

ARBIOS SYSTEMS INC  
Form 10QSB  
May 18, 2007

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-QSB**

(MARK ONE)

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2007

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-32603

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**ARBIOS SYSTEMS, INC.**

(Exact name of small business issuer as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or  
organization)

91-1955323  
(I.R.S. Employer Identification No.)

1050 Winter Street, Suite 1000, Waltham, MA  
(Address of principal executive offices)

02451  
(Zip Code)

(781) 839-7293  
(Issuer's telephone number)

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 reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No .

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

On May 7, 2007, there were 24,956,643 shares of common stock, \$.001 par value per share, issued and outstanding.

Transitional Small Business Disclosure Format (Check one): Yes  No

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**FORM 10-QSB**  
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**ARBIOS SYSTEMS, INC.**  
(A development stage company)  
**CONDENSED BALANCE SHEETS**

**PART I - FINANCIAL INFORMATION**

**ITEM 1. Condensed Financial Statements**

	March 31, 2007 (Unaudited)	December 31, 2006 (Audited)
<b><u>ASSETS</u></b>		
Current assets		
Cash and cash equivalents	\$ 1,344,817	\$ 2,054,280
Prepaid expenses	105,300	147,163
Total current assets	1,450,117	2,201,443
Net property and equipment	66,256	73,110
Patent rights, net of accumulated amortization of \$119,014 and \$113,894, respectively	147,653	152,773
Other assets	50,818	62,827
Total assets	\$ 1,714,844	\$ 2,490,153
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
Current liabilities		
Accounts payable	\$ 446,933	\$ 310,162
Accrued expenses	550,941	132,073
Total current liabilities	997,874	442,235
Long term contract obligations	250,000	-
Accrued warrant liability	-	763,654
Total liabilities	1,247,874	1,205,889
Stockholders' equity		
Preferred stock, \$.001 par value; 5,000,000 shares authorized: none issued and outstanding	-	-
Common stock, \$.001 par value; 60,000,000 shares authorized; 17,460,181 shares issued and outstanding at March 31, 2007 and December 31, 2006	17,460	17,460
Additional paid-in capital	16,080,301	14,507,939
Deficit accumulated during the development stage	(15,630,791)	(13,241,135)
Total stockholders' equity	466,970	1,284,264
Total liabilities and stockholders' equity	\$ 1,714,844	\$ 2,490,153

The accompanying notes are an integral part of these condensed financial statements.

**ARBIOS SYSTEMS, INC.**  
(A development stage company)  
**CONDENSED STATEMENTS OF OPERATIONS**  
(Unaudited)

	For the three months ended March 31,		Inception to
	2007	2006	March 31, 2007
Revenues	\$ -	\$ -	\$ 320,966
<b>Operating expenses:</b>			
General and administrative	675,831	744,064	8,997,920
Research and development	1,030,993	366,190	6,844,169
Total operating expenses	1,706,824	1,110,254	15,842,089
Loss before other income (expense)	(1,706,824)	(1,110,254)	(15,521,123)
<b>Other income (expense):</b>			
Change in fair value of warrant liability	-	-	521,187
Equity offering contingency	(180,000)	-	(180,000)
Interest income	18,355	40,786	314,470
Interest expense	-	-	(244,138)
Total other income (expense)	(161,645)	40,786	411,519
Net loss	\$ (1,868,469)	\$ (1,069,468)	\$ (15,109,604)
<b>Net loss per share:</b>			
Basic and diluted	\$ (0.11)	\$ (0.06)	
<b>Weighted-average shares:</b>			
Basic and diluted	17,460,181	16,587,454	

The accompanying notes are an integral part of these condensed financial statements.

**ARBIOS SYSTEMS, INC.**  
(A development stage company)  
**CONDENSED STATEMENTS OF CASH FLOWS**  
(Unaudited)

	For the three months ended March 31,		Inception to
	2007	2006 (Restated)	March 31, 2007
<b>Cash flows from operating activities:</b>			
Net loss	\$ (1,868,469)	\$ (1,069,468)	\$ (15,109,604)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of debt discount	-	-	244,795
Depreciation and amortization	11,974	12,651	264,193
Change in fair value of warrant liability	-	-	(521,187)
Patent rights impairment	-	-	91,694
Interest earned on discounted short term investments	-	8,406	-
Issuance of common stock, options and warrants for compensation	212,951	210,739	3,012,885
Insurance of warrant for patent acquisition	74,570	-	74,570
Settlement of accrued expense	-	-	54,401
Deferred compensation costs	-	-	319,553
Changes in operating assets and liabilities:			
Prepaid expenses	41,863	43,348	(105,302)
Other assets	12,009	4,987	(50,818)
Accounts payable and accrued expenses	555,639	(24,758)	904,372
Other liabilities	-	-	64,695
Contractual obligation	250,000	-	250,000
Net cash provided by operating activities	(709,463)	(814,095)	(10,505,753)
<b>Cash flows from investing activities:</b>			
Additions of property and equipment	-	(3,447)	(144,796)
Purchase of short term investments	-	(5,954,653)	(21,866,787)
Maturities of short term investments	-	4,965,947	21,866,787
Net cash provided by and (used in) investing activities	-	(992,153)	(144,796)
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of convertible debt	-	-	400,000
Proceeds from common stock option/warrant exercise	-	-	65,200
Net proceeds from issuance of common stock and warrants	-	1,310,092	11,313,249
Net proceeds from issuance of preferred stock	-	-	238,732
Payments on capital lease obligation, net	-	-	(21,815)
Net cash provided by financing activities	-	1,310,092	11,995,366
Net (decrease) increase in cash	(709,463)	(496,156)	1,344,817
Cash at beginning of period	2,054,280	2,379,738	-

Cash at end of period	\$	1,344,817	\$	1,883,582	\$	1,344,817
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**Supplemental disclosures of non-cash financing activity**

Issuance of securities for obligation related to finder's fees		-		-	\$	47,500
Accrued warrant liability	\$	-	\$	951,841	\$	1,284,841

The accompanying notes are an integral part of these condensed financial statements.

**ARBIOS SYSTEMS, INC.**  
**(A Development Stage Company)**  
**CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY**  
**PERIOD FROM AUGUST 23, 2000 (INCEPTION) TO MARCH 31, 2007**  
**(Unaudited)**

	Preferred Stock		Common Stock		Additional	Deferred	Deficit	
	Shares	Amount	Shares	Amount	Paid-In	Costs	Accumulated	Total
					Capital		During the	
							Development	
							Stage	
Balance, August 23, 2000 (inception) restated for effect of reverse merger with Historical Autographs U.S.A. Inc.			-	\$ -	\$ -			\$ -
Stock issuance in exchange for cash			5,000,000	50	4,950			5,000
Net loss							(9,454)	(9,454)
Balance, December 31, 2000, as restated	-	-	5,000,000	50	4,950	-	(9,454)	(4,454)
Issuance of junior preferred stock for cash of \$250,000 and in exchange for \$400,000 in patent rights, research and development costs, and employee loanout costs less issuance expenses of \$11,268, June 29, 2001	681,818	7			958,278	(343,553)		614,732
Issuance of common stock in exchange for patent rights and deferred research and development costs			362,669	4	547,284			547,288

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Services receivable						(550,000)		(550,000)
Deferred employee loan-out costs receivable earned						82,888		82,888
Net loss							(237,574)	(237,574)
Balance, December 31, 2001	681,818	7	5,362,669	54	1,510,512	(810,665)	(247,028)	452,880

The accompanying notes are an integral part of these condensed financial statements.



**ARBIOS SYSTEMS, INC.**  
**(A Development Stage Company)**  
**CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY**  
**PERIOD FROM AUGUST 23, 2000 (INCEPTION) TO MARCH 31, 2007**  
**(Unaudited)**

	Preferred Stock		Common Stock		Additional	Deferred	Deficit	
	Shares	Amount	Shares	Amount	Paid-In	Costs	Accumulated	Total
					Capital		During the	
							Development	
							Stage	
Amendment of December 31, 2001 agreement for the issuance of common stock agreement in exchange for research and development services					(495,599)	550,000		54,401
Deferred employee loan out costs receivable earned						171,776		171,776
Issuance of common stock for compensation			70,000	1	10,499			10,500
Issuance of common stock for cash			999,111	9	149,857			149,866
Net loss							(494,780)	(494,780)
Balance, December 31, 2002	681,818	7	6,431,780	64	1,175,269	(88,889)	(741,808)	344,643
Issuance of common stock for cash less issuance expense of \$2,956			417,000	417	246,827			247,244
Issuance of common stock in private placement for cash less issuance expense of \$519,230			4,000,000	4,000	3,476,770			3,480,770

Issuance of common stock for convertible debenture less issuance expense of \$49,500	400,000	400	350,100	350,500
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Shares issued in connection with acquisition of Historical Autographs U.S.A., Inc. on October 30, 2003	1,220,000	8,263	(8,263)	-
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The accompanying notes are an integral part of these condensed financial statements.

**ARBIOS SYSTEMS, INC.**  
**(A Development Stage Company)**  
**CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY**  
**PERIOD FROM AUGUST 23, 2000 (INCEPTION) TO MARCH 31, 2007**  
**(Unaudited)**

	Preferred Stock		Common Stock		Additional	Deferred	Deficit	
	Shares	Amount	Shares	Amount	Paid-In	Costs	Accumulated	Total
					Capital		During the	
							Development	
							Stage	
Value of warrants and beneficial conversion feature of bridge loan					244,795			244,795
Deferred employee loan-out costs receivable earned						88,889		88,889
Preferred Stock converted to Common Stock	(681,818)	(7)	681,818	7				
Net loss							(885,693)	(885,693)
Balance, December 31, 2003	-	-	13,150,598	13,151	5,485,498	-	(1,627,501)	3,871,148
Issuance of common stock options and warrants for compensation					972,430			972,430
Exercise of common stock options			18,000	18	2,682			2,700
Issuance of securities for payable			47,499	47	47,451			47,498
Net loss							(3,327,827)	(3,327,827)
Balance, December 31, 2004	-	-	13,216,097	13,216	6,508,061	-	(4,955,328)	1,565,949
Issuance of common stock in private								

placement for cash less issuance expense of \$384,312	2,991,812	2,992	6,224,601	6,227,593
Issuance of common stock options and warrants for compensation			557,080	557,080
Exercise of common stock options	25,000	25	62,475	62,500

The accompanying notes are an integral part of these condensed financial statements.

**ARBIOS SYSTEMS, INC.**  
**(A Development Stage Company)**  
**CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY**  
**PERIOD FROM AUGUST 23, 2000 (INCEPTION) TO MARCH 31, 2007**  
**(Unaudited)**

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deferred Development Costs	Accumulated During the Development Stage	Total
Net loss							(3,823,903)	(3,823,903)
Balance, December 31, 2005	-	-	16,232,909	\$ 16,233	\$ 13,352,217	-	(\$8,779,231)	\$ 4,589,219
Issuance of common stock in private placement for cash less issuance expense of \$95,013			1,227,272	1,227	1,253,760			1,254,987
Issuance of common stock options and warrants for compensation					703,839			703,839
Stock warrant term extension			-		482,964			482,964
Warrant liability					(1,284,841)			(1,284,841)
Net loss							(4,461,904)	(4,461,904)
Balance, December 31, 2006	-	-	17,460,181	\$ 17,460	\$ 14,507,939	-	(\$13,241,135)	\$ 1,284,264
Cumulative effect of change in accounting principle:								
Adjust retained earnings at January 1, 2007 for change in accounting principle							(521,187)	(521,187)
Reclassification of warrants					1,284,841			1,284,841
Issuance of common stock, options and warrants for compensation					153,926			153,926

Stock warrant term extension	-	59,025	59,025					
Insurance of warrant for patent acquisition		74,570	74,570					
Net loss		(1,868,469)	(1,868,469)					
Balance, March 31, 2007	-	-	17,460,181	\$ 17,460	\$ 16,080,301	-	(\$15,630,791)	\$ 466,970

The accompanying notes are an integral part of these condensed financial statements.

**Arbios Systems, Inc. (A Development Stage Company)**  
**Notes to Condensed Financial Statements (Unaudited)**  
**Three Months Ended March 31, 2007**

**(1) Basis of Presentation:**

Arbios Systems, Inc., a Delaware corporation (the "Company"), seeks to develop, manufacture and market liver assist devices to meet the urgent need for therapy of liver failure. On July 25, 2005, Arbios Systems, Inc. changed its state of incorporation from Nevada to Delaware. On July 26, 2005, Arbios Technologies, Inc., the wholly-owned subsidiary of Arbios Systems, Inc., merged with and into Arbios Systems, Inc. Unless the context indicates otherwise, references herein to the "Company" during periods prior to July 26, 2005 include both Arbios Systems, Inc., a Nevada corporation and Arbios Technologies, Inc.

On October 30, 2003, Historical Autographs U.S.A., Inc. and Arbios Technologies, Inc. consummated a reverse merger, in which Arbios Technologies, Inc. became the wholly owned subsidiary of Historical Autographs U.S.A., Inc. Concurrently with the merger, Historical Autographs U.S.A., Inc. changed its name to Arbios Systems, Inc. and is herein referred to as "Arbios Systems". The stockholders of Arbios Technologies, Inc. transferred ownership of one hundred percent of all the issued and outstanding shares of their capital stock of Arbios Technologies, Inc. in exchange for 11,930,598 newly issued shares, or approximately 91%, of the common stock, \$.001 par value, of Arbios Systems. At that time, the former management of Arbios Systems resigned and was replaced by the same persons who served as officers and directors of Arbios Technologies, Inc. The former owners of Arbios Technologies, Inc. controlled the combined entity after the merger, and the combination was accounted for as a purchase by Arbios Technologies, Inc. as the acquirer, for accounting purposes in accordance with Statement of Financial Accounting Standards No. 141: Business combinations, using reverse merger accounting, and no adjustments to the carrying values of the assets or liabilities of the acquired entity were required. Pro forma operating results, as if the acquisition had taken place at the beginning of the period, have not been presented as the operations of the acquiree were negligible. The financial position and results of operations of Arbios Systems are included in the statements of the Company from the date of acquisition.

The unaudited condensed financial statements and notes are presented as permitted by Form 10-QSB. These unaudited financial statements have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures, normally included in financial statements prepared in accordance with generally accepted accounting principles, have been omitted pursuant to such SEC rules and regulations. In the opinion of the management of the Company, the accompanying unaudited financial statements include all adjustments, including those that are normal and recurring considered necessary to present fairly the financial position as of March 31, 2007, and the results of operations for the period presented. These condensed financial statements should be read in conjunction with the Company's audited financial statements and the accompanying notes included in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2006 filed with the SEC. The Company's operating results will fluctuate for the foreseeable future. Therefore, period-to-period comparisons should not be relied upon as predictive of the results in future periods. The results of operations for the period ended March 31, 2007 are not necessarily indicative of the results to be expected for any subsequent periods or for the entire fiscal year. As of the date of the filing of the Company's Quarterly Report on Form 10-QSB for the quarter ended March 31, 2007, the Company estimates that it has cash to operate for at least the next twelve months, based in part upon the private placement on April 23, 2007 which raised gross proceeds of \$4,861,000 reduced by estimated fund raising costs of \$400,000 resulting in estimated net proceeds of \$4,461,000.

**(2) Restatement of Condensed Financial Statements**

In January 2005 and March 2006, we closed financing transactions that included the issuance of warrants and the grant of registration rights for securities issued in the transactions. The Company has been accounting for the warrants in accordance with “EITF 00-19: Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock” (“EITF 00-19”). Beginning in the quarter ended March 31, 2006 for the warrants issued in the January 2005 financing and in the quarter ended September 30, 2006 for the warrants issued in the March 2006 financing, in accordance with EITF 00-19, the Company recorded the fair value of these warrants as an accrued warrant liability and reduced additional paid-in capital by the amount of the recorded liability. The Company has determined that it should have included in the calculation of the fair value of the warrant the value of the anti-dilution provisions contained in the warrant agreements. The calculations of the fair value of the warrants did not include the value of the anti-dilutions provision for the filed financial statements included in our Quarterly Report Form 10-QSB for the quarter ended March 31, 2006. Therefore, we restated the financial statements for the three month period ended March 31, 2006 to reflect that additional paid in capital decreased by \$271,000 and the accrued warrant liability increased by a corresponding amount. The following table shows the net effect of the restatement on net loss, accrued warrant liability and additional paid in capital for the three months ended March 31, 2006.

	Three months ended March 31, 2006
Net loss	
As originally reported	\$ (1,069,468)
Adjustment	
As adjusted	\$ (1,069,468)
Accrued warrant liability	
As originally reported	\$ 680,841
Adjustment	271,000
As adjusted	\$ 951,841
Additional paid-in capital	
As originally reported	\$ 14,190,980
Adjustment	(271,000)
As adjusted	\$ 13,919,980

**(3) Recent Accounting Pronouncements**

None.

**(4) Stock-Based Compensation:**

In the quarter ended March 31, 2007, the Company granted 120,000 options to directors with exercise prices of \$0.51 per share which vest over one year. The fair value of the options was determined using the Black Scholes option pricing model utilizing the following assumptions: risk free interest rate 4.75%, stock price volatility 0.79, expected life 7 years, dividend yield 0%.

In the quarter ended March 31, 2007, the Company granted 82,354 shares of restricted stock to consultants at a price of \$0.01 per share. The amount of restricted shares issued was based on the closing price of the Company’s common stock on the date of grant.





A grant of 225,000 warrants to purchase common stock exercisable at \$1.50 per share was made in conjunction with the acquisition of certain patents. The warrants were fair valued using the Black Scholes pricing model utilizing the following assumptions: risk free interest rate 4.48%, stock price volatility 0.79, expected life 7 years, dividend yield 0%.

#### **(5) Accrued Warrant Liability**

In accordance with EITF 00-19 and other authoritative literature, it was determined that the warrants issued in the January 2005 and March 2006 private placements and the related registration rights agreements, discussed below, are free-standing derivative financial instruments as defined in EITF 00-19. In accordance with EITF 00-19, the value and balance sheet classification of the warrants are reviewed each reporting period and, while the warrants are classified as a liability, any changes in the value of the warrants on a re-measurement date will be recorded in the statement of operations.

On March 6, 2006, the Company completed a \$1,350,000 private equity financing to a group of institutional investors and an accredited investor. In the offering, the Company sold 1,227,272 shares of its common stock at a price of \$1.10 per share to the investors and issued to them warrants to purchase an additional 613,634 shares of its common stock at an exercise price of \$1.50 per share. The Company also entered into a Registration Rights Agreement with the investors in the March 2006 private placement pursuant to which the Company agreed to register and to maintain an effective registration statement for the shares of common stock issued in the private placement and for the common stock to be issued upon the exercise of warrants issued in the transaction.

In January 2005, the Company completed a \$6,611,905 private equity financing to a group of institutional investors and accredited investors. In the offering, 2,991,812 shares of the Company's common stock were sold, at a price of \$2.21 per share and the investors also received 5-year warrants to purchase an additional 1,495,906 shares of our common stock at an exercise price of \$2.90 per share. The placement agent received 5-year warrants to purchase 114,404 shares of the Company's common stock in addition to cash compensation of \$253,000 plus expenses. The Company also entered into a Registration Rights Agreement with the investors in the January 2005 private placement pursuant to which the Company agreed to register and to maintain an effective registration statement for the shares of common stock issued in the private placement and for the common stock to be issued upon exercise of warrants issued in the transaction. As a result of the Company's March 6, 2006 private equity financing discussed above, an anti-dilution provision from the January 2005 private equity financing was triggered which resulted in an additional 94,033 warrant shares being issuable to warrant holders from the January 2005 private equity financing. Additionally, the exercise price of the warrants was adjusted from \$2.90 to \$2.74 per share. The warrants are exercisable for five years from the date of issuance and can be redeemed by the Company after January 11, 2007 if the average trading price of the Company's common stock for 20 consecutive trading days is equal to or greater than \$5.80 and the average trading volume of the common stock is at least 100,000 shares during those 20 days.

The registration rights agreements associated with the January 2005 and March 2006 private placements provide for liquidated damages of 1.5% of the aggregate purchase price for each 30 day period for a maximum of eight 30 day periods, capped at 12%, if the Company fails to register such shares, or fails to maintain the effectiveness of such registration. As of the date the warrants were issued and for each subsequent reporting period through December 31, 2005, the Company determined that settlement in unregistered shares was an economic settlement alternative to delivering unregistered shares and consequently recorded the fair value of the warrants as equity. However, as of March 31, 2006 for the January 2005 private placement financing and as of September 30, 2006 for the March 2006 private placement, due primarily to a reduction in the fair market value of the Company's common stock share price, the potential liquidated damages exceeded the reasonable discount between registered and unregistered shares thereby making the settlement alternative uneconomic, and the warrants, valued using the Black Scholes pricing model were reclassified from equity to accrued warrant liability, based on the fair value of the warrants. For the quarters ended June 30, September 30 and December 31, 2006 the potential liquidated damages continued to exceed a reasonable

discount between the fair value of the registered and unregistered shares, thereby making net share settlement an uneconomic alternative.

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The warrant agreements from the January 2005 and March 2006 financings contain anti-dilution provisions whereby in the event that, during the five year life of the warrants, the Company issues additional shares of common stock, subject to certain exceptions, at a lower common stock offering price than the then effective exercise price of the warrants, 1) the exercise price of the warrants would be adjusted downward based on a weighted average formula described in the agreement and 2) additional warrant shares would be allocated to the warrant holder based on the described formula. Such potential changes in exercise price and additional warrant shares were taken into account in the valuation of the anti-dilution provision based on the estimated potential dilutive effects of future successive equity financings including consideration of potential cash requirements, potential size, timing and terms of such financings, projected future prices and volatility of the Company's stock, and other factors. The value of those estimated warrant shares issuable, together with the adjusted value of the estimated warrant shares with reduced exercise price, were determined using the Black Scholes pricing model.

For the valuation of all warrants including their anti-dilution provisions, the assumptions used in the applications of the Black Scholes pricing model are as follows: risk free interest rate 3.71%-5.07%, stock price volatility 0.71-0.83, expected life 1-5 years, dividend yield 0%.

In accordance with the Financial Accounting Standards No. 154, Accounting Changes and Error Corrections, or FASB 154, the Company is recording a change in accounting principal related to Financial Accounting Standards Board Staff Position No. Emerging Issues Task Force 00-19-2, "Accounting for Registration Payment Arrangements", ("EITF 00-19-2"). EITF 00-19-2 was issued December 21, 2006 and is effective for fiscal periods beginning after December 15, 2006, and calls for the registration right agreement and any registration rights payments to be considered separately from the financial instruments. In accordance with EITF 00-19-2, the Company has reversed the classification of the warrant liability from debt to equity during the period ended March 31, 2007 as the warrants and registration rights agreement were previously accounted for as a single instrument, and without the consideration of the registration rights payments, the warrants are properly classified as equity in accordance with EITF 00-19. In accordance with Financial Accounting Standards No. 5, Accounting for Contingencies, or FASB, the Company has booked as estimated accrual of \$180,000 to the balance sheet to estimate the contingent liability related to the probability of registration rights payments.

#### **(6) Warrant Extension**

On February 2, 2007, the Company amended certain terms of outstanding warrants to purchase an aggregate of 907,500 shares of common stock of the Company; 900,000 shares have an exercise price of \$1.00 and 7,500 shares have an exercise price of \$2.50. The warrants were originally issued in 2003 and 2004 in connection with certain financing transactions and were scheduled to expire in February 2007, the amendments extend the expiration date for warrants to purchase 900,000 shares of common stock with an exercise price of \$1.00 until February 15, 2008 and extend the expiration date for the warrants to purchase 7,500 shares of common stock with an exercise price of \$2.50 until October 29, 2008. The extension of the warrants was calculated using the Black Scholes option pricing model and resulted in a charge of approximately \$59,000, which was recorded to the income statement during the first quarter of FY 2007.

In addition, all of the warrants contain a call provision whereby the Company can require the holders of the warrants to exercise the warrants if the market trading price of the Company's common stock trades at a level of at least \$4.00 per share for 20 consecutive trading days (the "Call Provision"). In addition to amending the expiration date of the warrants as described in the preceding paragraph, the Company amended the Call Provision by lowering the trading price at which the Call Provision may be triggered from \$4.00 per share to \$3.25 per share.

#### **(7) Patent Acquisitions**

On March 29, 2007, the Company entered into a license agreement pursuant to which we in-licensed a family of issued U.S. patents and various U.S. and foreign patent applications which include claims for methods of treating liver failure, multi-organ failure, multi-organ dysfunction syndrome, sepsis, septic shock, systemic inflammatory response syndrome, and related inflammatory disorders by selective blood filtration. Included in this in-licensed family are five issued U.S. patents, four pending U.S. patents, and two pending European patents. The license is an exclusive, worldwide license to research, develop, make, import, have made, use, offer for sale, sell and have sold the patented technologies and products employing such technologies. The Company will owe royalties on net sales of products which are covered by the license, including potentially the SEPET™ Liver Assist Device. The Company will also owe maintenance fees, certain other minimum spending obligations and contingent milestone payments under the license. The Company's fixed obligations under the license will total less than \$500,000 over the next 4 years. Our contingent obligations under the license will total less than \$500,000 over approximately the same period, however, the timing of these contingent obligations will depend on the pace of potential future patent issuances.

In accordance with FASB No. 2, Accounting for Research and Development Costs, the Company has expensed the patent acquisition costs since they do not have alternative future uses.

In connection with this license agreement, the Company issued a warrant to the licensor to acquire up to 225,000 shares of its common stock at a purchase price per share of \$1.50. The warrant is immediately exercisable and expires on March 29, 2013. The warrants were valued at \$74,570 using the Black Scholes pricing model as discussed in note 4.

### **(8) Subsequent Event**

On April 23, 2007, the Company completed a \$4,861,000 private equity financing reduced by estimated fund raising costs of \$400,000 resulting in estimated net proceeds of \$4,461,000 to a group of current and new accredited investors. In the offering, the Company sold 3,739,231 Units. Each Unit was sold at a price of \$1.30 per Unit. Each Unit consists of: 1) two shares of the Company's common stock, 2) one warrant to purchase one share of the Company's common stock exercisable for a period of 2.5 years at an exercise price of \$1.00 ("A Warrants") and 3) one warrant to purchase one share of the Company's common stock exercisable for a period of 5 years at an exercise price of \$1.40 ("B Warrants"), comprising a total of 7,478,462 shares of the Company's common stock and warrants to purchase 7,478,462 shares of the Company's common stock. The warrants have no provision for cashless exercise and, subject to certain requirements, may be called by the Company provided that the common stock of the Company trades above \$1.50 for the A Warrants and above \$2.80 for the B Warrants for a specified time period. The Company is obligated to pay to the placement agent, Musket Research Associates: 1) a cash fee of \$252,000, 2) a warrant to purchase 576,615 shares of common stock with an exercise price of \$0.65 and a term of five years, and 3) a contingent cash fee of 7% of cash proceeds generated in connection with any additional payments, equity purchases or warrant exercises originating from investors from the April 2007 financing within 12 months of the closing of the financing. As a result of the April 2007 financing and pursuant to certain anti-dilution terms of the Company's prior equity financings, the Company adjusted upwards the number of shares issuable under the warrants issued in the 2005 and 2006 financing by approximately 702,000 shares.

## **ITEM 2. Management's Discussion and Analysis or Plan of Operation**

### **SAFE HARBOR STATEMENT**

*In addition to historical information, the information included in this Form 10-QSB contains forward-looking statements, such as those pertaining to our capital resources, our ability to complete the research and development of our products, and our ability to obtain regulatory approval for our products. Forward-looking statements involve numerous risks and uncertainties and should not be relied upon as predictions of future events. Certain such forward-looking statements can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," "seeks," "approximately," "intends," "plans," "pro forma," "estimates," or "anticipates" or other variations thereof or comparable terminology, or by discussions of strategy, plans or intentions. Such forward-looking statements are necessarily dependent on assumptions, data or methods that may be incorrect or imprecise and may be incapable of being realized. The following factors, among others, could cause actual results and future events to differ materially from those set forth or contemplated in the forward-looking statements: need for a significant amount of additional capital, lack of revenue, uncertainty of product development, ability to obtain regulatory approvals in the United States and other countries, and competition. Readers are cautioned not to place undue reliance on forward-looking statements, which reflect our management's analysis only. We assume no obligation to update forward-looking statements.*

### **Overview**

To date, we have been principally engaged in research and development of our products, management of clinical trials, raising capital and recruitment of additional scientific and management personnel and advisors. We have not marketed or sold any products and have not generated any revenues from commercial activities; however, from inception, we have recorded revenues of approximately \$321,000 of Small Business Innovation Research, or SBIR

grants that have been awarded by the United States Small Business Administration.

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Our current plan of operations for the next 12 months primarily involves research and development activities, including clinical trials for the SEPET™ liver assist device, and the preparation and submission of applications to the United States Food and Drug Administration, or FDA. We submitted an investigational device exemption, or IDE, application for SEPET™ in March 2005 and commenced clinical studies for SEPET™ in the third quarter of 2005. We also intend to reactivate work on the HepatAssist™ cell-based liver support system by modifying the FDA-reviewed Phase III investigational new drug, or IND, protocol. Because the anticipated cost of conducting clinical trials for the HepatAssist™ cell-based liver support system exceeds our current financial resources, we will not, however, be able to commence clinical trials for the HepatAssist™ cell-based liver support system until we raise significant additional capital. The actual amounts we may expend on research and development and related activities during the next 12 months may vary significantly depending on numerous factors, including the results of our clinical trials and the timing and cost of regulatory submissions. Based on our current estimates, we believe that we may have sufficient financial resources to conduct our planned operations for at the least the next twelve months after including the private placement completed on April 23, 2007 which raised gross proceeds of \$4,861,000. We do not expect to make any significant purchases or sales of plant or equipment during the next twelve months, nor do we expect to hire a significant number of employees during that period.

Our research offices and laboratories are located at Cedars-Sinai Medical Center, Los Angeles, California subject to a lease that expires in June 2007 which will not be extended, and we are in the process of identifying a suitable laboratory space in the Boston, Massachusetts area. We also maintain administrative offices in Los Angeles, California and Waltham, Massachusetts.

### **Critical Accounting Policies**

This is based on our unaudited financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, impairment of long-lived assets and their useful lives, including finite lived intangible costs, accrued liabilities and certain expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Our significant accounting policies are summarized in Note 1 to our audited financial statements for the year ended December 31, 2006. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our unaudited financial statements:

#### *Development Stage Enterprise*

We are a development stage enterprise as defined by the Financial Accounting Standards Board's, or FASB, Statement of Financial Accounting Standards, or SFAS No. 7, "Accounting and Reporting by Development Stage Enterprises." We are devoting substantially all of our present efforts to research and development. All losses accumulated since inception have been considered part of our development stage activities.

#### *Patents*

In accordance with SFAS No. 2, Accounting for Research and Development Costs, the costs of intangibles purchased from others for use in research and development activities and that have alternative future uses are capitalized and amortized. We capitalize certain patent rights that are believed to have future economic benefit. The licensed capitalized patents costs were recorded based on the estimated value of the equity security issued by us to the licensor.



The value ascribed to the equity security took into account, among other factors, our stage of development and the value of other companies developing extracorporeal bioartificial liver assist devices. These patent rights are amortized using the straight-line method over the remaining life of the patent. Certain patent rights received in conjunction with purchased research and development costs have been expensed. Legal costs incurred in obtaining, recording and defending patents are expensed as incurred.

### *Stock-Based Compensation*

Commencing January 1, 2006, we adopted SFAS No. 123R, "Share Based Payment", or SFAS 123R, which requires all share based payments, including grants of stock options, to be recognized in the income statement as an operating expense, based on fair values.

Prior to adopting SFAS 123R, we accounted for stock-based employee compensation under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," as allowed by SFAS No. 123, "Accounting for Stock-Based Compensation." We have applied the modified prospective method in adopting SFAS 123R. Accordingly, periods prior to adoption have not been restated.

### **Results of Operations**

Since we are still developing our products and do not have any products available for sale, we have not yet generated any revenue from sales. Inception to date revenue represents revenue recognized from a government research grant.

General and administrative expenses of \$676,000 and \$744,000 were incurred for the three months ended March 31, 2007 and 2006, respectively. General and administrative expenses for the three months ended March 31, 2007 and 2006 decreased by \$68,000 over the prior year level. The decrease is primarily attributed to decreases in investor relation costs of \$50,000, Board of Director costs of \$33,000, non-cash option charges of \$57,000 and a decline in other general and administrative expenses offset in part by \$59,000 increase in warrant charges due to warrant extensions granted in connection with expiring warrants.

Research and development expenses of \$1,031,000 and \$366,000 were incurred for the three months ended March 31, 2007 and 2006, respectively. The research and development expenses for the three months ended March 31, 2007 increased by \$665,000 over the comparable prior year levels primarily as a result of \$425,000 in accrued expenses related to the patent portfolio acquisition in March 2007 and an increase of \$241,000 in SEPET™ program costs which reflect the increased number of patients enrolled in the SEPET™ clinical trial.

An equity offerings contingency for \$180,000 was accrued for potential registration agreement obligations. Interest income of \$18,000 and \$41,000 was earned for the three months ended March 31, 2007 and 2006, respectively. The decrease in interest income primarily reflects declining cash and cash equivalent balances in 2007 from prior year levels.

Our net loss was \$1,868,000 and \$1,069,000 for the three months ended March 31, 2007 and 2006, respectively. The increase in net loss for the quarter ended March 31, 2007 compared to the comparable period in 2006 is attributable to increases in research and development expenses and potential registration agreement obligations.

### **Liquidity and Capital Resources**

As of March 31, 2007, we had cash of \$1,345,000 and \$998,000 of current liabilities. We do not have any bank credit lines. To date, we have funded our operations primarily from the sale of debt and equity securities and to a lesser extent, SBIR government grants.

On April 23, 2007, we completed a \$4,861,000 private equity financing to a group of current and new accredited investors. In the offering, we sold 3,739,231 Units. Each Unit was sold at a price of \$1.30 per Unit. Each Unit consists of: i) two shares of our common stock, ii) one warrant to purchase one share of our common stock exercisable for a period of 2.5 years at an exercise price of \$1.00 ("A Warrants") and iii) one warrant to purchase one share of our common stock exercisable for a period of 5 years at an exercise price of \$1.40 ("B Warrants"), comprising a total of 7,478,462 shares of our common stock and warrants to purchase 7,478,462 shares of our common stock. The warrants

have no provision for cashless exercise and, subject to certain requirements, may be called by us provided that our common stock trades above \$1.50 for the A Warrants and above \$2.80 for the B Warrants for a specified time period.

Based on our current plan and the above private placement, we believe that our current cash balances will be sufficient to fund our operations through for the next twelve months from the date of this report.

We do not currently anticipate that we will derive any revenue from either product sales or from governmental research grants during the next twelve months. The cost of completing the development of our products and of obtaining all required regulatory approvals to market our products is substantially greater than the amount of funds we currently have available and substantially greater than the amount we could possibly receive under any governmental grant program. As a result, we will have to obtain significant additional funds after the date of this report. We currently expect to attempt to obtain additional financing through the sale of additional equity and possibly through strategic alliances with larger pharmaceutical or biomedical companies. We cannot be sure that we will be able to obtain additional funding from either of these sources, or that the terms under which we obtain such funding will be beneficial to us or the shareholders.

The following is a summary of our contractual cash obligations for the following fiscal years:

<b>Contractual Obligations</b>	<b>Total</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>
Long-Term Leases	\$ 41,000	\$ 41,000	\$ -	\$ -	\$ -
License Agreement	300,000		50,000	100,000	150,000
<b>Total</b>	<b>\$ 341,000</b>	<b>\$ 41,000</b>	<b>\$ 50,000</b>	<b>\$ 100,000</b>	<b>\$ 150,000</b>

We do not believe that inflation has had a material impact on our business or operations.

We do not engage in trading activities involving non-exchange traded contracts. In addition, we have no financial guarantees, debt or lease agreements or other arrangements that could trigger a requirement for an early payment or that could change the value of our assets.

#### **Off- Balance Sheet Arrangements**

We are not a party to any off-balance sheet arrangements.

#### **Factors That May Affect Our Business And Our Future Results**

We face a number of substantial risks. Our business, financial condition, results of operations and stock price could be harmed by any of these risks. The following factors should be considered in connection with the other information, including any forward-looking statements, contained in this Quarterly Report on Form 10-QSB.

#### **RISKS RELATED TO OUR BUSINESS**

*We are an early-stage company subject to all of the risks and uncertainties of a new business, including the risk that we may never market any products or generate revenues.*

We are an early-stage company that has not generated any operating revenues to date (our only revenues were from two government research grants). Accordingly, while we have been in existence for over five years, we should be evaluated as an early-stage company, subject to all of the risks and uncertainties normally associated with an early-stage company. As an early-stage company, we expect to incur significant operating losses for the foreseeable future, and there can be no assurance that we will be able to validate and market products in the future that will generate revenues or that any revenues generated will be sufficient for us to become profitable or thereafter maintain profitability.



*We have had no product sales to date, and we can give no assurance that there will ever be any sales in the future.*

All of our products are still in research or development, and no revenues have been generated to date from product sales. There is no guarantee that we will ever develop commercially viable products. To become profitable, we will have to successfully develop, obtain regulatory approval for, produce, market and sell our products. There can be no assurance that our product development efforts will be successfully completed, that we will be able to obtain all required regulatory approvals, that we will be able to manufacture our products at an acceptable cost and with acceptable quality, or that our products can be successfully marketed in the future. We currently do not expect to receive revenues from the sale of any of our products for at least one to two years.

*Before we can market any of our products, we must obtain governmental approval for each of our products, the application and receipt of which is time-consuming, costly and uncertain.*

The development, production and marketing of our products are subject to extensive regulation by government authorities in the United States and other countries. In the United States, our SEPET™ Liver Assist Device and our HepatAssist™ Cell-Based Liver Support System will require approval from the FDA prior to clinical testing and commercialization. The process for obtaining FDA approval to market therapeutic products is both time-consuming and costly, with no certainty of a successful outcome. This process includes the conduct of extensive pre-clinical and clinical testing, which may take longer or cost more than we currently anticipate due to numerous factors, including, without limitation, difficulty in securing centers to conduct trials, difficulty in enrolling patients in conformity with required protocols and/or projected timelines, unexpected adverse reactions by patients in the trials to our liver assist systems, temporary suspension and/or complete ban on trials of our products due to the risk of transmitting pathogens from the xenogeneic biologic component, and changes in the FDA's requirements for our testing during the course of that testing. We have not yet established with the FDA the nature and number of clinical trials that the FDA will require in connection with its review and approval of either SEPET™ or our HepatAssist™ products and these requirements may be more costly or time-consuming than we currently anticipate.

SEPET™ and HepatAssist™ are both novel in terms of their composition and function. Thus, we may encounter unexpected safety, efficacy or manufacturing issues as we seek to obtain marketing approval for products from the FDA, and there can be no assurance that we will be able to obtain approval from the FDA or any foreign governmental agencies for marketing of any of our products. The failure to receive, or any significant delay in receiving, FDA approval, or the imposition of significant limitations on the indicated uses of our products, would have a material adverse effect on our business, operating results and financial condition. The health regulatory authorities of certain countries, including those of Japan, France and the United Kingdom, have previously objected, and other countries' regulatory authorities could potentially object, to the marketing of any therapy that uses pig liver cells (which our bioartificial liver systems are designed to utilize) due to safety concerns that pig cells may transmit viruses or diseases to humans. If the health regulatory agencies of other countries impose a ban on the use of therapies that incorporate pig cells, such as our HepatAssist™ Cell-Based Liver Support System, we would be prevented from marketing our products in those countries. If we are unable to obtain the approval of the health regulatory authorities in Japan, France, the United Kingdom or other countries, the potential market for our products will be reduced.

*Because our products are at an early stage of development and have never been marketed, we do not know if any of our products will ever be approved for marketing, and any such approval will take several years to obtain.*

Before obtaining regulatory approvals for the commercial sale of our products, significant and potentially very costly preclinical and clinical work will be necessary. There can be no assurance that we will be able to successfully complete all required testing of the SEPET™ liver assist device or our HepatAssist™ cell-based liver support system. While the time periods for testing our products and obtaining the FDA's approval are dependent upon many future variable and unpredictable events, we estimate that it could take between two to three years to obtain approval for the SEPET™ liver assist device and three to four years for the HepatAssist™ cell-based liver support system. We have not

independently confirmed any of the third-party claims made with respect to patents, licenses or technologies we have acquired concerning the potential safety or efficacy of these products and technologies. Before we can begin clinical testing of our HepatAssist™ cell-based liver support system, we will need to amend our active Phase III IND to resume clinical testing, which application will have to be cleared by the FDA. The FDA may require significant revisions to our clinical testing plans or require us to demonstrate efficacy endpoints that are more time-consuming or difficult to achieve than what we currently anticipate. Because of the early stage of development of each of our products, we do not know if we will be able to generate clinical data that will support the filing of the FDA applications for these products or the FDA's approval of any product marketing approval application or IND that we do file.

*The cost of conducting pivotal clinical studies for the SEPET™ liver assist device and HepatAssist™ cell-based liver support system exceeds our current financial resources. Accordingly, we will not be able to conduct such studies until we obtain additional funding.*

If the feasibility clinical trial for the SEPET™ liver assist device is successful, we will have to obtain the FDA's approval to conduct a pivotal trial. We have not yet established with the FDA the nature and number of additional clinical trials that the FDA may require in connection with its review and approval of the SEPET™ liver assist device. Based on our internal projections of our operating costs and the costs normally associated with pivotal trials, we do not believe that we currently have sufficient funds to conduct any such pivotal trial(s) nor have we identified any sources for obtaining the required funds.

We have considered requesting FDA approval to commence a Phase III clinical trial of the HepatAssist™ cell-based liver support system. Such a request will require that we supplement and/or amend the existing Phase III clinical protocol that was approved by the FDA for the original HepatAssist system. The preparation of a modified or supplemented Phase III clinical protocol will be expensive and difficult to prepare. Although the cost of completing the Phase III clinical trial in the manner that we currently contemplate is uncertain and could vary significantly, if that Phase III clinical trial is authorized by the FDA, we currently estimate that the cost of conducting that study would approximately be between \$10 million and \$15 million, excluding the manufacturing infrastructure. We currently do not have sufficient funds to conduct this study and have not identified any sources for obtaining the required funds. In addition, no assurance can be given that the FDA will accept our proposed changes to the previously approved Phase III clinical protocol. The clinical tests that we would conduct under any FDA-approved protocol are very expensive and will cost much more than our current financial resources. Accordingly, even if the FDA approves the modified Phase III clinical protocol that we submit for HepatAssist™ cell-based liver support system, we will not be able to conduct any clinical trials until we raise substantial amounts of additional financing.

*Our cell based liver support system utilizes a biological component obtained from pigs that could prevent or restrict the release and use of those products.*

Use of liver cells harvested from pig livers carries a risk of transmitting viruses harmless to pigs but potentially deadly to humans. For instance, all pig cells carry genetic material of the porcine endogenous retrovirus ("PERV"), but its ability to infect people is unknown. Repeated testing, including a 1999 study of 160 xenotransplantation (transplantation from animals to humans) patients and the Phase II/III testing of the HepatAssist™ cell-based liver support system by Circe Biomedical, Inc., has produced no sign of the transmission of PERV to humans. Still, no one can prove that PERV or another virus would not infect bioartificial liver-treated patients and cause potentially serious disease. This may result in the FDA or other health regulatory agencies not approving our HepatAssist™ cell-based liver support system or subsequently banning any further use of our product should health concerns arise after the product has been approved. At this time, it is unclear whether we will be able to obtain clinical and product liability insurance that covers the PERV risk.

In addition to the potential health risks associated with the use of pig liver cells, our use of xenotransplantation technologies may be opposed by individuals or organizations on health, religious or ethical grounds. Certain animal rights groups and other organizations are known to protest animal research and development programs or to boycott products resulting from such programs. Previously, some groups have objected to the use of pig liver cells by other companies, including Circe Biomedical, Inc., that were developing bioartificial liver support systems, and it is possible that such groups could object to our bioartificial liver system. Litigation instituted by any of these organizations, and negative publicity regarding our use of pig liver cells in a bioartificial liver device, could have a material adverse effect on our business, operating results and financial condition.



Because our products represent new approaches to treatment of liver disease, there are many uncertainties regarding the development, the market acceptance and the commercial potential of our products.

Our products will represent new therapeutic approaches for disease conditions. We may, as a result, encounter delays as compared to other products under development in reaching agreements with the FDA or other applicable governmental agencies as to the development plans and data that will be required to obtain marketing approvals from these agencies. There can be no assurance that these approaches will gain acceptance among doctors or patients or that governmental or third party medical reimbursement payers will be willing to provide reimbursement coverage for our products. Moreover, we do not have the marketing data resources possessed by the major pharmaceutical companies, and we have not independently verified the potential size of the commercial markets for any of our products. Since our products will represent new approaches to treating liver diseases, it may be difficult, in any event, to accurately estimate the potential revenues from our products, as there currently are no directly comparable products being marketed.

We need to obtain significant additional capital to complete the development of our liver assist devices, which additional funding may dilute our existing stockholders.

Based on our current proposed plans and assumptions, the Company estimates that it has cash to operate through the second quarter of calendar year 2008, and therefore will need to obtain significant additional funds during the first half of 2008. The clinical development expenses of our products will be very substantial. Based on our current assumptions, we estimate that the clinical cost of developing the SEPET™ liver assist device will be approximately \$5 million to \$10 million, and the clinical cost of developing the HepatAssist™ cell-based liver support system will be between \$10 million and \$15 million, in excess of the cost of basic operations of the Company. These amounts, which could vary substantially if our assumptions are not correct, are well in excess of the amount of cash that we currently have available to us. Accordingly, we will be required to (i) obtain additional debt or equity financing in order to fund the further development of our products and working capital needs, and/or (ii) enter into a strategic alliance with a larger pharmaceutical or biomedical company to provide its required funding. The amount of funding needed to complete the development of one or both of our products will be very substantial and may be in excess of our ability to raise capital.

We have not identified the sources for the additional financing that we will require, and we do not have commitments from any third parties to provide this financing. There can be no assurance that sufficient funding will be available to us at acceptable terms or at all. If we are unable to obtain sufficient financing on a timely basis, the development of our products could be delayed and we could be forced to reduce the scope of our pre-clinical and clinical trials or otherwise limit or terminate our operations altogether. Any equity additional funding that we obtain will reduce the percentage ownership held by our existing security holders.

As a new small company that will be competing against numerous large, established companies that have substantially greater financial, technical, manufacturing, marketing, distribution and other resources than us, we will be at a competitive disadvantage.

The pharmaceutical, biopharmaceutical and biotechnology industry is characterized by intense competition and rapid and significant technological advancements. Many companies, research institutions and universities are working in a number of areas similar to our primary fields of interest to develop new products, some of which may be similar and/or competitive to our products. Furthermore, many companies are engaged in the development of medical devices or products that are or will be competitive with our proposed products. Most of the companies with which we compete have substantially greater financial, technical, manufacturing, marketing, distribution and other resources than us.

*We will need to outsource and rely on third parties for the clinical development and manufacture and marketing of our products.*

Our business model calls for the outsourcing of the clinical development, manufacturing and marketing of our products in order to reduce our capital and infrastructure costs as a means of potentially improving the profitability of these products for us. We have not yet entered into any strategic alliances or other licensing or contract manufacturing arrangements (except for the contractual manufacturing of LIVERAID™ modules by Spectrum Laboratories which we have indefinitely placed on hold) and there can be no assurance that we will be able to enter into satisfactory arrangements for these services or the manufacture or marketing of our products. We will be required to expend substantial amounts to retain and continue to utilize the services of one or more clinical research management organizations without any assurance that the products covered by the clinical trials conducted under their management ultimately will generate any revenues for the SEPET™ liver assist device and/or our HepatAssist™ cell-based liver support system. Consistent with our business model, we will seek to enter into strategic alliances with other larger companies to market and sell our products. In addition, we may need to utilize contract manufacturers to manufacture our products or even our commercial supplies, and we may contract with independent sales and marketing firms to use their pharmaceutical sales force on a contract basis.

To the extent that we rely on other companies or institutions to manage the conduct of our clinical trials and to manufacture or market our products, we will be dependent on the timeliness and effectiveness of their efforts. If the clinical research management organization that we utilize is unable to allocate sufficient qualified personnel to our studies or if the work performed by them does not fully satisfy the rigorous requirement of the FDA, we may encounter substantial delays and increased costs in completing our clinical trials. If the manufacturers of the raw material and finished product for our clinical trials are unable to meet our time schedules or cost parameters, the timing of our clinical trials and development of our products may be adversely affected. Any manufacturer that we select may encounter difficulties in scaling-up the manufacture of new products in commercial quantities, including problems involving product yields, product stability or shelf life, quality control, adequacy of control procedures and policies, compliance with FDA regulations and the need for further FDA approval of any new manufacturing processes and facilities. Should our manufacturing or marketing company encounter regulatory problems with the FDA, FDA approval of our products could be delayed or the marketing of our products could be suspended or otherwise adversely affected.

*Because we are currently dependent on Spectrum Laboratories, Inc. as the manufacturer of our SEPET™ cartridges, any failure or delay by Spectrum Laboratories to manufacture the cartridges will negatively affect our future operations.*

We have an exclusive manufacturing arrangement with Spectrum Laboratories for our fiber-within-fiber LIVERAID™ cartridges, the development of which we have placed on indefinite hold. Although we have no agreement with Spectrum Laboratories for the manufacture of the SEPET™ cartridges, Spectrum Laboratories has also been providing us with cartridges for prototypes of the SEPET™ liver assist device and has expressed an interest in manufacturing the HepatAssist™ cartridge. Although Spectrum Laboratories has agreed to transfer all of the know-how related to these products to any other manufacturer of our products if Spectrum Laboratories is unable to meet its contractual obligations to us, we may have difficulty in finding a replacement manufacturer if we are unable to effectively transfer the Spectrum Laboratories know-how to another manufacturer. We have no control over Spectrum Laboratories or its suppliers, and if Spectrum Laboratories is unable to produce SEPET™ cartridges on a timely basis, our business may be adversely affected.

We currently do not have a manufacturing arrangement for the cartridges used in the HepatAssist™ cell-based liver support system. While we believe there are several potential contract manufacturers who can produce these cartridges, there can be no assurance that we will be able to enter into such an arrangement on commercially favorable terms, or at all.

*Because we are dependent on Medtronic, Inc. for the perfusion platform used in our HepatAssist™ cell-based liver support system, any failure or delay by Medtronic to make the perfusion platform commercially available will negatively affect our future operations.*

We currently expect that a perfusion system known as the PERFORMER will become the platform for our HepatAssist™ cell-based liver support system. The PERFORMER has been equipped with proprietary software and our tubing in order to enable the machine to work with our HepatAssist™ cell-based liver support system. A limited number of the PERFORMER units have been manufactured to date. The PERFORMER is being manufactured by RanD, S.r.l. (Italy) and marketed by Medtronic, Inc. We currently do not have an agreement to purchase the PERFORMER from Medtronic or any other source. In the event that RanD and Medtronic are either unable or unwilling to manufacture the number of PERFORMERS needed to ensure that the HepatAssist™ cell-based liver support system is commercially viable, we would not have an alternate platform immediately available for use, and the development and sales of such a system would cease until an alternate platform is developed or found. We may have difficulty in finding a replacement platform and may be required to develop a new platform in collaboration with a third party contract manufacturer. While we believe there are several potential contract manufacturers who can develop and manufacture perfusion platforms meeting the HepatAssist™ cell-based liver support system functional and operational characteristics, there can be no assurance that we will be able to enter into such an arrangement on commercially favorable terms, or at all. In addition, we may encounter substantial delays and increased costs in completing our clinical trials if we have difficulty in finding a replacement platform or if we are required to develop a new platform for bioartificial liver use.

*We may not have sufficient legal protection of our proprietary rights, which could result in the use of our intellectual properties by our competitors.*

Our ability to compete successfully will depend, in part, on our ability to defend patents that have issued, obtain new patents, protect trade secrets and operate without infringing the proprietary rights of others. We currently own four U.S. and five foreign patents on our liver support products, have two patent applications pending, and are the licensee of twelve additional liver support patents. We have relied substantially on the patent legal work that was performed for our assignors and licensors with respect to all of these patents, application and licenses, and have not independently verified the validity or any other aspects of the patents or patent applications covering our products with our own patent counsel. For example, we have recently received from the European Patent Office references to certain issued patents that may represent prior art in the field of large-pore hemofiltration. This prior art may prevent us from obtaining sufficient legal protection of our proprietary rights to our SEPET liver assist device.

Even when we have obtained patent protection for our products, there is no guarantee that the coverage of these patents will be sufficiently broad to protect us from competitors or that we will be able to enforce our patents against potential infringers. Patent litigation is expensive, and we may not be able to afford the costs. Third parties could also assert that our products infringe patents or other proprietary rights held by them.

We will attempt to protect our proprietary information as trade secrets through nondisclosure agreements with each of our employees, licensing partners, consultants, agents and other organizations to which we disclose our proprietary information. There can be no assurance, however, that these agreements will provide effective protection for our proprietary information in the event of unauthorized use or disclosure of such information.

*The development of our products is dependent upon certain key persons, and the loss of one or more of these key persons would materially and adversely affect our business and prospects.*

We are dependent upon our business and scientific personnel. We also depend upon the medical and scientific advisory services that we receive from the members of our Board of Directors and Scientific Advisory Board, many of whom have extensive backgrounds in the biomedical industry. We do not carry key man life insurance on any of these individuals.

As we expand the scope of our operations by preparing FDA submissions, conducting multiple clinical trials, and potentially acquiring related technologies, we will need to obtain the services of additional senior scientific and management personnel. Competition for these personnel is intense, and there can be no assurance that we will be able to attract or retain qualified senior personnel. As we retain senior personnel, our overhead expenses for salaries and related items will increase substantially from current levels.

*The market success of our products will be dependent in part upon third-party reimbursement policies that have not yet been established.*

Our ability to successfully penetrate the market for our products may depend significantly on the availability of reimbursement for our products from third-party payers, such as governmental programs, private insurance and private health plans. We have not yet established with Medicare or any third-party payers what level of reimbursement, if any, will be available for our products, and we cannot predict whether levels of reimbursement for our products, if any, will be high enough to allow us to charge a reasonable profit margin. Even with FDA approval, third-party payers may deny reimbursement if the payer determines that our particular new products are unnecessary, inappropriate or not cost effective. If patients are not entitled to receive reimbursement similar to reimbursement for competing products, they may be unwilling to use our products since they will have to pay for the unreimbursed amounts, which may well be substantial. The reimbursement status of newly approved health care products is highly uncertain. If levels of reimbursement are decreased in the future, the demand for our products could diminish or our ability to sell our products on a profitable basis could be adversely affected.

*We may be subject to product liability claims that could have a material negative effect on our operations and on our financial condition.*

The development, manufacture and sale of medical products expose us to the risk of significant damages from product liability claims. We have obtained clinical trial insurance for our SEPET™ trials. We plan to obtain and maintain product liability insurance for coverage of our clinical trial activities. However, there can be no assurance that we will be able to continue to secure such insurance for clinical trials for either of our two current products under development. We intend to obtain coverage for our products when they enter the marketplace (as well as requiring the manufacturers of our products to maintain insurance). We do not know if it will be available to us at acceptable costs. We may encounter difficulty in obtaining clinical trial or commercial product liability insurance for our bioartificial liver device that we develop since this therapy includes the use of pig liver cells and we are not aware of any therapy using these cells that has sought or obtained such insurance. If the cost of insurance is too high or insurance is unavailable to us, we will have to self-insure. A successful claim in excess of product liability coverage could have a material adverse effect on our business, financial condition and results of operations. The costs for many forms of liability insurance have risen substantially during the past year, and such costs may continue to increase in the future, which could materially impact our costs for clinical or product liability insurance.

*If we are not able to implement the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 in a timely manner or with adequate compliance, we may be unable to provide the required financial information in a timely and reliable manner and may be subject to sanction to regulatory authorities.*

We cannot be certain at this time that we will have the expertise and resources to be able to comply with all of our reporting obligations and successfully complete the procedures, certification and attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 by the time that we are required to do so. If we fail to comply with the requirements of Section 404, or if we or our independent registered public accounting firm identifies any material weaknesses, the accuracy and timeliness of the filing of our annual and quarterly reports may be negatively affected and could cause investors to lose confidence in our financial statements, impair our ability to obtain financing or result in regulatory sanctions. Remediating any material weakness could require additional management attention and increased compliance costs.

*If we make any further acquisitions, we will incur a variety of costs and might never successfully integrate the acquired product or business into ours.*

Following our acquisition of the HepatAssist™ cell-based liver support system from Circe Biomedical, Inc., we might attempt to acquire products or businesses that we believe are a strategic complement to our business model. We might

encounter operating difficulties and expenditures relating to integrating the HepatAssist™ cell-based liver support system or any other acquired product or business. These acquisitions might require significant management attention that would otherwise be available for ongoing development of our business. In addition, we might never realize the anticipated benefits of any acquisition. We might also make dilutive issuances of equity securities, incur debt or experience a decrease in cash available for our operations, incur contingent liabilities and/or amortization expenses relating to goodwill and other intangible assets, or incur employee dissatisfaction in connection with future acquisitions.

*If we are unable to comply with the terms of registration rights agreements to which we are a party, we may be obligated to pay liquidated damages to some of our stockholders and recharacterize outstanding warrants as debt.*

We are a party to registration rights agreements with some of our stockholders. The registration rights agreements provide, among other things, that we register shares of our common stock held by those stockholders within a specified period of time and that we keep the registration statement associated with those shares continuously effective. If we are unable to comply with these provisions of the registration rights agreements, we may be obligated to pay those stockholders liquidated damages. Because of the potential operation of these provisions of our registration rights agreements, we have re-characterized some of our outstanding warrants from equity to debt, and this is reflected in our financial statements. These penalty provisions may also force us to re-characterize some of our other outstanding warrants from equity to debt. If we have to make this re-characterization, our liabilities would increase and our financial statements would be negatively impacted.

## **RISKS RELATED TO OUR COMMON STOCK**

*Our stock is thinly traded, so you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.*

The shares of our common stock are thinly-traded on the OTC Bulletin Board, meaning that the number of persons interested in purchasing our common shares at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven, early stage company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained. Due to these conditions, we can give you no assurance that you will be able to sell your shares at or near ask prices or at all if you need money or otherwise desire to liquidate your shares.

*If securities or independent industry analysts do not publish research reports about our business, our stock price and trading volume could decline.*

Small, relatively unknown companies can achieve visibility in the trading market through research and reports that industry or securities analysts publish. However, to our knowledge, no independent analysts cover our company. The lack of published reports by independent securities analysts could limit the interest in our stock and negatively affect our stock price. We do not have any control over research and reports these analysts publish or whether they will be published at all. If any analyst who does cover us downgrades our stock, our stock price would likely decline. If any independent analyst ceases coverage of our company or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

*You may have difficulty selling our shares because they are deemed "penny stocks."*

Since our common stock is not listed on the Nasdaq Stock Market, if the trading price of our common stock is below \$5.00 per share, trading in our common stock will be subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a penny stock (generally, any non-Nasdaq equity security that has a market price of less than \$5.00 per share, subject to certain exceptions) and a two business

day "cooling off period" before brokers and dealers can effect transactions in penny stocks. Such rules impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors (generally defined as an investor with a net worth in excess of \$1,000,000 or annual income exceeding \$200,000 individually or \$300,000 together with a spouse). For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to the sale. The broker-dealer also must disclose the commissions payable to the broker-dealer, current bid and offer quotations for the penny stock and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Such information must be provided to the customer orally or in writing before or with the written confirmation of trade sent to the customer. Monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. The additional burdens imposed upon broker-dealers by such requirements could discourage broker-dealers from effecting transactions in our common stock, which could severely limit the market liquidity of the common stock and the ability of holders of the common stock to sell their shares.



Anti-takeover provisions in our certificate of incorporation could affect the value of our stock

Our certificate of incorporation contains certain provisions that could be an impediment to a non-negotiated change in control. In particular, without stockholder approval we can issue up to 5,000,000 shares of preferred stock with rights and preferences determined by the board of directors. These provisions could make a hostile takeover or other non-negotiated change in control difficult, so that stockholders would not be able to receive a premium for their common stock.

Potential issuance of additional common and preferred stock could dilute existing stockholders

We are authorized to issue up to 60,000,000 shares of common stock. To the extent of such authorization, our board of directors has the ability, without seeking stockholder approval, to issue additional shares of common stock in the future for such consideration as the board of directors may consider sufficient. The issuance of additional common stock in the future will reduce the proportionate ownership and voting power of the common stock offered hereby. We are also authorized to issue up to 5,000,000 shares of preferred stock, the rights and preferences of which may be designated in series by the board of directors. Such designation of new series of preferred stock may be made without stockholder approval, and could create additional securities which would have dividend and liquidation preferences over the common stock offered hereby. Preferred stockholders could adversely affect the rights of holders of common stock by:

- exercising voting, redemption and conversion rights to the detriment of the holders of common stock;
- receiving preferences over the holders of common stock regarding or surplus funds in the event of our dissolution or liquidation;
- delaying, deferring or preventing a change in control of our company; and
- discouraging bids for our common stock.

Additionally, some of our outstanding warrants to purchase common stock have anti-dilution protection. This means that if we issue securities for a price less than the price at which the warrants are exercisable for shares of common stock, the warrants will become eligible to purchase more shares of common stock at a lower price, which will dilute the ownership of our common stockholders.

Substantial number of shares of common stock may be released onto the market at any time, and the sales of such additional shares of common stock could cause stock price to fall.

As of May 2, 2007, we had outstanding 24,956,643 shares of common stock. However, in the past year, the average daily trading volume of our shares has only been a few thousand shares, and there have been many days in which no shares were traded at all. In October 2004 and in February 2005, we registered a total of 7,207,810 shares of our common stock issuable upon the exercise of outstanding warrants. Of these shares, 25,000 have been issued upon the exercise of a warrant and a warrant for 75,000 of the shares has been cancelled without being registered. The remaining 7,107,810 shares underlying warrants have not yet been issued and will not be issued until the warrants are exercised. Since the shares underlying these warrants have been registered, they can be sold immediately following the exercise. Accordingly, 7,107,810 additional shares could be released onto the trading market at any time. Because of the limited trading volume, the sudden release of 7,107,810 additional freely trading shares onto the market, or the perception that such shares will come onto the market, could have an adverse affect on the trading price of the stock. In addition, there are currently 5,972,272 shares of unregistered, restricted stock that are currently eligible for public resale under Rule 144 promulgated under the Securities Act, some of which shares also may be offered and sold on the market from time to time. No prediction can be made as to the effect, if any, that sales of the 7,107,810 registered

warrant shares, or the sale of any of the 5,972,272 shares subject to Rule 144 sales will have on the market prices prevailing from time to time. Nevertheless, the possibility that substantial amounts of common stock may be sold in the public market may adversely affect prevailing market prices for our common stock and could impair our ability to raise capital through the sale of our equity securities.

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The market price of our stock may be adversely affected by market volatility.

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors,
- developments with respect to patents or proprietary rights,
- announcements of technological innovations by us or our competitors,
- announcements of new products or new contracts by us or our competitors,
- actual or anticipated variations in our operating results due to the level of development expenses and other factors,
- changes in financial estimates by securities analysts and whether our earnings meet or exceed such estimates,
- conditions and trends in the pharmaceutical and other industries,
- new accounting standards,
- general economic, political and market conditions and other factors, and the occurrence of any of the risks described in this Quarterly Report.

### **ITEM 3A(T). Controls and Procedures**

#### **(a) Disclosure Controls and Procedures**

Our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, as amended, Rules 13a-15(e) and 15d-15(e)) are adequate and effective to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

#### **(b) Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting that occurred during the quarter ended March 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. However as this Company continues to expand its operations, we have implemented, and will continue to implement, additional disclosure and procedure controls, which encompass internal controls over financial reporting, that are appropriate for the Company's size and stage of development.

**(c) Limitations on the Effectiveness of Controls**

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within an organization have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake.

Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in the cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**PART II. OTHER INFORMATION**

**ITEM 1. Legal Proceedings**

None.

**ITEM 2. Unregistered Sale of Equity Securities and Use of Proceeds**

None.

**ITEM 3. Defaults Upon Senior Securities**

None.

**ITEM 4. Submission of Matters to a Vote of Security Holders**

None.

**ITEM 5. Other Information**

None.

**ITEM 6. Exhibits**

31.1 Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2 Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32.1

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Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section  
1350

32.2 Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section  
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SIGNATURES

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

ARBIOS SYSTEMS, INC.

DATE: May 18, 2007

By: /S/ Walter C. Ogier

\_\_\_\_\_  
Walter C. Ogier  
Chief Executive Officer (Principal Executive Officer)

DATE: May 18, 2007

By: /S/ Scott L. Hayashi

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Scott L. Hayashi  
Chief Financial Officer (Principal Financial Officer)