

ADVENTRX PHARMACEUTICALS INC

Form 10-Q/A

March 20, 2006

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**FORM 10-Q/A  
(Amendment No. 1)  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**(Mark One)**

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

**For the quarterly period ended September 30, 2005**

**OR**

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

**For the Transition Period from**

**to**

**Commission File Number 001-32157**

**ADVENTRX Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or  
organization)

**84-1318182**

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

**6725 Mesa Ridge Road, Suite 100**

**San Diego, California 92121**

**858-552-0866**

(Address of principal executive offices, zip code and telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12-b-2 of the Exchange Act): Yes  No

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

The number of shares outstanding of the registrant's common stock, \$.001 par value, as of November 9, 2005 was 67,142,447.

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**Explanatory Note**

ADVENTRX Pharmaceuticals, Inc. (the Company or we ) is filing this amendment to amend Part I, Items 1 and 2 to (1) restate our financial statements and notes thereto to correct the accounting treatment under EITF 00-19,

Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock ( EITF 00-19 ), of an equity financing we closed in July 2005; (2) amend certain portions of the sections titled Overview and

Results of Operations under Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations, that did not adequately disclose the effect of the July 2005 financing in light of EITF 00-19; and

(3) add two new risk factors to the section titled Risk Factors under Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations.

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**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**  
**FORM 10-Q QUARTERLY REPORT**  
**For the Period Ended September 30, 2005**  
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**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements****ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets

	<b>September 30, 2005 (unaudited) (restated)</b>	<b>December 31, 2004</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 18,506,914	\$ 13,032,263
Accrued interest income	9,365	10,808
Prepaid expenses	537,400	115,144
Short-term investments	7,007,637	
Other current assets	88,755	
Assets available for sale		108,000
Total current assets	26,150,071	13,266,215
Property and equipment, net	348,142	285,304
Other assets	58,386	57,268
Total assets	\$ 26,556,599	\$ 13,608,787
<b>Liabilities and Shareholders Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 417,309	\$ 532,327
Accrued liabilities	1,088,272	628,754
Accrued salary and related taxes	186,804	57,315
Warrant liability	30,891,817	
Total current liabilities	32,584,202	1,218,396
Long-term liabilities	62,429	
Total liabilities	32,646,631	1,218,396
Commitments and contingencies		
Temporary equity:		
Common stock subject to continuing registration, \$.001 par value; 10,810,809 shares issued and outstanding		
Shareholders equity (deficit):		
Common stock, \$.001 par value. Authorized 100,000,000 shares; issued 56,335,489 shares in 2005 and 53,834,237 shares in 2004	67,147	53,835
Additional paid-in capital	51,691,743	47,553,497
Accumulated other comprehensive loss	(1,625)	
Deficit accumulated during the development stage	(57,812,550)	(35,182,194)
Treasury stock, 23,165 shares at cost	(34,747)	(34,747)

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Total shareholders' equity (deficit)	(6,090,032)	12,390,391
Total liabilities and shareholders' equity (deficit)	\$ 26,556,599	\$ 13,608,787

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Three months ended</b>		<b>Nine months ended</b>		<b>Inception</b>
	<b>September 30,</b>		<b>September 30,</b>		<b>(June 12,</b>
	<b>2005</b>	<b>2004</b>	<b>2005</b>	<b>2004</b>	<b>1996)</b>
	<b>(restated)</b>		<b>(restated)</b>		<b>through</b>
					<b>September</b>
					<b>30,</b>
					<b>2005</b>
					<b>(restated)</b>
Net sales	\$	\$	\$	\$	\$ 174,830
Cost of goods sold					51,094
Gross margin					123,736
Grant revenue					129,733
Interest income	159,373	28,055	261,292	44,742	463,570
	159,373	28,055	261,292	44,742	717,039
Operating expenses:					
Research and development	1,720,257	983,665	5,661,663	2,053,131	13,135,917
General and administrative	1,887,260	1,155,716	4,161,171	2,315,936	16,594,468
Depreciation and amortization	34,331	12,481	96,422	19,199	10,236,438
Impairment loss write off of goodwill					5,702,130
Interest expense					179,090
Equity in loss of investee					178,936
Total operating expenses	3,641,848	2,151,862	9,919,256	4,388,266	46,026,979
Loss from operations	(3,482,475)	(2,123,807)	(9,657,964)	(4,343,524)	(45,309,940)
Loss on fair value of warrants	(12,972,392)		(12,972,392)		(12,972,392)
Loss before cumulative effect of change in accounting principle	(16,454,867)	(2,123,807)	(22,630,356)	(4,343,524)	(58,282,332)
Cumulative effect of change in accounting principle					(25,821)
Net loss	(16,454,867)	(2,123,807)	(22,630,356)	(4,343,524)	(58,308,153)
Preferred stock dividends					(621,240)

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Net loss applicable to common stock	\$ (16,454,867)	\$ (2,123,807)	\$ (22,630,356)	\$ (4,343,524)	\$ (58,929,393)
Loss per common share - basic and diluted	\$ (.26)	\$ (.04)	\$ (.39)	\$ (.09)	
Weighted average number of common shares outstanding - basic and diluted	63,255,407	53,811,072	57,346,039	49,715,980	

See accompanying notes to unaudited condensed consolidated financial statements.



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**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**  
(A Development Stage Enterprise)  
Condensed Consolidated Statements of Shareholders' Equity (Deficit)  
Inception (June 12, 1996) through June 30, 2005

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

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

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

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

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**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Condensed Consolidated Statements of Shareholders' Equity (Deficit)

Inception (June 12, 1996) through June 30, 2005

CONTINUED FROM PREVIOUS PAGE

	Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock		Deficit Accumulated			Total Shareholders' equity (deficit)	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional paid-in capital	other comprehensive loss	during the development stage		Treasurer's stock, at cost
Dividends payable on preferred stock													
Purchase of warrants													
Exercise of warrants							240,000	240		117,613			117,8
Exercise of warrants							100,201	100		(100)			
Exercise of warrants							344,573	345		168,477			168,8
Exercise of warrants			200,000	2,000						298,000			300,0
Exercise of warrants							70,109	701		700,392			701,0
Conversion of preferred stock into common stock	(3,000)	(30)					1,800,000	1,800		(1,770)			
Dividends given										335,440			335,4
Expense of warrants to operating expenses										163,109			163,1
Expense of common stock pay operating							6,292	6		12,263			12,2

expenses												
balance of												
deferred												
stock to pay												
operating												
expenses	136	1							6,000			6,000
balance of												
stock options												
employees									329,296			329,296
net loss										(2,105,727)		(2,105,727)
balances at												
December 31,												
2012	473	4	200,000	2,000	70,109	701	17,496,257	17,496	25,276,138	(26,149,069)		(852,727)
dividends												
payable on												
deferred												
stock									(37,840)			(37,840)
conversion of												
Series C												
deferred												
stock into												
common stock					(70,109)	(701)	14,021,860	14,022	(13,321)			
balance of												
common stock												
pay interest												
Bridge												
notes							165,830	165	53,326			53,491
balance of												
common stock												
\$0.40 per												
share, net of												
balance costs							6,640,737	6,676	2,590,656			2,597,333
balance of												
common stock												
\$1.00 per												
share, net of												
balance costs							3,701,733	3,668	3,989,181			3,992,849
change of												
grants							235,291	235	49,486			49,721
balance of												
common stock												
pay												
operating												
expenses							230,000	230	206,569			206,799
balance of												
grants to												
operating												
expenses									156,735			156,735
balance of									286,033			286,033
stock options												

employees			
loss		(2,332,077)	(2,332,077)

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	Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock		Additional paid-in capital	Deficit Accumulated			Treasury Stock, at cost	Shares
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount		Other Comprehensive Loss	development stage			
at 31, 2003	473	4	200,000	2,000	42,491,708	42,492	32,556,963				(28,481,146)			
ment of payable on stock							72,800							
n of cumulative stock	(473)	(4)			236,500	236	(232)							
n of preferred			(200,000)	(2,000)	200,000	200	1,800							
xercise of					464,573	465	(465)							
f warrants					23,832	23	27,330							
f warrants														
ent of a								86,375						
mmon .50 per					10,417,624	10,419	15,616,031							
f financing								(1,366,774)						
g costs														
f stock								524,922						
employees														
n of stock								34,747				(34,747)		
											(6,701,048)			
at 31, 2004					53,834,237	53,835	47,553,497				(35,182,194)	(34,747)		
nsive											(22,630,356)			
change in of or sale											(1,625)			
prehensive														



of shares in conjunction with the exercise of									
of warrants			10,810,809	10,811	(10,811)				
of stock			2,376,252	2,376	3,060,486				
of stock					757,133				
of stock to					73,063				
			125,000	125	258,375				
at March 31, 2005 (restated)	\$	\$	\$ 67,146,398	\$ 67,147	\$ 51,691,743	\$ (1,625)	\$ (57,812,550)	\$ (34,747)	\$ (

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine months ended September 30,		Inception (June 12, 1996) through September 30, 2005 (restated)
	2005 (restated)	2004	
Cash flows from operating activities:			
Net loss	\$ (22,630,356)	\$ (4,343,524)	\$ (58,308,153)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	96,422	19,199	9,786,438
Fair value of warrant liability	12,972,392		12,972,392
Amortization of debt discount			450,000
Forgiveness of employee receivable			30,036
Impairment loss write-off of goodwill			5,702,130
Expenses paid by warrants		86,375	573,357
Expenses paid by preferred stock			142,501
Expenses related to stock warrants issued			612,000
Expenses related to employee stock options issued	757,133	412,271	1,897,383
Expense related to stock options issued to non-employee	73,063		73,063
Expenses paid by issuance of common stock	82,250		1,076,048
Equity in loss of investee			178,936
Write-off of license agreement			152,866
Write-off of assets available for sale	108,000		108,000
Cumulative effect of change in accounting principle			25,821
Changes in assets and liabilities, net of effect of acquisitions:			
(Increase) decrease in prepaid and other assets	(334,436)	(257,174)	(941,273)
Increase (decrease) in accounts payable and accrued liabilities	473,989	603,435	1,171,114
Increase (decrease) in other long-term liabilities	62,429		62,429
Increase in sponsored research payable and license obligation			924,318
Net cash used in operating activities	(8,339,114)	(3,479,418)	(23,310,594)
Cash flows from investing activities:			
Purchase of certificate of deposit			(1,016,330)
Maturity of certificate of deposit			1,016,330
Purchases of property and equipment	(159,260)	(289,884)	(587,502)
Purchases of short-term investments	(7,009,262)		(7,009,262)

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Payment on obligation under license agreement			(106,250)
Cash acquired in acquisition of subsidiary			64,233
Issuance of note receivable related party			(35,000)
Payments on note receivable			405,993
Advance to investee			(90,475)
Cash transferred in rescission of acquisition			(19,475)
Cash received in rescission of acquisition			230,000
Net cash used in investing activities	(7,168,522)	(289,884)	(7,147,738)
Cash flows from financing activities:			
Proceeds from sale of preferred stock			4,200,993
Proceeds from sale of common stock	19,999,997	15,626,450	44,152,593
Proceeds from sale or exercise of warrants	3,062,862	27,353	3,474,452
Repurchase of warrants			(55,279)
Payment of financing and offering costs	(2,080,572)	(1,354,541)	(3,546,322)
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	20,982,287	14,299,262	48,965,246
Net increase in cash and cash equivalents	5,474,651	10,529,960	18,506,914
Cash and cash equivalents at beginning of period	13,032,263	4,226,397	
Cash and cash equivalents at end of period	\$ 18,506,914	\$ 14,756,357	\$ 18,506,914

See accompanying notes to unaudited condensed consolidated financial statements.

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

**1. Description of the Company**

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation, (the Company), is a biopharmaceutical research and development company focused on introducing new technologies for anticancer and antiviral treatments that improve the performance and safety of existing drugs by addressing significant problems such as drug metabolism, toxicity, bioavailability and resistance. The Company currently does not manufacture, market, sell or distribute any products. Pursuant to license agreements with University of Southern California National Institutes of Health and SD Pharmaceuticals, Inc. the Company has rights to drug candidates in varying stages of development.

On May 30, 2003, the Company merged its wholly owned subsidiary, Biokeys, Inc., into itself and changed the name of the Company from Biokeys Pharmaceuticals, Inc. to ADVENTRX Pharmaceuticals, Inc. The merger had no effect on the financial statements of the Company.

In July 2004, the Company formed a wholly owned subsidiary, ADVENTRX (Europe) Ltd., in the United Kingdom for the purpose of conducting drug trials in the European Union.

**2. Unaudited interim financial statements**

In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, necessary to present fairly the financial position of the Company as of September 30, 2005 and its results of operations and cash flows for the three and/or nine months ended September 30, 2005 and 2004 and for the period from inception (June 12, 1996) through September 30, 2005.

Information included in the consolidated balance sheet as of December 31, 2004 has been derived from the audited consolidated financial statements of the Company as of December 31, 2004 (the Audited Financial Statements ) included in the Company's Annual Report on Form 10-KSB (the 10-KSB ) for the year ended December 31, 2004 that was previously filed with the Securities and Exchange Commission (the SEC ). Pursuant to the rules and regulations of the SEC, certain information and disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted from these financial statements unless significant changes have taken place since the end of the most recent fiscal year.

Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the Audited Financial Statements and the other information also included in the 10-KSB.

The results of the Company's operations for the nine months ended September 30, 2005 are not necessarily indicative of the results of operations for the full year ending December 31, 2005.

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

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Noncash investing and financing transactions excluded from the condensed statements of cash flows for the nine months ended September 30, 2005 and 2004 and for the period from inception (June 12, 1996) through September 30, 2005 are as follows:

	Nine months ended September 30,		Inception (June 12, 1996) through September 30, 2005
	2005	2004	
Issuance of warrants, common stock and preferred stock for:			
Conversion of notes payable and accrued interest	\$	\$	\$ 1,213,988
Payment of operating expenses	258,500		1,482,781
Conversion of preferred stock		2,000	2,705
Acquisitions			14,617,603
Payment of dividends			213,000
Financial advisor services in conjunction with private placement		1,137,456	1,137,456
Settlement of claim			86,375
Acquisition of treasury stock in settlement of a claim			34,747
Assumptions of liabilities in acquisitions			1,009,567
Acquisition of license agreement for long-term debt			161,180
Cashless exercise of warrants	130	465	3,872
Dividends accrued			621,040
Trade asset converted to available for sale asset			108,000
Dividends extinguished		72,800	408,240
Trade payable converted to note payable			83,948
Issuance of warrants for return of common stock			50,852
Detachable warrants issued with notes payable			450,000
Unrealized loss on short-term investments	1,625		1,625

**3. Net Loss Per Common Share**

Net loss per common share is calculated according to Statement of Financial Accounting Standards No. 128, Earnings per Share, using the weighted average number of shares of common stock outstanding during the period.

The following potentially dilutive shares were not included in the computation of net loss per common share diluted, as their effect would have been antidilutive due to the Company's net losses as of September 30, 2005 and 2004:

	September 30, 2005	September 30, 2004
Warrants	19,668,012	11,154,964
Options	2,742,000	3,456,000
Total	22,410,012	14,610,964

**Table of Contents****4. Stock Compensation Plans**

On May 24, 2005, at the Company's annual meeting of stockholders, the Company's stockholders approved the 2005 Equity Incentive Plan (the "2005 Plan") and the 2005 Employee Stock Purchase Plan. The 2005 Plan is intended to encourage ownership of shares of common stock by directors, officers, employees, consultants and advisors of the Company and its affiliates and to provide additional incentive for them to promote the success of the Company's business through the grant of equity-based awards. The 2005 Plan permits the Company to issue options, share appreciation rights, restricted shares, restricted share units, performance awards, annual incentive awards and other share-based awards and cash-based awards. The maximum aggregate number of shares of common stock which may be issued pursuant to or subject to the foregoing types of awards granted under the 2005 Plan currently is 8,000,000. This maximum number is subject to an annual increase beginning on January 1, 2006 equal to the lesser of (i) one percent of the number of outstanding shares of common stock on such day, (ii) 750,000 and (iii) such other amount as the Company's board of directors may specify. The 2005 Plan is intended to comply with applicable securities law requirements, permit performance-based awards that qualify for deductibility under Section 162(m) of the Internal Revenue Code and allow for the issuance of incentive stock options.

The Company applies Statement of Financial Accounting Standards No. 123 (revised) and related interpretations in accounting for employee stock-based compensation.

In July 2005, the Company granted 1,625,000 options to employees under the 2005 Plan under pre-existing option agreements. In addition in July 2005, the Company granted 1,103,000 new options to employees under the 2005 Plan. For purposes of Black-Scholes pricing model the following assumptions were used to estimate a fair value for these option grants: no dividend yield, expected volatility 81% to 90%, risk-free interest rates 3.30% to 4.74% and expected lives of 3 to 5 years. The Company cancelled 100,000 options in the nine months ended September 30, 2005 related to terminated employees.

In July 2005, the Company granted 114,000 options to consultants. These option grants were valued as of September 30, 2005 using the Black-Scholes pricing model with the following assumptions: no dividend yield, expected volatility of 90%, risk-free interest rate 4% and expected life of 3 or 5 years. The Company recognized \$73,063 in compensation expense for these options in the three and nine months ended September 30, 2005.

The Company recognized compensation expense of \$526,973 and \$230,971 in the three months ended September 30, 2005 and 2004, respectively, and \$757,132 and \$412,271 in the nine months ended September 30, 2005 and 2004, respectively, related to the portion of employee stock options which vested in those periods.

**5. Financing Activities**

On July 21, 2005, the Company entered into a Securities Purchase Agreement with Icahn Partners LP, Icahn Partners Master Fund LP, High River Limited Partnership, Viking Global Equities LP, VGE III Portfolio Ltd., North Sound Legacy Institutional Fund LLC, North Sound Legacy International Ltd. and the Royal Bank of Canada for the sale of 10,810,809 shares of Common Stock at a purchase price of \$1.85 per share for aggregate gross proceeds of \$19,999,996.65, and the issuance of 7-year warrants to purchase 10,810,809 shares of Common Stock at an exercise price of \$2.26 per share. The Company received net proceeds of \$18,116,751 as of July 21, 2005. The private placement consisted of accredited institutional investors.

Pursuant to the terms of the Securities Purchase Agreement entered into in connection with the transaction, 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 the Company is (A) not filed with the SEC on or before forty-five (45) days after the Closing Date (a "Filing Failure") or (B) if such Registration Statement is not declared effective by the SEC on or before (1) ninety (90) days after the Closing Date (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 this Agreement) pursuant to such Registration Statement (including, without limitation, because of a failure to keep such Registration Statement effective, to disclose such information as is necessary for sales to be made pursuant to such Registration Statement or to register sufficient shares of Shares) (a "Maintenance Failure"), then, the Company shall pay as liquidated damages

(the Liquidated Damages ) for such failure and not as a penalty to any Purchaser an amount in cash determined in accordance with the formula set forth below:

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

Payments to be made pursuant to this Agreement shall be due and payable to the Purchasers at the end of each calendar month during which Liquidated Damages shall have accrued. No Liquidated Damages shall be due or payable to a Purchaser in any event if as of the date of the Filing Failure, Effectiveness Failure or Maintenance Failure such Purchaser could sell all of the Registrable Shares such Purchaser then holds without registration by reason of Rule 144(k) of the Securities Act.

The registration statement was filed and declared effective by the SEC within the allowed time. The Company has not yet been required to pay any liquidated damages in connection with the filing or effectiveness of the registration. In accordance with Emerging Issues Task Force (EITF) Issue No. 00-19, Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company's Own Stock, the terms of the warrants and the transaction documents, the fair value of the warrants was accounted for as a liability, with an offsetting reduction to additional paid-in capital at the closing date (July 21, 2005). At the end of each reporting period, the value of the warrants will be remeasured based on the fair market value of the underlying shares, and changes to the warrant liability and related gain or loss will be made appropriately. The warrant liability will be reclassified to equity when the registration statement is no longer subject to risk for Maintenance Failures.

The fair value of the warrants was estimated using the Black-Scholes option-pricing model with the following assumptions: no dividends; risk-free (10-year Treasury yield) interest rate of 4.39%; the contractual life of 7 years and volatility of 90%. The fair value of the warrants was estimated to be \$19,439,185 on the closing date of the transaction. The difference between the fair value of the warrants of \$19,439,185 and the gross proceeds from the offering was classified as Loss on fair value of warrants in the Company's statement of operations, and included in

Warrant liability on the Company's balance sheet. The fair value of the warrants was then re-measured at September 30, 2005 and estimated to be \$30,891,817 with the increase in fair value due to the increase in the market value of the Company's common stock. The increase in fair value of the warrants of \$11,452,632 from the transaction date to September 30, 2005 was recorded as Loss on fair value of warrants in the Company's statement of operations, and included in Warrant liability on the Company's balance sheet.

The Company paid the placement agents \$1,600,000 in cash as fees for services performed in conjunction with the private placement. The Company also incurred \$283,246 in other legal and accounting fees.

The adjustments required by EITF Issue No. 00-19 were triggered by the terms of the Company's agreements for the private placement it completed in July 2005, specifically related to the potential penalties if the Company did not timely register the common stock underlying the warrants issued in the transaction, and remain effective during the registration period. The adjustments for EITF Issue No. 00-19 had no impact on the Company's cash flow, or day to day business operations.

The Company intends to utilize the net proceeds of \$18,313,751 to fund pivotal clinical trials for its various compounds, and meet working capital needs through December 31, 2005.

## **6. Equity Transactions**

In the nine months ended September 30, 2005, the Company's warrant holders exercised warrants for an aggregate of 2,376,253 shares of common stock, with proceeds to the Company of \$3,062,863.

On April 14, 2005, the Company issued 25,000 shares of common stock as partial payment for services rendered by a consulting firm. Those shares were recognized at fair market value as of the date of obligation and resulted in compensation expense of \$23,500 in the first quarter of 2005, when the services were performed.

On July 13, 2005, the Company issued 100,000 shares of common stock pursuant to a consulting agreement entered into in January 2005. Those shares were recognized at fair market value as of the date of issuance and resulted in compensation expense of \$58,750 in the third quarter of 2005.

On July 28, 2005 the Company issued 10,810,809 shares in conjunction with a private placement which resulted in net proceeds of \$17,919,425. The Company also issued warrants to purchase 10,810,809 shares of common stock with this placement.

## 7. Commitments and Contingencies

### *Litigation*

In the normal course of business, the Company may become subject to lawsuits and other claims and proceedings. Such matters are subject to uncertainty and outcomes are often not predictable with assurance. Management is not aware of any pending or threatened lawsuit or proceeding that would have a material adverse effect on the Company's financial position, results of operations or cash flows. Notwithstanding the foregoing, in March 2005, the Company received a letter from counsel to a former executive in which the former executive claimed that the Company constructively terminated him, discriminated against him on the basis of age and committed various torts against him. No settlement demand was specifically made by the former executive in this letter and the letter otherwise did not state any specific monetary damages that this former executive had purportedly sustained. The Company believes that these claims lack merit. In October 2005, the Company executed a binding settlement memorandum with this former executive to settle this dispute and currently expects to execute a fully-negotiated settlement agreement and release of claims in November 2005. In consideration of this settlement, the Company agreed to pay this former executive \$180,000 and the parties agreed to execute a mutual release of claims. This settlement has been accrued for at September 30, 2005 and is included in accrued liabilities.

## 8. Restatement

On March 15, 2006, the management of the Company determined that an interpretation of EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock would affect our accounting treatment of an equity financing that we consummated on July 27, 2005 and determined, after consultation with the independent registered public accounting firm J.H. Cohn LLP, which is the auditor of our financial statements, that we would restate our financial statements for the quarter ended September 30, 2005 included in our Quarterly Report on Form 10-Q.

The restated condensed consolidated financial statements accompanying these notes reflect the effects of change in accounting treatment of an equity financing that we consummated on July 27, 2005. These financial statements will be part of a Form 10-Q/A to amend our previously filed Form 10-Q for the period ended September 30, 2005 to reflect the following changes:

<b>Financial statement and associated account</b>	<b>Form 10-Q</b>	<b>Form 10-Q/A</b>
Condensed Consolidated Balance Sheets		
Warrant liability	\$ 0	\$ 30,891,817
Total liabilities	\$ 1,692,385	\$ 32,584,202
Additional paid in capital	\$ 69,611,168	\$ 51,691,743
Deficit accumulated during development stage	\$ 44,840,158	\$ 57,812,550
Total shareholders' equity (deficit)	\$ 24,801,785	\$ (6,090,032)
Condensed Consolidated Statements of Operations		
Increase in fair value of warrants	\$ 0	\$ 12,972,372
Net loss	\$ (3,482,475)	\$ (16,454,867)
Loss per common share	\$ (0.06)	\$ (0.41)
Condensed Consolidated Statements of Cash Flows		



Fair value of warrant liability		\$	0	\$ 12,972,392
	12			

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

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

#### **Forward Looking Statements**

*This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which include, without limitation, statements about the market for our technology, our strategy, competition, expected financial performance and other aspects of our business identified in this Quarterly Report, as well as other reports that we file from time to time with the Securities and Exchange Commission. Any statements about our business, financial results, financial condition and operations contained in this Quarterly Report that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words believes, anticipates, expects, intends, projects, or similar expressions are intended to identify forward-looking statements. Our actual results could differ materially from those expressed or implied by these forward-looking statements as a result of various factors, including the risk factors described under the heading Risk Factors and elsewhere in this report. We undertake no obligation to update publicly any forward-looking statements for any reason, except as required by law, even as new information becomes available or other events occur in the future.*

#### **Overview**

We are a biopharmaceutical research and development company focused on introducing new technologies for anticancer and antiviral treatments that improve the performance and safety of existing drugs by addressing significant problems such as drug metabolism, toxicity, bioavailability and resistance. We do not manufacture, market, sell or distribute any product. Pursuant to license agreements with University of Southern California, the National Institutes of Health and SD Pharmaceuticals, Inc., we have rights to drug candidates in varying stages of development. Our current drug candidates are CoFactor, ANX-530, Selone, Thiovir and BlockAide/CR. All of these drug candidates, other than ANX-530, are described in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004. ANX-530 is a novel emulsion formulation of vinorelbine tartrate. Vinorelbine is currently used as a monotherapy or in combination with other chemotherapeutic agents for the treatment of non-small-cell lung, breast, ovarian and other cancers. Severe phlebitis, an injection site reaction, is a known complication of standard vinorelbine therapy. In preclinical testing, ANX-530 demonstrated markedly reduced vein irritation following repeated intravenous injections compared with Navelbine, GlaxoSmithKline's form of vinorelbine that the US Food and Drug Administration (the FDA) has approved for marketing. We currently plan to pursue a 505(b)(2) regulatory path for ANX-530. We have initiated discussions with the FDA for the clinical trial design and are preparing for a pre-Investigational New Drug (IND) meeting with the FDA scheduled for December 2005.

On May 30, 2003, we merged our wholly-owned subsidiary, Biokeys, Inc., into the Company and changed our name from Biokeys Pharmaceuticals, Inc. to ADVENTRX Pharmaceuticals, Inc. The merger had no effect on our financial statements.

In July 2004, we formed a wholly-owned subsidiary, ADVENTRX (Europe) Ltd., in the United Kingdom for the purpose of conducting drug trials in the European Union.

We have incurred net losses since our inception. As of September 30, 2005, our accumulated deficit was approximately \$58 million. We expect to incur substantial and increasing losses for the next several years as we continue development and possible commercialization of new products.

To date, we have funded our operations primarily through sales of equity securities.

Our business is subject to significant risks, including risks inherent in our ongoing clinical trials, the regulatory approval processes, the results of our research and development efforts, commercialization, and competition from other pharmaceutical companies.

#### **Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of the consolidated financial statements requires us to make estimates and judgments that

affect the reported amounts of assets, liabilities and expenses and the related disclosure of contingent assets and liabilities. We review our estimates on an on-going basis, including those

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related to valuation of goodwill, intangibles and other long-lived assets. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the bases for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Our accounting policies are described in more detail in Note 1 to our consolidated financial statements included in our Annual Report on Form 10-KSB. We have identified the following as the most critical accounting policies and estimates used in the preparation of our consolidated financial statements.

*Stock Compensation Plans.* In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (SFAS 123R). We currently recognize our option grants and associated expenses in accordance with SFAS 123R guidance.

**Results of Operations****Three Months Ended September 30, 2005**

*Research and Development Expenses.* Total research and development expenses were \$1.7 million for the three months ended September 30, 2005 compared to \$984,000 for the comparable period in 2004, an increase of \$737,000 or 75%. The quarter to quarter increase in research and development expenses was primarily related to an increase of \$336,000 in clinical trial expenses for our Phase IIb clinical trials of CoFactor which commenced in May 2005. Other factors include an increase of \$185,000 in headcount and personnel costs due to hiring related to expansion of our clinical operations, an increase of \$149,000 in pre-clinical costs related to our drug candidates and an increase in consulting fees of \$73,000. These increases were partially offset by individually minor items.

We currently expect that our research and development expenses will significantly increase from the level of expenses in the quarter ended September 30, 2005 as we ramp up our Phase III pivotal clinical trial of CoFactor for the treatment of metastatic colorectal cancer in the United States, and continue enrolling patients in our Phase IIb clinical trial of CoFactor for the treatment of metastatic colorectal cancer in Europe. The timing of the increase in expense will be directly related to the launch of the Phase III trial, and the amount of increase will be directly related to the success and speed of patient enrollment in the Phase IIb and Phase III trials.

*General and Administrative Expenses.* General and administrative expenses were \$1.9 million for the three months ended September 30, 2005 compared to \$1.2 million for the comparable period in 2004, an increase of \$732,000 or 63%. The quarter to quarter increase in general and administrative expenses was due to a \$58,000 compensation charge resulting from the issuance of shares of common stock pursuant to a consulting agreement, a one time charge of \$204,000 to record the fair value and related expense for employee options granted in July 2005 with retroactive vesting dates, an increase in employee stock option expense of \$92,000, a \$73,000 expense for options issued to non-employees and a \$180,000 accrual for a legal settlement which was executed in October of 2005. The remainder of the fluctuation in general and administrative expenses was caused by individually minor items. We currently expect our general and administrative expenses excluding non-recurring charges to continue at current levels through the fourth quarter as we continue evaluating, testing and documenting our system of internal controls over financial reporting and preparing to comply with Section 404 of the Sarbanes-Oxley Act of 2002.

*Interest Income.* Interest income for the three months ended September 30, 2005 was \$159,000 compared to \$28,000 of net interest income for the comparable period in 2004. The increase is attributable to higher invested balances from funds received in July 2005 from our most recent financing and from the exercise of warrants during the quarter and higher interest rate yield on these balances.

*Revaluation of Warrants and Related Loss.* In accordance with Emerging Issues Task Force (EITF) Issue No. 00-19, Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company's Own Stock, the terms of the warrants and the transaction documents, the fair value of the warrants related to the July 2005 financing was accounted for as a liability of \$19,439,185, with an offsetting reduction to additional paid-in capital at the closing date of \$17,919,425 and an additional increase in fair value of warrants of \$1,519,760. At September 30, 2005, the value of the warrants was remeasured and based on the fair market value at September 30, 2005, an \$11,452,632 change to the warrant liability and related loss were made appropriately. The warrant liability will be reclassified to equity when the registration statement is no longer subject to risk for Maintenance Failures.

**Nine Months Ended September 30, 2005**

*Research and Development Expenses.* Total research and development expenses were \$5.7 million for the nine months ended September 30, 2005 compared to \$2.1 million for the comparable period in 2004, an increase of \$3.6 million or 176%. The year over year increase in research and development expenses was primarily related to an increase of \$2.6 million of clinical trial expenses for our Phase II and Phase IIb clinical trials of CoFactor, which commenced in May 2005. Other factors include an increase of \$419,000 in headcount and personnel costs and an increase of \$699,000 in preclinical costs related to our drug candidates . These increases were partially offset by individually minor items.

As stated above, we currently expect that our research and development expenses will significantly increase from the level of expenses in the nine months ended September 30, 2005 as we ramp up our Phase III pivotal clinical trial of CoFactor for the treatment of metastatic colorectal cancer in the United States, and continue enrolling patients in our Phase IIb clinical trial of CoFactor for the treatment of metastatic colorectal cancer in Europe.

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*General and Administrative Expenses.* General and administrative expenses were \$4.2 million for the nine months ended September 30, 2005 compared to \$2.3 million for the comparable period in 2004, an increase of \$1.8 million or 80%. The year over year increase in general and administrative expenses was primarily due to the following increases: \$491,000 due to the hiring of additional personnel in the finance and marketing and business development departments, \$58,000 due a compensation charge resulting from the issuance of shares of common stock pursuant to a consulting agreement, a one time charge of \$204,000 to record the fair value and related expense for employee options granted in July 2005 with retroactive vesting dates, \$141,000 in expense for employee options, \$73,000 expense for options issued to non-employees, \$217,000 in consulting expenses primarily due to SOX compliance efforts and a related systems implementation, \$180,000 due to an accrual for a legal settlement which executed in October 2005, \$150,000 in rent and facilities costs and \$103,000 in legal fees. We expect that our general and administrative expenses will maintain these levels in the fourth quarter as we continue evaluating, testing and documenting of our system of internal controls over financial reporting and preparing to comply with Section 404 of the Sarbanes-Oxley Act of 2002 .

*Interest Income.* Interest income for the nine months ended September 30, 2005 was \$262,000 compared to \$45,000 of net interest income for the comparable period in 2004. This increase is primarily due to interest earned on funds received from our latest financing which closed in July 2005 and warrants exercised during this period and higher interest rate yield on these balances.

*Revaluation of Warrants and Related Loss.* In accordance with Emerging Issues Task Force (EITF) Issue No. 00-19, Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company's Own Stock, the terms of the warrants and the transaction documents, the fair value of the warrants related to the July 2005 financing was accounted for as a liability of \$19,439,185, with an offsetting reduction to additional paid-in capital at the closing date of \$17,919,425 and an additional increase in fair value of warrants of \$1,519,760. At September 30, 2005, the value of the warrants was remeasured and based on the fair market value at September 30, 2005, an \$11,452,632 change to the warrant liability and related loss were made appropriately. The warrant liability will be reclassified to equity when the registration statement is no longer subject to risk for Maintenance Failures.

**Liquidity and Capital Resources**

As of September 30, 2005, our principal sources of liquidity were our cash and cash equivalents and short-term investments which totaled \$25.5 million as compared to \$13.0 million as of December 31, 2004. This increase is primarily due to the closing of a financing round in July 2005 which raised \$17.9 million net of issuance costs and the exercise of warrants during this period pursuant to which we received \$3.1 million. As of September 30, 2005 we held \$18.5 million in cash and \$7.0 million in short-term investments. As of September 30, 2005, our short-term investments consisted primarily of commercial paper and U.S. Govt Agencies.

Net cash used in operating activities was \$8.3 million during the nine months ended September 30, 2005, compared with \$3.5 million during the nine months ended September 30, 2004. The increase in net cash used in operating activities was due to increased funding for clinical trials, and our increased operating expenses as we added additional personnel in general and administrative functions to support our expanded research and development activities and business development activities.

Net cash used in investing activities was \$7.2 million during the nine months ended September 30, 2005 compared with \$290,000 during the nine months ended September 30, 2004. The increase in cash used for investing activities was caused primarily by the purchase of short-term investments with the proceeds of our financing round which closed in July 2005 and from the exercise of warrants during this period.

Net cash provided by financing activities was \$21 million during the nine months ended September 30, 2005 compared with net cash provided by financing activities of \$14.3 million during the nine months ended September 30, 2004. The cash flows from financing activities for the nine months ended September 30, 2005 were primarily proceeds from our sale of common stock in a private placement financing which closed in July 2005 and proceeds from the exercise of warrants. The cash flows from financing activities for the nine months ended September 30, 2004 were primarily due to the sale of common stock in a private placement financing which occurred in April 2004.

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

the timing and results of our clinical trials;

the progress of our research activities;

the number and scope of our research programs;

the progress of our preclinical development activities;

our ability to establish and maintain strategic collaborations;

the costs involved in enforcing or defending patent claims and other intellectual property rights;

the costs and timing of regulatory approvals;

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the costs of establishing or expanding manufacturing, sales and distribution capabilities;

the success of the commercialization of our products; and

the extent to which we license, acquire or invest in other products, technologies and businesses.

To date, we have funded our operations primarily through the sale of equity securities. Through September 30, 2005, we had an accumulated deficit of approximately \$58 million, with total additional paid-in capital of approximately \$52 million. The \$52 million of additional paid-in capital is comprised of \$30 million in net proceeds from the sale of equity securities, plus non-cash equity issuances for acquisitions of \$15 million, plus other non-cash equity transactions for operating expenses of \$7 million. We also closed a private placement in July 2005 which provided us with approximately \$18 million in net proceeds. As a result, we believe that our existing cash and cash equivalents as of September 30, 2005 will be sufficient to meet our projected operating requirements through December 31, 2006. We intend to finance our operations and capital expenditure needs through the sale of additional equity securities, debt financing or strategic collaboration agreements. We cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on favorable terms. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, which is not likely given our lack of operating revenue, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. In addition, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern.

### **Risk Factors**

*If any of the following risks actually occur, our business, results of operations and financial condition could suffer significantly.*

#### **We have a substantial accumulated deficit.**

We had an accumulated deficit of \$58 million as of September 30, 2005. Since we presently have no source of revenues and are committed to continuing our product research and development program, significant expenditures and losses will continue until development of new products is completed and such products have been clinically tested, approved by the FDA or other regulatory agencies and successfully marketed. In addition, we fund our operations primarily through the sale of securities, and have had limited working capital for our product development and other activities. We do not believe that debt financing from financial institutions will be available until at least the time that one of our products is approved for commercial production.

#### **We have no current product sales revenues or profits.**

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

#### **It is uncertain that we will have access to future capital.**

It is not expected that we will generate positive cash flow from operations for at least the next several years. As a result, substantial additional equity or debt financing for research and development or clinical development will be required to fund our activities. Although we have raised such equity financing in April 2004 and July 2005, we cannot be certain that we will be able to continue to obtain such financing on favorable or satisfactory terms, if at all, or that it will be sufficient to meet our cash requirements. Any additional equity financing could result in substantial dilution to stockholders, and debt financing, if available, will most likely involve restrictive covenants that preclude us from making distributions to stockholders and taking other actions beneficial to stockholders. If adequate funds are not



available, we may be required to delay or reduce the scope of our drug development program or attempt to continue development by entering into arrangements with collaborative partners or others that may require us to relinquish some or all of our rights to proprietary drugs. The inability to fund our capital requirements would have a material adverse effect on us.

**Table of Contents****We are not certain that we will be successful in the development of our drug candidates.**

The successful development of any new drug is highly uncertain and is subject to a number of significant risks. Our drug candidates, all of which are in a development stage, require significant, time-consuming and costly development, testing and regulatory clearance. This process typically takes several years and can require substantially more time. Risks include, among others, the possibility that a drug candidate will (i) be found to be ineffective or unacceptably toxic, (ii) have unacceptable side effects, (iii) fail to receive necessary regulatory clearances, (iv) not achieve broad market acceptance, (v) be subject to competition from third parties who may market equivalent or superior products, (vi) be affected by third parties holding proprietary rights that will preclude us from marketing a drug product, or (vii) not be able to be immediately manufactured by manufacturers in a timely manner in accordance with required standards of quality. There can be no assurance that the development of our drug candidates will demonstrate the efficacy and safety of our drug candidates as therapeutic drugs, or, even if demonstrated, that there will be sufficient advantages to their use over other drugs or treatments so as to render the drug product commercially viable. In the past, we have been faced with limiting the scope and/or delaying the launch of preclinical and clinical drug trials due to limited cash and personnel resources. We have also chosen to terminate licenses of some drug candidates that were not showing sufficient promise to justify continued expense and development. In the event that we are not successful in developing and commercializing one or more drug candidates, investors are likely to realize a loss of their entire investment.

We have been delayed at certain times in the past in the development of our drug products by limited funding. In addition, if certain of our scientific and technical personnel resigned at or about the same time, the development of our drug products would probably be delayed until new personnel were hired and became familiar with the development programs.

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

Success in preclinical and clinical trials does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict. In the past, we have terminated licenses of drug candidates when our preclinical trials did not support or verify earlier preclinical data. There is a significant risk that any of our drug candidates could fail to show satisfactory results in continued trials, and would not justify further development.

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

We are engaged in a segment of the pharmaceutical industry that is highly competitive and rapidly changing. If successfully developed and approved, any of our drug candidates will likely compete with several existing therapies. CoFactor, our leading drug candidate, would likely compete against a well-established product, leucovorin. In addition, there are numerous companies with a focus in oncology and/or anti-viral therapeutics that are pursuing the development of new pharmaceuticals that target the same diseases as are targeted by the drugs 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. We cannot assure 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 drugs obsolete or noncompetitive prior to our recovery of development and commercialization expenses.

Many of our competitors such as Merck and Pfizer will also have significantly greater financial, technical and human resources and will likely be better equipped to develop, manufacture and market products. In addition, many of these competitors have extensive experience in preclinical testing and clinical trials, obtaining FDA and other regulatory approvals and manufacturing and marketing pharmaceutical products. A number of these competitors also 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. Companies such as Gilead, Roche, GlaxoSmithKline all have drugs in various stages of development that could become competitors. Accordingly, competitors may succeed in commercializing products more rapidly or effectively than us, which would have a material adverse effect on us.

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**There is no assurance that our products will have market acceptance.**

Our success will depend in substantial part on the extent to which a drug product, once approved, achieves market acceptance. The degree of market acceptance will depend upon a number of factors, including (i) the receipt and scope of regulatory approvals, (ii) the establishment and demonstration in the medical community of the safety and efficacy of a drug product, (iii) the product's potential advantages over existing treatment methods and (iv) reimbursement policies of government and third party payors. 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 drug products.

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

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

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

There have been some federal and state proposals in the past to subject the pricing of health care goods and services, including prescription drugs, to government control and to make other changes to the U.S. health care system. None of the proposals seems to have affected any of the drugs in our programs. However, it is uncertain if future legislative proposals would be adopted that might affect the drugs in our programs or what actions federal, state, or private payors for health care treatment and services may take in response to any such health care reform proposals or legislation. Any such health care reforms could have a material adverse effect on the marketability of any drugs for which we ultimately require FDA approval.

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

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of medical products, through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more and varies substantially based upon the type, complexity, and novelty of the product.

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

Human pharmaceutical products are subject to rigorous preclinical testing and clinical trials and other approval procedures mandated by the FDA and foreign regulatory authorities. Various federal and foreign statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of

pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U.S. and foreign statutes and regulations are time-consuming and require the expenditure of substantial resources. In addition, these requirements and processes vary widely from country to country.

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Among the uncertainties and risks of the FDA approval process are the following: (i) the possibility that studies and clinical trials will fail to prove the safety and efficacy of the drug, or that any demonstrated efficacy will be so limited as to significantly reduce or altogether eliminate the acceptability of the drug in the marketplace, (ii) the possibility that the costs of development, which can far exceed the best of estimates, may render commercialization of the drug marginally profitable or altogether unprofitable, and (iii) the possibility that the amount of time required for FDA approval of a drug may extend for years beyond that which is originally estimated. In addition, the FDA or similar foreign regulatory authorities may require additional clinical trials, which could result in increased costs and significant development delays. Delays or rejections may also be encountered based upon changes in FDA policy and the establishment of additional regulations during the period of product development and FDA review. Similar delays or rejections may be encountered in other countries.

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

Our success will depend in large part on our ability and our licensors' ability to (i) maintain license and patent protection with respect to their drug products, (ii) defend patents and licenses once obtained, (iii) maintain trade secrets, (iv) operate without infringing upon the patents and proprietary rights of others and (iv) 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. We have obtained licenses to patents and other proprietary rights from University of Southern California, the National Institutes of Health and SD Pharmaceuticals, Inc.

The patent positions of pharmaceutical 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 of the pending applications or that claims allowed will be sufficient to protect the technology licensed to us. In addition, we cannot be certain that any patents issued to or licensed by us will not be challenged, invalidated, infringed or circumvented, or that the rights granted thereunder will provide competitive disadvantages to us.

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

We may also rely on unpatented trade secrets and know-how to maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants and others. There can be no assurance that these agreements will not be breached or terminated, that we will have adequate remedies for any breach, or that trade secrets will not otherwise become known or be independently discovered by competitors.

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

The license agreements pursuant to which we license our core technologies for our potential drug products permit the licensors, respectively National Institutes of Health, the University of Southern California and SD Pharmaceuticals, Inc., to terminate the agreement under certain circumstances, such as the failure by us to use our reasonable best efforts to commercialize the subject drug or the occurrence of any other uncured material breach by us. The 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. The 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. In the past, we have let lapse certain licenses for drug candidates when we determined that the expense and risk of continued development outweighed the likely benefits of that continued development. The termination of any license agreement could have a material adverse effect on us.

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**Protecting our proprietary rights is difficult and costly.**

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict the breadth of claims allowed in these companies' patents or whether we may infringe or be infringing these claims. Although we have not been notified of any patent infringement, nor notified others of patent infringement, such patent disputes are common and could preclude the commercialization of our products. Patent litigation is costly in its own right and could subject us to significant liabilities to third parties. In addition, an adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or product in dispute.

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

The success of our business depends, in large part, on our ability to attract and retain highly qualified management, scientific and other personnel, and on our ability to develop and maintain important relationships with leading research institutions and consultants and advisors. Competition for these types of personnel and relationships is intense from numerous pharmaceutical and biotechnology companies, universities and other research institutions. We are currently dependent upon our scientific staff, which has a deep background in our drug candidates and the ongoing preclinical and clinical trials. Recruiting and retaining senior employees with relevant drug development experience in oncology and anti-viral therapeutics is costly and time-consuming. There can be no assurance that we will be able to attract and retain such individuals on an uninterrupted basis and on commercially acceptable terms, and the failure to do so could have a material adverse effect on us by significantly delaying one or more of our drug development programs. The loss of any of our senior executive officers, including our chief executive officer and chief financial officer, in particular, could have a material adverse effect on the company and the market for our common stock, particularly if such loss was abrupt or unexpected. All of our employees are employed on an at-will basis under offer letters. We do not have non-competition agreements with any of our employees.

**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. We will have to develop a sales force, or rely on marketing partners or other arrangements with third parties for the marketing, distribution and sale of any drug product which is ready for distribution. 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.

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

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

We do not have any manufacturing capacity. When required, we will seek to establish relationships with third-party manufacturers for the manufacture of clinical trial material and the commercial production of drug products as we have with our current manufacturing partners. There can be no assurance that we will be able to establish relationships with third-party manufacturers on commercially acceptable terms or that third-party manufacturers will be able to manufacture a drug product on a cost-effective basis in commercial quantities under good manufacturing practices mandated by the FDA.

The dependence upon third parties for the manufacture of products may adversely affect future costs and the ability to develop and commercialize a drug product on a timely and competitive basis. Further, there can be no assurance that manufacturing or quality control problems will not arise in connection with the manufacture of our drug products or that third party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such products. Any failure to establish relationships with third parties for our manufacturing requirements on commercially acceptable terms would have a material adverse effect on us.

**We are dependent in part on third parties for drug development and research facilities.**

We do not possess research and development facilities necessary to conduct all of our drug development activities. We engage consultants and independent contract research organizations to design and conduct clinical trials in connection with the development



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of our drugs. As a result, these important aspects of a drug's development will be 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.

**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 will expose us to potential product liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. There can be no assurance that product liability claims will not be asserted against us. We intend to obtain additional limited product liability insurance for our clinical trials, directly or through our marketing development partners or contract research organization (CRO) partners, when they begin in the U.S. and to expand our insurance coverage if and when we begin marketing commercial products. However, there can be no assurance that we will be able to obtain product liability insurance on commercially acceptable terms or that we will be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect against potential losses. A successful product liability claim or series of claims brought against us could have a material adverse effect on us.

**The market price of our shares, like that of many biotechnology companies, is highly volatile.**

Market prices for the our Common Stock and the securities of other medical and biomedical technology companies have been highly volatile and may continue to be highly volatile in the future. Factors such as announcements of technological innovations or new products by us or our competitors, government regulatory action, litigation, patent or proprietary rights developments, and market conditions for medical and high technology stocks in general can have a significant impact on any future market for the Common Stock.

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

Our common stock is quoted on the American Stock Exchange. To continue to be listed, we are required to maintain shareholders equity of \$6,000,000 among other requirements. We do not satisfy that requirement as of September 30, 2005. The American Stock Exchange may consider delisting our Common Stock and suspend trading in the common stock in which case the Stock would likely trade in the over-the-counter market in the so-called "pink sheets" or, if available, the OTC Bulletin Board Service. As a result, an investor would likely find it significantly more difficult to dispose of, or to obtain accurate quotations as to the value of, our shares. Our ability to raise capital would most likely also be impaired due to our ineligibility to file resale registration statements under the Securities Act.

**If our Common Stock is delisted, it may become subject to the SEC's Penny Stock rules and more difficult to sell.**

SEC rules require brokers to provide information to purchasers of securities traded at less than \$5.00 and not traded on a national securities exchange or quoted on the Nasdaq Stock Market. If our common stock becomes a penny stock that is not exempt from these SEC rules, these disclosure requirements may have the effect of reducing trading activity in our common stock and making it more difficult for investors to sell. The rules require a broker-dealer to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny market. The broker must also give bid and offer quotations and broker and salesperson compensation information to the customer orally or in writing before or with the confirmation. The SEC rules also require a broker to make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction before a transaction in a penny stock.

**Changes in laws and regulations that affect the governance of public companies has increased our operating expenses and will 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 the listing requirements for American Stock Exchange 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 and expect to hire additional personnel and use additional 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 implement Section 404 of the Sarbanes-Oxley Act, which requires

management to report on, and our independent registered public accounting firm to attest to, our internal controls. For example, we expect to incur significant expenses in connection with the 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, expend additional money and management time on remedial efforts which could adversely affect our results of operations.

**Failure to implement effective control systems, or failure to complete our assessment of the effectiveness of our internal control over financial reporting, may subject us to regulatory sanctions and could result in a loss of public confidence, which could harm our operating results.**

Pursuant to Section 404 of the Sarbanes-Oxley Act, beginning with our year ending December 31, 2005, we will be required to include in our annual report our assessment of the effectiveness of our internal control over financial reporting and our audited financial statements as of the end of that fiscal year. Furthermore, our independent registered public accounting firm will be required to attest to whether our assessment of the effectiveness of our internal control over financial reporting is fairly stated in all material

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respects and separately report on whether it believes we maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005.

If we fail to remedy these material weaknesses, fail to timely complete our assessment, or if our independent registered public accounting firm cannot timely attest to our assessment, we could be subject to regulatory sanctions and a loss of public confidence in our internal control. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to timely meet our regulatory reporting obligations.

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**PART II. OTHER INFORMATION**

**Item 6. Exhibits.**

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

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**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.

Date: March 20, 2006

ADVENTRX Pharmaceuticals, Inc.  
By: /s/ Evan M. Levine

Evan M. Levine  
President and Chief Executive Officer (principal executive officer)

Date: March 20, 2006

ADVENTRX Pharmaceuticals, Inc.  
By: /s/ Carrie Carlander

Carrie Carlander  
Chief Financial Officer, Senior Vice President,  
Finance, Secretary and Treasurer (principal financial officer)

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**Exhibit Index**

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

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