

ADVENTRX PHARMACEUTICALS INC  
Form 10QSB  
November 15, 2004

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**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 20549**

**FORM 10-QSB**

x Quarterly report under Section 13 or 15(d) of the Securities Exchange Act of 1934

**For the quarterly period ended September 30, 2004**

.. Transition report under 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 small business issuer as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**84-1318182**  
(IRS Employer  
Identification No.)

**6725 Mesa Ridge Road, Suite 100**  
**San Diego, California 92121**  
(Address of principal executive offices)

**(858) 552-0866**  
(Issuer's telephone number, including area code)

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

As of October 31, 2004, 53,811,072 shares of the issuer's common stock, par value \$0.001 per share, were outstanding.

Transitional Small Business Disclosure Format (Check One): YES .. NO x

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**ADVENTRX PHARMACEUTICALS, INC.**  
**FORM 10-QSB**  
**September 30, 2004**  
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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets

**September 30,**

**December 31,**

**2004**

**2003**

**(unaudited)**

**Assets**

Current assets:

Cash and cash equivalents

\$		14,756,357
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\$		4,226,397
----	--	-----------

Prepaid expenses		237,538
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28,376

Total current assets		14,993,895
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4,254,773

Property and equipment, net		291,525
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20,840

Other assets		55,755
		7,743
Total assets		
\$		15,341,175
\$		4,283,356

**Liabilities and Shareholders Equity**

Current liabilities:

Accounts payable and accrued liabilities

\$ 693,678

\$ 90,243

Accrued dividends payable

72,800

Total liabilities

693,678

163,043

Commitments and contingencies

Shareholders equity:

Series A cumulative convertible preferred stock, \$0.01 par value.

Authorized 8,000 shares; issued and outstanding, 473

shares in 2003 (aggregate involuntary liquidation preference

\$473,000 at December 31, 2003)

4

Series B convertible preferred stock, \$0.01 par value.

Authorized 200,000 shares; issued and outstanding, 200,000

shares in 2003 (no liquidation preference)

2,000

Common stock, \$0.001 par value. Authorized 100,000,000 shares;

issued 53,834,237 shares in 2004 and

issued and outstanding 42,491,708 shares in 2003

53,835

42,492

Additional paid-in capital

47,453,079

32,556,963

Deficit accumulated during the development stage

(32,824,670

)

(28,481,146

)

Treasury stock, at cost; 23,165 shares

(34,747

)

Total shareholders equity

14,647,497

5

	4,120,313
Total liabilities and shareholders' equity	
\$	15,341,175
\$	4,283,356

See accompanying notes to condensed consolidated financial statements.

**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(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, 2004
	2004	2003	2004	2003	2004
Net sales	\$	\$	\$	\$	\$ 174,830
Cost of goods sold					51,094
Gross margin					123,736
Grant revenue				3,603	129,733
Interest income	28,055	2,740	44,742	4,464	143,978
	28,055	2,740	44,742	8,067	397,447
Operating expenses:					
Research and development	983,665	208,778	2,053,131	415,301	6,783,057
General and administrative	1,155,716	277,248	2,315,936	1,103,176	10,730,780
Depreciation and amortization	12,481	1,969	19,199	5,146	10,117,906
Impairment loss write off of goodwill					5,702,130
Interest expense		212		1,386	179,090
Equity in loss of investee					178,936
Total operating expenses	2,151,862	488,207	4,388,266	1,525,009	33,691,899
Loss before cumulative effect of change in accounting principle	(2,123,807)	(485,467)	(4,343,524)	(1,516,942)	(33,294,452)
Cumulative effect of change in accounting principle					(25,821)
Net loss	(2,123,807)	(485,467)	(4,343,524)	(1,516,942)	(33,320,273)
Preferred stock dividends		(9,460)		(28,380)	(602,320)
Net loss applicable to common stock	\$ (2,123,807)	\$ (494,927)	\$ (4,343,524)	\$ (1,545,322)	\$ (33,922,593)
Loss per common share basic and diluted	\$ (0.04)	\$ (0.02)	\$ (0.09)	\$ (0.05)	

See accompanying notes to condensed consolidated financial statements.





**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Condensed Consolidated Statements of Shareholders' Equity (Deficit)

Inception (June 12, 1996) through September 30, 2004

(unaudited)

	Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock		Additional paid-in capital	Deficit accumulated during the development stage	Treasury Stock at cost
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at June 12, 1996 (date of incorporation)		\$		\$		\$		\$	\$	\$	\$
Sale of common stock without par value							503	5	5		
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)	
Issuance of common stock							2,010,111	2,010	456	(2,466)	
Net loss										(259,476)	
Balances at December 31, 1996							3,726,746	3,727	3,689	(280,036)	
Sale of common stock, net of offering costs of \$9,976							1,004,554	1,004	1,789,975		
Issuance of common stock in acquisition							375,891	376	887,874		
Minority interest deficiency at acquisition										(45,003)	

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charged to the Company					
Net loss				(1,979,400)	
Balances at December 31, 1997		5,107,191	5,107	2,681,538	(2,304,439)
Rescission of acquisition		(375,891)	(376)	(887,874)	561,166
Issuance of common stock at conversion of notes payable		450,264	451	363,549	
Expense related to stock warrants issued				260,000	
Net loss					(1,204,380)
Balances at December 31, 1998		5,181,564	5,182	2,417,213	(2,947,653)
Sale of common stock		678,412	678	134,322	
Expense related to stock warrants issued				212,000	
Net loss					(1,055,485)
Balances at December 31, 1999		5,859,976	5,860	2,763,535	(4,003,138)
Sale of preferred stock, net of offering costs of \$76,500	3,200	32		3,123,468	
Issuance of common stock at conversion of notes and interest payable		412,487	412	492,085	
Issuance of common stock at conversion of notes payable		70,354	70	83,930	
Issuance of common stock to settle obligations		495,111	496	1,201,664	

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Issuance of common stock for acquisition			6,999,990	7,000	9,325,769	
Issuance of warrants for acquisition					4,767,664	
Stock issued for acquisition costs			150,000	150	487,350	
Expense related to stock warrants issued					140,000	
Dividends payable on preferred stock					(85,000)	
Cashless exercise of warrants			599,066	599	(599)	
Net loss						(3,701,084)
Balances at December 31, 2000	3,200	32	14,586,984	14,587	22,299,866	(7,704,222)
Dividends payable on preferred stock					(256,000)	
Repurchase of warrants					(55,279)	
Sale of warrants					47,741	
Cashless exercise of warrants			218,493	219	(219)	
Issuance of common stock to pay preferred dividends			93,421	93	212,907	
Detachable warrants issued with notes payable					450,000	
Issuance of warrants to pay operating expenses					167,138	
Issuance of common stock to pay operating expenses			106,293	106	387,165	

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Issuance of preferred stock to pay operating expenses	137	1								136,499	
Net loss											(16,339,120)
Balances at December 31, 2001	3,337	33				15,005,191	15,005	23,389,818			(24,043,342)
Dividends payable on preferred stock										(242,400)	
Repurchase of warrants											
Sale of warrants						240,000	240			117,613	
Cashless exercise of warrants						100,201	100			(100)	
Excercise of warrants						344,573	345			168,477	
Sale of preferred stock			200,000	2,000	70,109	701				998,392	
Conversion of preferred stock into common stock	(3,000)	(30)						1,800,000	1,800	(1,770)	
Preferred stock dividends forgiven										335,440	
Issuance of warrants to pay operating expenses										163,109	
Issuance of common stock to pay operating expenses								6,292	6	12,263	
Issuance of preferred stock to pay operating expenses	136	1								6,000	
Issuance of stock options to employees										329,296	
Net loss											(2,105,727)
	473	4	200,000	2,000	70,109	701	17,496,257	17,496	25,276,138		(26,149,069)

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Balances at December 31, 2002									
Dividends payable on preferred stock									(37,840)
Conversion of Series C preferred stock into common stock	(70,109)	(701)	14,021,860	14,022					(13,321)
Issuance of common stock to pay interest on Bridge Notes				165,830	165				53,326
Sale of common stock at \$0.40 per share, net of issuance costs				6,640,737	6,676				2,590,656
Sale of common stock at \$1.00 per share, net of issuance costs				3,701,733	3,668				3,989,181
Exchange of warrants				235,291	235				49,486
Issuance of common stock to pay operating expenses				230,000	230				206,569
Issuance of warrants to pay operating expenses									156,735
Issuance of stock options to employees									286,033
Net loss									(2,332,077)
Balances at December 31, 2003	473	4	200,000	2,000		42,491,708	42,492	32,556,963	(28,481,146)
Extinguishment of dividends payable on preferred stock									72,800
Conversion of Series A	(473)	(4)				236,500	236		(232)

cummulative preferred stock							
Conversion of Series B preferred stock	(200,000)	(2,000)	200,000	200	1,800		
Issuance of warrants in settlement of a claim					86,375		
Exercise of warrants			488,405	488	26,865		
Issuance of common stock at \$1.50 per share			10,417,624	10,419	15,616,031		
Payment of financing and offering costs					(1,354,541)		
Issuance of stock options to employees					412,271		
Acquisition of treasury stock					34,747		(34,747)
Net loss							(4,343,524)

Balances at September 30, 2004

\$	\$	\$	53,834,237	\$ 53,835	\$ 47,453,079	\$ (32,824,670)	\$ (34,747)
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See accompanying notes to condensed financial statements.

**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Condensed Consolidated Statements of Cash Flows

(unaudited)

	<b>Nine months ended September 30,</b>		<b>Inception (June 12, 1996) through September 30, 2004</b>
	<b>2004</b>	<b>2003</b>	
Cash flows from operating activities:			
Net loss	\$ (4,343,524)	\$ (1,516,942)	\$ (33,320,273)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	19,199	5,146	10,117,906
Forgiveness of employee receivable			30,036
Impairment loss write off of goodwill			5,702,130
Expenses paid by warrants	86,375	105,883	573,357
Expenses paid by preferred stock			142,501
Expenses related to stock warrants issued			612,000
Expenses related to employee stock options issued	412,271	249,969	1,027,600
Expenses paid by issuance of common stock		160,299	817,548
Equity in loss of investee			178,936
Write-off of license agreement			152,866
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	(257,174)	(42,707)	(432,661)
Increase (decrease) in accounts payable and accrued liabilities	603,435	(184,877)	172,407
Increase in sponsored research payable and license obligation			924,318
Net cash used in operating activities	(3,479,418)	(1,223,229)	(13,275,508)
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	(289,884)	(7,191)	(412,353)
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

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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	(289,884)	(7,191)	36,673
Cash flows from financing activities:			
Proceeds from sale of preferred stock			4,200,993
Proceeds from sale of common stock	15,626,450	5,164,745	24,152,596
Proceeds from sale or exercise of warrants	27,353		411,590
Repurchase of warrants			(55,279)
Payment of financing and offering costs	(1,354,541)		(1,453,517)
Payments of notes payable and long-term debt		(253,948)	(605,909)
Proceeds from issuance of notes payable and detachable warrants			1,344,718
Net cash provided by financing activities	14,299,262	4,910,797	27,995,192
Net increase in cash and cash equivalents	10,529,960	3,680,377	14,756,357
Cash and cash equivalents at beginning of period	4,226,397	103,928	
Cash and cash equivalents at end of period	\$ 14,756,357	\$ 3,784,305	\$ 14,756,357
See accompanying notes to condensed consolidated financial statements.			



**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Notes to Condensed Consolidated Financial Statements

Nine months ended September 30, 2004 and 2003

(Unaudited)

**(1) Description of the Company**

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation, (the Company) is a development stage enterprise that conducts biomedical research and development focused on treatments for cancer and certain viral infections, including HIV. The Company currently does not manufacture, market, sell or distribute any product. Through its license agreements with University of Texas M.D. Anderson Cancer Center (M.D. Anderson), The University of Southern California (USC), and the National Institutes of Health (NIH), the Company has rights to drug candidates in varying early 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) Basis of Presentation**

In management's opinion, the accompanying unaudited condensed financial statements of the Company have been prepared in accordance with the interim reporting requirements of Form 10-QSB, pursuant to the rules and regulations of the Securities and Exchange Commission. However, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

In management's opinion, all adjustments (consisting of only normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2004 are not necessarily indicative of results that may be expected for the year ending December 31, 2004. For additional information, refer to the Company's financial statements and notes thereto for the year ended December 31, 2003, contained in the Company's Form 10-KSB.

**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Notes to Condensed Consolidated Financial Statements

Nine months ended September 30, 2004 and 2003

(Unaudited)

***Supplementary Cash Flow Information***

Interest of \$212 and \$1,386 was paid during the three and nine months ended September 30, 2003, respectively. No income taxes were paid during 2004 and 2003.

Noncash investing and financing transactions excluded from the condensed statements of cash flows for the nine months ended September 30, 2004 and 2003 and for the period from Inception (June 12, 1996) through September 30, 2004 are as follows:

	<b>2004</b>	<b>2003</b>	<b>Inception (June 12, 1996) through September 30, 2004</b>
Issuance of warrants, common stock and preferred stock for:			
Conversion of notes payable and accrued interest	\$	\$ 53,326	\$ 1,213,988
Payment of operating expenses			1,224,281
Conversion of preferred stock	2,000	701	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		86,375
Assumptions of liabilities in acquisitions			1,009,567
Acquisition of license agreement for long-term debt			161,180
Cashless exercise of warrants	465		3,743
Dividends accrued		18,920	621,040
Dividends extinguished	72,800		408,240
Trade payable converted to note payable			83,948
Issuance of warrants for return of common stock		50,852	50,852
Acquisition of treasury stock in settlement of a claim	34,747		34,747
Detachable warrants issued with notes payable			450,000

***New Accounting Pronouncements***

No new pronouncements were issued during the nine months ended September 30, 2004 that are expected to have a material effect on the Company's financial position or results of operations.

**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Notes to Condensed Consolidated Financial Statements

Nine months ended September 30, 2004 and 2003

(Unaudited)

**(3) Equity Transactions**

In March 2004, a warrant to purchase 3,750 shares of common stock at \$0.60 per share was exercised for proceeds of \$2,250 and the Company issued 38,372 shares of common stock upon the cashless exercise of a warrant to purchase 50,000 shares of common stock at \$0.50 per share.

In March 2004, 473 shares of Series A cumulative convertible preferred stock, representing all of the Series A cumulative convertible preferred stock then outstanding, was converted into 236,500 shares of common stock. In conjunction with the conversion, dividends payable of \$72,800 at December 31, 2003, were extinguished.

In March 2004, 200,000 shares of Series B convertible preferred stock, representing all of the Series B convertible preferred stock then outstanding, were converted into 200,000 shares of common stock.

In April 2004, the Company sold 10,417,624 shares of common stock and issued warrants to purchase 3,125,272 shares of common stock at \$2.00 and warrants to purchase 2,083,518 shares of common stock at \$2.50 per share to accredited investors in a private placement for aggregate gross proceeds of \$15,626,450 in cash. In connection with the private placement, the Company paid cash commissions of \$900,452 and other related expenses of \$454,089 and issued warrants to purchase 632,547 shares of common stock at \$2.00 per share to two placement agents, having a fair market value of \$890,963 on the date of issuance.

In April 2004, the Company engaged W.R. Hambrecht + Co., LLC for financial advisory and investment banking services and, in connection with that engagement, issued to it a warrant to purchase 175,000 shares of common stock at \$2.00 per share, having a fair market value of \$246,493 on the date of issuance.

In May 2004, a warrant to purchase 20,082 shares of common stock at \$1.25 per share was exercised for gross proceeds of \$25,103.

In May 2004, the Company issued 46,784 shares of common stock upon the cashless exercise of two warrants to purchase a total of 60,000 shares of common stock.

In June 2004, the Company issued 379,417 shares of common stock upon the cashless exercise of a warrant to purchase 502,540 shares of common stock.

Nonemployee stock-based compensation that is not valued at the fair value of consideration received is valued, as of the grant date, using the Black-Scholes pricing model with the following assumptions for grants in 2004 and 2003: no dividend yield for either year; expected weighted average volatility of 88% and 187%, respectively; risk-free interest rates 2.78% to 4.74%; and expected lives of three and seven years, respectively.

**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Notes to Condensed Consolidated Financial Statements

Nine months ended September 30, 2004 and 2003

(Unaudited)

At September 30, 2004, there were outstanding warrants to purchase a total of 10,854,964 shares of common stock as follows:

<b>Warrants</b>	<b>Exercise price</b>	<b>Expiration date</b>
118,094	\$0.49	September 2005
440,000	0.50	October 2005
100,000	3.00	April 2006
2,090,537	0.60	May 2006
502,528	0.49	June 2006
914,175	1.25	October 2006
150,000	0.50	December 2006
523,293	1.25	December 2006
300,000	2.50	October 2007
3,932,819	2.00	April 2009
2,083,518	2.50	April 2009
11,154,964		

**(4) Stock Compensation Plans**

The Company applies Statement of Financial Accounting Standards No. 123 and related interpretations in accounting for employee stock-based compensation, and includes the required footnote disclosures thereon.

In January and February 2004, three individuals became members of the Company's board of directors. Each new director was granted an option to purchase 50,000 shares of common stock at a purchase price of \$1.50 per share. The options begin vesting 90 days from the date of grant and vest in equal installments over the next four quarters. The options expire on December 30, 2008. The value of the options on the dates of grant was \$223,826.

In February 2004, an individual became a member of the Company's Scientific Advisory Board. The new member was granted an option to purchase 30,000 shares of common stock at a purchase price of \$1.50 per share. The option will vest in equal installments over eight quarters, starting March 1, 2004. The option will expire on December 30, 2008. The value of the option on the date of grant was \$45,350.

In March 2004, the Company granted an option to purchase 100,000 shares of common stock at a purchase price of \$1.50 per share to the Company's Vice President of Clinical and Medical Affairs. The option will vest in three installments over three years starting March 2004. The value of the option on the date of grant was \$152,050.

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In April 2004, the Company granted an option to purchase 30,000 shares of common stock at a purchase price of \$1.50 per share to the Director of Antiviral Research. The option will vest in three installments over three years starting April 2004. The value of the option on the date of grant was \$37,600.

In May 2004, the Company granted an option to purchase 30,000 shares of common stock at a purchase price of \$1.50 per share to the Director of Marketing and Technical Support. The option will vest in three installments over three years starting May 2004. The value of the option on the date of grant was \$36,782.

**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Notes to Condensed Consolidated Financial Statements

Nine months ended September 30, 2004 and 2003

(Unaudited)

In July 2004, the Company granted an option to purchase 15,000 shares of common stock at a purchase price of \$1.80 per share to an employee. The option will vest in three installments over three years starting June 2004. The value of the option on the date of grant was \$16,545.

In August 2004, the Company granted an option to purchase 21,000 shares of common stock at a purchase price of \$1.20 per share to an employee. The option will vest in three installments over three years starting August 2004. The value of the option on the date of grant was \$18,765.

In September 2004, the Company granted an option to purchase 100,000 shares of common stock at a purchase price of \$1.30 per share to the Chief Technical Officer. The option will vest as follows: 25,000 shares will vest on October 1, 2005. The remaining 75,000 shares will vest ratably at the end of each month from October 31, 2005 through September 30, 2008. The value of the option on the date of grant was \$79,989.

The Company recognized compensation expense of \$412,271 and \$249,969 in the nine months ended September 30, 2004 and 2003, respectively, related to the portion of the options which vested in that period.

	September 30, 2004		December 31, 2003	
	Shares (000)	Weighted-Average Exercise Price	Shares (000)	Weighted-Average Exercise Price
<b>Non-statutory Stock Options</b>				
Outstanding at beginning of period	2,980	\$ 0.38	1,690	\$ 0.23
Granted	476	\$ 1.45	2,040	\$ 0.58
Exercised				
Forfeited			(750)	\$ 0.50
Outstanding at end of period	3,456	\$ 0.53	2,980	\$ 0.38
Options exercisable at period end	2,628		1,808	
Weighted-average fair value of options granted during the period	\$ 1.15		\$ 0.54	

Range of Exercise Price	Number Outstanding at 9/30/04	Options Outstanding		Options Exercisable	
		Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable at 9/30/04	Weighted-Average Exercise Price
\$0.20 to \$1.80	3,456,000	4.4 years	\$0.529	2,627,835	\$0.398

None of the foregoing options were issued pursuant to a stock option plan. The options expire on December 30, 2008 and vest on varying dates through September 2008.

**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Notes to Condensed Consolidated Financial Statements

Nine months ended September 30, 2004 and 2003

(Unaudited)

**(5) Net Loss per Common Share**

The computation of basic and diluted net loss per share for the three and nine months ended September 30, 2004 and 2003 is as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Numerator:				
Net loss	\$ (2,123,807)	\$ (485,467)	\$ (4,343,524)	\$ (1,516,942)
Preferred stock dividends		(9,460)		(28,380)
Numerator for basic and diluted loss per share	\$ (2,123,807)	\$ (494,927)	\$ (4,343,524)	\$ (1,545,322)
Denominator for basic and diluted loss per share - weighted average common shares outstanding	53,811,072	23,839,669	49,715,980	30,245,421
Loss per common share-basic and diluted	\$ (0.04)	\$ (0.02)	\$ (0.09)	\$ (0.05)

Net loss per common share is calculated according to Statement of Financial Accounting 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 in 2004 and 2003:

	September 30,	
	2004	2003
Preferred stock		318,250
Warrants	11,154,964	5,551,167
Options	3,456,000	2,930,000
Totals	14,610,964	8,799,417

**(6) 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.

(7)

**Subsequent Event**

In October 2004, the Company settled a claim by paying \$150,000 and issuing a warrant to purchase 300,000 shares of the Company's common stock at a price of \$2.50 per share. The warrant, which expires in October 2007, had a value of \$86,375 on the date of issuance. The Company accrued \$236,375 to reflect the value of the settlement at September 30, 2004.



## Item 2. Plan of Operation.

*This Plan of Operation should be read in conjunction with the accompanying condensed financial statements and notes included in this report. This Quarterly Report on Form 10-QSB 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 products and 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 Annual 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 in 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.*

CoFactor, BlockAide/CR, BlockAide/VP, Thiovir, EradicAide and Selone are our trademarks. Product names, trade names and trademarks of other entities are also referred to in this report.

In this report, the terms Company, we, us, and our refer to ADVENTRX Pharmaceuticals, Inc. The term Common Stock refers to our Common Stock, par value \$0.001 per share.

### Plan of Operation.

We are a development stage enterprise which conducts biomedical research and development focused on treatments for cancer and certain viral infections, including HIV. Our business is in the development stage; we have not generated any significant revenues and we have not yet marketed any product.

We have used the proceeds from private placements of our capital stock primarily to expand our clinical efforts for CoFactor and our preclinical efforts for BlockAide/CR, EradicAide and Thiovir as well as for general working capital.

We began dosing metastatic colorectal cancer patients with 5-FU and our drug CoFactor in Q1 2004, based upon an approved IND Application in the United States to treat metastatic colorectal cancer patients in conjunction with 5-FU. In Q2 2004 we increased the number of sites at which metastatic colorectal cancer patients are being dosed with CoFactor in our first-line Phase II clinical trial. In Q4 2004 the FDA granted allowance to begin recruiting patients for the second stage of our Phase II trial of CoFactor to treat metastatic colorectal cancer patients. We currently plan to file during Q4 2004 for approval for a Phase II trial for CoFactor for metastatic colorectal cancer patients in the United Kingdom. We previously reported that we intended to file for this approval in Q3 2004. The data that we needed to submit with this filing took longer than anticipated to collect and compile and we accordingly have revised our expectations. We also currently plan to file in Q1 2005 for approvals to begin treatment of pancreatic cancer patients with 5-FU and CoFactor in two separate Phase II trials in the United States and Europe. We previously reported that we intended to file for this approval in Q3 2004 as we had expected to receive from the EMEA a response regarding our protocol design for these trials in time to file for these approvals in Q3 2004. We currently anticipate that the EMEA will provide a response regarding these protocol designs in time to file for these approvals in Q1 2005.

We received FDA clearance for the IND Application filed in Q1 2004 to treat HIV patients with BlockAide/CR during 2004 in a Phase Ib/IIa trial to study the safety and initial efficacy of the drug for patients who are on HAART therapy and are experiencing a rise in HIV viral load. We currently plan to file an IND application in Q1 2005 to treat HIV patients with Thiovir, beginning in Q2 2005. We previously reported that we intended to file for this IND application

in QIII 2004 and to begin treating HIV patients with Thiovir beginning in QIV 2004. Because of unexpected manufacturing delays that occurred after our last quarterly report, we do not currently anticipate having the necessary GMP material and toxicology and other data to include in this IND application until QI 2005. We also currently plan to file an IND application in QIV 2005 to treat HIV patients with a reformulation of EradicAide vaccine in 2006. We previously reported that we intended to file for this IND application in QIII 2004. Subsequent to the filing of our last quarterly report, we determined to reformulate Eradicaide prior to submitting this IND application. We currently expect that this reformulation will be completed in time to file this IND application in late 2005.

We currently expect that our clinical efforts for CoFactor and our preclinical efforts for BlockAide/CR, Eradicaide and Thiovir to require the expenditure of approximately \$8,000,000 in research and development costs during the next 12 months. During this same period of time, we currently expect to expend approximately \$3,000,000 for general and administrative costs.

The total estimated expenditures that we currently expect to incur in executing our plan of operation during the next 12 months have increased from the estimate included in our last quarterly report due to additional estimated pre clinical and clinical trial costs and due to an increase in estimated general and administrative costs. The increase in general and administrative costs is primarily due to higher rent on a new facility, salary increases of officers and employees, and planned new hire of four employees.

Our total actual expenses have increased from the prior quarter. Our total operating expenses for the three months ended September 30, 2004 and June 30, 2004 were \$2,151,862 and \$1,522,009, respectively. The increase is due primarily to increases in research and development costs as we continue and expand our clinical trials, the effect of the cost of settling a claim and higher general and administrative costs. Research and development costs increased from \$773,091 during the three months ended June 30, 2004 to \$983,665 during the three months ended September 30, 2004 as a result of expanded research and development and clinical trial operations for our lead products, CoFactor and BlockAide/CR, and preclinical compounds, Thiovir and Eradicaide. General and administrative costs increased from \$745,838 during the three months ended June 30, 2004 to \$1,155,716 during the three months ended September 30, 2004, as a result of the cost of settling a claim and higher salary and related benefits for new administrative employees, and higher legal and accounting fees related to work on our resale registration statement which recently went effective.

We presently expect our quarterly total operating expenses to continue into the foreseeable future at the same level as those expenses for the quarter ended September 30, 2004.

Our cash position at October 31, 2004 of approximately \$14,000,000 is sufficient to meet our goals as set forth above. Accordingly, we do not presently anticipate having to raise money for our business operations in the next 12 months. Our cash requirements after that time, however, are not known with any degree of certainty at this time and will depend in large part on the results of the trials we have described above and our ongoing research. The continued development of our products may require additional significant funding as early as the fourth quarter of 2005, and in any event the additional clinical development necessary to bring some or all of our products to market will require significant additional capital. We have no assurance that we will be able to raise additional capital.

In the last quarter, we increased the number of our employees from 9 to 10. This increase was made to support our increased research and development activities. We currently expect to hire one additional administrative staff and three research and development support personnel in the next 12 months.

The proceeds from our April 2004 private placement have been placed in interest-bearing money market accounts. We do not intend to invest these funds in other investment vehicles, as we are aiming to obtain only as high a return as possible in relatively risk-free investments. The Company maintains cash and cash equivalents with financial institutions, which from time to time may exceed federally insured limits. The Company periodically assesses the financial condition of the institutions and believes that the risk of any loss is minimal. At October 31, 2004, cash and cash equivalents with banks exceeded federally insured limits by approximately \$13,938,000.

We currently have no plans for any significant new equipment or other capital expenditures.

## **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 and limited working capital.**

We had an accumulated deficit of \$28,481,146 as of December 31, 2003 and \$32,824,670 as of September 30, 2004. 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 Food and Drug Administration 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 Food and Drug Administration 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 or government grants.**

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 or the receipt of one or more government grants for research and development or clinical development will be required to fund our activities. We cannot be certain that we will be able to consummate any such financing on favorable terms, if at all, or receive any such government grants or that such financing or government grants will be adequate to meet our capital requirements. Any additional equity financing could result in substantial dilution to stockholders, and debt financing, if available, will most likely involve restrictive covenants which 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.

### **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, or (vi) be affected by third parties holding proprietary rights that will preclude us from marketing a drug product. 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 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.

**Positive results in preclinical and early 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 early 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.

**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. In addition, other companies are pursuing the development of 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 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 Food and Drug Administration 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. Accordingly, competitors may succeed in commercializing products more rapidly or effectively than us, which would have a material adverse effect on us.

**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 its investments in developing new therapies. 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 Food and Drug Administration. 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 a number of federal and state proposals during the last few years to subject the pricing of health care goods and services, including prescription drugs, to government control and to make other changes to U.S. health care system. It is uncertain which legislative proposals will be adopted or what actions federal, state, or private payors for health care treatment and services may take in response to any health care reform proposals or legislation. We cannot predict the effect health care reforms may have on our business, and there is no guarantee that any such reforms will not have a material adverse effect on us.

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

The Food and Drug Administration 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 Food and Drug Administration 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 Food and Drug Administration 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 Food and Drug Administration 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.

Among the uncertainties and risks of the Food and Drug Administration 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 Food and Drug Administration approval of a drug may extend for years beyond that which is originally estimated. In addition, the Food and Drug Administration 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 Food and Drug Administration policy and the establishment of additional regulations during the period of product development and Food and Drug Administration 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 (v) 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 M.D. Anderson, University of Southern California and the National Institutes of Health.

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 M.D. Anderson, National Institutes of Health and University of Southern California, 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. The termination of any license agreement would have a material adverse effect on us.

**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. 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.

**Our success is dependent on our key personnel.**

We depend on a small management and scientific/clinical group and on independent researchers, some of whom are inventors of the patents licensed to us for core technologies and drugs developed at M.D. Anderson and University of Southern California. Scientific personnel may from time to time serve as consultants to us and may devote a portion of their time to our business, as well as continue to devote substantial time to the furtherance of our sponsored research at M.D. Anderson, University of Southern California and other affiliated institutions as may be agreed to in the future, but such personnel are not our employees and are not bound under written employment agreements. The services of such persons are important to us, and the loss of any of these services may adversely affect us.

**We may be unable to retain skilled personnel 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. There can be no assurance that we will be able to attract and retain such individuals on commercially acceptable terms or at all, and the failure to do so would have a material adverse effect on us.

**We currently have no sales or marketing capability.**

We currently do not have marketing or sales 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 Merck Eprova AG, Multiple Peptide Systems, Inc., Peptisyntha, Inc., and MediChem Research, Inc. 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 Food and Drug Administration.

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 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.

**Insurance coverage is increasingly more difficult to obtain or maintain.**

Obtaining insurance for our business, property and products is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to third-party claims or suffer a loss or damage in excess of our insurance coverage, we may be required to pay claims in excess of our insurance coverage on our own. Furthermore, any first- or third-party claims made on any of our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all in the future.

**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.

**We are not paying dividends on our common stock.**

We have never paid cash dividends on our common stock, and do not intend to do so in the foreseeable future.

**The issuance of shares of our preferred stock may adversely affect our common stock.**

Our Board of Directors is authorized to designate one or more series of preferred stock and to fix the rights, preferences, privileges and restrictions thereof, without any action by the stockholders. The designation and issuance of such shares of our preferred stock may adversely affect the common stock, if the rights, preferences and privileges of such preferred stock (i) restrict the declaration or payment of dividends on common stock, (ii) dilute the voting power of common stock, (iii) impair the liquidation rights of the common stock or (iv) delay or prevent a change in control for us from occurring, among other possibilities.

**Under provisions of our certificate of incorporation, bylaws and Delaware law, our management may be able to block or impede a change in control.**

Our certificate of incorporation authorizes our Board of Directors to designate shares of preferred stock without stockholder approval on such terms as our Board of Directors may determine. The rights of the holders of common stock may be subject to or adversely affected by, the rights of the holders of any such preferred stock that may be issued in the future. The issuance of preferred stock may make it more difficult for a third party to acquire, or may discourage a third party from acquiring, a majority of the voting stock. These and other provisions of our certificate of incorporation and our by-laws, as well as certain provisions of Delaware law, could delay or impede the removal of incumbent directors and could make more difficult a merger, tender offer or proxy contest involving a change of control of the company, even if such events could be beneficial to the interest of the stockholders as a whole. Such provisions could limit the price that certain investors might be willing to pay in the future for our common stock.

**Officers and directors liabilities are limited under Delaware law.**

Pursuant to our certificate of incorporation and by-laws, as authorized under applicable Delaware law, directors are not liable for monetary damages for breach of fiduciary duty, except in connection with a breach of the duty of loyalty, for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, for dividend payments or stock repurchases illegal under Delaware law or for any transaction in which a director has derived an improper personal benefit. Our certificate of incorporation and by-laws provide that we must indemnify our officers and directors to the fullest extent permitted by Delaware law for all expenses incurred in the settlement of any actions against such persons in connection with their having served as officers or directors.

**Item 3. Controls and Procedures.**

**Evaluation of disclosure controls and procedures.**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of the Company's disclosure controls and procedures as of September 30, 2004. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2004 for gathering, analyzing and disclosing the information we are required to disclose in the reports we file under the Securities Exchange Act of 1934, within the time periods specified in the SEC's rules and forms.

During the fiscal three months ended September 30, 2004, there was no change in our internal control over financial reporting that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings.

In December 2003, we filed a complaint in the Superior Court of California in and for the County of San Diego, alleging claims against Bengt G. Gustavsson and Biofol AB (collectively, the Defendants), who are former consultants of the company, for misappropriation of trade secrets, breach of written contracts, breach of the implied covenant of good faith and fair dealing, breach of fiduciary duty, breach of duty of confidence, aiding and abetting breach of fiduciary duty and breach of duty of confidence, unfair competition, intentional interference with prospective economic relations, and seeking damages, declaratory and injunctive relief. In January 2004, the Defendants filed a Notice of Removal of Action in the U.S. District Court in and for the Southern District of California. In March 2004, the Defendants filed an answer denying the material allegations of our complaint. In July 2004, the company and Defendants participated in a court-sponsored case review and mediation known as an Early Neutral Evaluation, which is procedurally required by the federal court. A further settlement conference is scheduled for November 29, 2004, and discovery between the parties has commenced. To our knowledge, as of the date of this report, no other substantive filings have been made by us or the Defendants regarding this lawsuit. The outcome of and the amount of any damages that may be recovered in this lawsuit is uncertain.

On October 5, 2004, we filed a complaint in the Superior Court of California in and for the County of San Diego, Case No. GIC836663, alleging claims against Numoda Corporation (Numoda) for negligent misrepresentation and declaratory relief arising out of a prospective but unconsummated business transaction in which Numoda sought to provide certain data management services in the role of a contract research organization for an upcoming clinical trial of the company. Numoda's response to the complaint is expected to be filed on or before November 15, 2004. To our knowledge, as of the date of this report, no other substantive filings have been made by us or Numoda regarding this lawsuit. The outcome of and the amount of any damages that may be recovered in this lawsuit are uncertain.

From time to time we may be subject to additional legal proceedings and claims in the ordinary course of business. These claims, even if not meritorious, could result in the expenditure of significant financial and managerial resources. We are not aware of any legal proceedings or claims that we believe could harm our business or cause our stock price to fall.

### Item 2. Changes In Securities.

In July 2004, the Company granted an option to purchase 15,000 shares of common stock at a purchase price of \$1.80 per share to an employee. The option will vest in three installments over three years starting June 2004.

In August 2004, the Company granted an option to purchase 21,000 shares of common stock at a purchase price of \$1.20 per share to an employee. The option will vest in three installments over three years starting August 2004.

In September 2004, the Company granted an option to purchase 100,000 shares of common stock at a purchase price of \$1.30 per share to the Chief Technical Officer. The option will vest as follows: 25,000 shares will vest on October 1, 2005. The remaining 75,000 shares will vest ratably at the end of each month from October 31, 2005 through September 30, 2008.

In October 2004, the Company issued a warrant to purchase 300,000 shares of common stock at \$2.50 per share in settlement of a claim.

No commission was paid or given, directly or indirectly, in connection with any of the above sales, issuances, or exchanges.





The issuances of the above securities were deemed to be exempt from registration under the Securities Act of 1933, as amended (the Securities Act ), in reliance on Section 4(2) of the Securities Act.

**Item 6. Exhibits And Reports On Form 8-K.**

(a) The exhibits to this report are incorporated by reference to the documents set forth on the exhibit index which is attached hereto.

(b) On September 8, 2004, we filed a current report on Form 8-K to report, under Items 5, 8, and 9 of such report, the resignation of Nicholas J. Virca from his positions as President and Chief Executive Officer of the Company (principal executive officer) and member of the Board of Directors of the Company, effective on September 4, 2004 and that effective September 4, 2004, Evan M. Levine, the Vice Chairman of the Board of Directors, Chief Operating Officer and Secretary of the Company, was appointed by the Board of Directors of the Company to also serve as President and Chief Executive Officer of the Company.

On November 3, 2004, we filed a current report on Form 8-K to report, under Items 8 and 9 of such report, the announcement of certain developments regarding our CoFactor Phase II trial and current plans regarding certain regulatory filings.

We have not filed any current reports on Form 8-K since November 3, 2004.

**Signatures**

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

ADVENTRX Pharmaceuticals, Inc.  
November 15, 2004 By: /s/ Steven M. Plumb  
Steven M. Plumb, CPA  
Chief Financial Officer

**Exhibit Index**

<u>Exhibit</u>	<u>Description</u>
3.1 <sup>(1)</sup>	Certificate of Incorporation of Victoria Enterprises, Inc.
3.2 <sup>(1)</sup>	Certificate of Amendment of Certificate of Incorporation of Victoria Enterprises, Inc.
3.3 <sup>(1)</sup>	Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc.
3.4 <sup>(1)</sup>	Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc.
3.5 <sup>(1)</sup>	Certificate of Ownership and Merger Merging Biokeys, Inc. with and into Biokeys Pharmaceuticals, Inc.
3.6 <sup>(2)</sup>	Amended and Restated Bylaws of Biokeys Pharmaceuticals, Inc.
3.7 <sup>(1)</sup>	Certificate of Amendment to the Certificate of Incorporation of ADVENTRX Pharmaceuticals, Inc.
3.8 <sup>(3)</sup>	Certificate of Designation of BioQuest, Inc.
3.9 <sup>(4)</sup>	Certificate of Designation of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock of Biokeys Pharmaceuticals, Inc.
4.1 <sup>(5)</sup>	Common Stock and Warrant Purchase Agreement, dated as of April 5, 2004, among the Company and the Investors named therein
4.2 <sup>(5)</sup>	A-1 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement with the Investors
4.3 <sup>(5)</sup>	A-2 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement with the Investors
4.4 <sup>(6)</sup>	Common Stock and Warrant Purchase Agreement, dated April 8, 2004, between the Company and CD Investment Partners, Ltd.
4.5 <sup>(6)</sup>	A-1 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
4.6 <sup>(6)</sup>	A-2 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
4.7 <sup>(6)</sup>	Warrant to Purchase Common Stock issued on April 8, 2004 to Burnham Hill Partners
4.8 <sup>(6)</sup>	Warrant to Purchase Common Stock issued on April 8, 2004 to Ernest Pernet
4.9 <sup>(6)</sup>	Warrant to Purchase Common Stock issued on April 8, 2004 to W.R. Hambrecht + Co., LLC

- 4.10 <sup>(5)</sup> Registration Rights Agreement, dated as of April 5, 2004, among the Company and the Investors named therein
- 4.11 <sup>(6)</sup> Registration Rights Agreement, dated as of April 8, 2004, between the Company and CD Investment Partners, Ltd.
- 4.12 Not used
- 4.13 Not used

- 4.14 <sup>(7)</sup> Common Stock and Warrant Purchase Agreement, dated April 19, 2004, between the Company and Franklin Berger
- 4.15 <sup>(7)</sup> A-1 Warrant to Purchase Common Stock issued to Franklin Berger
- 4.16 <sup>(7)</sup> A-2 Warrant to Purchase Common Stock issued to Franklin Berger
- 4.17 <sup>(7)</sup> Registration Rights Agreement, dated as of April 19, 2004, between the Company and Franklin Berger
- 4.18 <sup>(5)</sup> Registration Rights Agreement, dated \_\_\_\_\_, 2001, between the Company and certain stockholders
- 4.19 <sup>(5)</sup> Warrant to Purchase Common Stock issued by the Company
- 4.20 <sup>(5)</sup> Stock Subscription Agreement
- 4.21 <sup>(5)</sup> Warrant to Purchase Common Stock issued by the Company
- 4.22 <sup>(5)</sup> Warrant for the Purchase of Shares of Common Stock No. WA-2A issued June 14, 2001 to Robert J. Neborsky and Sandra S. Neborsky, JTWROS
- 10.1 <sup>(8)</sup> Patent and Technology License Agreement, dated June 14, 1996, among the Company, the Board of Regents of the University of Texas System and the University of Texas M. D. Anderson Cancer Center (Request for confidential treatment of certain data)
- 10.2 <sup>(8)</sup> Amendment No. 1 to Patent and Technology License Agreement, dated June 15, 2000, between the Company and the University of Texas M. D. Anderson Cancer Center (Request for confidential treatment of certain data)
- 10.3 <sup>(8)</sup> Option and License Agreement, dated January 23, 1998, between the Company and the University of Southern California (Request for confidential treatment of certain data)
- 10.4 <sup>(2)</sup> First Amendment to License Agreement, dated August 16, 2000, between the Company and the University of Southern California (Request for confidential treatment of certain data)
- 10.5 <sup>(8)</sup> Option and License Agreement, dated August 17, 2000, between the Company and the University of Southern California (Request for confidential treatment of certain data)
- 10.6 <sup>(9)</sup> Standard Multi-Tenant Office Lease - Gross, dated June 3, 2004, between the Company and George V. Casey & Ellen M. Casey, Trustees of the Casey Family Trust dated June 22, 1998
- 10.7 <sup>(10)</sup> Patent License Agreement, effective August 1, 2002, between the Company and the National Institutes of Health

10.8 <sup>(11)</sup> Letter Agreement, effective January 1, 2003, between the Company and Steven M. Plumb, P.C.

10.9 <sup>(11)</sup> Offer Letter, dated March 5, 2003, from the Company to Joan M. Robbins, Ph.D.

10.10 <sup>(12)</sup> Amendment to Option and License Agreement, dated April 21, 2003, the Company and the University of Southern California

31.1 Rule 13a-14(a)/15d-14(a) Certification

31.2 Rule 13a-14(a)/15d-14(a) Certification

32 Section 1350 Certifications

- (1) Incorporated by reference to the same-numbered exhibit to the Company's Form 8-A, filed April 27, 2004
- (2) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 10-SB, filed October 2, 2001.
- (3) Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 10-SB, filed October 2, 2001.
- (4) Incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-QSB, filed November 26, 2002 (exhibit included in the body of the Form 10-QSB and not filed as a separate exhibit file).
- (5) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form S-3, filed June 30, 2004.
- (6) Incorporated by reference to the same-numbered exhibit to the Company's Current Report on Form 8-K, filed April 13, 2004.
- (7) Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB, filed May 12, 2004.
- (8) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 10-SB/A, filed January 14, 2002.
- (9) Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB, filed August 10, 2004.
- (10) Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB, filed November 26, 2002.
- (11) Incorporated by reference to the same-numbered exhibit to the Company's Annual Report on Form 10-KSB, filed April 16, 2003.
- (12) Incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-QSB, filed August 14, 2003.

