

ADVENTRX PHARMACEUTICALS INC  
Form 10QSB  
May 12, 2004

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 20549**

**FORM 10-QSB**

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

**For the quarterly period ended March 31, 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.**

(formerly Biokeys 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.)  
**9948 Hibert Street, Suite 100**  
**San Diego, California 92131**  
(Address of principal executive offices)

**(858) 271-9671**  
(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  No

As of April 30, 2004, 53,387,954 shares of the issuer's common stock, par value \$0.001 per share, were outstanding.

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

**ADVENTRX PHARMACEUTICALS, INC.**  
 (formerly Biokeys Pharmaceuticals, Inc.)  
**FORM 10-QSB**  
**March 31, 2004**  
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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**ADVENTRX PHARMACEUTICALS, INC**  
 (Formerly Biokeys Pharmaceuticals, Inc.)  
 (A Development Stage Enterprise)  
 Condensed Balance Sheets

	<u>March 31,</u> <u>2004</u>	<u>December 31,</u> <u>2003</u>
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,423,918	
		\$
4,226,397		
Prepaid expenses		135,735
		28,376
		<hr/>
		<hr/>
		<hr/>
Total current assets		3,559,653
		4,254,773
Property and equipment, net		54,582
		20,840
Other assets		7,743
		7,743
		<hr/>
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		<hr/>
Total assets		

\$  
3,621,978  
\$  
4,283,356

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**Liabilities and Shareholders' Equity**

Current liabilities:

Accounts payable and accrued liabilities

\$  
51,469

Accrued dividends payable

\$  
90,243

72,800

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Total liabilities

51,469  
163,043

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Commitments and contingencies

Shareholders' equity:

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

Authorized 8,000 shares; issued and outstanding, 473

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shares in 2003 (aggregate involuntary liquidation preference

\$473,000 December 31, 2003)

4

Series B convertible preferred series 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 42,970,330 shares in 2004 and

issued and outstanding 42,491,708 shares in 2003

42,970

42,492

Additional paid-in capital

32,753,895

32,556,963

Deficit accumulated during the development stage

(29,191,609)

(28,481,146)

Treasury Stock, shares at cost; issued 23,165 shares

(34,747)

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Total shareholders' equity

3,570,509

4,120,313

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Total liabilities and shareholders' equity

\$  
3,621,978  
\$  
4,283,356

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See accompanying notes to condensed financial statements.

**ADVENTRX PHARMACEUTICALS, INC.**  
 (Formerly Biokeys Pharmaceuticals, Inc.)  
 (A Development Stage Enterprise)  
 Condensed Statements of Operations  
 (unaudited)

	Three months ended March 31,		Inception (June 12, 1996)
	2004	2003	through March 31, 2004
Net sales	\$	\$	\$ 174,830
Cost of goods sold			51,094
<b>Gross margin</b>			<b>123,736</b>
Grant revenue		3,603	129,733
Interest income	3,346	675	102,582
	<b>3,346</b>	<b>4,278</b>	<b>356,051</b>
<b>Operating expenses:</b>			
Research and development	296,375	(16,188)	5,026,301
General and administrative	414,382	423,504	8,829,226
Depreciation and amortization	3,052	1,494	10,101,759
Impairment loss write off of goodwill			5,702,130
Interest expense		962	179,090
Equity in loss of investee			178,936
<b>Total operating expenses</b>	<b>713,809</b>	<b>409,772</b>	<b>30,017,442</b>
Loss before cumulative effect of change in accounting principle			(710,463)
			(405,494)
			(29,661,391)
Cumulative effect of change in accounting principle			(25,821)

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Net loss

(710,463)

(405,494)

Preferred stock dividends

(29,687,212)

(9,460)

(602,320)

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Net loss applicable to common stock

\$  
(710,463)

\$  
(414,954)

\$  
(30,289,532)

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Loss per common share basic and diluted

\$  
(.02)

\$  
(.02)



See accompanying notes to condensed financial statements.

**ADVENTRX PHARMACEUTICALS, INC.**  
**(Formerly Biokeys Pharmaceuticals, Inc.)**  
 (A Development Stage Enterprise)  
 Condensed Statements of Shareholders' Equity (Deficit)  
 Inception (June 12, 1996) through March 31, 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	Deficit accumulated during the development	Treasury Stock,	Total shareholders equity
		Shares					
		Amount					Shares Amount
		Shares					
		Amount					
		Shares					
		Amount					
		capital					
		stage					
		at cost					
		(deficit)					

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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	10
	(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	(13,154)



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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 Company	
	(45,003)
Net loss	(45,003)





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	(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



Balances at December 31, 1998

	5,181,564
	5,182
	2,417,213
	(2,947,653)
Sale of common stock	(525,258)
	678,412
	678
	134,322

Expense related to stock warrants issued	135,000
	212,000
Net loss	212,000
	(1,055,485)
	(1,055,485)

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Issuance of common stock at conversion of notes and interest payable	3,123,500
	412,487
	412
	492,085
Issuance of common stock at conversion of notes payable	492,497
	70,354
	70
	83,930
Issuance of common stock to settle obligations	84,000

	495,111
	496
	1,201,664
Issuance of common stock for acquisition	1,202,160
	6,999,990
	7,000
	9,325,769
Issuance of warrants for acquisition	9,332,769

	4,767,664
Stock issued for acquisition costs	4,767,664
	150,000
	150
	487,350
Expense related to stock warrants issued	487,500
	140,000



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Dividends payable on preferred stock	140,000
	(85,000)
Cashless exercise of warrants	(85,000)
	599,066
	599
	(599)
Net loss	



	(256,000)
Repurchase of warrants	(256,000)
	(55,279)
Sale of warrants	(55,279)

	47,741
Cashless exercise of warrants	47,741
	218,493
	219
	(219)
Issuance of common stock to pay preferred dividends	
	93,421
	93
	212,907

Detachable warrants issued with notes payable	213,000
	450,000
Issuance of warrants to pay operating expenses	450,000
	167,138
Issuance of common stock to pay operating expenses	167,138

	106,293
	106
	387,165
	387,271
Issuance of preferred stock to pay operating expenses	137
	1
	136,499
	136,500
Net loss	



	(242,400)
Repurchase of warrants	(242,400)

Sale of warrants

240,000



	240
	117,613
Cashless exercise of warrants	117,853
	100,201
	100
	(100)
Excercise of warrants	
	344,573
	345
	168,477

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Sale of preferred stock	168,822
	200,000
	2,000
	70,109
	701
	998,392
Conversion of preferred stock into common stock	1,001,093
	(3,000)
	(30)
	1,800,000
	1,800
	(1,770)
Preferred stock dividends forgiven	

	335,440
Issuance of warrants to pay operating expenses	335,440

	163,109
Issuance of common stock to pay operating expenses	163,109

6,292

6

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	12,263
Issuance of preferred stock to pay operating expenses	12,269
	136
	1
	6,000
Issuance of stock options to employees	6,001
	329,296
Net loss	329,296



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	(26,149,069)
Dividends payable on preferred stock	(852,730)
	(37,840)
Conversion of Series C preferred stock into common stock	(37,840)
	(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
	53,491
Sale of common stock at \$0.40 per share, net of issuance costs	
	6,640,737
	6,676
	2,590,656
	2,597,332
Sale of common stock at \$1.00 per share, net of issuance costs	

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	3,701,733
	3,668
	3,989,181
Exchange of warrants	3,992,849
	235,291
	235
	49,486
Issuance of common stock to pay operating expenses	49,721
	230,000
	230
	206,569



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Issuance of warrants to pay operating expenses	206,799
	156,735
Issuance of stock options to employees	156,735
	286,033
Net loss	286,033



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Extinquishment of dividends payable on preferred stock	4,120,313
	72,800
Conversion of Series A cummulative preferred stock	72,800
	(473)
	(4)
	236,500
	236
	(232)
Conversion of Series B preferred stock	

	(200,000)
	(2,000)
	200,000
	200
	1,800
Exercise of warrants	
	42,122
	42
	2,208
Payment of financing and offering costs	2,250

	(1,251)
Issuance of stock options to employees	(1,251)
	86,860
Acquisition of treasury stock	86,860
	34,747





**ADVENTRX PHARMACEUTICALS, INC.**  
 (Formerly Biokeys Pharmaceuticals, Inc.)  
 (A Development Stage Enterprise)  
 Condensed Statements of Cash Flows  
 (unaudited)

	<b>Three months ended March 31,</b>		<b>Inception (June 12, 1996) through March 31, 2004</b>
	<b>2004</b>	<b>2003</b>	<b>2004</b>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (710,463)	\$ (405,494)	\$ (29,687,212)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation and amortization			3,052
			1,494
Forgiveness of employee receivable			10,101,759
			30,036
Impairment loss write off of goodwill			5,702,130
Expenses paid by warrants			5,702,130



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	105,883
Expenses paid by preferred stock	486,982
	142,501
Expenses related to stock warrants issued	
	612,000
Expenses related to employee stock options issued	
	86,860
	49,919
Expenses paid by issuance of common stock	702,189
	68,750
Equity in loss of investee	817,548
	178,936
Write-off of license agreement	
	152,866
Cumulative effect of change in accounting principle	

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25,821

Changes in assets and liabilities, net of effect of acquisitions:

(Increase) decrease in prepaid expenses

(107,359)

(3,690)

(282,846)

Increase (decrease) in accounts payable and accrued liabilities

(38,774)

(100,703)

(469,802)

Increase in sponsored research payable and license obligation

924,318

Net cash used in operating activities

(766,684)

(283,841)

(10,562,774)

Cash flows from investing activities:

Purchase of certificate of deposit

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Maturity of certificate of deposit	(1,016,330)
Purchases of property and equipment	1,016,330
	(36,794)
Payment on obligation under license agreement	(159,263)
Cash acquired in acquisition of subsidiary	(106,250)
Issuance of note receivable related party	64,233
Payments on note receivable	(35,000)
Advance to investee	405,993

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Cash transferred in rescission of acquisition (90,475)

Cash received in rescission of acquisition (19,475)

230,000

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Net cash provided by (used in) investing activities

(36,794)

289,763

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Cash flows from financing activities:

Proceeds from sale of preferred stock

Proceeds from sale of common stock

4,200,993

635,946

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Proceeds from sale or exercise of warrants	8,528,396
	2,250
Repurchase of warrants	384,237
	(55,279)
Payment of financing and offering costs	(1,251)
	(100,227)
Payments of notes payable and long-term debt	(605,909)
Proceeds from issuance of notes payable and detachable warrants	1,344,718
<hr/>	
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Net cash provided by financing activities	999
	635,946
	13,696,929
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Net increase (decrease) in cash and cash equivalents

(802,479)

352,105

Cash and cash equivalents at beginning of period

3,423,918

4,226,397

103,928

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Cash and cash equivalents at end of period

3,423,918 \$

456,033 \$

3,423,918 \$

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See accompanying notes to condensed financial statements.

**ADVENTRX PHARMACEUTICALS, INC.**

(A Development Stage Enterprise)

Notes to Condensed Financial Statements

Three months ended March 31, 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), 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.

**(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 months ended March 31, 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.**  
(A Development Stage Enterprise)  
Notes to Condensed Financial Statements  
Three months ended March 31, 2004 and 2003(Unaudited)

**Supplementary Cash Flow Information**

Interest of \$962 was paid during the three months ended March 31, 2003. No income taxes were paid during 2004 and 2003.

Noncash investing and financing transactions excluded from the condensed statements of cash flows for the three months ended March 31, 2004 and 2003 and for the period from inception (June 12, 1996) through March 31, 2004 are as follows:

	<u>2004</u>	<u>2003</u>	<u>Inception (June 12, 1996) through March 31, 2004</u>
Issuance of warrants, common stock and preferred stock for:			
Conversion of notes payable and accrued interest	\$	\$ 26,649	\$ 1,213,988
Payment of operating expenses			1,224,281
Conversion of preferred stock	2,004	701	2,705
Acquisitions			14,617,603
Payment of dividends			213,000
Assumptions of liabilities in acquisitions			1,009,567
Acquisition of license agreement for long-term debt			161,180
Cashless exercise of warrants	38		3,316
Dividends accrued		9,460	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
Detachable warrants issued with notes payable			450,000

**New Accounting Pronouncements**

No new pronouncements were issued during the three months ended March 31, 2004 that are expected to have a material effect on the Company's financial position or results of operations.



**ADVENTRX PHARMACEUTICALS, INC.**

(A Development Stage Enterprise)

Notes to Condensed Financial Statements

Three months ended March 31, 2004 and 2003

(Unaudited)

**(3) Equity Transactions**

In March 2004, warrants to purchase a total of 53,750 shares of common stock at between \$0.50 and \$0.60 per share were exercised for aggregate gross proceeds of \$2,250. In addition, a warrant to purchase 3,750 shares of common stock 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.

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.

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 volatility of 125% to 199%; risk-free interest rates 2.78% to 6.8%; and expected lives of three and seven years, respectively.

**ADVENTRX PHARMACEUTICALS, INC.**  
(A Development Stage Enterprise)  
Notes to Condensed Financial Statements  
Three months ended March 31, 2004 and 2003  
(Unaudited)

**(4) Stock Compensation Plans**

The value assigned to stock warrants granted to non-employees is accounted for in accordance with SFAS No. 123 and Emerging Issues Task Force (EITF) Issue 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* (EITF 96-18). The Company values warrants using the Black-Scholes option pricing model. Common stock is valued using the market price of common stock on the measurement date as defined in EITF 96-18. Series A 8% convertible preferred stock is valued at the liquidation value of \$1,000 per share. Series B Preferred stock is valued at the purchase price of \$1 per share. The Company applies Statement of Financial Accounting Standards No. 123 and related interpretations in accounting for employee stock-based compensation.

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 option will expire on March 1, 2007. The value of the option on the date of grant was \$152,050.

The Company recognized compensation expense of \$86,860 and \$49,919 in the three months ended March 31, 2004 and 2003, respectively, related to the portion of the options which vested in that period.

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 April 2006.

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

The computation of basic and diluted net loss per share for the three months ended March 31, 2004 and 2003 is as follows:

	2004	2003
Numerator:		
Net loss	\$ (710,463)	\$ (405,494)
Preferred stock dividends		(9,460)
<b>Numerator for basic and diluted loss per share</b>	<b>\$ (710,463)</b>	<b>\$ (414,954)</b>
Denominator for basic and diluted loss per share weighted average common shares outstanding		
	42,886,237	17,916,027
<b>Loss per common share basic and diluted</b>	<b>\$ (0.02)</b>	<b>\$ (0.02)</b>

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. At March 31, 2004 and 2003, 5,421,237 and 2,823,586 potentially dilutive shares, respectively, 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 incurred in 2004 and 2003.

**(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.

**ADVENTRX PHARMACEUTICALS, INC.**  
**(A Development Stage Enterprise)**  
**Notes to Condensed Financial Statements**  
**Three months ended March 31, 2004 and 2003**  
**(Unaudited)**

**(7) Subsequent Events**

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 issued warrants to purchase 642,547 shares of common stock at \$2.00 per share to two placement agents. 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.

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 Anti-Viral Research. The option will vest in three installments over three years starting April 2004. The option will expire on April 1, 2007. The value of the option on the date of grant was \$56,412.

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.

## 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 the Company's Common Stock, par value \$0.001 per share.

### Plan of Operation.

The Company is 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 preclinical and clinical efforts for CoFactor, BlockAide/CR and EradicAide as well as for general working capital. At this time we are beginning to commit additional resource to the development of Thiovir and are committing only minimal resources to the development of BlockAide/VP and Selone.

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. We also intend to file for approval for a Phase II trial for CoFactor for metastatic colorectal cancer patients in the United Kingdom during QIII 2004 and also file in QIII 2004 for approvals to begin treatment of pancreatic cancer patients with 5-U and CoFactor in two separate Phase II trials in the United States and Europe. We also intend to file for approval during QIII 2004 and QIV 2004, to begin second-line therapy trials for CoFactor use with 5-FU for metastatic colorectal cancer for the United States and United Kingdom.

We received FDA clearance for the IND Application filed in Q1 2004 to treat HIV patients with BlockAide/CR during 2004. We also intend to file an IND application in QIII 2004 to treat HIV patients with Thiovir, beginning in QIV 2004 and file an IND application in QIII 2004 to treat HIV patients with the initial formulation of EradicAide vaccine later in 2004.

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We currently expect the foregoing to require the expenditures set forth below during the next twelve months:

Expenditure	Estimated Cost
CoFactor trials	\$ 4,900,000
BlockAide/CR trials	900,000
First Thiovir Trial	400,000
First EradicAide trial	300,000
Total estimated research and development	6,500,000
Estimated general and administrative	1,581,000
Total estimated costs	\$ 8,081,000

The Company's cash position at April 30, 2004 of \$17,594,195 is sufficient to meet the Company's 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 middle 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 February 2004, the Company purchased 18 Rhesus monkeys for use in future research at M.D. Anderson in Houston, Texas for \$118,000. We purchased laboratory equipment totaling approximately \$40,000 during the first quarter of 2004.

Our facility lease expires in June 2004. We are currently undergoing a search for new office and laboratory space that would meet our forecast research and administrative needs for several years to come. In conjunction with this anticipated move to a new location we expect to spend \$50,000 on telephone and computer equipment and increased rent on the newly leased space beginning in the third quarter of 2004.

In conjunction with the additional research and development activities we expect to conduct, we anticipate adding two administrative staff and four research and development support personnel in the next 12 months. In March 2004, we hired a Vice President of Clinical and Medical Affairs at an annual salary of \$160,000.

The proceeds from our April 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 April 30, 2004, cash and cash equivalents with banks exceeded federally insured limits by approximately \$17,494,000.

## 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.**

The Company is a development stage enterprise and had an accumulated deficit of \$29,191,609 as of March 31, 2004. Since the Company presently has no source of revenues and is committed to continuing its 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 and successfully marketed. In addition, the Company has funded its operations primarily through the sale of Company securities, and has had limited working capital for its product development and other activities.

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

The Company has devoted its 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 the Company's present activities, and no revenues will likely be available until, and unless the new products are clinically tested, approved by the FDA and successfully marketed, either by the Company or a marketing partner, an outcome which the Company is not able to guarantee.

### **It is uncertain that the Company will have access to future capital or government grants.**

It is not expected that the Company 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 and/or clinical development may be required to fund our activities. We cannot assure 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, may involve restrictive covenants which preclude the Company from making distributions to stockholders and taking other actions beneficial to stockholders. If adequate funds are not available, the Company may be required to delay or reduce the scope of its drug development program or attempt to continue development by entering into arrangements with collaborative partners or others that may require the Company to relinquish some or all of its rights to proprietary drugs. The inability to fund its capital requirements would have a material adverse effect on the Company.

### **The Company is not certain that it will be successful in the development of its drug candidates.**

The successful development of any new drug is highly uncertain and is subject to a number of significant risks. Our drug candidates, 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 the Company from marketing a drug product. There can be no assurance that the development of drug candidates will demonstrate the efficacy and safety of a drug candidate as a therapeutic drug, or, even if demonstrated, that there will be sufficient advantages to its use over other drugs or treatments so as to render the drug product commercially viable. In the event that the Company is 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.

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

The Company is engaged in a segment of the pharmaceutical industry that is highly competitive and rapidly changing. If successfully developed and approved, any of the Company's 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 the Company. The Company anticipates that it 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 by the Company. Competitive products may render the Company's drugs obsolete or noncompetitive prior to the Company's recovery of development and commercialization expenses.

Many of the Company's 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 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. Accordingly, competitors may succeed in commercializing products more rapidly or effectively than the Company, which would have a material adverse effect on the Company.

**There is no assurance that the Company's products will have market acceptance.**

The success of the Company will depend in substantial part on the extent to which a drug product 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 drug product of the Company.

**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.**



The Company's ability to commercialize its 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. The Company cannot guarantee that adequate third-party insurance coverage will be available for the Company 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 FDA. Accordingly, even if coverage and reimbursement are provided by government, private health insurers, and third-party payors for uses of the Company's products, the market acceptance of these products would be adversely affected if the amount of reimbursement available for the use of the Company's therapies proved to be unprofitable for health care providers.

**Uncertainties related to health care reform measures may affect the Company's 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. The Company cannot predict the effect health care reforms may have on its business, and there is no guarantee that any such reforms will not have a material adverse effect on the Company.

**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 may be to delay marketing of new products for a considerable period of time, to impose costly procedures upon the Company's activities, and to provide an advantage to larger companies that compete with the Company. There can be no assurance that FDA or other regulatory approval for any products developed by the Company 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 the Company's ability to utilize any of its technologies, thereby adversely affecting the Company's 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.

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.

**The Company's success will be dependent on licenses and proprietary rights it receives from other parties, and on any patents it may obtain.**

Our success will depend in large part on the ability of the Company and its licensors 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. The Company has obtained licenses to patents and other proprietary rights from M.D. Anderson, USC and the NIH.

The patent positions of pharmaceutical companies, including those of the Company, are uncertain and involve complex legal and factual questions. There is no guarantee that the Company or its 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 the Company. In addition, we cannot assure that any patents issued to or licensed by the Company will not be challenged, invalidated, infringed or circumvented, or that the rights granted thereunder will provide competitive disadvantages to the Company.

Litigation, which could result in substantial cost, may also be necessary to enforce any patents to which the Company has rights, or to determine the scope, validity and unenforceability of other parties' proprietary rights, which may affect the rights of the Company. 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 the Company's 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 the Company pending resolution of the disputed matters.

The Company may also rely on unpatented trade secrets and know-how to maintain its competitive position, which it seeks 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 the Company will have adequate remedies for any breach, or that trade secrets will not otherwise become known or be independently discovered by competitors.

**The Company's license agreements can be terminated in the event of a breach.**

The license agreements pursuant to which the Company has licensed its core technologies for its potential drug products permit the licensors, respectively M.D. Anderson, NIH and USC, to terminate the agreement under certain circumstances, such as the failure by the licensee to use its reasonable best efforts to commercialize the subject drug or the occurrence of any other uncured material breach by the licensee. The license agreements also provide that the licensor is primarily responsible for obtaining patent protection for the technology licensed, and the licensee is required to reimburse it 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 the Company.

**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 the Company 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.

**The Company's success is dependent on its key personnel.**

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

**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 the Company 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 the Company.

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

The Company does not have marketing or sales personnel. The Company 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 the Company will be able to establish marketing, distribution or sales capabilities or make arrangements with third parties to perform those activities on terms satisfactory to the Company, or that any internal capabilities or third party arrangements will be cost-effective.

In addition, any third parties with which the Company 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 the Company will be able to control the amount and timing of resources that any third party may devote to the products of the Company or prevent any third party from pursuing alternative technologies or products that could result in the development of products that compete with, and/or the withdrawal of support for, the products of the Company.

**The Company does 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.**

The Company will not have any manufacturing capacity. When required, the Company will seek to establish relationships with third-party manufacturers for the manufacture of clinical trial material and the commercial production of a drug product just as it has with Merck Eprova AG, Multiple Peptide Systems, Inc., and Peptisyntha, Inc. There can be no assurance that the Company 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 the drug product 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 its manufacturing requirements on commercially acceptable terms would have a material adverse effect on the Company.

**The Company does not have its own research facilities and will be dependent on third parties for drug development.**

The Company does not have its own research and development facilities and engages consultants and independent contract research organizations to design and conduct clinical trials in connection with the development of a drug. As a result, these important aspects of a drug's development will be outside the direct control of the Company. In addition, there can be no assurance that such third parties will perform all of their obligations under arrangements with the Company 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.**

The business of the Company will expose it 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 the Company. The Company intends to obtain additional limited product liability insurance for its clinical trials, directly or through its marketing development partners or contract research organization (CRO) partners, when they begin in the U.S. and to expand its insurance coverage if and when the Company begins marketing commercial products. However, there can be no assurance that the Company will be able to obtain product liability insurance on commercially acceptable terms or that the Company will be able to maintain such insurance at a reasonable cost or insufficient amounts to protect against potential losses. A successful product liability claim or series of claims brought against the Company could have a material adverse effect on the Company.

**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 share that risk in excess of our insurance limits. 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 Company's 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 the Company or its 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.**

The Company has never paid cash dividends on Common Stock, and does not intend to do so in the foreseeable future.

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

The Board of Directors is authorized to designate one or more series 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 of the Company from occurring, among other possibilities.

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

The Company's Certificate of Incorporation authorizes the Board of Directors (the Board) to issue shares of undesignated preferred stock without stockholder approval on such terms as the Board may determine. The rights of the holders of Common Stock will be subject to, and may be adversely affected by, the rights of the holders of any such preferred stock that may be issued in the future. Moreover, 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 the Certificate of Incorporation and the 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 the Common Stock.

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

Pursuant to the Company's 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. The Certificate of Incorporation and by-laws provide that the Company must indemnify its 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.**

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer has evaluated the effectiveness of the Company's disclosure controls and procedures as of March 31, 2004. Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective for gathering, analyzing and disclosing the information the Company is required to disclose in the reports it files 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 March 31, 2004, there was no change in the Company's internal control over financial reporting that materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings.

In December 2003, the Company 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 February 2004, the federal court adopted a stipulation of the Company and the Defendants pursuant to which the Defendants accepted service of the lawsuit effective as of January 14, 2004 and agreed to file their response to the Company's complaint by March 1, 2004. On March 1, 2004, the Defendants filed an answer denying the material allegations of the Company's complaint. The Company and Defendants are currently scheduled to participate in a court-sponsored case review and mediation known as an Early Neutral Evaluation, which is procedurally required by the federal court, on July 1, 2004. To the Company's knowledge, as of the date of this report, no other substantive filings have been made by the Company 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 February 26, 2004, the Company received a letter from counsel to a stockholder in which the stockholder demanded to inspect certain books and records of the Company. One stated purpose for the stockholder's demand is to determine whether corporate wrongdoing occurred in connection with certain private placements of the Company's securities. On March 2, 2004, the Company timely responded to this stockholder's demand and agreed to make documents available for inspection on or after March 15, 2004. On April 16, 2004, the Company received a letter from counsel to the stockholder acknowledging receipt of the Company's letter dated March 2, 2004 and that the stockholder would shortly contact the Company to schedule the requested inspection. As of the date of this report, the inspection has neither taken place nor been scheduled by the stockholder. The Company believes that there is no reasonable basis for any claim by this stockholder. The Company will vigorously defend any such claim, if asserted.

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 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.

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.

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In March 2004, the sole holder of shares of Series A 8% Convertible Preferred Stock of the Company agreed to exchange all of his 237 shares of Series A 8% Convertible Preferred Stock for 136,500 shares of common stock.

In March 2004, warrants to purchase a total of 53,750 shares of common stock at between \$0.50 and \$0.60 per share were exercised for aggregate gross proceeds of \$2,250. A warrant representing 3,750 shares of common stock was exercised for proceeds of \$2,250. In addition, the Company issued 38,372 shares of common stock upon the cashless exercise of a warrant to purchase 50,000 shares of common stock.

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 option will expire on March 1, 2007.

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 issued warrants to purchase 642,547 shares of common stock at \$2.00 per share to two placement agents.

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.

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 Anti-Viral Research. The option will vest in three installments over three years starting April 2004. The option will expire on April 1, 2007.

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.

Except as otherwise noted above, 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 Sections 3(a)(9) or 4(2) of the Securities Act or Regulation D promulgated under the Securities Act.

### **Item 3. Defaults Upon Senior Securities.**

Not applicable.

### **Item 4. Submission Of Matters To A Vote Of Security Holders.**

Not applicable.

### **Item 5. Other Information.**

Not applicable.

**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 April 12, 2004, we filed a current report on Form 8-K to report, under Items 5 and 7 of such report, the sale of shares of common stock and issuance of warrants to purchase shares of common stock for aggregate gross proceeds of \$15,376,450. On April 13, 2004, we amended the current report on Form 8-K filed on April 12, 2004 to include a missing exhibit and implement a few clarifying revisions.

**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.

May 12, 2004

/s/ Steven M. Plumb  
Steven M. Plumb, CPA  
Chief Financial Officer



**Exhibit Index**

Exhibit	Description
2.1 <sup>(1)</sup>	Agreement and Plan of Merger dated May 19, 2000 among BioQuest, Inc.; BioQuest Acquisition Corp.; and Biokeys, Inc.
3.1 <sup>(2)</sup>	Certificate of Incorporation of Victoria Enterprises, Inc.
3.2 <sup>(2)</sup>	Certificate of Amendment of Certificate of Incorporation of Victoria Enterprises, Inc.
3.3 <sup>(2)</sup>	Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc.
3.4 <sup>(2)</sup>	Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc.
3.5 <sup>(2)</sup>	Certificate of Ownership and Merger Merging Biokeys, Inc. with and into Biokeys Pharmaceuticals, Inc.
3.6 <sup>(1)</sup>	Amended and Restated Bylaws of Biokeys Pharmaceuticals, Inc.
3.7 <sup>(2)</sup>	Certificate of Amendment to the Certificate of Incorporation of ADVENTRX Pharmaceuticals, Inc.
4.1 <sup>(1)</sup>	Certificate of Designation of BioQuest, Inc.
4.2 <sup>(3)</sup>	Certificate of Designation of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock of Biokeys Pharmaceuticals, Inc.
4.3	Common Stock and Warrant Purchase Agreement, dated as of April 5, 2004, among the Company and the Investors named therein
4.4 <sup>(4)</sup>	Common Stock and Warrant Purchase Agreement, dated April 8, 2004, between the Company and CD Investment Partners, Ltd.
4.5 <sup>(5)</sup>	A-1 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
4.6 <sup>(5)</sup>	A-2 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
4.7 <sup>(5)</sup>	Warrant to Purchase Common Stock issued on April 8, 2004 to Burnham Hill Partners
4.8 <sup>(5)</sup>	Warrant to Purchase Common Stock issued on April 8, 2004 to Ernest Pernet
4.9 <sup>(5)</sup>	Warrant to Purchase Common Stock issued on April 8, 2004 to W.R. Hambrecht + Co., LLC
4.10	Form of A-1 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement
4.11	Form of A-2 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement
4.12	Registration Rights Agreement, dated as of April 5, 2004, among the Company and the Investors named therein
4.13 <sup>(6)</sup>	Registration Rights Agreement, dated as of April 8, 2004, between the Company and CD Investment Partners, Ltd.

4.14	Common Stock and Warrant Purchase Agreement, dated April 19, 2004, between the Company and Franklin Berger
4.15	A-1 Warrant to Purchase Common Stock issued to Franklin Berger
4.16	A-2 Warrant to Purchase Common Stock issued to Franklin Berger
4.17	Registration Rights Agreement, dated as of April 19, 2004, between the Company and Franklin Berger
10.1 <sup>(7)</sup>	Patent and Technology License Agreement with M.D. Anderson - June, 1996 (Request for confidential treatment of certain data)
10.2 <sup>(7)</sup>	Amendment to M.D. Anderson Licensing Agreement June 15, 2000 (Request for confidential treatment of certain data)
10.3 <sup>(7)</sup>	Option and License Agreement with USC - June 23, 1998 (Co Factor and Selone) (Request for confidential treatment of certain data)
10.4 <sup>(1)</sup>	Amendment to Option and License Agreement with USC dated August 16, 2000 (Co Factor and Selone) (Request for confidential treatment of certain data)
10.5 <sup>(7)</sup>	Option and License Agreement with USC dated August 17, 2000 (Thiovir) (Request for confidential treatment of certain data)
10.6	Not currently in use
10.7 <sup>(8)</sup>	Patent License Agreement, effective August 1, 2002, between Biokeys, Inc. and the National Institutes of Health
10.8 <sup>(9)</sup>	Letter Agreement, effective January 1, 2003, between Biokeys Pharmaceuticals, Inc. and Steven M. Plumb, P.C.
10.9 <sup>(9)</sup>	Offer Letter, dated March 5, 2003, from Biokeys Pharmaceuticals, Inc. to Joan M. Robbins, Ph.D.
31.1	Rule 13a-14(a)/15d-14(a) Certification
31.2	Rule 13a-14(a)/15d-14(a) Certification
32	Section 1350 Certifications

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- (1) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 10-SB, filed October 2, 2001.
  - (2) Incorporated by reference to the same-numbered exhibit to the Company's Form 8-A, filed April 27, 2004.
  - (3) Incorporated by reference to the same-numbered exhibit 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).
  - (4) Incorporated by reference to exhibit 4.2 to the Company's Current Report on Form 8-K, filed April 13, 2004.
  - (5) Incorporated by reference to the same-numbered exhibit to the Company's Current Report on Form 8-K, filed April 13, 2004.
  - (6) Incorporated by reference to exhibit 4.11 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 Registration Statement on Form 10-SB/A, filed January 11, 2002.
  - (8) Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB, filed November 26, 2002.
  - (9) Incorporated by reference to the same-numbered exhibit to the Company's Annual Report on Form 10-KSB, filed April 16, 2003.

