ADVENTRX PHARMACEUTICALS INC
Form 10-Q
November 07, 2007

Table of Contents

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

(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, 2007

OR

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

For the transition period from to

Commission File Number 001-32157

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

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
6725 Mesa Ridge Road, Suite 100, San Diego, CA	**92121**
(Address of principal executive offices)	*(Zip Code)*

(858) 552-0866
(Registrant s telephone number, including area code)
N/A
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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, $0.001 par value, as of November 1, 2007 was 90,252,572.

TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

ADVENTRX Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets

	September 30, 2007 (unaudited)	December 31, 2006 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 19,279,913	$ 25,974,041
Short-term investments	19,334,436	25,771,406
Interest receivable	57,633	80,338
Prepaid expenses	774,175	511,327
Total current assets	39,446,157	52,337,112
Property and equipment, net	372,518	402,968
Other assets	58,305	58,305
Total assets	$ 39,876,980	$ 52,798,385
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 1,078,661	$ 480,402
Accrued liabilities	2,031,561	1,675,226
Accrued compensation and payroll taxes	847,195	292,896
Total current liabilities	3,957,417	2,448,524
Long-term liabilities	19,621	35,674
Total liabilities	3,977,038	2,484,198
Commitments and contingencies		
Stockholders equity:		
Preferred stock; 1,000,000 shares authorized; no shares issued or outstanding		
Common stock, $0.001 par value; 200,000,000 shares authorized; 90,252,572 and 89,676,739 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	90,254	89,678
Additional paid-in capital	129,621,916	127,283,524
Deficit accumulated during the development stage	(93,817,691)	(77,056,925)
Accumulated other comprehensive gain (loss)	5,463	(2,090)
Total stockholders equity	35,899,942	50,314,187

Total liabilities and stockholders equity	$ 39,876,980	$ 52,798,385

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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

	Three months ended September 30,		Nine months ended September 30,		Inception (June 12, 1996) through September 30,
	2007	2006 (Note 1)	2007	2006 (Note 1)	2007 (Note 1)
Revenues:					
Net sales	$	$	$	$	$ 174,830
Cost of goods sold					51,094
Gross margin					123,736
Grant revenue					129,733
Licensing revenue			500,000		500,000
Total revenues			500,000		753,469
Operating expenses:					
Research and development	4,422,259	3,223,554	12,046,997	8,941,147	40,204,961
Selling, general and administrative	1,979,257	2,055,441	6,794,634	5,545,370	31,365,370
Depreciation and amortization	44,899	49,326	149,824	127,528	10,582,073
In-process research and development				10,422,130	10,422,130
Impairment loss write off of goodwill					5,702,130
Equity in loss of investee					178,936
Total operating expenses	6,446,415	5,328,321	18,991,455	25,036,175	98,455,600
Loss from operations	(6,446,415)	(5,328,321)	(18,491,455)	(25,036,175)	(97,702,131)
Interest income	532,291	221,271	1,730,689	709,912	3,593,748
Interest expense					(179,090)
Loss before cumulative effect of change in accounting principle	(5,914,124)	(5,107,050)	(16,760,766)	(24,326,263)	(94,287,473)
					(25,821)

Cumulative effect of change in accounting principle					
Net loss	(5,914,124)	(5,107,050)	(16,760,766)	(24,326,263)	(94,313,294)
Preferred stock dividends					(621,240)
Net loss applicable to common stock	$ (5,914,124)	$ (5,107,050)	$ (16,760,766)	$ (24,326,263)	$ (94,934,534)
Net loss per common share basic and diluted	$ (0.07)	$ (0.07)	$ (0.19)	$ (0.34)	
Weighted average shares basic and diluted	90,007,509	73,435,715	89,798,207	70,895,528	

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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

	Nine months ended September 30,		Inception (June 12, 1996) through
	2007	**2006** (Note 1)	**September 30, 2007** (Note 1)
Cash flows from operating activities:			
Net loss	$ (16,760,766)	$ (24,326,263)	$ (94,313,294)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	149,824	127,528	10,132,073
In-process research and development		10,422,130	10,422,130
Share-based compensation for employee equity awards	1,853,839	1,445,061	5,883,091
Share-based compensation for non-employee options	43,513	67,939	241,287
Expenses paid by issuance of common stock to non-employees	58,750	127,399	1,125,114
Expenses paid by issuance of warrants			573,357
Expenses paid by issuance of preferred stock			142,501
Expenses related to stock warrants issued			612,000
Accretion of discount on investments in securities	(838,563)	(104,831)	(1,193,204)
Amortization of debt discount			450,000
Forgiveness of employee receivable			30,036
Impairment loss write-off of goodwill			5,702,130
Equity in loss of investee			178,936
Write-off of license agreement			152,866
Write-off of assets available for sale			108,000
Cumulative effect of change in accounting principle			25,821
Changes in assets and liabilities, net of effect of acquisitions:			
Increase in prepaid expenses and other assets	(298,893)	(668,401)	(1,117,899)
Increase in accounts payable and accrued liabilities	1,488,893	685,686	4,114,124
Increase (decrease) in other long-term liabilities	(16,053)	(16,059)	19,621
Net cash used in operating activities	(14,319,456)	(12,239,811)	(56,711,310)
Cash flows from investing activities:			
Purchases of short-term investments	(35,556,914)	(5,358,384)	(81,280,545)
	42,840,000	12,529,776	63,144,776

Proceeds from sales and maturities of short-term investments			
Cash paid for acquisitions, net of cash acquired		(258,178)	32,395
Purchases of property and equipment	(99,374)	(167,429)	(937,513)
Purchase of certificate of deposit			(1,016,330)
Maturity of certificate of deposit			1,016,330
Payment on obligation under license agreement			(106,250)
Issuance of note receivable related party			(35,000)
Payments on note receivable			405,993
Advance to investee			(90,475)
Cash transferred in rescission of acquisition			(19,475)
Cash received in rescission of acquisition			230,000
Net cash provided by (used in) investing activities	7,183,712	6,745,785	(18,656,094)
Cash flows from financing activities:			
Proceeds from sale of preferred stock			4,200,993
Proceeds from sale of common stock			84,151,342
Proceeds from exercise of stock options	441,616	125,751	712,367
Proceeds from sale or exercise of warrants		7,129,264	11,382,894
Repurchase of warrants			(55,279)
Payments of financing and offering costs		(194,588)	(6,483,809)
Payments of notes payable and long-term debt			(605,909)
Proceeds from issuance of notes payable and detachable warrants			1,344,718
Net cash provided by financing activities	441,616	7,060,427	94,647,317
Net increase (decrease) in cash and cash equivalents	(6,694,128)	1,566,401	19,279,913
Cash and cash equivalents at beginning of period	25,974,041	14,634,618	
Cash and cash equivalents at end of period	$ 19,279,913	$ 16,201,019	$ 19,279,913

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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

1. Summary of Significant Accounting Policies

Basis of Presentation. ADVENTRX Pharmaceuticals, Inc., a Delaware corporation (ADVENTRX, we or the Company) prepared the unaudited interim condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and with the instructions of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for annual audited financial statements and should be read in conjunction with the Company s audited consolidated financial statements and related notes for the year ended December 31, 2006 included in the Company s Annual Report on Form 10-K and Form 10-K/A filed with the SEC on March 15, 2007 and August 24, 2007, respectively, (2006 Annual Report). The financial statements and related notes appearing in the Form 10-K/A are identical to those appearing in the Form 10-K. The condensed consolidated balance sheet as of December 31, 2006 has been derived from the audited consolidated financial statements included in the 2006 Annual Report. In the opinion of management, these consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of the financial position, results of operations, and cash flows for the periods presented. The results of operations for the interim periods shown in this report are not necessarily indicative of results expected for the full year.

Since our inception, we have reported accumulated net losses of approximately $94.3 million and recurring negative cash flows from operations. In order to maintain sufficient cash and investments to fund future operations, we anticipate raising additional capital in the next 12 months through various financing alternatives including licensing or selling our technologies, issuing debt securities, or selling and issuing shares of our common stock or preferred stock or rights to purchase these securities. The balance of securities available for sale under our existing shelf registration was approximately $60.0 million as of September 30, 2007. We believe our cash, cash equivalents and investments in securities of approximately $38.6 million as of September 30, 2007 will be sufficient to sustain our planned level of operations for at least the next 12 months.

Principles of Consolidation. The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, SD Pharmaceuticals, Inc. and ADVENTRX (Europe) Ltd. All intercompany accounts and transactions have been eliminated in consolidation. Certain amounts in the prior year consolidated financial statements have been reclassified to conform to the current year presentation.

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

Change in Accounting Principle for Registration Payment Arrangements. In December 2006, the Financial Accounting Standards Board (FASB) issued FASB Staff Position on No. EITF 00-19-2, *Accounting for Registration Payment Arrangements* (FSP EITF 00-19-2). FSP EITF 00-19-2 provides that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement should be separately recognized and measured in accordance with Statement of Financial Accounting Standards (FAS) No. 5, *Accounting for Contingencies*, which provides that loss contingencies should be recognized as liabilities if they are probable and reasonably estimable. Subsequent to the adoption of FSP EITF 00-19-2, any changes in the carrying amount of the contingent liability will result in a gain or loss that will be recognized in the consolidated statement of operations in the period the changes occur. The guidance in FSP EITF 00-19-2 is

effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of FSP EITF 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of FSP EITF 00-19-2, this guidance is effective for our consolidated financial statements issued for the year beginning January 1, 2007, and interim periods within that year.

On January 1, 2007, we adopted the provisions of FSP EITF 00-19-2 to account for the registration payment arrangement associated with our July 2005 financing (the July 2005 Registration Payment Arrangement). As of September 30, 2007, management determined that it was not probable that we would have any payment obligation under the July 2005 Registration Payment Arrangement; therefore, no accrual for contingent obligation is required under the provisions of FSP EITF 00-19-2. The comparative condensed consolidated financial statements of periods prior to January 1, 2007 have been adjusted to apply the new method retrospectively. The following financial statement line items for the three and nine months ended September 30, 2006 and from inception through September 30, 2006 were affected by the change in accounting principle:

Table of Contents

Consolidated Statements of Operations

	As Originally Reported	As Adjusted	Effect of Change
Three Months Ended September 30, 2006			
Loss from operations	$ (5,328,321)	$ (5,328,321)	$
Gain on fair value warrants	497,869		(497,869)
Net loss	(4,609,181)	(5,107,050)	(497,869)
Net loss per share basic and diluted	$ (0.06)	$ (0.07)	$ (0.01)
Nine Months Ended September 30, 2006			
Loss from operations	$(25,036,175)	$(25,036,175)	$
Gain on fair value warrants	1,434,115		(1,434,115)
Net loss	(22,892,148)	(24,326,263)	(1,434,115)
Net loss per share basic and diluted	$ (0.32)	$ (0.34)	$ (0.02)
Inception (June 12, 1996) Through September 30, 2006			
Loss from operations	$(74,410,384)	$(74,410,384)	$
Loss on fair value warrants	(10,145,545)		10,145,545
Net loss	(83,352,591)	(73,207,046)	10,145,545
Net loss applicable to common stock	(83,973,831)	(73,828,286)	10,145,545

Consolidated Statements of Cash Flows

	As Originally Reported	As Adjusted	Effect of Change
Nine Months Ended September 30, 2006			
Net loss	$(22,892,148)	$(24,326,263)	$ (1,434,115)
Gain on value of warrant liability	(1,434,115)		1,434,115
Inception (June 12, 1996) through September 30, 2006			
Net loss	$(83,352,591)	$(73,207,046)	$ 10,145,545
Loss on value of warrant liability	10,145,545		(10,145,545)

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

Computation of Net Loss per Common Share. We calculate basic and diluted net loss per common share in accordance with the FAS No. 128, *Earnings Per Share*. Basic net loss per common share was calculated by dividing the net loss for the period by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per common share was calculated by dividing the net loss for the period by the weighted-average number of common stock equivalents outstanding during the

period. For purposes of this calculation, options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per common share when their effect is dilutive.

Table of Contents

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

	2007	2006
Warrants	13,408,549	14,880,495
Options	4,055,733	3,550,500
	17,464,282	18,430,995

Comprehensive Loss. Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, including foreign currency translation adjustments and unrealized gains and losses on short-term investments. Our components of comprehensive loss consist of net loss and unrealized gains or losses on short-term investments in securities. For the three months ended September 30, 2007 and 2006, comprehensive loss was $5.9 million and $5.1 million, respectively. For the nine months ended September 30, 2007 and 2006 and the period from inception (June 12, 1996) through September 30, 2007, comprehensive loss was $16.8 million, $24.3 million and $94.3 million, respectively.

Share-Based Payments. Estimated share-based compensation expense related to equity awards granted to employees for the three and nine months ended September 30, 2007 and 2006 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Selling, general and administrative expense	$ 374,434	$ 496,534	$ 1,060,096	$ 1,077,805
Research and development expense	290,343	110,040	793,743	367,256
Share-based compensation expense before taxes	664,777	606,574	1,853,839	1,445,061
Related income tax benefits				
Share-based compensation expense	$ 664,777	$ 606,574	$ 1,853,839	$ 1,445,061
Net share-based compensation expense per common share basic and diluted	$ 0.01	$ 0.01	$ 0.02	$ 0.02

Since we have a net operating loss carryforward as of September 30, 2007, no excess tax benefits for the tax deductions related to share-based awards were recognized in the condensed consolidated statement of operations. For the nine-month periods ended September 30, 2007 and 2006, employees exercised stock options to purchase 575,833 and 92,500 shares of common stock, respectively, for aggregate proceeds of $442,000 and $126,000, respectively.

At September 30, 2007, total unrecognized estimated compensation cost related to non-vested employee share-based awards granted prior to that date was $4.8 million, which is expected to be recognized over a weighted-average period of 2.8 years. During the nine months ended September 30, 2007 and 2006, we granted 1,155,733 and 1,566,000 stock options, respectively, to our employees with the estimated weighted-average grant-date fair value of $2.62 and $4.04 per share, respectively. During the nine months ended 2006, we also granted to an employee 60,145 shares of common stock that had a grant-date fair value of $197,000. No stock has been granted to any employees for the nine months ended September 30, 2007.

Estimated share-based compensation expense related to equity awards granted to non-employee consultants was $24,000 and $49,000 for the three months ended September 30, 2007 and 2006, respectively, and $102,000 and $195,000 for the nine months ended September 30, 2007 and 2006, respectively.

Table of Contents

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

	Nine months ended September 30,		Inception (June 12, 1996) through September 30,
	2007	**2006**	**2007**
Supplemental disclosures of cash flow information:			
Interest paid	$	$	$ 179,090
Income taxes paid			
Issuance of warrants, common stock and preferred stock for:			
Conversion of notes payable and accrued interest	$	$	$ 1,213,988
Prepaid services to consultants			1,482,781
Conversion of preferred stock			2,705
Acquisitions		10,163,952	24,781,555
Payment of dividends			213,000
Financial advisor services in connection with private placement			1,137,456
Acquisition of treasury stock in settlement of a claim			34,747
Cancellation of treasury stock			(34,747)
Assumptions of liabilities in acquisitions			1,235,907
Acquisition of license agreement for long-term debt			161,180
Cashless exercise of warrants		13	4,312
Dividends accrued			621,040
Trade asset converted to available for sale asset			108,000
Dividends extinguished			408,240
Trade payable converted to note payable			83,948
Issuance of warrants for return of common stock			50,852
Detachable warrants issued with notes payable			450,000
Purchases of equipment, which are included in accounts payable	20,000		20,000
Unrealized (gain) loss on short-term investments	(7,553)	2,592	(5,463)

Recent Accounting Pronouncements. In June 2007, FASB ratified the EITF consensus on EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). EITF 07-3 provides that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be capitalized and deferred. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed or such time when an entity does not expect the goods to be delivered or services to be performed. EITF 07-3 is effective for fiscal periods beginning after December 15, 2007. We do not expect the adoption of EITF 07-3 will have a material impact on our consolidated results of operations or financial position.

2. Registration Payment Arrangement

On July 21, 2005, we entered into a securities purchase agreement (the Agreement) with certain accredited institutional investors (the Purchasers) for the sale of 10,810,809 shares of our common stock (the Shares) at a

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

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

Table of Contents

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

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

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

The registration statement was filed and declared effective by the SEC on September 2, 2005, which was within the allowed time. As of October 31, 2007, we have not incurred nor paid any Liquidated Damages in connection with the July 2005 Registration Payment Arrangement.

Effective January 1, 2007, we accounted for the July 2005 Registration Payment Arrangement under the provisions of FSP EITF 00-19-2. See Note 1, *Significant Accounting Policies Change in Accounting Principle for Registration Payment Arrangement*, for a detailed discussion. As of October 31 2007, management determined that it is not probable that we will be obligated to pay any Liquidated Damages in connection with the July 2005 Registration Payment Arrangement. Accordingly, no accrual for contingent obligation is required at September 30, 2007.

3. License Fee Revenue

In October 2006, we entered into a license agreement with Theragenex, LLC. Under the agreement, we granted Theragenex exclusive rights to develop and commercialize ANX-211 in the Unites States of America in exchange for a licensing fee of $1.0 million ($500,000 of which we received in January 2007 and $500,000 of which was due in June 2007 but remains unpaid), milestone payments and royalties. In May 2007, we received a letter from TRx Pharma, a subsidiary of Theragenex, that we believe was intended to constitute notice of termination of the agreement with Theragenex, though the letter did not explicitly state that it constituted notice of termination. In its letter, TRx Pharma requested a refund of the initial $500,000 payment and, in subsequent discussions, has indicated that it does not intend to pay the remaining $500,000. On July 3, 2007, we notified Theragenex that, among other things, its failure to make the final $500,000 payment constituted a material breach of the agreement. On August 9, 2007, we delivered a letter to Theragenex confirming our termination of the agreement as a result of Theragenex s breach, pursuant to the terms of the agreement. On October 11, 2007, we filed a demand for arbitration against Theragenex and David M. Preston, its founder, Chairman, President and Chief Executive Officer in his individual capacity as its alter ego, seeking damages of up to $10 million with respect to breach of the agreement. We are unable to predict the outcome of our claim against Theragenex and the amount that we could receive, if any, from the arbitration proceedings.

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

Table of Contents

4. Income Taxes

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

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

At January 1, 2007, we had net deferred tax assets of $20.0 million. The deferred tax assets are primarily composed of federal and state tax net operating loss carryforwards, federal and state R&D credit carryforwards, share-based compensation expense and intangibles. Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset our net deferred tax asset. Additionally, the future utilization of our net operating loss and R&D credit carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of ownership changes that may have occurred previously or that could occur in the future. We have not yet determined whether such an ownership change has occurred, however, we plan to complete a Section 382/383 analysis regarding the limitation of the net operating losses and R&D credits. When this analysis is completed, we plan to update our unrecognized tax benefits under FIN 48. Therefore, we expect that the unrecognized tax benefits may change following completion of our analysis. At this time, we cannot estimate how much the unrecognized tax benefits may change. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

5. Commitments and Contingencies

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

6. Subsequent Events

In October 2007, we announced results from our Phase 2b clinical trial of ANX-510, or CoFactor, for the treatment of metastatic colorectal cancer. The CoFactor/5-FU (5-fluorouracil) arm did not demonstrate statistically significant improved safety in the trial s primary endpoint, a reduction in the proportion of patients reporting at least one hematological or gastrointestinal adverse event of grade 3 or greater. In addition, no statistically significant differences between the arms were observed across overall safety and efficacy variables. In November 2007, we announced that we will discontinue enrolling patients in our Phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. This decision followed advice we received from the Data Safety Monitoring Board, or DSMB, and comprehensive analysis of our recently completed Phase 2b clinical trial of CoFactor for the treatment of metastatic colorectal cancer. While the DSMB did not identify safety concerns with CoFactor, it recommended closure of the Phase 3 study, citing a slow accrual rate due, in part, to current and projected treatment preferences for colorectal cancer. Further analysis of the Phase 2b study, in which 5-FU was administered by infusion, has uncovered no significant differences between the study arms with regard to either efficacy or safety. In addition, we announced that we will continue our on-going Phase 2 clinical trial of CoFactor for the treatment of advanced breast cancer, in which 5-FU is administered as a bolus. We expect that any reduced

spending on CoFactor will be offset by increases in spending in research and development related to our other product candidates.

In October 2007, we filed a demand for arbitration against Theragenex, LLC (doing business as TRx Pharma, LLC and/or TRx Pharmaceuticals, LLC) and David M. Preston, founder, Chairman, President and Chief Executive Officer of Theragenex in his individual capacity as the alter ego of Theragenex, seeking damages of up to $10 million with respect to breach of the license agreement, dated October 20, 2006, between us and Theragenex. We terminated the license agreement in August 2007 as a result of Theragenex s breach. In accordance with the terms of the license agreement, we filed our demand with the American Arbitration Association and requested that the hearing take place in San Diego, California. We are unable to predict the outcome of our claim against Theragenex and the amount that we could receive, if any, from the arbitration proceedings.

Table of Contents

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

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

Overview

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

In October 2007, we announced results from our Phase 2b clinical trial of CoFactor for the treatment of metastatic colorectal cancer. The CoFactor/5-FU (5-fluorouracil) arm did not demonstrate statistically significant improved safety in the trial s primary endpoint, a reduction in the proportion of patients reporting at least one hematological or gastrointestinal adverse event of grade 3 or greater. In addition, no statistically significant differences between the arms were observed across overall safety and efficacy variables. In November 2007, we announced that we will discontinue enrolling patients in our Phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. This decision followed advice we received from the DSMB and comprehensive analysis of our recently completed Phase 2b clinical trial of CoFactor for the treatment of metastatic colorectal cancer. While the DSMB did not identify safety concerns with CoFactor, it recommended closure of the Phase 3 study, citing a slow accrual rate due, in part, to current and projected treatment preferences for colorectal cancer. Further analysis of the Phase 2b study, in which 5-FU was administered by infusion, has uncovered no significant differences between the study arms with regard to either efficacy or safety. In addition, we announced that we will continue our on-going Phase 2 clinical trial of CoFactor for the treatment of advanced breast cancer, in which 5-FU is administered as a bolus. We expect that any reduced spending on CoFactor will be offset by increases in spending in R&D related to our other product candidates.

Other recent developments:

In October 2007, we completed enrollment in a bioequivalence study of ANX-530, a new emulsion formulation of the anti-cancer chemotherapy drug Navelbine® (vinorelbine), that is designed to reduce the incidence and severity of vein irritation resulting from intravenous delivery of Navelbine. We expect to complete this trial later this year. Assuming the results of this study demonstrate bioequivalence of ANX-530 to Navelbine, we expect to submit a New Drug Application, or NDA, to the United States Food and Drug Administration, or FDA, seeking marketing approval under Section 505(b)(2) of the FDCA.

In October 2007, we appointed Mark Erwin to the new position of vice president of commercialization. Mr. Erwin will be responsible for defining, developing and leading our commercial operations.

In September 2007, we received confirmation from the FDA regarding our proposed 505(b)(2) NDA regulatory path for ANX-514. The FDA has indicated that data from a single study of approximately 28 patients that demonstrates the bioequivalence of ANX-514 and Taxotere® (docetaxel) is sufficient clinical data to support an NDA. ANX-514 is a new emulsion formulation of the anti-cancer chemotherapy drug Taxotere that is designed to reduce the incidence and severity of hypersensitivity reactions that follow administration of Taxotere. We plan to initiate this bioequivalence study later this year.

In August 2007, we terminated our license agreement with Theragenex, LLC following Theragenex s breach of the agreement by, among other things, its failure to make a $500,000 license fee payment to us in June 2007. Under the agreement, Theragenex had U.S. rights to our ANX-211 product. In October 2007, we filed a demand for arbitration against Theragenex and David M. Preston, its founder, Chairman, President and Chief Executive Officer in his individual capacity as its alter ego, seeking damages of up to $10 million with respect to breach of the agreement.

Table of Contents

We are a development stage company and have incurred annual net losses since inception. We have devoted substantially all of our resources to research and development or acquisition of our product candidates. We have not yet marketed any products or generated any significant revenue. As of September 30, 2007, our accumulated net losses amounted to $94.3 million. We expect that our R&D, selling, marketing and other operating costs will continue to exceed revenues from existing sources for the foreseeable future. We expect to raise additional capital in the next 12 months through various financing alternatives to support our operations, including selling shares of our common or preferred stock or rights to acquire our common or preferred stock, licensing or selling our technologies and product candidates, or through the issuance of one or more forms of senior or subordinated debt.

If the results of our ongoing bioequivalence study of ANX-530 are positive, we may seek to commercialize ANX-530 ourselves. In that event, we will likely incur substantial costs undertaking the activities associated with the commercial launch of a product, including hiring sales personnel and creating and maintaining a sales and distribution organization and associated regulatory compliance infrastructure. Substantial costs may be incurred in advance of the FDA s decision regarding marketing approval of ANX-530.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based upon unaudited consolidated financial statements that we have prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires management to make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our consolidated financial statements and accompanying notes. On an on-going basis, we evaluate these estimates and assumptions, including those related to recognition of expenses in research contracts, license agreements, share-based compensation and registration payment arrangements. Management bases its estimates on historical information and assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

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

Revenue Recognition. We recognize revenue in accordance with Topic 13, *Revenue Recognition*, and EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables*, or EITF 00-21. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. Revenue from licensing agreements is recognized based on the performance requirements of the agreement. Revenue is deferred for fees received before earned. Nonrefundable upfront fees that are not contingent on any future performance by us are recognized as revenue when revenue recognition criteria under Topic 13 and EITF 00-21 are

met and the license term commences. Nonrefundable upfront fees, where we have an ongoing involvement or performance obligations, are recorded as deferred revenue and recognized as revenue over the life of the contract, the period of the performance obligation or the development period, whichever is appropriate in light of the circumstances.

Table of Contents

Payments related to substantive, performance-based milestones in an agreement are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process. Royalty revenue from licensed products will be recognized when earned in accordance with the terms of the license agreements.

Research and Development Expenses. R&D expenses consist of expenses incurred in performing R&D activities, including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. R&D expenses are charged to operations as they are incurred. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future R&D activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

Milestone payments that we make in connection with in-licensed technology or product candidates are expensed as incurred when there is uncertainty in receiving future economic benefits from the licensed technology or product candidates. We consider the future economic benefits from the licensed technology or product candidates to be uncertain until such licensed technology or product candidates are approved for marketing by the FDA or when other significant risk factors are abated. For expense accounting purposes, management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain.

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

Purchased In-Process Research and Development. In accordance with FAS No. 141, *Business Combinations*, we immediately charge the costs associated with purchased in-process research and development, or IPR&D, to statement of operations upon acquisition. These amounts represent an estimate of the fair value of purchased IPR&D for projects that, as of the acquisition date, had not yet reached technological feasibility, had no alternative future use, and had uncertainty in receiving future economic benefits from the purchased IPR&D. We determine the future economic benefits from the purchased IPR&D to be uncertain until such technology is approved by the FDA or when other significant risk factors are abated. We incurred significant IPR&D expense related to our acquisition of SD Pharmaceuticals, Inc.

Share-based Compensation Expenses. Effective January 1, 2006, we accounted for share-based compensation awards granted to employees in accordance with the revised FAS No. 123, *Share-Based Payment,* or FAS 123R, including the provisions of Staff Accounting Bulletin No. 107. Share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee s requisite service period. We have no awards with market or performance conditions. As share-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. Although estimates of share-based compensation

expenses are significant to our consolidated financial statements, they are not related to the payment of any cash by us. Prior to January 1, 2006, we accounted for share-based compensation under the recognition and measurement principles of FAS 123, *Accounting for Stock-Based Compensation*.

We estimate the fair value of stock option awards on the date of grant using the Black-Scholes option-pricing model, or Black-Scholes model. The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, a risk-free interest rate and expected dividends. We may elect to use different assumptions under the Black-Scholes option valuation model in the future, which could materially affect our net income or loss and net income or loss per share.

Table of Contents

We account for share-based compensation awards granted to non-employees in accordance with EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or EITF 96-18. Under EITF 96-18, we determine the fair value of the share-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured using the stock price and other measurement assumptions as of the earlier of either of (1) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached or (2) the date at which the counterparty s performance is complete.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In most cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States of America.

Results of Operations

A general understanding of the drug development process is critical to understanding our results of operations. Drug development in the United States of America and most countries throughout the world is a process that includes several steps defined by the FDA and similar regulatory authorities in foreign countries. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit an NDA, which includes complete reports of pre-clinical, clinical and laboratory studies and extensive manufacturing information to prove such product s safety and effectiveness. The NDA process generally requires, before the submission of the NDA, filing of an investigational new drug application, or IND, pursuant to which permission is sought to begin clinical testing of the new drug product. An NDA based on published safety and effectiveness studies conducted by others, or previous findings of safety and effectiveness by the FDA, may be submitted under Section 505(b)(2) of the FDCA for a drug product if there are only certain changes to the active ingredient. Development of new formulations of pharmaceutical products under Section 505(b)(2) of the FDCA may have shorter timelines than those associated with developing new chemical entities.

Generally, with respect to any drug product with active ingredients not previously approved by the FDA, an NDA must be supported by data from at least Phase 1, Phase 2 and Phase 3 clinical trials. Phase 1 clinical trials can be expected to last from 6 to 18 months, Phase 2 clinical trials can be expected to last from 12 to 24 months and Phase 3 clinical trials can be expected to last from 18 to 36 months. However, clinical development timelines vary widely, as do the total costs of clinical trials and the likelihood of success. We anticipate that we will make determinations as to which R&D programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, our ongoing assessment of its market potential and our available resources.

Our expenditures on R&D programs are subject to many uncertainties, including whether we develop our product candidates with a partner or independently. At this time, due to such uncertainties and the risks inherent in the clinical trial process and given the early stage of development of many of our product candidates, we cannot estimate with reasonable certainty the duration of or costs to complete our R&D programs or whether or when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of our R&D programs, in particular those associated with clinical trials, vary significantly among programs or within a particular program as a result of a variety of factors, including:

- the number of trials necessary to demonstrate the safety and efficacy of a product candidate;
- the number of patients who participate in the trials;
- the number of sites included in the trials and rate of site approval for the trial;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;

the costs of manufacturing our product candidates; and

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

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

Table of Contents

Comparison of Three Months Ended September 30, 2007 and 2006

Revenue. No revenue was recognized for the three months ended September 30, 2007 and 2006. We have not generated any revenue from product sales to date, and we do not expect to generate revenue from product sales until such time that we have obtained approval from a regulatory agency to sell one of our product candidates, which we cannot predict will occur. We anticipate that licensing, partnering, and other collaborations will increase in importance as part of our business development strategy through 2007 and 2008.

Research and Development Expenses. We maintain and evaluate our R&D expenses by the type of cost incurred rather than by project. We maintain and evaluate R&D expenses by type primarily because of the aforementioned uncertainties, as well as because we out-source a substantial portion of our work and our R&D personnel work across multiple programs rather than dedicating their time to one particular program. We began maintaining such expenses by type on January 1, 2005. The following table summarizes our consolidated R&D expenses by type for each of the periods listed and since January 1, 2005 (unaudited):

	Three months ended September 30,		Nine months ended September 30,		January 1, 2005 through September 30,
	2007	2006	2007	2006	2007
External clinical study fees and expenses	$ 1,936,308	$ 2,225,027	$ 5,612,856	$ 5,415,123	$ 17,902,547
External non-clinical study fees and expenses (1)	1,417,001	276,984	3,242,496	1,650,207	7,255,878
Personnel costs	778,607	611,503	2,397,902	1,508,561	5,674,080
Share-based compensation expense	290,343	110,040	793,743	367,256	1,898,202
Total	$ 4,422,259	$ 3,223,554	$ 12,046,997	$ 8,941,147	$ 32,730,707

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

R&D expenses increased by $1.2 million, or 37%, to $4.4 million for the three months ended September 30, 2007, compared to $3.2 million for the comparable period in 2006. The increase in R&D expenses was primarily due to an $835,000 increase in expenses related to research-related manufacturing and quality assurance activities for our product candidates and a $347,000 increase in personnel and related costs.

We expect that our R&D expenses for the fourth quarter of 2007 will remain about the same as the level of expenses incurred in the three months ended September 30, 2007. While we have discontinued enrolling patients in our Phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer, we will continue to incur expenses for treatment and monitoring of patients enrolled to date and data analysis as we wind-down the study. In addition, we expect that any reduced spending on CoFactor will be offset by increases in spending in R&D related to our other

product candidates.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses decreased slightly by $76,000, or 4%, to $2.0 million for the three months ended September 30, 2007, compared to $2.1 million for the comparable period in 2006. The decrease was substantially due to a $120,000 decrease in business development expense and a $147,000 decrease in share-based compensation expense, partially offset by a $164,000 increase in legal fees primarily related to patent applications. We expect that SG&A expenses in the fourth quarter of 2007 will remain about the same as the level of expenses incurred in the three months ended September 30, 2007 as we modestly expand our staff to enhance our in-house commercialization expertise, particularly with respect to ANX-530, and realize savings in outside legal expenses.

Interest Income. Interest income for the three months ended September 30, 2007 was $532,000 compared to $221,000 for the comparable period in 2006. The increase was primarily attributable to higher invested balances resulting from the receipt of $37.1 million in net proceeds from the sale of common stock to institutional investors in November 2006.

Table of Contents

Comparison of Nine Months Ended September 30, 2007 and 2006

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

Research and Development Expenses. R&D expenses increased by $3.1 million, or 35%, to $12.0 million for the nine months ended September 30, 2007, compared to $8.9 million for the comparable period in 2006. The increase in R&D expenses was primarily related to a $1.4 million increase in expenses related to research-related manufacturing and quality assurance activities for our product candidates, a $214,000 increase in external preclinical study fees and expenses mostly related to ANX-201 and a $1.3 million increase in personnel and related costs.

Selling, General and Administrative Expenses. SG&A expenses increased by $1.3 million, or 23%, to $6.8 million for the nine months ended September 30, 2007, compared to $5.5 million for the comparable period in 2006. The increase in SG&A expenses was substantially due to a $1.1 million increase in personnel and related costs and a $251,000 increase in legal fees primarily related to patent applications.

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

Interest Income. Interest income for the nine months ended September 30, 2007 was $1.7 million compared to $710,000 for the comparable period in 2006. The increase was primarily attributable to higher invested balances resulting from funds received from our most recent equity financing, which we completed in November 2006.

Liquidity and Capital Resources

Since our inception we have funded our operations primarily through sales of our equity securities. As of September 30, 2007, we had cash and cash equivalents and short-term investments in securities totaling $38.6 million, compared to $51.7 million as of December 31, 2006. The decrease in cash and investments in securities was attributed to cash used for operations. As of September 30, 2007, we held $19.3 million in cash and cash equivalents and $19.3 million in short-term investments in securities.

Operating Activities. Net cash used in operating activities was $14.3 million during the nine months ended September 30, 2007, compared to $12.2 million during the nine months ended September 30, 2006. The increase in net cash used in operating activities was due to an increase in payments for R&D activities, primarily related to CoFactor, ANX-530, and ANX-201.

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

Investing Activities. Net cash provided by investing activities was $7.2 million during the nine months ended September 30, 2007 compared to $6.7 million during the nine months ended September 30, 2006. Net cash provided by investing activities in the first nine months of 2007 and 2006 was primarily attributable to proceeds from sales and maturities of short-term investments in securities, net of purchases of short-term investments in securities.

Financing Activities. Net cash provided by financing activities was $442,000 in the nine months ended September 30, 2007 from the exercise of employee stock options. Net cash provided by financing activities amounted to $7.1 million for the nine months ended September 30, 2006. Net cash provided by financing activities in 2006 primarily reflects proceeds that were received from the exercise of warrants to purchase common stock.

Management Outlook

We believe that cash, cash equivalents, and short-term investments of approximately $38.6 million at September 30, 2007 should be sufficient to sustain our planned level of operations for at least the next twelve months. We expect that our cash requirements for operating activities net of interest income projected to be received for the fourth quarter of 2007 will be no more than about $5.2 million based on existing business activities. While we have discontinued enrolling patients in our Phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer, we will continue to incur expenses for treatment and monitoring of patients

Table of Contents

enrolled to date and data analysis as we wind-down the study. In addition, we expect that any reduced spending on CoFactor will be offset by increases in spending in R&D related to our other product candidates. In order to maintain sufficient cash and investments to fund future operations longer term, and to continue developing our existing product candidates, we anticipate raising additional capital in the next 12 months through one or more financing alternatives, including selling shares of our common or preferred stock or rights to acquire our common or preferred stock, licensing or selling our technologies and product candidates, or through the issuance of one or more forms of senior or subordinated debt. The balance of securities available for sale under our existing shelf registration was approximately $60.0 million as of September 30, 2007. If we are unable to raise capital as needed to fund future operations, then we may defer or abandon one or more of our R&D programs and may need to take additional cost-cutting measures. Our ability to timely raise capital on commercially reasonably terms may be limited by requirements, rules and regulations of the SEC and the American Stock Exchange, or AMEX. For information regarding the risks associated with our need to raise additional capital and limitations on our ability to do so, see Item 1A of Part II, Risk Factors, in this report.

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

Recent Accounting Pronouncements

See Note 1, Summary of Significant Accounting Policies, Recent Accounting Pronouncements, in the Notes to the Condensed Consolidated Financial Statements (unaudited) in this report for a discussion of recent accounting announcements and their effect, if any, on us.

Forward Looking Statements

This Quarterly Report on Form 10-Q, particularly in Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements regarding our future financial position, business strategy, clinical trials, partnering arrangements and plans and objectives of management for future operations. When used in this report, the words believe, may, could, will, estimate, continue, anticipate, intend, expect and similar expression identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to certain risks and uncertainties that could cause our actual results to differ materially from those expressed or implied in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Item 1A of Part II, Risk Factors, in this report and those discussed in other documents we file with the Securities and Exchange Commission. Except as required by law, we do not intend to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report and in the documents incorporated in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in such forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on such forward-looking statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are not subject to any meaningful market risk related to foreign currency exchange rates, commodity prices or similar market risks. Substantially all of our expenses and capital purchasing activities are transacted in U.S. dollars. We are sensitive to interest rate fluctuations. The primary objective of our investing activities is to preserve principal

while maximizing the income we receive from our investments without significantly increasing the risk of loss. Some of the investable securities permitted under our cash management policy may be subject to market risk for changes in interest rates. To mitigate this risk, we maintain a portfolio of cash equivalent and short-term investments in a variety of securities which may include investment grade commercial paper, money market

Table of Contents

funds, government debt issued by the United States of America, state debt, certificates of deposit and investment grade corporate debt. Presently, we are exposed to minimal market risks associated with interest rate changes because of the relatively short maturities of our investments and we do not expect interest rate fluctuations to materially affect the aggregate value of our financial instruments. We manage our sensitivity to these risks by maintaining investment grade short-term investments. Our cash management policy does not allow us to purchase or hold derivative or commodity instruments or other financial instruments for trading purposes. Additionally, our policy stipulates that we periodically monitor our investments for adverse material holdings related to the underlying financial solvency of the issuer. As of September 30, 2007, our investments consisted mostly of cash, commercial paper and U.S. government debt. Our results of operations and financial condition would not be significantly impacted by either a 10% increase or decrease in interest rates due mainly to the short-term nature of our investment portfolio. We have not used derivative financial instruments in our investment portfolio. Additionally, we do not invest in foreign currencies or other foreign investments.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures

As of the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act). Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms and is accumulated and communicated to our management, including our principal executive and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

In the normal course of business, we may become subject to lawsuits and other claims and proceedings. Such matters are subject to uncertainty and outcomes are often not predictable with assurance.

On October 11, 2007, we filed a demand for arbitration against Theragenex, LLC (doing business as TRx Pharma, LLC and/or TRx Pharmaceuticals, LLC) and David M. Preston, founder, Chairman, President and Chief Executive Officer of Theragenex in his individual capacity as the alter ego of Theragenex, seeking damages of up to $10 million with respect to breach of the license agreement, dated October 20, 2006, between us and Theragenex. We terminated the license agreement in August 2007 as a result of Theragenex s breach. In accordance with the terms of the license agreement, we filed our demand with the American Arbitration Association and requested that the hearing take place in San Diego, California. We are unable to predict the outcome of our claim against Theragenex and the amount that we could receive, if any, from the arbitration proceedings.

Item 1A. Risk Factors.

Set forth below and elsewhere in this report and in other documents we file with the Securities and Exchange Commission, or SEC, are descriptions of the risks and uncertainties that could cause our actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. The risks and uncertainties described below contain changes to and supersede those previously described in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the fiscal year ended December 31, 2006. If any of these risks or uncertainties actually occurs, our business, financial condition and results of operations could be materially and adversely affected and the value of our securities could decline significantly.

Table of Contents

RISKS RELATED TO OUR BUSINESS

Risks Related to Our Financial Performance and Operations

We have not generated sustainable revenues or profits from operations and we may not be able to generate revenues sufficient to achieve profitability.

We are a development stage company and have not generated sustainable revenues from operations or been profitable since inception, and it is possible we will never achieve profitability. 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 from operations, much less profits, to sustain our present activities, and no revenues from operations will likely be available until, and unless, our product candidates are clinically tested, approved by the FDA or other regulatory agencies and successfully marketed, either by us or a partner, an outcome which we are not able to guarantee.

We have limited capital resources and anticipate raising additional capital in the next 12 months to support our operations, which may cause dilution to our existing stockholders, require us to relinquish proprietary rights or restrict our operations.

We have experienced significant operating losses in funding our research, development and clinical testing of product candidates, accumulating operating losses totaling over $94.3 million as of September 30, 2007, and we expect to continue to incur substantial operating losses for the foreseeable future. As of September 30, 2007, we had approximately $38.6 million in cash and cash equivalents and short-term investments in securities and we do not expect to generate positive net cash flows for the foreseeable future.

We anticipate raising additional capital in the next 12 months to finance our ongoing operations. We cannot be certain we will be able to obtain such financing on satisfactory terms, if at all, or that it will be sufficient to meet our cash requirements. Based on our current loss rate and existing capital resources as of the date of the filing of this report, we estimate that we have sufficient funds to sustain our operations at their current levels for at least the next twelve months; however, we plan to raise additional funds much earlier. Because we do not know whether our clinical research and development programs will progress at the rates expected, it is difficult to estimate our projected capital needs beyond our current spending levels.

We may raise additional capital at any time and may do so through various financing alternatives, including selling shares of our common or preferred stock and rights to acquire our common or preferred stock, licensing or selling our technologies and product candidates or issuing one or more forms of senior or subordinated debt. Each of these financing alternatives carries certain risks. Raising capital through the issuance of common stock may depress the market price of our stock and may substantially dilute our existing stockholders. If we instead seek to raise capital through licensing transactions or sales of one or more of our technologies or product candidates, we may be required to relinquish valuable rights. For example, we will likely need to share a significant portion of future revenues from these product candidates with our licensees. Additionally, the development of any product candidates licensed or sold to third parties will no longer be in our control and thus we may not realize the full value of any such product candidates. Debt financing could involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens or make investments and may, among other things, preclude us from making distributions to stockholders (either by paying dividends or redeeming stock) and taking other actions beneficial to our stockholders. In addition, investors could impose more one-sided investment terms and conditions on companies that have or are perceived to have limited remaining funds or limited ability to raise additional funds. As we continue our research and development programs without raising additional funds, it may become more difficult to raise capital in the future on commercially reasonable terms, or at all.

In addition, in connection with past financings, we provided certain investors with warrants that contained price-based anti-dilution protection. Among other things, this protection lowers the exercise price of the warrants issued in connection with these financings in the event we issue common stock at a price per share that is less than the warrants then-effective exercise price, thereby allowing the warrant-holders to receive the same number of shares of our common stock for less consideration. If we raise additional capital by selling shares of our common stock at less than the then-effective exercise price of these warrants, their exercise price may be reduced. Existing stockholders could

experience significant dilution in the future as a result of these or other provisions we provide in the future to investors. For example, if we were to sell approximately 15.4 million shares of common stock at $0.65 per share, the closing price of a share of our common stock, as reported on AMEX, as of November 1, 2007 (for gross proceeds of $10.0 million), the currently outstanding warrants to purchase 2,445,740 shares of common stock at $1.975 a share and currently outstanding warrants to purchase 117,000 shares of common stock at $2.375 a share would be re-priced to $1.782 (a 10% reduction in price) and $2.124 a share (an 11% reduction in price), respectively. The number of shares issuable upon exercise of these warrants would not change.

Table of Contents

Our ability to timely raise additional capital on commercially reasonable terms may be limited by requirements, rules and regulations of the SEC and AMEX.

Our ability to timely raise capital on commercially reasonable terms may be impaired if we become ineligible to register our securities on 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 and, for primary offerings, maintaining an aggregate market value of our common stock held by non-affiliates of at least $75 million (calculated as set forth in Form S-3 and SEC rules and regulations). As of November 1, 2007, the aggregate market value of our common stock held by non-affiliates was approximately $53 million. Though we are a small company with limited resources, we are subject to the wide-ranging 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.

In addition, our ability to timely raise capital may be limited by the rules and regulations and other requirements of AMEX, which, as of November 1, 2007, is the exchange on which our common stock is listed. For instance, AMEX requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our presently outstanding common stock unless the transaction is deemed a public offering by the AMEX staff. Based on our outstanding common stock and closing price, as reported on AMEX, as of November 1, 2007, we could not raise more than approximately $12 million without stockholder approval, unless the transaction is deemed a public offering. Obtaining stockholder approval is a costly and time-consuming process. If we were required to obtain stockholder approval, we would expect to spend substantial additional money and resources and believe the process would distract management from our core business. In addition, obtaining stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our business, and there is no guarantee our stockholders would ultimately approve the transaction if proposed. A public offering typically requires broadly announcing the anticipated transaction, which often times depresses the issuer s stock price. Accordingly, the price at which we could sell our securities in a public offering may be less, and the dilution existing stockholders experience may in turn be greater, than if the offering were not public.

If we are unable to raise additional capital, we may be required to reduce or abandon research and development programs, partner product candidates at inopportune times or pursue less-expensive but higher-risk development paths.

If adequate funds are not available to fund our research and development programs and operations at current and anticipated levels, we may be required to delay or reduce the scope of our research and development programs, abandon them altogether or attempt to continue research and development by entering into arrangements with partners or others that, if available at all, may not be on favorable terms and may require us to relinquish some or all of our rights to our product candidates or the financial benefits thereof.

In addition, to conserve funds, we may pursue less expensive but higher-risk development paths. For instance, we may limit our process development activities to the minimum we feel is sufficient to support our development and commercialization goals, in particular, with respect to ANX-530. Process development helps define the various parameters and specifications for manufacturing products at commercial-scale. Without comprehensive process development activities, we may lack the information necessary to develop an accurate validation plan to support an NDA and may be unable to successfully manufacture at commercial scale. If we are unable to validate the manufacturing processes included in an NDA, we may be required to amend the NDA, which could result in substantial delays in commercializing the subject drug, as well as call into question our ability to ultimately obtain marketing approval for that drug. In addition, we would expect to spend significant funds undertaking the activities necessary to support an amendment to an NDA.

We may seek to merge with or be acquired by another company and the terms of that transaction may not be desirable.

Because of our limited ability to raise funds, including for the reasons noted above, we may seek to merge with another company with a stronger cash position, complementary work force or product candidate portfolio or for other

reasons. The market price for our common stock has been at a 4-year low following our announcement on October 1, 2007 of results of our Phase 2b clinical trial of CoFactor for the treatment of metastatic colorectal cancer and may not accurately reflect the value of our business. While we will continue to seek to maximize the value of our business to our stockholders, our short-term needs may require us to consummate a transaction involving an exchange of our common stock with that of another company, in which case our stockholders may not realize the full value of our business or their investment.

Table of Contents

In addition, there are numerous risks associated with merging or being acquired. These risks include, among others, incorrectly assessing the quality of a prospective acquirer or merger-partner, encountering greater than anticipated costs in integrating businesses, facing resistance from employees and being unable to profitably deploy the assets of the new entity. The operations, financial condition, and prospects of the post-transaction entity depend in part on our and our acquirer/merger-partner s ability to successfully integrate the operations of our product candidates, business and 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 operations.

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 commercial organizations 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, and our manufacturing and regulatory personnel, particularly with respect to ANX-530. Recruiting and retaining senior employees with relevant product development experience in cancer and infectious diseases and process development experience with emulsified cytotoxic drugs 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 and adverse effect on us by significantly delaying one or more of our research and development programs or commercialization of our products. The loss of any of our 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 us and the market for our common stock, particularly if such loss was abrupt or unexpected. None of our employees is obligated to provide services to us for any particular period of time. We do not have non-competition agreements with any of our employees. Furthermore, even if we successfully attract and retain qualified personnel, we may not select individuals with the appropriate skills for the jobs for which they are hired or that integrate well with our existing personnel. Underperforming employees and internal friction may divert the attention of our management and key personnel and negatively impact our product development efforts. In addition, we may incur costs and liabilities terminating our employment relationship with unsatisfactory employees.

If we are successful in our development efforts for our product candidates, we will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of November 1, 2007, we had 34 full-time employees. To the extent we are successful in our clinical trials, regulatory plans or other development efforts, we will need to continue to expand our managerial, financial, manufacturing, commercial, compliance and other resources in order to manage our operations and clinical trials, continue our research and development programs and commercialize our product candidates. Our management and personnel, systems and facilities currently in place will likely not be adequate to support this growth. Our need to effectively manage our operations, growth and various projects requires that we:

- manage our clinical trials effectively, including our ANX-530 bioequivalence study, our Phase 2 clinical trial of CoFactor for the treatment of advanced breast cancer and our anticipated ANX-514 bioequivalence study;
- manage our internal research and development efforts effectively while carrying out our contractual obligations to collaborators and other third parties;
- continue to improve our operational, financial and management controls, reporting systems and procedures; and;
- attract and retain sufficient numbers of talented employees.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

22

Table of Contents

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

Our corporate headquarters are located at a single business park in San Diego, California. Important documents and records, including copies of our laboratory books and records for our product candidates, are located at our facilities and we depend on our facilities for the continued operation of our business. Natural disasters and other catastrophic events, such as wildfires and other fires, earthquakes and extended power interruptions, which have impacted San Diego businesses in the past, and terrorist attacks, drought or flood, could significantly disrupt our operations and result in additional, unplanned expense. As a small company, we have limited capability to establish and maintain a comprehensive disaster recovery program and, accordingly, we do not have a formal business continuity or disaster recovery plan, and any natural disaster or catastrophic event could delay our research and development programs. Even though we believe we carry commercially reasonable insurance, we might suffer losses that exceed the coverage available under these insurance policies. In addition, we are not insured against terrorist attacks or earthquakes.

Risks Related to Drug Development and Commercialization

Further testing of our product candidates is required and regulatory approval may be delayed or denied, which would limit or prevent us from marketing our product candidates and significantly impair our ability to generate revenues.

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 United States of America, or U.S., and foreign statutes and regulations is time-consuming and requires the expenditure of substantial resources. In addition, these requirements and processes vary widely from country to country.

To varying degrees based on the regulatory plan for each product candidate, the effect of government regulation and the need for FDA and other regulatory agency approval will delay commercialization of our product candidates, impose costly procedures upon our activities, and put us at a disadvantage relative to larger companies with which we compete. There can be no assurance that FDA or other regulatory approval for any products developed by us will be granted on a timely basis, or at all. Even though the FDA has confirmed the appropriateness of a Section 505(b)(2) regulatory path for ANX-530 and ANX-514, the FDA s views may change. If the FDA requires the longer-term regulatory approval pathway associated with traditional drug development for ANX-530 and ANX-514, we may determine that the associated time and cost is not financially justifiable and, as a result, discontinue those development programs. If we discontinue the development of one or both of these product candidates, our business and stock price may suffer.

We may not achieve our projected development goals in the time frames we announce. Delays in the commencement or completion of preclinical testing or clinical trials could result in increased costs to us and delay or limit our ability to generate revenues.

We set goals for and make public statements regarding our estimates of the timing of the accomplishment of objectives material to our success. The actual timing of these events can vary dramatically due to any number of factors, including delays or failures in our preclinical testing and clinical trials and the uncertainties inherent in the regulatory approval process.

We have an active preclinical program that we use to assess the merits of potential product candidates and future research and development activities. Delays in our preclinical program could occur for a number of reasons, including:

- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs;
- failures on the part of our CROs in developing study procedures or otherwise conducting the studies on timeframes requested by us;
- changes in regulatory requirements or other standards or guidance relating to preclinical testing, including testing of pharmaceutical products in animals;

a lack of availability of animals that are suitable for the types of studies we plan to conduct; and

unforeseen results of preclinical testing that require us to amend study designs or delay future preclinical testing, clinical trials and related regulatory filings.

Table of Contents

In addition, we do not know whether planned clinical trials will commence on time or be completed on schedule, if at all. 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 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, or IRB, 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 the perception that the design of a clinical trial or the proposed treatment regimen is less beneficial to patients than available alternatives; 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;
- lack of adequate funding to continue the clinical trial; or
- the impact that results of one clinical trial of a product candidate may have on other clinical trials for the product candidate, even if the trials involve different indications, administration methods or dosing regimens.

For example, in October 2007, we announced results of our Phase 2b clinical trial of CoFactor for the treatment of metastatic colorectal cancer, which demonstrated that the CoFactor/5-FU arm did not demonstrate statistically significant improved safety in the trial s primary endpoint. In November 2007, we announced that we will discontinue enrolling patients in our Phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. Additionally, changes in regulatory requirements and guidance relating to clinical trials may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination or renegotiate terms with CROs, trial sites and clinical investigators, all of which may impact the costs, timing or successful completion of a clinical trial.

There can be no assurance that our preclinical testing and 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 experience delays in completion of, or if we terminate, our clinical trials or preclinical testing, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials or preclinical testing may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same indications may have been introduced to the market and established a competitive advantage.

Table of Contents

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 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, 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 that could materially and adversely affect our business, financial condition and results of operations and cause our stock price to decline.

Even if initial regulatory approval is obtained, the FDA or a foreign regulatory agency 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. For instance, in September 2007, amendments to the FDCA were signed into law. These amendments significantly strengthen the FDA s regulatory authority over drugs, including new controls over the post-approval monitoring of drugs. The FDA may now require changes to approved drug labels, require post-approval clinical trials and impose distribution and use restrictions on certain drugs. In addition, approved products, manufacturers and manufacturers facilities are subject to continuing regulatory review and periodic inspections. If previously unknown problems with a product are discovered, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, the FDA may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we or a contract manufacturer of ours fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend or terminate 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;
- close the facilities of a contract manufacturer; or

seize or detain products or require a product recall.

Table of Contents

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, which would limit our ability to realize the full market potential of our product candidates.

In order to market any products outside of 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 validation 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 our preclinical testing and clinical trials do not ensure that future clinical trials will be successful or that our product candidates will receive the regulatory approvals necessary for their commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through preclinical testing and clinical trials that each product is safe and effective for use in each target indication. Success in preclinical testing and clinical trials does not ensure that subsequent or large-scale clinical trials will be successful. For instance, CoFactor plus 5-FU failed to show improved safety in our Phase 2b clinical trial of CoFactor for the treatment of metastatic colorectal cancer despite generating positive safety data in our Phase 2 clinical trial of CoFactor for the treatment of metastatic colorectal cancer. 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 an NDA. There is a significant risk that any of our product candidates could fail to show satisfactory results in clinical 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.

If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues we generate from their sales will be limited and our business may not be profitable.

Our success will depend in substantial part on the extent to which our products for which we obtain marketing approval from the FDA and comparable foreign regulatory authorities are accepted by the medical community and reimbursed by third-party payors, including government payors. The degree of market acceptance will depend upon a number of factors, including, among other things:

- limitations or warnings in a product s 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;
- availability of alternative treatments;
- the product s perceived advantages over existing treatment methods (including relative convenience and ease of administration and prevalence and severity of any adverse side effects);

pricing and cost-effectiveness;

reimbursement and coverage policies of government and third-party payors; and

the prevalence of off-label substitution of chemically equivalent products.

Table of Contents

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 revenues 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.

We rely in part on third parties to conduct our clinical trials and other aspects of our research and development programs.

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 preclinical and clinical trials in connection with the research and 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.

The CROs with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and subsequent collection and analysis of data, and we will likely depend on other CROs and clinical investigators to conduct our future clinical trials or assist with our on-going clinical trials. Individuals working at these companies, as well as clinical investigators at the sites at which our clinical trials are conducted, 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 applications to regulatory agencies and the 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.

We do not have manufacturing capabilities and may not be able to effectively develop manufacturing capabilities or 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 we anticipate establishing relationships with third-party manufacturers for the commercial production of our products, though we do not have any long-term agreements or commitments for the supply of these materials or products. Likewise, we do not have any long-term agreements or commitments with vendors to supply the underlying component materials of our product candidates. We cannot ensure that we will be able to establish relationships with third-party manufacturers or component suppliers on commercially acceptable terms, or at all.

ANX-530, for instance, is an emulsified cytotoxic product that must be aseptically-filled. There is a limited number of contract manufacturers capable and willing to manufacture this type of product at the commercial scale at which we anticipate requiring in accordance with our marketing plans for ANX-530, which will make identifying and establishing short- or long-term relationships with willing manufacturers more difficult and provide them with substantial leverage over us in any negotiations. Furthermore, certain of the underlying component materials of ANX-530 are available only from a particular supplier, and we do not have any short- or long-term agreements for the supply of these materials. 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.

Even if we successfully establish relationships with third-party suppliers and manufacturers on commercially acceptable terms, our suppliers and manufacturers may not perform as agreed or may terminate their agreements with us. Even if we successfully establish a long-term relationship with our current contract manufacturer for ANX-530 on commercially acceptable terms, our contract manufacturer may be unable to successfully and consistently manufacture ANX-530 at commercial scale. We and our current contract manufacturer have limited experience manufacturing ANX-530, and the experience we and they do have is limited to manufacturing at non-commercial scales. Because data from a single clinical trial of ANX-530 may be sufficient clinical data to support an NDA, our and our current contract manufacturer s ability to gain experience manufacturing ANX-530, in particular at various scales, has been limited. If our current contract manufacturer is unable to manufacture ANX-530 successfully and consistently at commercial scale and within established parameters, we may be unable to validate our manufacturing process, even if

the FDA approves our NDA, and therefore unable to sell ANX-530.

In addition, all manufacturers of our products and product candidates must comply with current good manufacturing practice, or cGMP, requirements enforced by the FDA through its facilities inspection program, as well as applicable requirements of foreign regulatory authorities. These requirements include quality control, quality assurance and the maintenance of records and

Table of Contents

documentation. Manufacturers of our products and product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. We have little control over our manufacturers compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval.

Furthermore, 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. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing and shortages of qualified personnel. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their contractual obligations, our ability to provide product candidates to patients in our clinical trials may be jeopardized.

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. We cannot ensure that manufacturing or quality control problems will not arise in connection with the manufacture of our products or product candidates, or that third-party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such products or product candidates. Any of the above factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, entail higher costs or result in our being unable to effectively commercialize our products. Our dependence upon third parties for the manufacture of our products and product candidates may adversely affect our future costs and our ability to develop and commercialize our products and product candidates on a timely and competitive basis.

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 and only recently hired a vice president, commercialization. To commercialize our products, including ANX-530, we will have to acquire or develop sales, marketing and distribution capabilities, or rely on marketing partners or other arrangements with third parties for the marketing, distribution and sale of our 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 and associated regulatory compliance 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 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.

Risks Related to Our Intellectual Property

Our success will depend on patents and other protection we and our licensors obtain on our product candidates and proprietary technology.

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 products;
- maintain our licenses;
- prevent third parties from infringing upon our proprietary rights;

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.

Table of Contents

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 or by us. In addition, we cannot be certain that 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.

Furthermore, 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 listed in any patent or patent application owned by 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.

We may also rely on unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants, collaborators 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.

Exclusivity for CoFactor and our emulsion-formulation product candidates may be limited because of the nature of patent protection available for these candidates.

While the patent applications covering CoFactor and our emulsion-formulation product candidates, including ANX-530 and ANX-514, include product claims, they cover only specific formulations of the underlying chemical entity, or active pharmaceutical ingredient, and not the active pharmaceutical ingredient, or API, itself. Such product claims are not as strong as claims covering new APIs, which are widely viewed as the strongest form of intellectual property protection for pharmaceutical products, as they apply without regard to how the API is formulated or the method in which the API is used. A competitor may modify our formulations and obtain regulatory approval for products with the same API as our products. Such competitive products may not infringe the patents we hold covering our specific formulations of the API.

In addition, the basic patents pertaining to CoFactor that we licensed from the University of Southern California, or USC, issued only in the U.S. and Canada. Additional patents pertaining to CoFactor are pending outside the U.S. and Canada, but they include only method claims; that is, methods of using CoFactor for the treatment of cancer in combination with other cancer therapies. This type of patent protection is limited, since it cannot be used to prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, physicians may prescribe a competitive product that is identical to ours for off-label indications that are covered by our patents. Although such off-label prescriptions may infringe or contribute to the infringement of method claims, the practice is common and such infringement is difficult to prevent or prosecute.

We have licensed several of our product candidates from third parties and, if we default on any of our obligations, we could lose rights to our product candidates.

We have licensed rights to our product candidates that are important to our business, and we expect to enter into similar licenses in the future. For instance, the license agreement pursuant to which we license CoFactor and the license agreement pursuant to which we license ANX-201 permit the licensor, USC, to terminate the agreement under certain circumstances, such as our failure to use our reasonable (for CoFactor) or diligent (for ANX-201) efforts to commercialize the licensed technology or the occurrence of any other uncured breach by us. In addition, in January 2006, we further amended the license agreement pursuant to which we license ANX-201 such that, among other things, we became subject to certain development milestone obligations that, if not achieved, provide USC a 30-day right to terminate the underlying license. 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.

Table of Contents

In October 2007, we announced results of our Phase 2b clinical trial of CoFactor for the treatment of metastatic colorectal cancer, which demonstrated that the CoFactor/5-FU arm did not demonstrate statistically significant improved safety in the trial s primary endpoint. In November 2007, we announced that we will discontinue enrolling patients in our Phase 3 clinical trial of CoFactor for the first-line treatment of metastatic colorectal cancer. In light of these events, there is no guarantee that we will be viewed by USC to be using reasonable (for CoFactor) or diligent (for ANX-201) efforts to commercialize the technology licensed from USC, which could lead USC to seek to terminate the related license agreement.

The United States government and USC retain certain rights in the technologies we have licensed from USC.

The technologies developed by USC were developed in part through funding provided by the U.S. government. Therefore, in addition to USC s termination rights described above, our licenses are subject to a non-exclusive, non-transferable, royalty-free right of the U.S. government and USC 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 that 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, USC 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 and product candidates 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 USC 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 or product candidates 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 USC licenses, which could materially harm our financial condition and operating results.

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 and the ability of our future collaborators to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our future collaborators are or may be developing products. As the biotechnology and pharmaceutical industry expands and more patents are issued, the risk increases that our products and product candidates may give rise to claims that our products or product candidates infringe the rights of others. Because patent applications can take many years to publish and issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our products, product candidates or technologies infringe.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our products, product candidates and/or technologies infringe their intellectual property rights. If one of these patents was found to cover our products, product candidates, technologies or their uses, we or our future collaborators could be required to pay damages and could be unable to commercialize our products or use our technologies or methods unless we or they are able to obtain a license to the patent or intellectual property right. A license may not be available to us or our future collaborators on acceptable terms, if at all. In addition, during litigation, a patent holder could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using or selling our products, technologies or methods.

In connection with any NDA that we file under Section 505(b)(2) of the FDCA, we may be required to notify third parties that we have certified to the FDA that any patents listed for the approved drug in the FDA s Orange Book publication are invalid or will not be infringed by the manufacture, use or sale of our drug. If the third-party files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our Section 505(b)(2) NDA until, subject to certain adjustments, the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to us. Accordingly, we may invest significant time and expense in the development of our product candidates, including ANX-530 and ANX-514, only to be subject to significant delay and patent litigation before our products may be commercialized.

Table of Contents

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert our management s attention from our core business;
- substantial damages for infringement, including treble damages and attorneys fees, which we may have to pay if a court decides that the product at issue infringes on or violates the third party s rights;
- a court prohibiting us from selling or licensing the product unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross-licenses to our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial funds and time.

No assurance can be given that patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering our products, technology or methods. Because of the number of patents issued and patent applications filed in our field, we believe there is a risk that third parties may allege they have patent rights encompassing our products, technology or methods.

In addition, it may be necessary for us to enforce patents under 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.

RISKS RELATED TO OUR INDUSTRY

We expect intense competition in the marketplace for all of our product candidates.

The industry in which we operate is highly competitive and rapidly changing. If successfully developed and approved, all of our product candidates will likely compete with 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. Our emulsion products, particularly ANX-530 and ANX-514, will compete against Navelbine and Taxotere, respectively, the already-approved drugs on which we would rely on the FDA s findings, as well as generic versions of Navelbine and Taxotere. CoFactor 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 our product candidates have significantly greater financial, technical and human resources and are better equipped to develop, manufacture, market and distribute products. Many of these companies have extensive experience in preclinical testing and clinical trials, obtaining FDA and other regulatory approvals and manufacturing and marketing products and have products that have been approved or are in late-stage development and operate large, well-funded research and development programs.

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.

Table of Contents

We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent our products commercial success.

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. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely effect:

our ability to set a price we believe is fair for our products;

our ability to generate revenues or achieve or maintain profitability;

the future revenues and profitability of our potential customers, suppliers and collaborators; and

the availability to us of capital.

If we are successful in getting FDA approval for ANX-530, we will compete with Navelbine and several generic versions of Navelbine. Our ability to commercialize ANX-530 will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate coverage and reimbursement levels for the cost of our products and related treatments. These payors are increasingly attempting to contain healthcare 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 healthcare providers.

There have been federal and state proposals to subject the pricing of healthcare goods and services, including prescription drugs, to government control and to make other changes to the U.S. healthcare 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. While we cannot predict the full outcome of the implementation of this legislation, it is possible that the new Medicare prescription drug benefit, which will be managed by private health insurers and other managed care organizations, will result in additional government reimbursement for prescription drugs, which may make some prescription drugs more affordable but may further exacerbate industry-wide pressure to reduce prescription drug prices. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain if future legislative proposals, whether domestic or abroad, will be adopted that might affect the product candidates in our programs or what actions federal, state, or private payors for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Any such healthcare reforms could have a material and adverse effect on the marketability of any products for which we ultimately receive FDA or other regulatory agency approval.

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. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. 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;

Table of Contents

substantial monetary awards to patients or other claimants;

loss of revenues; and

the inability to commercialize our products and product candidates.

We maintain limited product liability insurance for our clinical trials, but our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval of any of our product candidates, but we may be unable to obtain product liability insurance on commercially acceptable terms or may not be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect us against potential losses. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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, as well as disclosure requirements related to executive and director compensation, 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 continue to 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.

RISKS RELATED TO OUR COMMON STOCK

Our common stock may be delisted from AMEX if we fail to maintain compliance with continued listing criteria.

AMEX will normally consider suspending dealings in, or removing from the list, in the case of common stock selling for a substantial period of time at a low price per share if the issuer fails to effect a reverse split of such stock within a reasonable time after being notified that AMEX deems such action to be appropriate under the circumstances. While AMEX does not provide bright line minimum share price standards for continued listing, we believe that a price less than $1.00 per share for over 30 days will be investigated. On October 1, 2007, the closing price of a share of our common stock, as reported on AMEX, was $0.55 and, through November 1, 2007, it has closed at less than $1.00.

If we are unable to comply with AMEX s continued listing requirements, our common stock may be suspended from trading on and/or delisted from AMEX. The delisting of our common stock from AMEX may materially impair our stockholders ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. In addition, the delisting of our common stock could significantly impair our ability to raise capital.

The market price of our common stock has been and is likely to continue to be highly volatile.

On October 1, 2007, the market price for our common stock dropped almost 80% following our announcement of the results of our Phase 2b clinical trial of CoFactor for the treatment of metastatic colorectal cancer. In addition, the

market price for our common stock has historically been highly volatile, and the market for our common stock has from time to time experienced significant price

Table of Contents

and volume fluctuations that are unrelated to our operating performance. The market price of our common stock may fluctuate significantly in response to a number of factors, including:

- changes in the regulatory status of our product candidates, including results of our clinical trials and other research and development programs;
- FDA or international regulatory actions and regulatory developments in the U.S. and foreign countries;
- announcements of new products or technologies, commercial relationships or other events (including clinical trial results and regulatory events and actions) by us or our competitors;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors;
- developments concerning intellectual property rights generally or those of us or our competitors;
- litigation or public concern about the safety of our products or product candidates;
- changes in securities analysts estimates of our financial performance or deviations in our business and the trading price of our common stock from the estimates of securities analysts;
- events affecting our existing in-license agreements and any future collaborations, commercial agreements and grants;
- fluctuations in stock market prices and trading volumes of similar companies;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders or pursuant to effective shelf registration statements that register shares of our common stock that may be sold by certain of our current stockholders;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- additions or departures of key personnel; and
- changes in third party reimbursement policies.

As evidenced by the October 1, 2007 decline, the realization of any of the foregoing could have a dramatic and adverse impact on the market price of our common stock. In addition, 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.

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, us or 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 shelf and resale registration statements to register shares of our common stock that may be sold by us or certain of our stockholders, which may increase the likelihood of sales by, or the perception of an increased likelihood of sales by, us or 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 our board of directors or for proposing matters that can be acted upon at stockholders meetings. Delaware law also prohibits

Table of Contents

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 each of our president/chief medical officer and chief financial officer that, among other things, in the event of our acquisition, 50% of any unvested portion of an option we granted to them 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 or our chief financial officer following an acquisition, it may be required to provide additional incentives to each 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 may benefit 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.

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, in aggregate, beneficially own approximately 19% of our outstanding common stock as of November 1, 2007. These persons, if acting together, will be able to exercise significant influence over all matters requiring stockholders 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. Further, the interests of significant stockholders may be different than yours and they may support transactions that you feel are not in your best interest. 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

None.

Item 3. Defaults Upon Senior Securities

None.

35

Table of Contents

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

None.

Item 5. Other Information

None.

Item 6. Exhibits.

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

Table of Contents

Signatures

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

ADVENTRX Pharmaceuticals, Inc.

Date: November 7, 2007

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

Date: November 7, 2007

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

Table of Contents

Exhibit Index

Exhibit	Description
31.1	Certification of chief executive officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2	Certification of chief financial officer pursuant to Rule 13a-14(a)/15d-14(a)
32.1*	Certification of chief executive officer and chief financial officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.