ADVENTRX PHARMACEUTICALS INC
Form 10-Q
November 09, 2006

Table of Contents

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

(Mark One)

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

For the quarterly period ended September 30, 2006

OR

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

For the Transition Period from to

Commission File Number 001-32157

ADVENTRX Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

6725 Mesa Ridge Road, Suite 100
San Diego, California 92121
858-552-0866
(Address of principal executive offices, zip code and telephone number, including area code)

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 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 o Accelerated filer þ Non-accelerated filer o
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ
The number of shares outstanding of the registrant s common stock, $.001 par value, as of October 31, 2006 was 74,446,774.

ADVENTRX PHARMACEUTICALS, INC.
FORM 10-Q QUARTERLY REPORT
For the Period Ended September 30, 2006
TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

ADVENTRX PHARMACEUTICALS, INC.

(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets

	September 30, 2006 (unaudited)	December 31, 2005 (Note 2)
Assets		
Current assets:		
Cash and cash equivalents	$ 16,201,019	$ 14,634,618
Accrued interest income	13,384	10,214
Prepaid expenses	916,115	255,802
Short-term investments	894,489	7,958,458
Total current assets	18,025,007	22,859,092
Property and equipment, net	447,445	407,544
Other assets	301,305	355,137
Total assets	$ 18,773,757	$ 23,621,773
Liabilities and Shareholders Deficiency		
Current liabilities:		
Accounts payable	$ 73,584	$ 593,228
Accrued liabilities	1,873,091	930,274
Accrued salary and related taxes	435,911	173,398
Warrant liability	28,262,296	29,696,411
Total current liabilities	30,644,882	31,393,311
Long-term liabilities	41,019	57,078
Total liabilities	30,685,901	31,450,389
Commitments and contingencies		
Temporary equity:		
Common stock subject to continuing registration, $.001 par value; 10,810,809 shares issued and outstanding		
Shareholders deficiency:		
Common stock, $0.001 par value. Authorized 200,000,000 shares; issued 63,260,334 shares in 2006 and 56,529,388 shares in 2005	74,095	67,364
Additional paid-in capital	70,904,626	52,105,329
Accumulated other comprehensive income (loss)	870	(1,722)
Deficit accumulated during the development stage	(82,856,988)	(59,964,840)
Treasury stock, 23,165 shares at cost	(34,747)	(34,747)

Total shareholders deficiency	(11,912,144)	(7,828,616)
Total liabilities and shareholders deficiency	$ 18,773,757	$ 23,621,773

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

ADVENTRX PHARMACEUTICALS, INC.
(A Development Stage Enterprise)
Condensed Consolidated Statements of Operations
(unaudited)

	Three months ended September 30,		Nine months ended September 30,		Inception (June 12, 1996) through September 30,
	2006	2005	2006	2005	2006
Net sales	$	$	$	$	$ 174,830
Cost of goods sold					51,094
Gross margin					123,736
Grant revenue					129,733
Interest income	221,271	159,373	709,912	261,292	1,408,249
	221,271	159,373	709,912	261,292	1,661,718
Operating expenses:					
Research and development	3,223,554	1,870,465	8,941,147	5,893,288	25,097,899
General and administrative	2,055,441	1,737,052	5,545,370	3,929,546	22,879,669
Depreciation and amortization	49,326	34,331	127,528	96,422	10,383,089
In-process research and development			10,422,130		10,422,130
Impairment loss write off of goodwill					5,702,130
Interest expense					179,090
Equity in loss of investee					178,936
Total operating expenses	5,328,321	3,641,848	25,036,175	9,919,256	74,842,943
Loss from operations	(5,107,050)	(3,482,475)	(24,326,263)	(9,657,964)	(73,181,225)
Gain (loss) on fair value of warrants	497,869	(12,972,392)	1,434,115	(12,972,392)	(10,145,545)
Loss before cumulative effect of change in accounting principle	(4,609,181)	(16,454,867)	(22,892,148)	(22,630,356)	(83,326,770)
Cumulative effect of change in accounting principle					(25,821)
Net loss	(4,609,181)	(16,454,867)	(22,892,148)	(22,630,356)	(83,352,591)
Preferred stock dividends					(621,240)

Net loss applicable to common stock	$ (4,609,181)	$ (16,454,867)	$ (22,892,148)	$ (22,630,356)	$ (83,973,831)
Net loss per common share basic and diluted:	$ (.06)	$ (.26)	$ (.32)	$ (.39)	
Weighted average shares basic and diluted	73,435,715	63,255,407	70,895,528	57,346,039	

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

ADVENTRX PHARMACEUTICALS, INC.
(A Development Stage Enterprise)
Condensed Consolidated Statements of Shareholders Equity (Deficit)
From Inception (June 12, 1996) through September 30, 2006
(unaudited)

	Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Deficit accumulated during the development stage	Treasury Stock, at cost	Total shareholders equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balances at June 12, 1996 (date of incorporation)		$		$		$		$	$	$	$	$	$
Sale of common stock without par value							503	5	5				10
Change in par value of common stock								(4)	4				
Issuance of common stock and net liabilities assumed in acquisition							1,716,132	1,716	3,224		(18,094)		(13,154)
Issuance of common stock							2,010,111	2,010	456		(2,466)		
Net loss											(259,476)		(259,476)
Balances at December 31, 1996							3,726,746	3,727	3,689		(280,036)		(272,620)
Sale of common stock, net of offering costs of $9,976							1,004,554	1,004	1,789,975				1,790,979
Issuance of common stock in acquisition							375,891	376	887,874				888,250
Minority interest											(45,003)		(45,003)

deficiency at acquisition charged to the Company					
Net loss				(1,979,400)	(1,979,400)
Balances at December 31, 1997	5,107,191	5,107	2,681,538	(2,304,439)	382,206
Rescission of acquisition	(375,891)	(376)	(887,874)	561,166	(327,084)
Issuance of common stock at conversion of notes payable	450,264	451	363,549		364,000
Expense related to stock warrants issued			260,000		260,000
Net loss				(1,204,380)	(1,204,380)
Balances at December 31, 1998	5,181,564	5,182	2,417,213	(2,947,653)	(525,258)
Sale of common stock	678,412	678	134,322		135,000
Expense related to stock warrants issued			212,000		212,000
Net loss				(1,055,485)	(1,055,485)
Balances at December 31, 1999	5,859,976	5,860 5	2,763,535	(4,003,138)	(1,233,743)

Table of Contents

	Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Deficit accumulated during the development stage	Treasury Stock, at cost	Total shareholders equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Sale of preferred stock, net of offering costs of $76,500	3,200	32							3,123,468	$			3,123,500
Issuance of common stock at conversion of notes and interest payable							412,487	412	492,085				492,497
Issuance of common stock at conversion of notes payable							70,354	70	83,930				84,000
Issuance of common stock to settle obligations							495,111	496	1,201,664				1,202,160
Issuance of common stock for acquisition							6,999,990	7,000	9,325,769				9,332,769
Issuance of warrants for acquisition									4,767,664				4,767,664
Stock issued for acquisition costs							150,000	150	487,350				487,500
Expense related to stock warrants issued									140,000				140,000
Dividends payable on preferred stock									(85,000)				(85,000)
Cashless exercise of							599,066	599	(599)				

warrants							
Net loss						(3,701,084)	(3,701,084)
Balances at December 31, 2000	3,200	32	14,586,984	14,587	22,299,866	(7,704,222)	14,610,263
Dividends payable on preferred stock					(256,000)		(256,000)
Repurchase of warrants					(55,279)		(55,279)
Sale of warrants					47,741		47,741
Cashless exercise of warrants			218,493	219	(219)		
Issuance of common stock to pay preferred dividends			93,421	93	212,907		213,000
Detachable warrants issued with notes payable					450,000		450,000
Issuance of warrants to pay operating expenses					167,138		167,138
Issuance of common stock to pay operating expenses			106,293	106	387,165		387,271
Issuance of preferred stock to pay operating expenses	137	1			136,499		136,500
Net loss						(16,339,120)	(16,339,120)
Balances at December 31, 2001	3,337	33	15,005,191	15,005 6	23,389,818	(24,043,342)	(638,486)

Table of Contents

ADVENTRX PHARMACEUTICALS, INC.
(A Development Stage Enterprise)
Condensed Consolidated Statements of Shareholders Equity (Deficit)
From Inception (June 12, 1996) through September 30, 2006
(unaudited)
CONTINUED FROM PREVIOUS PAGE

	Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Deficit accumulated during the development stage	Treasury Stock, at cost	Total shareholders equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Dividends payable on preferred stock									(242,400)				(242,400)
Repurchase of warrants													
Sale of warrants							240,000	240	117,613				117,853
Cashless exercise of warrants							100,201	100	(100)				
Exercise of warrants							344,573	345	168,477				168,822
Sale of preferred stock at $1.50			200,000	2,000					298,000				300,000
Sale of preferred stock at $10.00					70,109	701			700,392				701,093
Conversion of preferred stock into common stock	(3,000)	(30)					1,800,000	1,800	(1,770)				
Dividends forgiven									335,440				335,440
Issuance of warrants to pay									163,109				163,109

perating xpenses										
suance of ommon ock to ay										
perating xpenses						6,292	6	12,263		12,269
suance of referred ock to ay										
perating xpenses	136	1						6,000		6,001
suance of ock ptions to mployees								329,296		329,296
et loss									(2,105,727)	(2,105,727
alances at ecember 1, 2002	473	4	200,000	2,000	70,109	701	17,496,257	17,496	25,276,138	(26,149,069)	(852,730
ividends ayable on referred ock									(37,840)		(37,840
onversion f Series C referred ock into ommon ock					(70,109)	(701)	14,021,860	14,022	(13,321)		
suance of ommon ock to ay interest n Bridge otes							165,830	165	53,326		53,491
ale of ommon ock at 0.40 per hare, net f issuance osts							6,640,737	6,676	2,590,656		2,597,332
ale of ommon ock at 1.00 per hare, net							3,701,733	3,668	3,989,181		3,992,849

f issuance osts xchange f warrants	235,291	235	49,486		49,721
suance of ommon ock to ay perating xpenses	230,000	230	206,569		206,799
suance of arrants to ay perating xpenses			156,735		156,735
suance of ock ptions to mployees			286,033		286,033
et loss				(2,332,077)	(2,332,077

Table of Contents

	Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock			Accumulated other	Deficit accumulated during the		To
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional paid-in capital	comprehensive income (loss)	development stage	Treasury Stock, at cost	shareh equ
es at ber 31,	473	4	200,000	2,000			42,491,708	42,492	32,556,963		(28,481,146)		4,1
ishment ends on d stock sion of A tive d stock sion of B d stock s e of s e of s e of s in ent of a									72,800				
	(473)	(4)					236,500	236	(232)				
			(200,000)	(2,000)			200,000	200	1,800				
							464,573	465	(465)				
							23,832	23	27,330				
									86,375				
n stock 0 per							10,417,624	10,419	15,616,031				15,6
t of g and costs e of ptions to ees tion of stock s									(1,366,774)				(1,3
									524,922				5
									34,747			(34,747)	
											(6,701,048)		(6,7
es at ber 31,							53,834,237	53,835	47,553,497		(35,182,194)	(34,747)	12,3

ehensive							
ss					(24,782,646)		(24,7
f							
in fair							
f							
e for							
urities				(1,722)			
hensive							
							(24,7
ue of							
ssued in							
tion							
ezzanine							
ng	10,810,809	10,811	(10,811)				
e of							
s	2,408,316	2,408	3,071,030				3,0
e of							
ptions	185,000	185	144,815				1
e of							
ptions to							
ees			994,874				9
e of							
ptions to							
ployee			93,549				
e of							
n stock							
or	125,000	125	258,375				2
s at							
ber 31,							
	67,363,362	67,364	52,105,329	(1,722)	(59,964,840)	(34,747)	(7,8
ehensive							
ss					(22,892,148)		(22,8
f							
in fair							
f							
e for							
urities				2,592			
hensive							
							(22,8
e of	4,463,311	4,463	6,930,213				6,9
s, net of							

ng costs e of or ion			2,099,990	2,100	10,161,852				10,1
e of or ce ent			60,145	60	196,614				1
e of ptions			92,500	93	125,658				1
e of ed stock ployees			15,000	15	68,635				
e of ptions to ees					1,248,386				1,2
e of ptions to ployee					67,939				
es at ber 30,									
ted)	$	$	$ 74,094,308	$ 74,095	$ 70,904,626	$ 870	$ (82,856,988)	$ (34,747)	$ (11,9

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

ADVENTRX PHARMACEUTICALS, INC.
(A Development Stage Enterprise)
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Nine months ended September 30,		Inception (June 12, 1996) through September 30,
	2006	2005	2006
Cash flows from operating activities:			
Net loss	$ (22,892,148)	$ (22,630,356)	$ (83,352,591)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	127,528	96,422	9,933,089
Fair value of warrant liability	(1,434,115)	12,972,392	10,145,545
Amortization of debt discount			450,000
Forgiveness of employee receivable			30,036
Impairment loss write off of goodwill			5,702,130
Expenses paid by warrants			573,357
Expenses paid by preferred stock			142,501
Expenses related to stock warrants issued			612,000
Expenses related to employee stock options issued	1,248,386	757,133	3,383,511
Expenses related to stock options issued to non-employees	67,939	73,063	161,488
Expenses paid by issuance of common stock	324,074	82,250	1,243,455
Equity in loss of investee			178,936
In-process research and development	10,422,130		10,422,130
Write-off of license agreement			152,866
Write-off of assets available for sale		108,000	108,000
Cumulative effect of change in accounting principle			25,821
Accretion of a discount	(104,831)		(216,791)
Changes in assets and liabilities, net of effect of acquisitions:			
Increase in prepaid and other assets	(668,401)	(334,436)	(1,380,255)
Increase in accounts payable and accrued liabilities	685,686	473,989	1,861,315
Increase (decrease) in long-term liabilities	(16,059)	62,429	41,019
Increase in sponsored research payable and license obligation			924,318
Net cash used in operating activities	(12,239,811)	(8,339,114)	(38,858,120)
Cash flows from investing activities:			
Purchase of certificate of deposit			(1,016,330)
Maturity of certificate of deposit			1,016,330
Purchases of property and equipment	(167,429)	(159,260)	(833,456)
Purchases of short-term investments	(5,358,384)	(7,009,262)	(18,481,604)
Proceeds from sales of short-term investments	12,529,776		17,804,776

Cash paid for acquisition	(258,178)		(258,178)
Payment on obligation under license agreement			(106,250)
Cash acquired in acquisition of subsidiary			64,233
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	6,745,785	(7,168,522)	(1,319,436)
Cash flows from financing activities:			
Proceeds from sale of preferred stock			4,200,993
Proceeds from sale of common stock		19,999,997	44,152,594
Proceeds from sale or exercise of stock options	125,751		270,750
Proceeds from exercise of warrants	7,129,264	3,062,862	10,614,292
Repurchase of warrants			(55,279)
Payment of financing and offering costs	(194,588)	(2,080,572)	(3,543,584)
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	7,060,427	20,982,287	56,378,575
Net increase in cash and cash equivalents	1,566,401	5,474,651	16,201,019
Cash and cash equivalents at beginning of period	14,634,618	13,032,263	
Cash and cash equivalents at end of period	$ 16,201,019	$ 18,506,914	$ 16,201,019

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

ADVENTRX Pharmaceuticals, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

1. Description of the Company

ADVENTRX Pharmaceuticals, Inc., or the Company, is a biopharmaceutical research and development company focused on commercializing low development risk pharmaceuticals for cancer and infectious disease that enhance the efficacy and/or safety of existing therapies. As of September 30, 2006, we have not commercially manufactured, marketed, sold or distributed any product. We have rights to drug candidates in varying stages of development. Our current drug candidates are ANX-510, or CoFactor (fotrexorin calcium), ANX-530 (vinorelbine emulsion), ANX-540, or Selone (2-chloroethylphenylselenone), ANX-201, or Thiovir (thiophosphonoformic acid), ANX-513 (paclitaxel emulsion), ANX-514 (docetaxel emulsion), ANX-015 (clarithromycin emulsion), ANX-016 (vancomycin emulsion), ANX-211 (chitosan gel), ANX-570 (beta-elemene) and ANX-575 (alpha-tocopherol succinate). CoFactor, Thiovir and Selone are licensed pursuant to agreements with the University of Southern California and, along with ANX-530, are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005. Our other product candidates, including additional rights to ANX-530, were acquired in our acquisition of SD Pharmaceuticals, Inc., or SDP, announced in April 2006.

On May 30, 2003, the Company merged its wholly owned subsidiary, Biokeys, Inc., into itself and changed the name of the Company from Biokeys Pharmaceuticals, Inc. to ADVENTRX Pharmaceuticals, Inc. The merger had no effect on the financial statements of the Company. In July 2004, the Company formed a wholly owned subsidiary, ADVENTRX (Europe) Ltd., in the United Kingdom for the purpose of conducting drug trials in the European Union. In April 2006 the Company closed its previously announced merger agreement with SD Pharmaceuticals, Inc. and issued approximately 2,100,000 shares of common stock as the merger consideration. The merger resulted in the acquisition of drug candidates owned by SD Pharmaceuticals, Inc. that were formerly under license to the Company as well as additional drug candidates.

2. Unaudited interim financial statements

In the opinion of the Company s management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, necessary to present fairly the financial position of the Company as of September 30, 2006 and its results of operations and cash flows for the three and nine months ended September 30, 2006 and 2005 and for the period from inception (June 12, 1996) through September 30, 2006. Information included in the condensed consolidated balance sheet as of December 31, 2005 has been derived from, and certain terms used herein are defined in, the audited consolidated financial statements of the Company as of December 31, 2005, or the Audited Financial Statements, included in the Company s Annual Report on Form 10-K, or the 10-K, for the year ended December 31, 2005 that was previously filed with the Securities and Exchange Commission, or the SEC. Pursuant to the rules and regulations of the SEC, certain information and disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (GAAP), have been condensed or omitted from these financial statements unless significant changes have taken place since the end of the most recent fiscal year. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the Audited Financial Statements and the other information also included in the 10-K.

The results of the Company s operations for the nine months ended September 30, 2006 are not necessarily indicative of the results of operations for the full year ending December 31, 2006.

The preparation of financial statements in conformity with GAAP requires the Company s management to make estimates and assumptions that affect reported amounts of assets and liabilities as of the dates of the condensed consolidated balance sheets and reported amount of revenues and expenses for the periods presented. Accordingly, actual results could materially differ from those reported amounts.

Supplementary Cash Flow Information

Noncash investing and financing transactions excluded from the condensed statements of cash flows for the nine months ended September 30, 2006 and 2005 and for the period from inception (June 12, 1996) through September 30, 2006 are as follows:

Table of Contents

	Nine months ended September 30,		Inception (June 12, 1996) through September 30,
	2006	2005	2006
Issuance of warrants, common stock and preferred stock for:			
Conversion of notes payable and accrued interest	$	$	$ 1,213,988
Payment of operating expenses		258,500	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
Settlement of claim			86,375
Acquisition of treasury stock in settlement of a claim			34,747
Assumptions of liabilities in acquisitions			1,009,567
Acquisition of license agreement for long term debt			161,180
Cashless exercise of warrants	13	130	3,905
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
Unrealized gain on short term investments	2,592	1,625	870

3. Net Loss Per Common Share

The Company calculates basic and diluted net loss per share for all periods presented in accordance with the Statement of Financial Accounting Standards (SFAS) No. 128, *Earnings Per Share*. Basic net loss per 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 share was calculated by dividing the net loss for the period by the weighted-average number of common stock equivalents outstanding during the period determined using the treasury-stock method. 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 share when their effect is dilutive. The Company has excluded the following options and warrants from the calculation of diluted net loss per common share for the three and nine months ended September 30, 2006 and 2005 because their effect is anti-dilutive:

	September 30,	
	2006	2005
Warrants	14,880,495	19,668,012
Options	3,550,500	2,742,000
Total	18,430,995	22,410,012

4. Stock Compensation Plans

In May 2005, at the Company s annual meeting of stockholders, the Company s stockholders approved the 2005 Equity Incentive Plan, or the 2005 Plan, and the 2005 Employee Stock Purchase Plan, or the ESPP. Though approved, the Company has not implemented the ESPP and, as of September 30, 2006, no shares of the Company s common stock have been issued under the ESPP. The 2005 Plan is intended to encourage ownership of shares of common stock by directors, officers, employees, consultants and advisors of the Company and its affiliates and to provide additional incentive for them to promote the success of the Company s business through the grant of equity-based awards. The 2005 Plan permits the Company to issue options, stock appreciation rights, restricted shares, restricted share units, performance awards, annual incentive awards and other share-based awards and cash-based awards. The maximum aggregate number of shares of common stock which may be issued pursuant to or subject to the foregoing types of awards granted under the 2005 Plan currently is 6,673,634. This maximum number is subject to an annual increase on the first day of the Company s fiscal year equal to the lesser of (i) one percent of the number of outstanding shares of common stock on such day, (ii) 750,000 or (iii) such other amount as the Company s board of directors may specify prior to such day. The 2005 Plan is intended to comply with applicable securities law requirements, permit performance-based awards that qualify for deductibility under Section 162(m) of the Internal Revenue Code and allow for the issuance of incentive stock options.

Table of Contents

In December 2005, the exercise prices on options to purchase up to 1,473,000 shares of the Company s common stock were increased to equal the fair market value of the Company s common stock on the grant dates (as opposed to the fair market value of the Company s common stock on the date of hire of the option holder). The increase in the strike price of these options resulted in a modification to these options and, as such, the fair value of the effected options was re-measured as of December 23, 2005.

Prior to January 1, 2006, the Company accounted for stock-based compensation under the recognition and measurement principles of SFAS 123, Accounting for Stock-Based Compensation, or SFAS 123. Effective January 1, 2006, the Company began recording compensation expense associated with stock options and other equity-based compensation in accordance with SFAS 123 (revised 2004), Share-Based Payment, or SFAS 123R. The Company recognizes these compensation costs on a straight-line basis over the requisite service period of the award, which is generally four years; however, the 2005 Plan allows for other vesting periods and we have granted employees options where the requisite service period is three years and we grant our directors options where the requisite service period is one year.

The compensation expense related to the Company s share-based compensation arrangements is recorded as components of general and administrative expense and research and development expense. SFAS 123R requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to the Company s cumulative net loss position, no tax benefits have been recognized in the cash flow statement.

The estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for option grants during the nine months ended September 30, 2006 and 2005:

	Three months ended September 30,		Nine months ended September 30,	
	2006	**2005**	**2006**	**2005**
Risk-free interest rate	4.9%	4.1%	4.6%	4.1%
Dividend yield	0%	0%	0%	0%
Volatility	142%	90%	107%	90%
Expected life	6.0	5.0	5.3	5.0

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the Company s employee stock options. The expected volatility is based on the historical volatility of the Company s common stock. The Company has not paid any dividends on its common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future. The computation of the expected option term is derived from the average midpoint between vesting and the contractual term, as described in SEC s Staff Accounting Bulletin No. 107, *Share-Based Payment*.

As share-based compensation expense recognized in the Unaudited Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2006 is based on awards ultimately expected to vest and become exercisable, it should be reduced for estimated forfeitures. SFAS 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 forfeiture experience. For fiscal periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred, as allowed under SFAS 123.

The Company s determination of fair value is affected by the Company s common stock price as well as a number of assumptions that require judgment. The weighted-average fair value of each option granted during the three and nine months ended September 30, 2006, estimated as of the grant date using the Black-Scholes option valuation model, was $2.70 per option and $3.06 per option, respectively.

A summary of the status of the 2005 Plan as of September 30, 2006 and of changes in options outstanding under the 2005 Plan during the nine months ended September 30, 2006 is as follows:

Table of Contents

	Shares	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2006	2,457,000	$ 1.45		
Options granted	1,566,000	4.04		
Options exercised	(92,500)	1.36		
Options cancelled	(380,000)	3.33		
Options outstanding at September 30, 2006	3,550,500	2.39	6.59	$ 2,955,780
Options exercisable at September 30, 2006	1,863,523	$ 1.31	4.16	$ 2,809,623

For the three and nine months ended September 30, 2006 and 2005, share-based compensation expense related to stock options was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2006	2005	2006	2005
Research and development	$ 110,040	$ 150,208	$ 367,256	$ 231,625
General and administrative	329,537	449,828	949,069	598,570
Total	$ 439,577	$ 600,036	$ 1,316,325	$ 830,195

As of September 30, 2006, there was $4.7 million of unamortized compensation cost related to unvested stock option awards which is expected to be recognized over a weighted average remaining period of approximately 2 years.
The intrinsic value of options exercised in the three and nine months ended September 30, 2006 was $151,200 and $153,850 respectively.
In July 2005, the Company granted options to purchase up to 114,000 shares of the Company s common stock to consultants. These option grants were valued as of September 30, 2006 using the Black-Scholes pricing model with the following assumptions: no dividend yield, expected volatility of 142%, risk-free interest rate 5.15% and expected life of 3 or 4 years. The Company recognized $67,939 in compensation expense for these options in the nine months ended September 30, 2006.

5. Equity Transactions

On April 14, 2005, the Company issued 25,000 shares of common stock as partial payment for services rendered by a consulting firm. Those shares were recognized at fair market value as of the date of obligation and resulted in compensation expense of $23,500 in the first quarter of 2005, when the services were performed.
On July 13, 2005, the Company issued 100,000 shares of common stock pursuant to a consulting agreement entered into in January 2005. Those shares were recognized at fair market value as of the date of issuance and resulted in compensation expense of $58,750 in the nine months ended September 30, 2006.
In July 2005, the Company issued 10,810,809 shares of common stock in conjunction with a private placement which resulted in net proceeds of $18,116,751. The net proceeds increased by $197,000 in the fourth quarter of 2005 due to a partial refund of commissions paid. The Company also issued warrants to purchase 10,810,809 shares of Common Stock at an exercise price of $2.26 per share with this placement (See Note 6).

In March 2006, the Company issued 7,000 shares of restricted stock to consultants for services performed with a fair value of $30,170.

In April 2006, the Company issued 8,000 shares of restricted stock to consultants for services performed with a fair value of $38,480.

In April 2006, the Company issued 2,099,990 shares of common stock to acquire SD Pharmaceuticals, Inc. See Note 8 below.

On September 7, 2006, the Company ended an employment relationship with its chief financial officer who also served as treasurer, vice president, finance and secretary. In connection with the separation from the Company, a severance agreement was entered into wherein in lieu of the former chief financial officer s outstanding vested and unvested options which were cancelled upon the separation, the Company issued 60,145 shares of common stock with a value of $196,674 and paid employment taxes totaling $109,434. The entire severance amount of $306,108 was charged to general and administrative expense for the three and nine months ended September 30, 2006.

Table of Contents

In the nine months ended September 30, 2006, the Company s warrant holders exercised warrants for an aggregate of 4,463,311 shares of common stock, with net proceeds to the Company of $6,934,676.

6. Fair Value of Warrants

On July 21, 2005, the Company entered into a Securities Purchase Agreement, or the Agreement, with Icahn Partners LP, Icahn Partners Master Fund LP, High River Limited Partnership, Viking Global Equities LP, VGE III Portfolio Ltd., North Sound Legacy Institutional Fund LLC, North Sound Legacy International Ltd. and the Royal Bank of Canada (each, a Purchaser) for the sale of 10,810,809 shares of the Company s common stock, or the Shares, at a purchase price of $1.85 per share for aggregate gross proceeds of $19,999,997, and the issuance of 7-year warrants, or the Warrants, to purchase 10,810,809 shares of the Company s common stock, or the Warrant Shares, at an exercise price of $2.26 per share. The Company received net proceeds of $18,116,751 as of July 21, 2005, which increased by $197,000 to $18,313,751 in the fourth quarter of 2005 due to a partial refund of commissions paid. The Purchasers consisted of accredited institutional investors.

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 the Company s 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 the Company is (A) not filed with the SEC on or before forty-five (45) days after the closing of such private placement (a Filing Failure) or (B) if such registration statement is not declared effective by the SEC on or before (1) ninety (90) days after the closing of such private placement (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 such registration statement effective, to disclose such information as is necessary for sales to be made pursuant to such registration statement or to register sufficient numbers of Shares) (a Maintenance Failure), then, the Company shall 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, the Company shall pay an amount equal to the purchase price paid to the Company 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. 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, the Company shall 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.

Payments to be made pursuant to the Agreement shall be due and payable to the Purchasers at the end of each calendar month during which Liquidated Damages shall have accrued. No Liquidated Damages shall 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.

The Registration Statement was filed and declared effective by the SEC within the allowed time. The Company has not been required to pay any Liquidated Damages in connection with the filing or effectiveness of the registration and there has not been any Maintenance Failure.

In accordance with Emerging Issues Task Force Issue No. 00-19, Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company s Own Stock, or, ETIF Issue No. 00-19, and the SEC s December 2005 interpretation, the terms of the Warrants and the transaction documents, the fair value of the Warrants

is accounted for as a liability, with an offsetting reduction to additional paid-in capital at the closing date (July 21, 2005). At the end of each reporting period, the value of the Warrants is remeasured based on the fair market value of the Warrant Shares, and changes to the warrant liability and related gain or loss is made appropriately. The warrant liability will be reclassified to equity when the registration statement is no longer subject to risk for Maintenance Failures.

Table of Contents

The fair value of the Warrants as of September 30, 2006 was estimated using the Black-Scholes option-pricing model with the following assumptions: no dividends; risk-free (10-year Treasury yield) interest rate of 4.85%; contractual life of 7 years and volatility of 142%. (See Note 9). The fair value of the Warrants was estimated to be $19,439,185 on the closing date of the transaction. The difference between the fair value of the Warrants of $19,439,185 and the gross proceeds from the offering were classified as Loss on fair value of warrants in the Company s statements of operations, and included in Warrant liability on the Company s balance sheet. The fair value of the Warrants was re-measured at December 31, 2005 and estimated to be $29,695,722 with the increase in fair value due to the increase in the market value of the Company s common stock. The fair value of the Warrants was re-measured at March 31, 2006 and estimated to be $46,732,476. The increase in fair value of the Warrants of $17,027,065 from December 31, 2005 to March 31, 2006 was recorded as Loss on fair value of warrants in the Company s statements of operations, and included in Warrant liability on the Company s balance sheet. The fair value of the Warrants was re-measured at June 30, 2006 and estimated to be $28,760,166. The decrease in fair value of the Warrants of $17,963,311 was recorded as Gain on fair value of warrants in the Company s statement of operations, and resulted in a corresponding reduction of Warrant liability on the Company s balance sheet. The fair value of the Warrants was re-measured at September 30, 2006 and estimated to be $28,262,296. The decrease in fair value of the Warrants of $497,869 was recorded as Gain on fair value of warrants in the Company s statement of operations and resulted in a corresponding reduction of Warrant liability on the Company s balance sheet. On a year-to-date basis, the Company has recorded a net gain of $1,434,115 related to the change in the fair value of the Warrants.

The adjustments required by EITF Issue No. 00-19 as interpreted by the SEC in December 2005 were triggered by the terms of the Company s agreements for the private placement it completed in July 2005, specifically the penalties if the Company did not timely register the Warrant Shares, and remain effective during the registration period. The adjustments for EITF Issue No. 00-19 had no impact on the Company s cash flow, liquidity, or business operations.

7. Commitments and Contingencies

Litigation

In the normal course of business, the Company may become subject to lawsuits and other claims and proceedings. Such matters are subject to uncertainty and outcomes are often not predictable with assurance. Management is not aware of any pending or threatened lawsuit or preceding that would have a material adverse effect on the Company s financial position, results of operations or cash flows.

8. Acquisition of Business

On April 26, 2006, the Company acquired SD Pharmaceuticals, Inc., a Delaware corporation, or SDP, a privately held drug development company, by acquiring all of the outstanding capital stock of SDP for a total purchase price of $10,422,130. The results of operations of SDP have been included in the accompanying unaudited condensed consolidated financial statements from the date of acquisition on April 26, 2006. The Company acquired SDP to obtain the ownership rights to its pipeline of drugs.

The aggregate purchase price of $10,422,130 consisted of 2,099,990 shares of common stock valued at $10,163,952, liabilities assumed (less cash acquired) of $104,150 and transaction costs of $154,028. The value of the common shares issued was determined based on the average market price of the Company s common shares over the 2-day period before and after the terms of the acquisition were agreed to and announced. The entire purchase price was allocated to in-process research and development expense.

Pro forma information showing what results of operations would have been had SDP been acquired as of January 1, 2006 and 2005 have not been presented as the results of operations of SDP for all such periods was immaterial.

9. Change in Accounting Estimate

During the quarterly period ended September 30, 2006, the Company s management evaluated the assumptions used in calculating the fair value of certain equity instruments. As a result of this evaluation, the Company determined that an alternative historical volatility based on the daily close price of the Company s common stock was a better indicator of volatility than the method previously used. The result of this change in estimate was an increase to the fair value of the warrant liability of $4,531,525 at September 30, 2006. This increase in the fair value of the warrant liability resulted in a decrease in the Gain on Fair Value of Warrants and an increase to Net Loss of $4,531,525 for the three and nine months ended September 30, 2006. The effect on earnings per share was $(0.06) for the three and nine months ended

September 30, 2006. The effect on stock compensation was not material.

Table of Contents

10. Subsequent Events

In October 2006, the Company s warrant holders exercised 19 warrants for an aggregate of 396,631 shares of common stock, with proceeds to the Company of $458,289.

On October 23, 2006, the Company licensed the U.S. rights to ANX-211, a proprietary antiviral product, to Theragenex, a life science and technology company focusing on commercializing therapies across a number of different therapeutic areas. Under the terms of the license, the Company will receive a licensing fee of $1 million, a milestone payment of $1 million for the launch of the first licensed product and $1 million for the launch of each additional licensed product, as well as royalty payments of 15% to 20% on licensed product sales.

On November 3, 2006, the Company announced a registered direct placement of its stock, consisting of the sale of 14,545,000 shares of the Company s common stock at $2.75 per share. Net proceeds from this placement are estimated to be $37.3 million.

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

The following discussion and analysis should be read in conjunction with the financial statements and related notes contained elsewhere in this Quarterly Report. See Item 1A of Part II Risk Factors regarding certain factors known to us that could cause reported financial information not to be necessarily indicative of future results.

Forward Looking Statements

This Quarterly Report on Form 10-Q contains 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, which include, without limitation, statements about the market for our technology, our strategy, competition, expected financial performance and other aspects of our business identified in this Quarterly Report, as well as other reports that we file from time to time with the Securities and Exchange Commission. Any statements about our business, financial results, financial condition and operations contained in this Quarterly Report that are not statements of historical fact may be deemed to be forward-looking statements that involve risks, uncertainties and assumptions. Without limiting the foregoing, the words believes, anticipates, expects, intends, projects, or similar expressions are intended to identify forward-looking statements. Our actual results may differ materially from those expressed or implied by these forward-looking statements as a result of various factors, including but not limited to those set forth under the caption Risk Factors in our Form 10-K for the year ended December 31, 2005 and the caption Risk Factors in this Quarterly Report, and elsewhere in this Quarterly Report. We do not intend to update publicly any forward-looking statements for any reason, except as required by law, even as new information becomes available or other events occur in the future.

Overview

We are a biopharmaceutical research and development company focused on commercializing low development risk pharmaceuticals for cancer and infectious disease that are intended to enhance the efficacy and/or safety of existing therapies. To date, we have not commercially manufactured, marketed, sold or distributed any product. We have rights to drug candidates in varying stages of development. Our current drug candidates are ANX-510, or CoFactor (fotrexorin calcium), ANX-530 (vinorelbine emulsion), ANX-540, or Selone (2-chloroethylphenylselenone), ANX-201, or Thiovir (thiophosphonoformic acid), ANX-513 (paclitaxel emulsion), ANX-514 (docetaxel emulsion), ANX-015 (clarithromycin emulsion), ANX-016 (vancomycin emulsion), ANX-211 (chitosan gel), ANX-570 (beta-elemene), ANX-575 (alpha-tocopherol succinate). CoFactor, Thiovir and Selone are licensed pursuant to agreements with the University of Southern California and, along with ANX-530, are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005. Our other product candidates, including additional rights to ANX-530, were acquired in our acquisition of SD Pharmaceuticals, Inc., or SDP, announced in April 2006 and are described in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2006.

The development of CoFactor, our lead product candidate, continues to progress. Patient dosing in our phase III clinical trial of CoFactor began in June 2006. This trial is a multicenter, 1200 patient, prospectively controlled study in first-line treatment of patients with metastatic colorectal cancer. Patients are being equally randomized to two arms containing either CoFactor or leucovorin, each in combination with 5-FU and bevacizumab (Avastin®). The primary endpoint for the study is progression-free survival. Secondary endpoints include response rate, overall survival and incidence and severity of adverse events. The protocol and planned analysis were accepted by the United States of

America Food and Drug Administration, or FDA, under a Special Protocol Assessment. In addition,

Table of Contents

enrollment in our 300 patient phase IIb prospectively randomized study in first line colorectal cancer clinical trial of CoFactor was completed in September 2006. The primary endpoint of the phase IIb trial is safety. Anti-tumor efficacy is a secondary endpoint. We are currently blinded with respect to the ongoing clinical data. We anticipate having initial clinical results of the primary endpoint in mid 2007. Finally, we continue to make preparations for a clinical trial of CoFactor in refractory breast cancer and plan to launch the trial in the fourth quarter of 2006.

The development of Thiovir is continuing. Preclinical testing demonstrated Thiovir activity against HIV-1 and HIV-2 (human immunodeficiency virus) and against complex NRTI- (nucleoside reverse transcriptase inhibitor) and NNRTI- (non-nucleoside reverse transcriptase inhibitor) resistant virus. Additional preclinical studies using Thiovir with zidovudine (AZT) showed synergistic activity against HIV strains, but without synergistic toxicity in human cells. In preclinical tests with influenza virus, Thiovir demonstrated antiviral activity against multiple subtypes of influenza B and influenza A, including a hybrid H5N1 avian influenza virus. These studies were conducted using tests measuring specific influenza virus antigens. Thiovir was also found to be active against HSV-1 and HSV-2 (herpes simplex virus) in preclinical testing as measured by virus infection assays in human cell lines. We currently plan to submit an investigational new drug application, or IND, and initiate a phase Ib/IIa clinical trial using Thiovir for treatment of HIV/AIDS in 2007.

We continue to prepare for a clinical study of ANX-530 (vinorelbine emulsion). We currently plan to file an IND and initiate a bioequivalency study of ANX-530 with vinorelbine in the fourth quarter of 2006. Our preclinical testing suggests ANX-530, an emulsion formulation of the FDA-approved version of vinorelbine, has lower venous toxicity compared to the FDA-approved version of vinorelbine.

On September 7, 2006, we ended our employment relationship with our chief financial officer who also served as treasurer, vice president, finance and secretary. We appointed our then-controller as acting chief financial officer and treasurer.

We have incurred significant net losses since our inception. As of September 30, 2006, our accumulated deficit was approximately $83 million. We expect to incur substantial and increasing losses for the next several years as we continue development and possible commercialization of our product candidates. To date, we have funded our operations primarily through sales of equity securities.

This Quarterly Report includes trademarks of other persons, including Avastin® and AZT .

Revenues

We have not generated any revenues to date, and we do not expect to generate any revenues from licensing, achieving milestones or product sales unless we execute a partnering arrangement with a third party or are able to commercialize one of our products ourselves.

Research and Development Expenses

Our research and development expenses consist primarily of salaries and related employee benefits, costs associated with preclinical testing and clinical trials managed by third-party clinical research organizations, or CROs, and costs associated with non-clinical activities, such as regulatory expenses. Our most significant costs are for clinical trials. These expenses include payments to vendors such as CROs, investigators and clinical suppliers, and related consulting.

Our license fee expenses consist of the costs incurred to license certain of our product candidates. We charge all license fee expenses and milestone payments to research and development as incurred since the underlying technology associated with these expenditures relates to our research and development efforts and has no alternative future use. We charge all research and development expenses to operations as incurred. We expect our research and development expenses to remain a significant component of our operating expenses in the future as we continue to develop our product candidates.

We use our internal research and development resources across several projects and many resources are not attributable to specific projects. Accordingly, we do not account for our internal research and development costs on a project basis. We use external service providers to conduct significant aspects of our preclinical testing and clinical trials and to manufacture our product candidates to be used in these activities. These external costs are tracked on a project basis and expensed as incurred.

We are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates. However, we expect our research and development costs associated with these product candidates to increase as we continue to

Table of Contents

develop our product candidates and move them through preclinical and clinical trials. Preclinical and clinical development timelines, likelihood of success and total costs vary widely. We anticipate we will make determinations as to which research and development projects to pursue and how much funding to direct to each project on an on-going basis in response to the scientific and clinical success of each product candidate, as well as our assessment of each product candidate s commercial potential.

The costs and timing for developing and obtaining regulatory approvals of our product candidates vary significantly for each product candidate and are difficult to estimate. The expenditure of substantial resources will be required for the lengthy process of clinical development and obtaining regulatory approvals as well as to comply with applicable regulations. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations.

In addition, we are unable to estimate with any reasonable certainty which product candidates will be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements will affect our development plans and capital requirements.

General and Administrative Expenses

Our general and administrative expenses consist primarily of compensation costs, benefits, and professional fees related to our administrative, finance, human resources, legal and internal systems support functions, as well as insurance and facility costs. We anticipate increases in general and administrative expenses as we add personnel, comply with obligations applicable to publicly-held companies and continue to develop and prepare for the commercialization of our product candidates.

Interest Income

Interest income consists primarily of interest earned on our cash, cash equivalents, and short-term investments.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and regulations of the Securities and Exchange Commission, or SEC. The preparation of our unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the related disclosure of contingent assets and liabilities. We review our estimates on an on-going basis, including those related to valuation of goodwill, intangibles and other long-lived assets. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the bases for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions not readily apparent from other sources. Our accounting policies are described in more detail in Note 1 to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005. We have identified the following as the most critical accounting policies used in the preparation of our unaudited condensed consolidated financial statements.

Recognition of Expenses in Research Contracts. Pursuant to management s assessment of the services that have been performed on clinical trials and other contracts, we recognize expenses as the services are provided. Such management assessments generally consist of, but are not limited to, an evaluation by the project manager of the work that has been completed during the period, management s assessment of progress generated internally and/or provided by the third-party service provider, analysis of data that justifies the progress and, finally, management s judgment. Several of our contracts extend across multiple reporting periods.

Stock Compensation Plans. We grant options to purchase our common stock to our employees, consultants and directors under our 2005 Equity Incentive Plan, or the 2005 Plan. The benefits provided under this plan are share-based payments subject to the provisions of revised Statement of Financial Accounting Standards, or SFAS, No. 123, or SFAS 123R, Share-Based Payment. Prior to January 1, 2006 we accounted for stock-based compensation under the recognition and measurement principles of SFAS No. 123 Accounting for Stock-Based Compensation, or SFAS 123. Effective January 1, 2006, we began recording compensation expense associated with stock options and other equity-based compensation in accordance with SFAS 123R. We recognize these compensation costs on a straight-line basis over the requisite service period of the award, which is generally four years; however, the 2005 Plan

allows for other vesting periods and we have granted employees options where the requisite service period is three years and we grant our directors options where the requisite service period is one year.

Table of Contents

We estimate the 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, risk-free interest rate and expected dividends.

If factors change or we employ different assumptions in the application of SFAS 123R in future periods, the compensation expense that we record under SFAS 123R may differ significantly from what is reflected in this Quarterly Report. Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions, are fully transferable and do not cause dilution. Because our share-based payments have characteristics significantly different from those of freely traded options, and because changes in the subjective input assumptions can materially affect our estimates of fair values, in our opinion, existing valuation models, including the Black-Scholes model, may not provide reliable measures of the fair values of our share-based compensation. There is currently no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee share-based awards is determined in accordance with SFAS 123R and the SEC s Staff Accounting Bulletin No. 107, or SAB 107, using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction. In addition, there are significant differences among valuation models, and there is a possibility that we will adopt different valuation models in the future. This may result in a lack of consistency in future periods and materially affect the fair value estimate of share-based payments. It may also result in a lack of comparability with other companies that use different models, methods and/or assumptions.

Estimates of share-based compensation expenses are significant to our financial statements, but these expenses are based on option valuation models, and by the terms of our outstanding options, will not result in the payment of cash by us. For this reason, and because we do not view share-based compensation as related to our operational performance, we exclude estimated share-based compensation expense when evaluating our business performance.

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 GAAP.

New Accounting Pronouncements

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FAS No. 109* (FIN 48), which clarifies the accounting for uncertainty in income taxes. Currently, the accounting for uncertainty in income taxes is subject to significant and varied interpretations that have resulted in diverse and inconsistent accounting practices and measurements. Addressing such diversity, FIN 48 prescribes a consistent recognition threshold and measurement attribute, as well as clear criteria for subsequently recognizing, derecognizing and measuring changes in such tax positions for financial statement purposes. FIN 48 also requires expanded disclosure with respect to the uncertainty in income taxes. FIN 48 is effective for fiscal years beginning after December 15, 2006. We have not yet determined the impact of FIN 48 on our consolidated financial position, results of operations, cash flows or financial statement disclosures.

In September 2006, FASB issued Statement 157, *Fair Value Measurements,* which defines fair value, establishes a framework for measuring fair value under GAAP and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. We do not expect the adoption of SFAS 157 will have a material impact on our consolidated results of operations or financial position.

In September 2006, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 108 (SAB 108). Due to diversity in practice among registrants, SAB 108 expresses SEC staff views regarding the process by which misstatements in financial statements are evaluated for purposes of determining whether financial statement restatement is necessary. SAB 108 is effective for fiscal years ending after November 15, 2006. We do not believe SAB 108 will have a material impact on our consolidated results from operations or financial position.

We have implemented all new accounting pronouncements that are in effect and that may impact our consolidated financial statements and do not believe that there are any other new accounting pronouncements that have been issued

that might have a material impact on our consolidated financial statements.

Table of Contents

Results of Operations

Comparisons for the Three Months Ended September 30, 2006 and 2005

Research and Development Expenses. Total research and development expenses was $3.2 million for the three months ended September 30, 2006 compared to $1.9 million for the comparable period in 2005, an increase of $1.4 million or 72%. The increase in research and development expenses was primarily related to an increase of $1.1 million in costs related to our CoFactor phase IIb and phase III trials. Other factors include an increase of $269,000 in personnel costs as we expand our clinical operations, a decrease of $83,000 in accrued pre-clinical costs, an increase of $50,000 in consulting fees, a decrease of $40,000 in stock compensation for employees, and an increase of $17,000 consisting of individually minor items.

We currently expect that our research and development expenses will increase from the level of expenses in the three months ended September 30, 2006 as we ramp up our phase III clinical trial of CoFactor, incur ongoing costs related to our fully enrolled phase IIb clinical trial of CoFactor and continue development of other drugs in our pipeline.

General and Administrative Expenses. General and administrative expenses were $2.1 million for the three months ended September 30, 2006 compared to $1.7 million for the comparable period in 2005, an increase of $318,000 or 18%. The increase in general and administrative expenses was primarily due to an increase of $101,000 associated with complying with obligations applicable to publicly-held companies, an increase of $77,000 in insurance expense, an increase of $66,000 in travel expenses, and an increase of $48,000 in consulting services. These are offset by a decrease in compensation expense of $57,000 and a decrease in legal expense of $77,000. The remainder caused by individually minor items. The stock compensation expense for employees for the three months ended September 30, 2006 included a non-recurring charge of $306,108 for shares of common stock issued to and employment taxes paid for our former chief financial officer in conjunction with the severance agreement. The non-recurring charge in the third quarter of 2006 did not result in a significant increase in general and administrative expenses as compared to the comparable period in 2005 due to non-recurring costs in the third quarter of 2005. We currently expect our general and administrative expenses, excluding non-recurring charges, to increase as we hire personnel to support our expanding operations.

Gain (Loss) on Fair Value of Warrants. In July 2005, we issued warrants to purchase 10,810,809 shares of our common stock in conjunction with a private placement. The fair value of these warrants is re-measured at each reporting date with a resulting gain or (loss) recorded on our statement of operations. For the three months ended September 30, 2006, the Company recorded a gain of $498,000 on the fair value of these warrants. This change was a result of a decrease in the fair market value of the warrants and related liability.

Interest Income. Interest income for the three months ended September 30, 2006 was $221,000 compared to $159,000 of interest income for the comparable period in 2005. The increase was attributable to higher invested balances from funds received from our July 2005 financing and from higher interest rate yields on these balances.

Comparisons for Nine months Ended September 30, 2006 and 2005

Research and Development Expenses. Total research and development expenses was $8.9 million for the nine months ended September 30, 2006 compared to $5.9 million for the comparable period in 2005, an increase of $3.0 million or 52%. The increase in research and development expenses was primarily due to $1.5 million in costs related to our CoFactor phase IIb and phase III trials. Other factors include an increase of $625,000 in personnel costs as we expand our clinical operations, an increase of $421,000 in consulting and contracting services, an increase of $276,000 in pre-clinical costs, an increase of $136,000 in stock compensation for employees, and an increase of $63,000 in travel expenses. The remaining increase of $27,000 was caused by other items which were individually insignificant.

As stated above, we currently expect that our research and development expenses will increase from the level of expenses in the nine months ended September 30, 2006 as we ramp up our phase III clinical trial of CoFactor, incur ongoing costs related to our fully enrolled phase IIb clinical trial of CoFactor, and continue development of other drugs in our pipeline.

General and Administrative Expenses. General and administrative expenses were $5.5 million for the nine months ended September 30, 2006 compared to $3.9 million for the comparable period in 2005, an increase of $1.6 million or 41%. The increase in general and administrative expenses was primarily due to stock compensation expense for employees of $603,000, costs associated with complying with obligations applicable to publicly-held companies of

$226,000, professional accounting and auditing fees related to the evaluation, testing, and documenting of our system of internal controls over financial reporting to comply with Section 404 of the Sarbanes-Oxley Act of 2002 of $169,000, insurance costs of $159,000, stock compensation expense for non-employees of $122,000,

Table of Contents

and consulting fees of $115,000. Other factors include an increase of $98,000 in travel expenses, $76,000 in legal fees, and $48,000 in compensation costs as we hire additional personnel to support our expanding operations. The remainder was caused by individually minor items. The nine months ended September 30, 2006 included a non-recurring charge of $306,108 in the employee stock compensation expense for the shares of common stock issued to and employment taxes paid for our former chief financial officer in conjunction with the severance agreement.

Gain (Loss) on Fair Value of Warrants. In July 2005 we issued warrants to purchase 10,810,809 shares of our common stock in conjunction with a private placement. The fair value of these warrants is re-measured at each reporting date with a resulting gain or (loss) recorded on our statement of operations. For the nine months ended September 30, 2006, the Company recorded a gain of $1.4 million on the fair value of these warrants compared to a loss of $13.0 million for the comparable period in 2005, a change of $14.4 million or 111%. This change was a result of a decrease in the fair market value of the warrants and related liability as compared to the comparable period in 2005.

In-Process Research and Development. In April 2006, the Company acquired SDP. The purchase price of the acquisition of $10,422,130 was paid with 2,099,990 shares of our common stock and recorded as in-process research and development expense in the quarterly period ended June 30, 2006.

Interest Income. Interest income for the nine months ended September 30, 2006 was $710,000 compared to $261,000 of interest income for the comparable period in 2005. The increase was attributable to higher invested balances from funds received from our July 2005 financing and from higher interest rate yields on these balances.

Liquidity and Capital Resources

To date, we have funded our operations primarily through the sale of equity securities. Through September 30, 2006, we had an accumulated deficit of approximately $83 million, with total additional paid-in capital of approximately $71 million. The $71 million of additional paid-in capital is comprised of $37 million in net proceeds from the sale of equity securities, plus non-cash equity issuances for acquisitions of $25 million, plus other non-cash equity transactions for operating expenses of $9 million. As a result of a registered direct offering which was announced on November 3, 2006 and the exercises of warrants through the date of this Quarterly Report we believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements for at least the next 24 months.

As of September 30, 2006, our principal sources of liquidity were our cash, cash equivalents and short-term investments which totaled $17.1 million as compared to $22.6 million as of December 31, 2005. This decrease was primarily due to the use of cash to fund our research and development and for general and administrative expenses. As of September 30, 2006, we held $16.2 million in cash and cash equivalents and $900,000 in short-term investments. As of September 30, 2006, our short-term investments consisted primarily of commercial paper. We have established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

Net cash used in operating activities was $12.2 million during the nine months ended September 30, 2006, compared with $8.3 million during the nine months ended September 30, 2005. The increase in net cash used in operating activities was primarily due to increased funding for clinical trials, and our increased operating expenses as we added additional personnel in general and administrative functions to support our expanded research and development activities. We cannot be certain if, when or to what extent we will receive cash inflows from commercialization of our product candidates or fundraising or partnering activities. We currently expect our expenses related to our research and development to be substantial and to increase over the next few years as we continue the advancement of our programs. Specifically, we currently estimate the cost of our phase III clinical trial of CoFactor alone to be approximately $40 million over the next four years.

Net cash provided by investing activities was $6.7 million during the nine months ended September 30, 2006 compared with net cash used in investing activities of $7.2 million during the nine months ended September 30, 2005. The difference was primarily the result of purchases of short-term investments in 2005 as compared to sales of short-term investments in 2006.

Net cash provided by financing activities was $7.1 million during the nine months ended September 30, 2006 compared with $21.0 million during the nine months ended September 30, 2005. The cash flows from financing activities for the nine months ended September 30, 2006 were primarily proceeds from the exercise of warrants. The

cash flows for the comparable period in 2005 were primarily proceeds from the sale of common stock in a private placement which closed in July 2005 and proceeds from the exercise of warrants.

Table of Contents

We also enter into agreements with third parties to manufacture our product candidates, conduct our preclinical testing and clinical trials, and to perform data collection and analysis. Our payment obligations under these agreements depend upon the progress of our development programs. Therefore, we are unable to estimate with reasonable certainty future costs we will incur under these agreements.

We do not have any off balance sheet arrangements.

Our future capital uses and requirements depend on numerous forward-looking factors and cannot be estimated with reasonable certainty. These factors include but are not limited to the following:

- the timing and results of our clinical trials;
- the progress of our research and development activities;
- the number and scope of our research and development programs;
- the progress of our preclinical development activities;
- the costs and timing of regulatory approvals;
- the success of the commercialization of our products;
- our ability to establish and maintain strategic collaborations;
- the costs involved in enforcing or defending patent claims and other intellectual property rights;
- the costs of establishing or expanding manufacturing, sales and distribution capabilities; and
- the extent to which we license, acquire or invest in other products, technologies and businesses.

We currently plan to focus primarily on our clinical trials for CoFactor and the development of ANX-530 (vinorelbine emulsion) and to develop our other product candidates as resources become available. We expect to finance our operations and capital expenditure needs through the sale of additional equity securities, debt financing or strategic collaboration agreements. We cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on favorable terms. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, which is not likely given our lack of operating revenue, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. In addition, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment 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 U.S., 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 the sensitivity of our results of operations 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 September 30, 2006, 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.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures.

As of September 30, 2006, we conducted an evaluation, under the supervision and with the participation of our principal executive and principal financial officers, of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act). Based on this evaluation, our principal executive and principal financial officers 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 SEC rules and forms and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. There was no change in our internal control over financial reporting identified in connection with this evaluation that occurred during the three months ended September 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In the normal course of business, we may become subject to lawsuits and other claims and proceedings. Such matters are subject to uncertainty and outcomes are often not predictable with assurance. We are not aware of any pending or threatened lawsuit or proceeding that would have a material adverse effect on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

An investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all other information contained or incorporated by reference in this Quarterly Report, before you decide to invest in our common stock. If any of the risks described in this Quarterly Report actually occurs, our business, financial condition, results of operations and our future growth prospects could be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment.

We have a substantial accumulated deficit and limited working capital.

We had an accumulated deficit of $82.9 million as of September 30, 2006. We have had losses from operations and negative cash flow from operations in each year since our inception. We had losses from operations of $2.3 million, $6.7 million and $13.2 million for the years ended December 31, 2003, 2004 and 2005, respectively. We had a loss from operations of $24.3 million for the nine months ended September 30, 2006 including a non-recurring non-cash charge of $10.4 million incurred in the second quarter in connection with our acquisition of SD Pharmaceuticals, which was characterized as in-process research and development. We used cash from operations of $2.2 million, $5.2 million, $11.6 million and $12.2 million during these same periods.

We expect to continue to incur significant operating and capital expenditures. Since we presently have no source of revenues and are committed to continuing our research and development programs, significant expenditures and losses will likely continue until development of our product candidates is completed and such product candidates have been clinically tested, approved by the United States of America Food and Drug Administration, or FDA, or other regulatory agencies and successfully marketed, or we are able to successfully partner one or more of our product candidates. In addition, we fund our operations primarily through the sale of equity securities, and have had limited working capital for our research and development programs and other activities.

We have never generated revenues or profits and we may not be able to generate revenues sufficient to achieve profitability.

We are a development stage company with no revenues, and our operations to date have generated substantial and increasing needs for cash. We have devoted our resources to developing a new generation of therapeutic products, but such products cannot be marketed until clinical testing is completed and governmental approvals have been obtained. Accordingly, there is no current source of revenues, much less profits, to sustain our present activities, and no revenues will likely be available until, and unless, the new products are clinically tested, approved by the FDA or other regulatory agencies and successfully marketed, either by us or a marketing partner, an outcome which we are not able to guarantee.

We will require substantial additional funding and it is uncertain that we will have access to future capital when needed, if at all, or on terms that are favorable to us or our stockholders.

We are a development stage company with no revenues, and our operations to date have generated substantial and increasing needs for cash. We do not expect to generate positive cash flow from operations for at least the next several years. As a result, substantial additional financing for our research and development programs will be required. We cannot be certain that we will be able to obtain such financing on favorable or satisfactory terms, if at all, or that it will be sufficient to meet our cash requirements. Any additional equity financing could result in substantial dilution to stockholders, and debt financing, if available, would likely involve covenants that restrict our operations, and may, among other things, preclude us from making distributions to stockholders and taking other actions beneficial to stockholders. In connection with certain past warrant issuances by us, we have provided the warrant holders with anti-dilution protections that, among other things, protect them against subsequent issuances by us of common stock at a price per share that is less than the exercise price of the warrants by lowering the exercise price of the warrants. In

July 2005, the exercise price of these warrants was lowered as a result of our issuance of common stock to certain new investors. You could experience additional significant dilution in the future as a result of these provisions if we are required to issue common stock or other equity securities below the exercise prices contained in the warrants or other provisions we provide in the future to our investors.

Table of Contents

Our ability to timely raise capital would most likely be impaired if we became ineligible to file shelf registration statements on Form S-3. We will become ineligible if we fail to comply with all applicable requirements of Form S-3, including filing in a timely manner all reports required to be filed by us. Though we are a small company with limited resources, we are subject to the wide-ranging, complicated laws and regulations applicable to public companies, including the provisions of the Sarbanes-Oxley Act of 2002, which may impair our ability to timely and completely comply with the requirements of Form S-3.

If adequate funds are not available, we may be required to delay or reduce the scope of our research and development programs or attempt to continue development by entering into arrangements with collaborative partners or others that, if available at all, may require us to relinquish some or all of our rights to our product candidates or the financial benefits thereof. Our inability to adequately and timely fund our capital requirements would have a material and adverse effect on us.

Further testing of our product candidates will be required and there is no assurance of FDA approval.

Human pharmaceutical products are subject to rigorous preclinical testing and clinical trials and other approval procedures mandated by the FDA and foreign regulatory authorities. Various federal and foreign statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U.S. and foreign statutes and regulations are time-consuming and require the expenditure of substantial resources. In addition, these requirements and processes vary widely from country to country.

The effect of government regulation and the need for FDA approval will delay commercialization of our product candidates for a considerable period of time, impose costly procedures upon our activities, and provide an advantage to larger companies that compete with us. There can be no assurance that the FDA or other regulatory approval for any products developed by us will be granted on a timely basis, or at all. Any such delay in obtaining, or failure to obtain, such approvals would materially and adversely affect the marketing of any contemplated products and the ability to earn product revenue. Further, regulation of manufacturing facilities by state, local, and other authorities is subject to change. Any additional regulation could result in limitations or restrictions on our ability to utilize any of our technologies, thereby adversely affecting our operations.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale.

In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;
- regulatory authorities may withdraw their approval of the product;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from its sale.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Our product candidates

will also be subject to ongoing FDA requirements related to the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the product. In addition, approved products, manufacturers and manufacturers facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is

Table of Contents

manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.

In order to market any products outside of the United States of America, or the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on potential royalties and product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

Positive results in preclinical testing and clinical trials do not ensure that future clinical trials will be successful or that product candidates will receive all necessary regulatory approvals for the marketing, distribution or sale of such product candidates.

Success in preclinical testing and clinical trials does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict. In addition, delays or rejections may be encountered based upon changes in FDA policy for drug approval during the period of product development and FDA regulatory review of each submitted new drug application, or NDA. There is a significant risk that any of our product candidates could fail to show satisfactory results in continued trials, and would not justify further development. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope requested will delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

We will face intense competition from other companies in the pharmaceutical industry.

We are engaged in a segment of the pharmaceutical industry that is highly competitive and rapidly changing. If successfully developed and approved, all of our product candidates will likely compete with several existing and new products and therapies and our competitors may succeed in commercializing products more rapidly or effectively than us, which would have a material and adverse effect on our results of operations and financial condition. ANX-510, or

CoFactor, our leading product candidate, would likely compete against a well-established generic product, leucovorin, as well as isovorin, which is marketed primarily in Japan. In addition, there are numerous companies with a focus in oncology and/or anti-viral therapeutics that are pursuing the development of pharmaceuticals that target the same diseases as are targeted by the products being developed by us. We anticipate that we will face intense and increasing competition in the future as new products enter the market and advanced technologies become available. There is no assurance that existing products or new products developed by competitors will not be more effective, or more effectively marketed and sold, than those we may market and sell. Competitive products may render our products and product candidates obsolete or noncompetitive.

Companies likely to have products that will compete with CoFactor, such as Wyeth and Roche, and our other product candidates have significantly greater financial, technical and human resources and are better equipped to develop, manufacture, market and distribute

Table of Contents

products. Many of these competitors have extensive experience in preclinical testing and clinical trials, obtaining FDA and other regulatory approvals and manufacturing and marketing pharmaceutical products and have products that have been approved or are in late-stage development and operate large, well-funded research and development programs. Other companies, such as Merck Eprova, with which we had a manufacturing relationship, may be developing products which compete with CoFactor.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, academic institutions, government agencies and other public and private research organizations are becoming increasingly aware of the commercial value of their inventions and are actively seeking to commercialize the technology they have developed. Companies such as Gilead and GlaxoSmithKline all have drugs in various stages of development that could become competitors of our other product candidates.

There is no assurance that our products will achieve broad market acceptance and, if they fail to do so, the revenues we generate from their sales will be limited.

Our success will depend in substantial part on the extent to which our products, if eventually approved for commercial distribution, are accepted by the medical community and reimbursement of them by third-party payors, including government payors. The degree of market acceptance will depend upon a number of factors including, among other things:

- the receipt and scope of regulatory approvals (including the existence of limitations or warnings in a product s FDA-approved labeling);
- the establishment and demonstration in the medical community of the safety and efficacy of our products and our ability to provide acceptable evidence of safety and efficacy;
- the product s potential advantages over existing treatment methods (including relative convenience and ease of administration, prevalence and severity of any adverse side effects);
- pricing and cost-effectiveness, and reimbursement policies of government and third party payors; and
- the prevalence of off-label substitution of chemically equivalent products.

We cannot predict or guarantee that physicians, patients, healthcare insurers or maintenance organizations, or the medical community in general, will accept or utilize any of our products. If our products are approved but do not achieve an adequate level of acceptance by these parties, we may not generate sufficient revenue from these products to become or remain profitable. In addition, our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

The unavailability of health care reimbursement for any of our products will likely adversely impact our ability to effectively market such products and whether health care reimbursement will be available for any of our products is uncertain.

Our ability to commercialize our products successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly approved medical products. We cannot guarantee that adequate third-party insurance coverage will be available for us to establish and maintain price levels we believe are fair for our products, which may affect our ability to generate revenues or achieve or maintain profitability. If we are successful in getting FDA approval for CoFactor, we will be competing against a generic drug, leucovorin, which has a lower cost and a long, established history of reimbursement. Receiving sufficient reimbursement for purchase costs of CoFactor will be necessary to make it cost effective and competitive versus the established drug, leucovorin, and other alternative products. Government, private health insurers, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement, particularly for new therapeutic products. Accordingly, even if coverage and reimbursement are provided, market acceptance of our products would be adversely affected if the amount of

coverage and/or reimbursement available for the use of our products proved to be unprofitable for health care providers.

Uncertainties related to health care reform measures may affect our success.

There have been federal and state proposals to subject the pricing of health care goods and services, including prescription drugs, to government control and to make other changes to the U.S. health care system. For example, the Medicare Prescription Drug Improvement Act of 2003 provides a new Medicare prescription drug benefit, which became effective January 1, 2006, and mandates other reforms. It is uncertain if future legislative proposals would be adopted that might affect the product candidates in our programs or what actions federal, state, or private payors for health care treatment and services may take in response to any such health care reform proposals or legislation. Any such health care reforms could have a material adverse effect on the marketability of any products for which we ultimately require or receive FDA approval.

Table of Contents

We may not achieve our projected development goals in the time frames we announce and expect.

We set goals for and make public statements regarding timing of the accomplishment of objectives material to our success, such as the commencement and completion of clinical trials. The actual timing of these events can vary dramatically due to factors such as delays or failures in our clinical trials, and the uncertainties inherent in the regulatory approval process. There can be no assurance that our clinical trials will commence or be completed, that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our current schedule for the launch of any of our products. If we fail to achieve one or more of these milestones as planned, the market price of our common stock could decline.

The commencement and completion of clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a clinical trial;
- identifying appropriate trial sites and reaching agreement on acceptable terms with prospective contract research organizations, or CROs, trial sites and clinical investigators, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and clinical investigators;
- manufacturing sufficient quantities of a product candidate;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the same indication as our product candidates; and
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

Our success will depend on licenses and proprietary rights we receive from other parties, and on any patents we or they may obtain.

Our success will depend in part on our ability and, in certain cases, our licensors ability to:

- obtain and maintain patent protection with respect to our product candidates;
- our ability to maintain our licenses;
- defend patents and licenses once obtained;
- maintain trade secrets;
- operate without infringing upon the patents and proprietary rights of others; and

obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, both in the U.S. and in foreign countries.

The patent and intellectual property positions of biopharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we or our licensors have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims allowed will be sufficient to protect the technology we develop or have developed or that is licensed to us. In addition, we cannot be certain that any patents issued or licensed to us will not be challenged, invalidated, infringed or circumvented, including by our competitors, or that the rights granted thereunder will provide competitive advantages to us. Patent applications in the U.S. are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months. As a result, we cannot be certain that the inventors of any patent or patent application owned or licensed to us were the first to conceive of the inventions covered by such patents and patent applications or that such inventors were the first to file patent applications for such inventions.

Table of Contents

We may also rely on unpatented trade secrets and know-how to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants and others. We also have invention or patent assignment agreements with our employees and certain consultants. There can be no assurance, however, that binding agreements will not be breached, that we will have adequate remedies for any breach, or that trade secrets will not otherwise become known or be independently discovered by competitors. In addition, there can be no assurance that inventions relevant to us will not be developed by a person not bound by an invention assignment agreement with us.

Our license agreements can be terminated in the event of our breach.

The license agreement pursuant to which we license our lead product candidate, CoFactor, which is also the agreement pursuant to which we license ANX-540, or Selone, and the license agreement pursuant to which we license ANX-201, or Thiovir, permit the licensor, the University of Southern California, to terminate the agreement under certain circumstances, such as our failure to use our reasonable best efforts to commercialize the licensed technology or the occurrence of any other uncured material breach by us. These license agreements also provide that the licensor is primarily responsible for obtaining patent protection for the technology licensed, and we are required to reimburse the licensor for the costs it incurs in performing these activities. These license agreements also require the payment of specified royalties. Any inability or failure to observe these terms or pay these costs or royalties could result in the termination of the applicable license agreement in certain cases. The termination of any license agreement could have a material and adverse effect on us.

The United States government and the University of Southern California retain certain rights in the technologies we have licensed from the University of Southern California.

The technologies developed by the University of Southern California were developed in part through funding provided by the U.S. government. Therefore, in addition to the University of Southern California s termination rights described above, our licenses are subject to a non-exclusive, non-transferable, royalty-free right of the U.S. government and the University of Southern California to practice the licensed technologies for research purposes and, in the case of the U.S. government, other governmental purposes on behalf of the U.S. and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the U.S., but only to the extent the government funded the research. The government also reserves the right to require us to grant sublicenses to third parties when necessary to fulfill public health and safety needs or if we do not reasonably satisfy government requirements for public use of the technology. In addition, the University of Southern California has the right to use all improvements to the licensed technology for research and educational purposes. Although we are currently the only parties licensed to actively develop the technology, we cannot assure you that the government will not in the future require us to sublicense the technology. Any action by the government to force us to issue such sublicenses or development activities pursuant to its reserved rights in the technology would erode our ability to exclusively develop our products based on the technology and could materially harm our financial condition and operating results.

Licenses of technology developed through funding provided by the U.S. government, including the University of Southern California licenses, require that licensees in this case, us and our affiliates and sub-licensees agree that products covered by the licenses will be manufactured substantially in the U.S.. We cannot assure you that we will be able to contract for manufacturing facilities in the U.S. on favorable terms or obtain waivers of such requirement, or that such requirement will not impede our ability to license our products to others. If we are unable to contract for manufacturing facilities in the U.S. or obtain an appropriate waiver, we risk losing our rights under the University of Southern California licenses, which could materially harm our financial condition and operating results.

Protecting our proprietary rights is difficult and costly. If we are sued for infringing the proprietary rights of third parties, it will be costly and time consuming, and an unfavorable outcome would have an adverse effect on our business.

Our commercial success depends on our ability to develop, manufacture, market and sell our products without infringing the proprietary rights of third parties. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Because patent applications take time to publish and issue, there may be currently pending applications, unknown to us, which may later result in issued

patents that our products or technologies infringe. We cannot predict the breadth of claims allowed in competitors or other companies patents or whether we may now or in the future infringe these claims. Although we have not been notified of any patent infringement, nor notified others of patent infringement, such patent

Table of Contents

disputes are common and could preclude the commercialization of our products. Patent litigation is costly in its own right and could subject us to significant liabilities to third parties. In addition, an adverse decision could force us to either obtain third-party licenses at substantial cost, if available at all, or cease using the technology or product in dispute. During litigation, the patent holder could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using or selling our products.

Litigation, which could result in substantial cost, may also be necessary to enforce any patents to which we have rights, or to determine the scope, validity and unenforceability of other parties proprietary rights, which may affect our rights. There can be no assurance that our owned or licensed patents would be held valid by a court or administrative body or that an alleged infringer would be found to be infringing. The uncertainty resulting from the mere institution and continuation of any technology-related litigation or interference proceeding could have a material and adverse effect on us.

If a trademark infringement action is commenced against us regarding the use of our corporate name, we could be required to pay monetary damages and/or change our name.

In March of 2005, we received correspondence from Aventis Pharmaceuticals, Inc. and its parent, Sanofi-Aventis (collectively, Sanofi) in which Sanofi asserted that our use of the word ADVENTRX infringes upon their trademark AVENTIS and demanded that we discontinue use of the word ADVENTRX. In May of 2005, we responded with a letter in which we outlined reasons why we do not believe that our name, ADVENTRX, infringes on Sanofi s trademark, AVENTIS. Since our response, counsel for both parties have exchanged further communications and Sanofi has made further inquiries regarding our use of the ADVENTRX mark. In June 2006, we received a letter from counsel to Sanofi that, based on the fact that we do not own any registrations or applications for the ADVENTRX name and that Sanofi is not aware of any instances of actual confusion in the marketplace, Sanofi has decided not to take any further action. Sanofi indicated that, if we attempt to secure trademark/service mark registration protection for the ADVENTRX name or should instances of actual confusion come to Sanofi s attention, it will reevaluate its position. Accordingly, Sanofi may take legal action in the future, including proceeding with an action for trademark infringement. Depending upon the circumstances, an adverse result in a trademark infringement action could require the payment of monetary damages by us and/or changing our corporate name.

We may be unable to retain skilled personnel and maintain key relationships.

The success of our business depends, in part, on our ability to attract and retain highly qualified management, scientific and other personnel, and on our ability to develop and maintain important relationships with leading research institutions and consultants and advisors. Competition for these types of personnel and relationships is intense from numerous pharmaceutical and biotechnology companies, universities and other research institutions, particularly in the San Diego, California area. We are currently dependent upon our scientific staff, which has a deep background in our product candidates and our research and development programs. Recruiting and retaining senior employees with relevant drug development experience in oncology and anti-viral therapeutics is costly and time-consuming. There can be no assurance that we will be able to attract and retain such individuals on an uninterrupted basis and on commercially acceptable terms, and the failure to do so could have a material adverse effect on us by significantly delaying one or more of our research and development programs. The loss of any of our senior executive officers, including our chief executive officer, president/chief medical officer, chief scientific officer or our vice president, medical affairs, in particular, could have a material and adverse effect on the company and the market for our common stock, particularly if such loss was abrupt or unexpected. All of our employees are employed on an at-will basis under offer letters. We do not have non-competition agreements with any of our employees. Furthermore, we are currently seeking a permanent chief financial officer. In addition to the fundamental role this position plays in ensuring the accuracy and timeliness of a company s financial reporting, and thereby its eligibility to file shelf registration statements on Form S-3, this position is often times critical to a company s ability to raise capital, both of which are of particular importance to us. Identifying and retaining a chief financial officer may be difficult and take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to meet our needs. Competition to hire from this limited pool is intense and, if we are unable to hire, train, retain and motivate an individual as our chief financial officer, it is uncertain what impact this may have on the accuracy and timeliness of our financial reporting, our ability to timely and completely comply with the

requirements of Form S-3 or our ability to raise capital.

We currently have no sales capability, and limited marketing capability.

We currently do not have sales personnel. We have limited marketing and business development personnel. To commercialize our products, we will have to acquire or develop sales, marketing and distribution capabilities, or rely on marketing partners or other

Table of Contents

arrangements with third parties for the marketing, distribution and sale of products. There is no guarantee that we will be able to establish marketing, distribution or sales capabilities or make arrangements with third parties to perform those activities on terms satisfactory to us, or that any internal capabilities or third party arrangements will be cost-effective. The acquisition or development of a sales and distribution infrastructure will require substantial resources, which may divert the attention of our management and key personnel and negatively impact our product development efforts.

In addition, any third parties with which we may establish marketing, distribution or sales arrangements may have significant control over important aspects of the commercialization of our products, including market identification, marketing methods, pricing, composition of sales force and promotional activities. There can be no assurance that we will be able to control the amount and timing of resources that any third party may devote to our products or prevent any third party from pursuing alternative technologies or products that could result in the development of products that compete with, or the withdrawal of support for, our products.

We do not have manufacturing capabilities and may not be able to contract for such services from third parties on commercially acceptable terms, or at all.

We do not have any manufacturing capability. We meet our manufacturing requirements by establishing relationships with third-party manufacturers for the manufacture of clinical trial material and the commercial production of our products, though we do not have any long-term agreements or commitments for the supply of these materials and products. We cannot assure you that we will be able to establish relationships with third-party manufacturers on commercially acceptable terms, or at all, or that third-party manufacturers will be able to manufacture our products on a cost-effective basis under good manufacturing practices mandated by the FDA or other regulatory bodies in quantities sufficient to meet our clinical and commercial needs.

Our dependence upon third parties for the manufacture of products may adversely affect our future costs and our ability to develop and commercialize our products on a timely and competitive basis. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production, as well as complying with strictly enforced federal, state and foreign regulations. We cannot assure you that manufacturing or quality control problems will not arise in connection with the manufacture of our products or that third-party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such products. Any delay or interruption in the supply of clinical supplies could delay the completion of our clinical trials, increase the costs associated with maintaining our research and development programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely. Any failure to establish relationships with third parties for our manufacturing requirements on commercially acceptable terms would have a material and adverse effect on us.

We are dependent in part on third parties for clinical trials and research facilities.

We do not possess research and development facilities necessary to conduct all of the activities associated with our research and development programs. We engage consultants, advisors and CROs to design and conduct clinical trials in connection with the development of our product candidates. As a result, these important aspects of our product candidates development are outside our direct control. In addition, there can be no assurance that such third parties will perform all of their obligations under arrangements with us or will perform those obligations satisfactorily.

For instance, for our CoFactor phase III clinical trial, we rely on Synteract, Inc., for data management, biostatistics and pharmacovigilance, and Pharmatech, Inc., for site management and enrollment support, both of which are CROs. Individuals working at these companies are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If these CROs fail to devote sufficient time and resources to our clinical trials, or if their performance is substandard, it will delay the approval of our FDA applications and our introduction of our products. Failure of these CROs to meet their obligations could adversely affect clinical development of our product candidates. Moreover, these CROs may have relationships with other commercial entities, some of which may compete with us. If they assist our competitors at our expense, it could harm our competitive position.

Table of Contents

We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization. In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage and it is uncertain that such increased or additional insurance coverage can be obtained on commercially reasonable terms.

Our business (in particular, the use of our product candidates in clinical trials and the sale of our products for which we obtain marketing approval) will expose us to product liability risks. We have obtained limited product liability insurance for our clinical trials, and intend to expand our insurance coverage if and when we begin marketing commercial products. However, there can be no assurance that we will be able to obtain product liability insurance on commercially acceptable terms or that we will be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect us against potential losses. A successful product liability claim or series of claims brought against us could have a material and adverse effect on us and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business. In addition, regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products or product candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our products and product candidates.

The price of our common stock has been and is likely to continue to be volatile, and your investment could suffer a decline in value.

Market prices for our common stock and the securities of other biotechnology and biopharmaceutical companies have been highly volatile and may continue to be highly volatile in the future. Our common stock has been, and is likely to be, highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- the timing and the results from our clinical trial programs;
- FDA or international regulatory actions;
- failure of any of our product candidates, if approved, to achieve commercial success;
- announcements of clinical trial results or new product introductions by our competitors;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors;
- developments concerning our or our competitors intellectual property rights;
- litigation or public concern about the safety of our product candidates;
- deviations in our business and the trading price of our common stock from the estimates of securities analysts;

additions or departures of key personnel; and

third party reimbursement policies.

The stock market in general experiences extreme price and volume fluctuations that are often unrelated and disproportionate to the operating performance of companies. Class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of management s attention and resources, which could hurt our business, operating results and financial condition.

If we cannot satisfy AMEX s listing requirements, it may delist our common stock and we may not have an active public market for our common stock. The absence of an active trading market would likely make our common stock an illiquid investment.

Our common stock is quoted on the American Stock Exchange, or AMEX. To continue to be listed, we are required to maintain stockholders equity of $6,000,000, among other requirements. We did not satisfy that requirement as of September 30, 2006. It is our understanding, however, that AMEX will not normally consider suspending dealings in, or removing from the listing of, the securities of a company if the company has a total value of market capitalization of at least $50,000,000 and has at least 1,100,000 shares publicly held, with a market value of publicly held shares of at least $15,000,000 and 400 round lot stockholders. We currently meet these criteria. If AMEX were to delist our common stock or suspend trading in our common stock, our common stock would likely trade in the over-the-counter market in the so-called pink sheets or, if available, the OTC Bulletin Board Service. As a result, an investor would likely find it significantly more difficult to dispose of, or to obtain accurate quotations as to the value of, our common stock.

Table of Contents

If our common stock is delisted, it may become subject to the SEC s penny stock rules and more difficult to sell.
SEC rules require brokers to provide information to purchasers of securities traded at less than $5.00 and not traded on a national securities exchange or quoted on the Nasdaq Stock Market. If our common stock becomes a penny stock that is not exempt from these SEC rules, these disclosure requirements may have the effect of reducing trading activity in our common stock and making it more difficult for investors to sell. The rules require a broker-dealer to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny market. The broker must also give bid and offer quotations and broker and salesperson compensation information to the customer orally or in writing before or with the confirmation. The SEC rules also require a broker to make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser s written agreement to the transaction before a transaction in a penny stock.
Changes in laws and regulations that affect the governance of public companies have increased our operating expenses and may continue to do so.
Recently enacted changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and AMEX listing requirements, have imposed new duties on us and on our executives, directors, attorneys and independent accountants. In order to comply with these new rules, we have hired additional personnel (and may hire additional personnel) and engaged outside legal, accounting and advisory services, which have increased and are likely to continue increasing our operating expenses. In particular, we expect to incur additional administrative expenses as we continue to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, which requires management to extensively evaluate and report on, and our independent registered public accounting firm to attest to, our internal controls. For example, we have incurred significant expenses, and expect to incur additional expenses, in connection with the evaluation, implementation, documentation and testing of our existing and newly implemented control systems. Management time associated with these compliance efforts necessarily reduces time available for other operating activities, which could adversely affect operating results. If we are unable to achieve full and timely compliance with these regulatory requirements, we could be required to incur additional costs and expend additional money and management time on additional remedial efforts, all of which could adversely affect our results of operations.
Failure to implement effective control systems, or failure to complete our assessment of the effectiveness of our internal control over financial reporting, may subject us to regulatory sanctions and could result in a loss of public confidence.
We are required to include in our annual report our assessment of the effectiveness of our internal control over financial reporting. Furthermore, our independent registered public accounting firm is required to issue an opinion on whether our assessment of the effectiveness of our internal control over financial reporting is fairly stated in all material respects and separately report on whether it believes we maintained, in all material respects, effective internal control over financial reporting on an annual basis.
Our management concluded that our internal controls over financial reporting were effective as of December 31, 2005, and our independent public accountants were able to attest to that assessment. However, in connection with the 2005 year-end audit, our independent public accountants identified certain internal control weaknesses that, although not rising to the level of material weaknesses, were significant deficiencies. Additionally, in prior years (most recently 2004), certain material weaknesses in our internal controls over financial reporting were identified in connection with our annual financial audits. While we believe we remediated the material weaknesses from prior years, including through adopting a new financial accounting system and adding a financial controller to our accounting staff, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence. In addition, on September 7, 2006, we ended our employment relationship with our chief financial officer who also served as treasurer, vice president, finance and secretary, and appointed our then-controller as acting chief financial officer and treasurer. We are uncertain what, if any, impact these events may have on the accuracy and timeliness of our financial reporting.
If we fail to remedy any material weaknesses which are uncovered in the future, fail to timely complete our assessment, or if our independent registered public accounting firm cannot timely attest to our assessment in the

future, we could be subject to regulatory sanctions and a loss of public confidence in our internal controls. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to timely meet our regulatory reporting obligations.

Table of Contents

We have engaged in and may continue to engage in opportunistic acquisitions of companies and intellectual property, which could negatively affect our business and earnings.

In April 2006, we acquired SD Pharmaceuticals, Inc., including its portfolio of product candidates. We intend to continue to be opportunistic in acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our business or complement our existing product candidates. There are risks associated with such activities. These risks include, among others, incorrectly assessing the asset quality of a prospective merger partner, encountering greater than anticipated costs in integrating acquired businesses, facing resistance from customers or employees, and being unable to profitably deploy assets acquired in the transaction. Additional country- and region-specific risks are associated with transactions outside the U.S. To the extent we issue securities in connection with additional transactions, these transactions and related issuances may have a dilutive effect on earnings per share and our ownership.

Our earnings, financial condition, and prospects after a merger or acquisition depend in part on our ability to successfully integrate the operations of the acquired or in-licensed products, business or technologies. We may be unable to integrate operations successfully or to achieve expected cost savings. Any cost savings which are realized may be offset by losses in revenues or other charges to earnings.

Sales of substantial amounts of our common stock or the perception that such sales may occur could cause the market price of our common stock to drop significantly, even if our business is performing well.

The market price of our common stock could decline as a result of sales by, or the perceived possibility of sales by, our existing stockholders of shares of our common stock. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate. In addition, we have filed resale shelf registration statements to register shares of our common stock that may be sold by certain of our stockholders, which may increase the likelihood of sales by, or the perception of an increased likelihood of sales by, our existing stockholders of shares of our common stock.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult, which could depress our stock price. Alternatively, prohibitions on anti-takeover provisions in our charter documents may restrict us from acting in the best interests of our stockholders.

We are incorporated in Delaware. Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change in control would be beneficial to our stockholders. Our bylaws limit who may call a special meeting of stockholders and establish advance notice requirements for nomination for election to the Board of Directors or for proposing matters that can be acted upon at stockholder meetings. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, the Board of Directors approves the transaction. Our Board of Directors may use these provisions to prevent changes in the management and control of our company. Also, under applicable Delaware law, our Board of Directors may adopt additional anti-takeover measures in the future. In addition, provisions of certain contracts, such as stock option agreements under our 2005 Equity Incentive Plan and employment agreements with our executive officers, may have an anti-takeover effect. In particular, we agreed with our president/chief medical officer that, among other things, in the event of our acquisition, 50% of any unvested portion of an option we granted to him would vest upon such acquisition, with the remaining unvested portion vesting monthly over the 12 months following such acquisition. As a result, if an acquirer desired to retain the services of our president/chief medical officer following an acquisition, it may be required to further incentive him with additional options or other securities, which may deter or affect the terms of an acquisition or potential acquisition.

In connection with a July 2005 private placement, we agreed with the investors in that transaction that we would not implement certain additional measures that would have an anti-takeover effect. As a result, under our amended and restated certificate of incorporation, we are prohibited from dividing our Board of Directors into classes and adopting or approving any rights plan, poison pill or other similar plan or device. A classified board of directors could serve to protect our stockholders against unfair treatment in takeover situations, by making it more difficult and time-consuming for a potential acquirer to take control of our Board of Directors. A company may also adopt a

classified board of directors to ensure stability in the board of directors and thereby improve long-term planning, which arguably benefits stockholders. A poison pill or similar plan or device may encourage potential acquirers to discuss their intentions with the board of directors of a company and avoid the time, expense and distraction of a hostile take-over. Any benefit to us and our stockholders from instituting a classified board or adopting or approving a poison pill or similar plan or device in these and other circumstances would be unavailable unless and until we amend our amended and restated certificate of incorporation.

Table of Contents

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers and directors and the beneficial owners of 5% or more of our common stock and their affiliates will, in aggregate, beneficially own approximately 29% of our outstanding common stock as of September 30, 2006. These persons, if acting together, will be able to exercise significant influence over all matters requiring stockholder approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control our management and affairs. This concentration of ownership may harm the market price of our common stock by delaying or preventing a change in control of our company at a premium price even if beneficial to our other stockholders.

Because we do not expect to pay dividends in the foreseeable future, you must rely on stock appreciation for any return on your investment.

We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our Board of Directors. Furthermore, we are subject to various laws and regulations that may restrict our ability to pay dividends and we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our capital stock will likely depend entirely upon any future appreciation and there is no guarantee that our capital stock will appreciate in value.

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

During the quarterly period ended September 30, 2006, we issued an aggregate of 1,614,462 shares of common stock to 32 of our warrant holders and received gross proceeds of approximately $3,500,000 in connection with their exercise of our outstanding warrants. We issued these shares in reliance on the exemption from registration under Section 4(2) of the Securities Act of 1933. Pursuant to the terms of an agreement we entered into with Burnham Hill Partners, a division of Pali Capital, Inc., in March 2004, we have an obligation to pay a 4% cash commission to Burnham Hill Partners with respect to the cash we receive upon exercise of each warrant issued in a financing we consummated in April 2004. Accordingly, we have paid Burnham Hill Partners approximately $131,000 in connection with the warrants exercised during the quarterly period ended September 30, 2006. No other commission or other remuneration was paid or given directly or indirectly in connection with these warrant exercises.

Item 3. Default upon Senior Securities

Not applicable

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

Not applicable

Item 5. Other Information

From October 1, 2006 through October 31, 2006, we issued an aggregate of 396,631 shares of common stock to 19 of our warrant holders and received gross proceeds of approximately $458,289 in connection with their exercise of our outstanding warrants. We issued these shares in reliance on the exemption from registration under Section 4(2) of the Securities Act of 1933. No commission or other remuneration was paid or given directly or indirectly in connection with these warrant exercises.

Table of Contents

Item 6. Exhibits

An exhibit index has been attached as part of this Quarterly Report and is incorporated herein by reference.

Signatures

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

ADVENTRX Pharmaceuticals, Inc.

Date: November 9, 2006 By: /s/ Evan M. Levine

Chief Executive Officer

ADVENTRX Pharmaceuticals, Inc.

Date: November 9, 2006 By: /s/ Robert A. Daniel

Acting Chief Financial Officer and Treasurer

Exhibit Index

Exhibit	Description
31.1	Rule 13a-14(a)/15d-14(a) Certification
31.2	Rule 13a-14(a)/15d-14(a) Certification
32.1	Section 1350 Certifications*

* These certifications are being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 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 ADVENTRX Pharmaceuticals, Inc., whether made before or

after the date hereof, regardless of any general incorporation language in such filing.