Recognition* (Topic 13), we recognized no revenue for the three months ended June 30, 2007, because collectibility was not assured. For the six months ended June 30, 2007, we recognized \$500,000 in license fee revenue, because our performance obligations were complete, collectibility was assured and we had no continuing obligations for performance under the agreement. We do not intend to refund the initial \$500,000 payment from Theragenex and we intend to pursue appropriate action to collect payment of the final \$500,000 payment due in June 2007; however, we will not recognize revenue with respect to this payment until collectibility is assured.

4. Income Taxes

We adopted the provisions of FIN 48 on January 1, 2007, which did not materially impact our consolidated results of operations or financial position. No unrecognized tax benefits were recorded as of the date of adoption. As a result of the implementation of FIN 48, we did not recognize any liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

Our policy is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrual for interest or penalties on our consolidated balance sheets at June 30, 2007 and at December 31, 2006, and have not recognized interest and/or penalties in the consolidated statement of operations for the three and six months ended June 30, 2007.

At January 1, 2007, we had net deferred tax assets of \$20.0 million. The deferred tax assets are primarily composed of federal and state tax net operating loss carryforwards, federal and state R&D credit carryforwards, share-based compensation expense and intangibles. Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset our net deferred tax asset. Additionally, the future utilization of our net operating loss and R&D credit carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of ownership changes that may have

occurred previously or that could occur in the future. We have not yet determined whether such an ownership change has occurred, however, we plan to complete a Section 382/383 analysis regarding the limitation of the net operating losses and R&D credits. When this analysis is completed, we plan to update our unrecognized tax benefits under FIN 48. Therefore, we expect that the unrecognized tax benefits may change following completion of our analysis. At this time, we cannot estimate how much the unrecognized tax benefits may change. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

5. 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. Management is not aware of any pending or threatened lawsuit or proceedings that would have a material adverse effect on our consolidated financial position, results of operations or cash flows.

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 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 II, Risk Factors, in this report and in Item 1A of Part I, Risk Factors, in our Annual Report on Form 10-K for the year ended December 31, 2006.

Overview

We are a biopharmaceutical research and development company focused on commercializing proprietary product candidates for the treatment of cancer and infectious diseases. We seek to improve the performance and safety of existing therapeutic products by addressing significant problems such as drug metabolism, bioavailability, excessive toxicity and treatment resistance. Our research and development, or R&D, programs include full clinical and preclinical development programs for new chemical entities. We are also developing novel emulsion formulations of several currently marketed products for which we anticipate seeking marketing approval under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, which may allow us to obtain marketing approval of these product candidates on timelines shorter than those associated with traditional development of new chemical entities. We are in partnering discussions regarding certain of our product candidates.

We are nearing completion of our Phase 2b clinical trial of CoFactor for the treatment of metastatic colorectal cancer. The last patient in the Phase 2b study finished the treatment phase on June 30, 2007. Following industry standards, we expect to remain blinded from the data until the various compliance activities, including quality checks, analyzing and resolving outstanding issues and data processing associated with the trial, are completed. These compliance activities usually take from two to three months from the end of the treatment phase before the database is locked and the information package is sent to us by our third-party reviewers and statisticians. Based on our expectations for the timing of this process, we anticipate announcing topline results from the Phase 2b study in the fourth quarter of 2007. The Phase 2b trial is a 300-patient randomized, controlled, two-arm open label safety study with a primary endpoint assessing the incidence and severity of grade 3 and grade 4 hematological and gastrointestinal toxicity of the two treatment groups CoFactor/5-FU and leucovorin/5-FU. Secondary endpoints include response rate, time-to-tumor progression and survival.

Additionally, we are testing CoFactor in a pivotal 1,200-patient Phase 3 clinical trial for the treatment of metastatic colorectal cancer under a Special Protocol Assessment with the FDA. Patients are randomized to either a leucovorin control arm, which is dosed via i.v. bolus injection over a period of two hours, or a CoFactor experimental arm, which is dosed via i.v. bolus injection over a period of two-to-three minutes. Both arms receive a bolus regimen of 5-FU and Avastin. The primary endpoint is an improvement in progression-free survival of at least 28 days, with secondary endpoints measuring response rate, duration of response, overall survival and adverse events.

Our goal is to complete enrollment in the Phase 3 trial around the end of 2008. We currently have 50 sites actively recruiting patients, with an additional 15 sites under various stages of review for possible addition to the number of actively enrolling sites. Our plan is to ultimately increase the number of sites actively enrolling patients to 100. We are taking a number of steps in order to meet our goal and to achieve the planned number of sites for this clinical trial, including a planned expansion of our clinical recruitment into Europe. Additionally, we believe that if the results of our Phase 2b study of CoFactor for the treatment of metastatic colorectal cancer are positive, those results should help us achieve our goal for the Phase 3 study.

In Europe, we currently plan to approach the European Medicines Agency (EMA) after we have analyzed our Phase 2b clinical trial results, regarding requirements for approval of CoFactor in the European Union and specifically whether our single Phase 3 pivotal clinical trial is sufficient for approval.

Also, in December 2006 we began a Phase 2 clinical trial of CoFactor for the treatment of advanced breast cancer. We expect to complete enrollment in this study by the end of 2007. The Phase 2 clinical trial is a 31-patient, single arm study, with a primary endpoint of objective response rate, and secondary endpoints of duration of response, progression-free survival, overall survival and incidence and severity of adverse events. This study should help us

determine a protocol for a Phase 3 study for the treatment of advanced breast cancer.

Table of Contents

We are also engaged in the clinical development of ANX-530, a new emulsion formulation of vinorelbine tartrate that is designed to reduce the incidence and severity of vein irritation from i.v. delivery of the drug. We are currently testing ANX-530 in a 28-patient bioequivalence study for the treatment of various cancers. The FDA has informed us that this single clinical trial, if it demonstrates bioequivalence between ANX-530 and the currently marketed product, should provide sufficient clinical data to support the submission of a new drug application, or NDA, with the FDA. The trial is a crossover comparison of ANX-530 and the reference drug, Navelbine[®], also available as generic vinorelbine tartrate, with the primary endpoint of pharmacokinetic equivalence of ANX-530 and Navelbine, and a secondary endpoint of the safety of a single dose of ANX-530. We expect to announce results from the pivotal bioequivalence study of ANX-530 in the fourth quarter of 2007. Following completion of the study, and assuming the study indicates the bioequivalence of ANX-530 to Navelbine, we will begin the preparation of an NDA. We anticipate seeking marketing approval of ANX-530 under Section 505(b)(2) of the FDCA, assuming the results of the study show bioequivalence to vinorelbine tartrate, the reference drug product.

We are also focusing substantial development efforts on ANX-201 (thiophosphonoformate). ANX-201 is a pyrophosphate analog and member of a novel class of reverse transcriptase inhibitors designed for the treatment of human immunodeficiency virus, or HIV. The FDA has recently informed us that additional preclinical studies will be required prior to the initiation of our clinical study of ANX-201 in the United States. However, we are concurrently executing our global development strategy for ANX-201 and are currently in discussions with international regulatory authorities to determine the necessary data needed to support the initiation of a clinical study. If we are able to receive clearance from international regulatory authorities on a timely basis, we would plan on initiating a clinical study of ANX-201 in an international location later in 2007.

We will also continue to focus our efforts in 2007 on developing ANX-514, a new emulsion formulation of the chemotherapy drug docetaxel. ANX-514's formulation is without polysorbate 80 or other detergents and is intended to reduce the incidence and severity of hypersensitivity reactions. In the first half of 2007, we announced preclinical results that indicated bioequivalent pharmacokinetics with a reduced risk of hypersensitivity reactions with ANX-514, compared to the FDA-approved version of docetaxel, marketed under the brand name Taxotere. Later this year, we plan to seek guidance from the FDA with respect to the appropriateness of a Section 505(b)(2) NDA regulatory path for ANX-514. At the same time, we are exploring a global development strategy for ANX-514 and we plan to initiate discussions with international regulatory authorities to determine the most expeditious regulatory approval strategy. If we are able to receive clearance from international regulatory authorities on a timely basis, we would plan to initiate a clinical study of ANX-514 later this year.

We have additional product candidates in our portfolio that we are currently evaluating for future preclinical and clinical development. We intend to continue to build a portfolio of product candidates for the treatment of cancer and infectious diseases that reflect an appropriate balance between the longer-term regulatory pathway associated with traditional drug development and the shorter regulatory timelines available under Section 505(b)(2).

In May 2007, we received a letter from TRx Pharma, a subsidiary of Theragenex, LLC, that we believe was intended to constitute notice of termination of our license agreement, dated October 20, 2006, with Theragenex, though the letter did not explicitly state that it constituted notice of termination. Under this license agreement, we granted to Theragenex an exclusive license to develop, make, have made, use, sell, offer for sale and import ANX-211 (chitosan gel) in the United States in exchange for, among other things, a licensing fee of \$1,000,000 (\$500,000 of which we received in January 2007 and \$500,000 of which was due in June 2007 but remains unpaid and unrecognized). In its letter, TRx Pharma requested a refund of its initial \$500,000 payment and, in subsequent discussions, has indicated that it does not intend to pay the remaining \$500,000. On July 3, 2007, we notified Theragenex that, among other things, its failure to make the final \$500,000 payment constituted a material breach of the agreement. Pursuant to the terms of the agreement, if Theragenex does not cure this breach within 30 days after receipt of this notice, we have the right to terminate the agreement, such termination to be effective upon expiration of the 30-day notice period. We do not intend to refund the initial \$500,000 payment from Theragenex and we intend to enforce our rights under the agreement, including rights to receive payment of the remaining \$500,000 that was due in June 2007, and will pursue such other remedies as we determine are appropriate. If we or Theragenex terminate this license agreement, we intend to seek a new partner(s) to market ANX-211 in the U.S. and throughout the world.

We have incurred annual net losses since inception, and as of June 30, 2007, our accumulated net losses amounted to \$88.4 million. Because we are a development stage company that has not yet marketed any products or generated any significant revenue, we intend to raise additional capital to fund operations through the receipt of upfront fees, milestone payments and royalties from licensing and partnering arrangements, and through other forms of financing such as debt financing or sales of shares of our common or preferred stock. If we are unable to enter into licensing or partnering arrangements, or if we enter into such arrangements and we or our partners incur delays or are unable to achieve established milestones that generate payments to us, then we may need to slow the rate of development of CoFactor or our other R&D programs, or we may need to raise additional capital through the other stated forms of financing.

Table of Contents

We expect that our R&D, selling, marketing and other operating costs will continue to exceed revenues from existing sources for the foreseeable future. Our total operating expenses are influenced substantially by the amount of spending devoted to our R&D programs. During the last three years, we have substantially expanded our product candidate pipeline, which requires that we allocate significant amounts of our resources to the underlying programs, including increased spending on clinical trials as those programs advance. We are currently responsible for all costs incurred for our clinical and preclinical activities. We expect R&D expenses will represent at least 60% of our operating expenses for 2007. We expect that selling, general and administrative expenses for 2007 will represent less than 40% of our operating expenses. Trends in various types of expenses and revenues are discussed further under Results of Operations.

A general understanding of the drug development process is critical to understanding our results of operations. Drug development in the United States 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 to prove such product's safety and efficacy. The NDA process generally requires, before the submission of the NDA, filing of an investigational new drug application, or IND, pursuant to which permission is sought to begin clinical testing of the new drug. An NDA based on published safety and efficacy studies conducted by others may be submitted for a drug product with a previously approved active ingredient if only the method of delivery, strength or dosage form is changed. 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. Although we are currently focused on advancing CoFactor, ANX-530 and ANX-201 through various stages of clinical development, 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 trial process and given the early stage of development of many of our product candidates, 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;

- the number of patients who participate in the trials;

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

- 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.

Table of Contents

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 unfavorable effect on our results of operations. We cannot be certain when or if any net cash inflow due to sales of any of our current product candidates will commence.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based upon unaudited consolidated financial statements that we have prepared in accordance with accounting principles generally accepted in the United States of America. 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 research 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.

Change in Accounting Principle for Registration Payment Arrangements. In December 2006, the FASB issued FSP EITF 00-19-2, *Accounting for Registration Payment Arrangements*. FSP EITF 00-19-2 provides that a contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement is separately recognized and measured in accordance with FAS 5 which provides that loss contingencies should be recognized as liabilities if they are probable and reasonably estimable. On January 1, 2007, the first day of our fiscal year ending December 31, 2007, we adopted the provisions of FSP EITF 00-19-2 to account for an outstanding registration payment arrangement. The comparative consolidated financial statements of prior periods have been adjusted to apply the new method retrospectively. See Note 1 in Notes to Condensed Consolidated Financial Statements (unaudited), *Change in Accounting Principle for Registration Payment Arrangements*, for a detailed discussion.

Income Taxes. In July 2006, FASB issued FIN 48, *Accounting for Uncertainty in Income Taxes-an Interpretation of FASB Statement 109*, which clarifies the accounting for uncertainty in tax positions. FIN 48 provides that the tax effects from an uncertain tax position can be recognized in our consolidated financial statements only if the position is more likely than not of being sustained upon an examination by tax authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The provisions of FIN 48 are effective for us as of January 1, 2007, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings in the year of adoption. We adopted FIN 48 on January 1, 2007, which did not have a material impact on our consolidated results of operations or financial position.

Revenue Recognition. We recognize revenue in accordance with Topic 13, *Revenue Recognition*, and EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables*, or 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) collectibility is reasonably assured. Revenue from licensing agreements is recognized based on the performance requirements of the agreement. Revenue is deferred for fees received before earned. Nonrefundable upfront fees that are not contingent on any future performance by us are recognized as revenue when revenue recognition criteria under Topic 13 and EITF 00-21 are met and the license term commences. Nonrefundable upfront fees, where we have an 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 agreements 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 license agreements.

Research and Development Expenses. R&D expenses consist of expenses incurred in performing R&D activities, including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. R&D expenses are charged to operations as they are incurred.

Table of Contents

Milestone payments that we make in connection with in-licensed technology or product candidates are expensed as incurred when there is uncertainty in receiving future economic benefits from the licensed technology or product candidates. We consider the future economic benefits from the licensed technology or product candidates to be uncertain until such licensed technology 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 research institutions and clinical 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 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 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 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, or 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. We incurred significant IPR&D expense related to our acquisition of SD Pharmaceuticals, Inc.

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*, or FAS 123R, including the provisions of Staff Accounting Bulletin No. 107. 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. Prior to January 1, 2006, we accounted for share-based compensation under the recognition and measurement principles of FAS 123, *Accounting for Stock-Based Compensation*.

We estimate the fair value of stock option awards on the date of grant using the Black-Scholes option-pricing model, or Black-Scholes model. The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by 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 option valuation 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*, or 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.

Table of Contents

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 accounting principles generally accepted in the United States of America.

Results of Operations**Comparison of Three Months Ended June 30, 2007 and 2006**

Revenue. No revenue was recognized for the three months ended June 30, 2007 and 2006. We anticipate that licensing, partnering, and other collaborations will increase in importance as part of our business development strategy through 2007 and 2008; and we are in discussions with other companies regarding potential arrangements for certain of our product candidates.

Research and Development 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 aforementioned uncertainties, 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 each of the periods listed and since January 1, 2005 (unaudited):

	Quarter ended June 30, 2007	Quarter ended June 30, 2006	Six months ended June 30, 2007	Six months ended June 30, 2006	January 1, 2005 through June 30, 2007
External clinical study fees and expenses	\$ 2,011,495	\$ 1,526,395	\$ 3,676,080	\$ 3,190,096	\$ 15,965,771
External preclinical study fees and expenses	1,120,246	1,062,949	1,825,495	1,373,223	5,838,877
Personnel costs	858,173	520,636	1,619,295	897,058	4,895,473
Share-based compensation expense	249,696	123,755	503,400	257,216	1,607,859
Total	\$ 4,239,610	\$ 3,233,735	\$ 7,624,270	\$ 5,717,593	\$ 28,307,980

R&D expenses increased by \$1.0 million, or 31%, to \$4.2 million for the three months ended June 30, 2007, compared to \$3.2 million for the comparable period in 2006. The increase in R&D expenses was primarily related to a \$485,000 increase in external clinical study fees and expenses related to CoFactor and ANX-530, a \$338,000 increase in personnel costs related to an increase in R&D personnel and a \$126,000 increase in share-based compensation expense.

We expect that our R&D expenses will continue to increase beyond the level of expenses incurred in the three months ended June 30, 2007 as we continue to ramp up enrollments in our clinical trials, including our Phase 3 clinical trial of CoFactor for the treatment of metastatic colorectal cancer. The amount of the increase in expense will be directly related to the success and speed of patient enrollment in these trials.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses increased by \$252,000, or 14%, to \$2.0 million for the three months ended June 30, 2007, compared to \$1.8 million for the comparable period in 2006. The increase in SG&A expenses was primarily due to a \$349,000 increase in personnel and related costs and a \$93,000 increase in travel expenses; offset in part by a \$235,000 decrease in legal fees relating to patent applications. We expect that SG&A expenses will continue to increase modestly through 2007 to support increased R&D activity and personnel.

IPR&D. For the three months ended June 30, 2006, we recorded a charge of \$10.4 million in connection with purchased IPR&D related to our acquisition of SD Pharmaceuticals in April 2006.

Interest Income. Interest income for the three months ended June 30, 2007 was \$576,000 compared to \$252,000 for the comparable period in 2006. The increase was primarily attributable to higher invested balances resulting from the

receipt of \$37.1 million in net proceeds from the sale of common stock to institutional investors in November 2006.

Comparison of Six Months Ended June 30, 2007 and 2006

Revenue. Revenue for the six months ended June 30, 2007 amounted to \$500,000, compared to no revenue for the same period a year ago. Revenue in the first six months of 2007 represents a \$500,000 nonrefundable license fee paid under our license agreement with Theragenex. We recognized the license fee as revenue in the period our performance obligations were complete, collectibility was assured and there were no continuing obligations for us to perform under the agreement.

Table of Contents

Research and Development Expenses. R&D expenses increased by \$1.9 million, or 33%, to \$7.6 million for the six months ended June 30, 2007, compared to \$5.7 million for the comparable period in 2006. The increase in R&D expenses was primarily related to a \$722,000 increase in personnel costs related to an increase in R&D personnel, a \$486,000 increase in external clinical study fees and expenses related to CoFactor and ANX-530, a \$452,000 increase in external preclinical study fees and expenses mostly related to ANX-201 and a \$246,000 increase in share-based compensation expense.

Selling, General and Administrative Expenses. SG&A expenses increased by \$1.3 million, or 38%, to \$4.8 million for the six months ended June 30, 2007, compared to \$3.5 million for the comparable period in 2006. The increase in SG&A expenses was primarily due to a \$960,000 increase in personnel and related costs and a \$125,000 increase in professional and consulting fees related to market research for our product candidates and investor relations.

IPR&D. For the six months ended June 30, 2006, we recorded a charge of \$10.4 million in connection with purchased IPR&D related to our acquisition of SD Pharmaceuticals in April 2006.

Interest Income. Interest income for the six months ended June 30, 2007 was \$1.2 million compared to \$489,000 for the comparable period in 2006. The increase was primarily attributable to higher invested balances resulting from funds received from our most recent equity financing, which we completed in November 2006.

Liquidity and Capital Resources

Since our inception we have funded our operations primarily through sales of our equity securities. As of June 30, 2007, we had cash and cash equivalents and short-term investments in securities totaling \$43.7 million, compared to \$51.7 million as of December 31, 2006. The decrease in cash and investments in securities was attributed to cash used for operations. As of June 30, 2007 we held \$16.7 million in cash and cash equivalents and \$27.0 million in short-term investments in securities.

Operating Activities. Net cash used in operating activities was \$8.6 million during the six months ended June 30, 2007, compared to \$7.1 million during the six months ended June 30, 2006. The increase in net cash used in operating activities was due to an increase in payments for R&D activities, primarily related to CoFactor, ANX-530, and ANX-201.

The increases in accounts payable and accrued expenses at June 30, 2007 as compared to those balances at December 31, 2006 are mainly due to increases in spending for external preclinical costs and clinical costs related to CoFactor, ANX-530, and ANX-201.

Investing Activities. Net cash used in investing activities was \$665,000 during the six months ended June 30, 2007 compared to net cash provided by investing activities of \$6.6 million during the six months ended June 30, 2006. Net cash used in investing activities in the first half of 2007 was primarily for purchases of short-term investments in securities, net of proceeds from sales and maturities of short-term investments in securities. Net cash provided by investing activities in the comparable period in 2006 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. Net cash provided in financing activities was \$61,000 in the six months ended June 30, 2007 from the exercise of an employee stock option. Net cash provided by financing activities amounted to \$3.5 million for the six months ended June 30, 2006. Net cash provided by financing activities in 2006 primarily reflects proceeds that were received from the exercise of warrants to purchase common stock.

Management Outlook

We believe that cash, cash equivalents, and short-term investments of approximately \$43.7 million at June 30, 2007 should be sufficient to sustain our planned level of operations for at least the next twelve months. We expect that our cash requirements will be from \$6.0 million to \$8.0 million in each of the remaining quarters in 2007, as we continue developing our existing product candidates and pipeline. In order to maintain sufficient cash and investments to fund future operations longer term, and to continue developing our existing product candidates, we will need to raise additional capital from time to time, and may do so through various financing alternatives, including selling shares of our common or preferred stock and rights to acquire our common or preferred stock, licensing or selling our technologies and product candidates, or through the issuance of one or more forms of senior or subordinated debt.

Table of Contents

The balance of securities available for sale under our existing shelf registration was approximately \$60.0 million as of June 30, 2007. If we are unable to raise capital as needed to fund future operations, then we may defer or abandon one or more of our R&D programs and may need to take additional cost-cutting measures.

We are in discussions with 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 deal, we may be entitled to upfront or license fees and milestone payments that we may receive in 2007. Of course, any such fees and payments will depend on successfully consummating a deal and achieving milestones under such arrangements.

Recent Accounting Pronouncements

None.

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 our future financial position, business strategy, clinical trials, partnering arrangements and plans and objectives of management for future operations. When used in this report, the words believe, may, could, will, estimate, continue, anticipate, intend, expect and similar expressions 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, those discussed in Item 1A of Part II, Risk Factors, in this report, Item 1A of Part I, Risk Factors, in our Annual Report on Form 10-K for the year ended December 31, 2006 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. 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

We are not subject to any meaningful market risk related to foreign currency exchange rates, commodity prices or similar market risks. Substantially all of our expenses and capital purchasing activities are transacted in U.S. dollars. We are sensitive to interest rate fluctuations. The primary objective of our investing activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing the risk of loss. Some of the investable securities permitted under our cash management policy may be subject to market risk for changes in interest rates. To mitigate this risk, we maintain a portfolio of cash equivalent and short-term investments in a variety of securities which may include investment grade commercial paper, money market funds, government debt issued by the United States of America, state debt, certificates of deposit and investment grade corporate debt. Presently, we are exposed to minimal market risks associated with interest rate changes because of the relatively short maturities of our investments and we do not expect interest rate fluctuations to materially affect the aggregate value of our financial instruments. We manage our sensitivity to these risks by maintaining investment grade short-term investments. Our cash management policy does not allow us to purchase or hold derivative or commodity instruments or other financial instruments for trading purposes. Additionally, our policy stipulates that we periodically monitor our investments for adverse material holdings related to the underlying financial solvency of the issuer. As of June 30, 2007, our investments consisted mostly of cash, commercial paper and U.S. government debt. Our results of operations and

financial condition would not be significantly impacted by either a 10% increase or decrease in interest rates due mainly to the short-term nature of our investment portfolio. We have not used derivative financial instruments in our investment portfolio. Additionally, we do not invest in foreign currencies or other foreign investments.

Table of Contents

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures

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

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. We are not aware of any material pending legal proceedings.

Item 1A. Risk Factors.

An investment in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described under Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2006, which is incorporated by reference into this quarterly report.

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

Our 2007 Annual Meeting of Stockholders was held on May 23, 2007. At this meeting, our stockholders voted on the following two proposals: (1) election of six nominees to our board of directors to hold office until our 2008 Annual Meeting of Stockholders or until their earlier resignation or removal, and (2) ratification of the appointment of J.H. Cohn LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2007.

Table of Contents**Proposal No. 1: Election of Directors**

Our stockholders voted to elect all six director nominees to the board of directors. The votes regarding Proposal No. 1 were as follows:

Nominees:	Votes For	Votes Withheld
Mark N.K. Bagnall	64,140,980	300,481
Alexander J. Denner	61,533,973	2,907,488
Michael M. Goldberg	64,084,550	356,911
Evan M. Levine	64,127,477	313,984
Jack Lief	64,139,180	302,281
Mark J. Pykett	64,138,480	302,981

Proposal No. 2: Ratification of Independent Registered Public Accounting Firm

Our stockholders voted to ratify the appointment of J.H. Cohn LLP. The votes regarding Proposal No. 2 were as follows:

	Votes For	Votes Withheld	Votes Abstained
J.H. Cohn LLP	62,935,242	1,297,093	209,126

Item 5. Other Information

None.

Item 6. Exhibits.

An Exhibit Index has been attached as part of this quarterly 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: August 7, 2007

By: /s/ Evan M. Levine
Evan M. Levine
Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2007

By: /s/ Gregory P. Hanson
Gregory P. Hanson, CMA
Chief Financial Officer, Senior Vice
President,
Finance, and Treasurer
(Principal Financial and Accounting
Officer)

Table of Contents

Exhibit Index

Exhibit	Description
31.1	Certification of chief executive officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2	Certification of chief financial officer pursuant to Rule 13a-14(a)/15d-14(a)
32.1*	Certification of chief executive officer and chief 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.