

ARBIOS SYSTEMS INC  
Form 10QSB  
November 14, 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 September 30, 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) 839-7292**

(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 October 31, 2007, there were 25,578,461 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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**PART I - FINANCIAL INFORMATION****ITEM 1. Condensed Financial Statements**

**ARBIOS SYSTEMS, INC.**  
(A Development Stage Company)  
**CONDENSED BALANCE SHEETS**

	September 30, 2007 (Unaudited)	December 31, 2006*
<b><u>ASSETS</u></b>		
Current assets		
Cash and cash equivalents	\$ 3,690,026	\$ 2,054,280
Prepaid expenses	50,775	147,163
Total current assets	3,740,801	2,201,443
Net property and equipment	50,698	73,110
Patent rights, net of accumulated amortization of \$129,254 and \$113,894, respectively	137,413	152,773
Other assets	76,014	62,827
Total assets	\$ 4,004,926	\$ 2,490,153
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
Current liabilities		
Accounts payable	\$ 385,264	\$ 310,162
Accrued expenses	681,214	132,073
Total current liabilities	1,066,478	442,235
Long term contract obligations	250,000	-
Accrued warrant liability	-	763,654
Total liabilities	1,316,478	1,205,889
Stockholders' equity		
Preferred stock, \$.001 par value; 5,000,000 shares authorized; none issued and outstanding	-	-
Common stock, \$.001 par value; 100,000,000 shares authorized; 25,578,461 and 17,460,181 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	25,578	17,460
Additional paid-in capital	20,931,139	14,507,939
Deficit accumulated during the development stage	(18,268,269)	(13,241,135)
Total stockholders' equity	2,688,448	1,284,264
Total liabilities and stockholders' equity	\$ 4,004,926	\$ 2,490,153

\* Balance sheet information at December 31, 2006 is derived from audited financial statements.

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 September 30,		For the nine months ended September 30,		Inception to September 30, 2007
	2007	2006 (Restated)	2007	2006 (Restated)	
Revenues	\$ -	\$ -	\$ -	\$ -	\$ 320,966
<b>Operating expenses:</b>					
General and administrative	1,025,108	753,604	2,651,264	2,210,018	10,973,353
Research and development	422,743	469,316	1,982,747	1,280,869	7,795,923
Total operating expenses	1,447,851	1,222,920	4,634,011	3,490,887	18,769,276
Loss before other income (expense)	(1,447,851)	(1,222,920)	(4,634,011)	(3,490,887)	(18,448,310)
<b>Other income (expense):</b>					
Change in fair value of warrant liability	-	53,546	-	263,670	
Interest income	53,445	38,964	128,064	127,137	424,179
Interest expense	-	-	-	-	(244,138)
Total other income (expense)	53,445	92,510	128,064	390,807	180,041
Net loss	\$ (1,394,406)	\$ (1,130,410)	\$ (4,505,947)	\$ (3,100,080)	\$ (18,268,269)
<b>Net loss per share:</b>					
Basic and diluted	\$ (0.05)	\$ (0.06)	\$ (0.20)	\$ (0.18)	
<b>Weighted-average shares:</b>					
Basic and diluted	25,446,803	17,460,181	22,021,676	17,172,469	

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 nine months ended September 30,		Inception to September 30,
	2007	2006 (Restated)	2007
<b>Cash flows from operating activities:</b>			
Net loss	\$ (4,505,947)	\$ (3,100,080)	\$ (18,268,269)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Amortization of debt discount	-	-	244,795
Depreciation and amortization	37,506	37,957	289,725
Change in fair value of warrant liability	-	(263,670)	-
Patent rights impairment	-	-	91,694
Interest earned on discounted short term investments	-	(86)	-
Issuance of common stock, options and warrants for compensation	585,376	595,114	3,385,310
Issuance of warrants for patent acquisition	74,570	-	74,570
Settlement of accrued expense	-	-	54,401
Deferred compensation costs	-	-	319,553
Loss on disposition of fixed assets	2,766	-	2,766
Changes in operating assets and liabilities:			
Prepaid expenses	96,388	79,848	(50,777)
Other assets	(13,187)	7,947	(76,014)
Accounts payable	75,102	(20,586)	385,264
Accrued expenses	549,141	(36,374)	587,712
Other liabilities	-	-	64,695
Contractual obligation	250,000	-	250,000
Net cash used in operating activities	(2,848,285)	(2,699,930)	(12,644,575)
<b>Cash flows from investing activities:</b>			
Additions of property and equipment	(2,500)	(3,447)	(147,296)
Purchase of short term investments	-	(10,904,894)	(21,866,787)
Maturities of short term investments	-	10,907,980	21,866,787
Net cash used in investing activities	(2,500)	(361)	(147,296)
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of convertible debt	-	-	400,000
Proceeds from common stock option/warrant exercise	2,700	-	67,900
Net proceeds from issuance of common stock and warrants	4,483,831	1,254,988	15,797,080
Net proceeds from issuance of preferred stock	-	-	238,732
Payments on capital lease obligation, net	-	-	(21,815)
Net cash provided by financing activities	4,486,531	1,254,988	16,481,897
Net increase (decrease) in cash	1,635,746	(1,445,303)	3,690,026

Cash at beginning of period	2,054,280	2,379,738	-
Cash at end of period	\$ 3,690,026	\$ 934,435	\$ 3,690,026

**Supplemental disclosures of non-cash financing activity**

Issuance of securities for obligation related to finder's fees	-	-	\$ 47,500
Accrued warrant liability	-	\$ 1,021,172	\$ -

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 SEPTEMBER 30, 2007**

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deferred Costs	Deficit Accumulated During the Development Stage	Total
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
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 SEPTEMBER 30, 2007**

	Preferred Stock		Common Stock		Additional	Deferred	Deficit	
	Shares	Amount	Shares	Amount	Paid-In Capital	Costs	Accumulated During the Development Stage	Total
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
Shares issued in connection with acquisition of Historical Autographs U.S.A., Inc. on October 30, 2003	1,220,000	8,263	(8,263)	-

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 SEPTEMBER 30, 2007**

	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								

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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 SEPTEMBER 30, 2007**

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deferred Development Costs	Accumulated During the 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

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 SEPTEMBER 30, 2007**  
**(Unaudited)**

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deferred Costs	Accumulated During the Development Stage	Total
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 and warrants in private placement for cash less issuance expense of \$377,169		7,478,462	7,479		4,476,352			4,483,831
Exercise of common stock warrants		18,000	18		2,682			2,700
Stock option based compensation expense					346,081			346,081
Stock warrant term extension			-		59,025			59,025
Restricted stock based compensation expense		621,818	621		179,649			180,270
Issuance of warrants for patent acquisition					74,570			74,570
Net loss						(4,505,947)		(4,505,947)
Balance, September 30, 2007	-	-	25,578,461	\$ 25,578	\$ 20,931,139	-	(\$18,268,269)	\$ 2,688,448

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)**  
**Nine Months Ended September 30, 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, the Company 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 Financial Accounting Standards Board (“FASB”) Statement of Financial Accounting Standards (“FASB Statement”) 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 condensed 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 condensed financial statements include all adjustments, including those that are normal and recurring considered necessary to present fairly the financial position as of September 30, 2007, and the results of operations for the periods presented. These unaudited 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 as filed with the SEC. The Company expects that its 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 three and nine months ended September 30, 2007 are not necessarily indicative of the results to be expected for any subsequent periods or for the entire 2007 fiscal year. As of the date of the filing of the Company’s Quarterly Report on Form 10-QSB for the quarter ended September 30, 2007, the Company estimates that it does not have sufficient cash to operate for the next twelve months.

**(2) Going Concern**

The Company’s financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, which contemplate continuation of the Company on a going concern basis, and which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company

has incurred a net operating loss of \$4,505,947 for the nine months ended September 30, 2007 and an accumulated deficit of \$18,268,269 at September 30, 2007. This factor raises substantial doubt about the Company's ability to continue as a going concern.

If the Company is unsuccessful in its efforts to raise additional funds through the sale of additional equity securities or if the level of cash and cash equivalents falls below anticipated levels, the Company will not have the ability to continue as a going concern after the second quarter of 2008. While the Company intends to pursue development of its product candidates, any significant continued development is contingent upon additional funding or a strategic partnership. The amount and timing of future capital requirements will depend on numerous factors, including the number and characteristics of product candidates that the Company pursues, the conduct of preclinical tests and clinical studies, the status and timelines of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the ability to complete strategic collaborations and the availability of third-party funding, if any. The Company may also seek additional funding through corporate collaborations and other financing vehicles. If funds are obtained through arrangements with collaborative partners or others, the Company may be required to relinquish rights to its technologies or product candidates.

Management's plans include the sale of additional equity securities through a private placement. However, no assurance can be given that the Company will be successful in raising additional capital. Furthermore, there can be no assurance, assuming the Company successfully raises additional equity, that the Company will achieve profitability or positive cash flow. If management is unable to raise additional capital and expected significant revenues do not result in positive cash flow, the Company will not be able to meet its obligations and will have to cease operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **(3) Restatement of Condensed Financial Statements**

The Company's previously issued financial statements for each of the three, six and nine month periods ended in 2006, which have been restated to correct the error in the manner in which the Company valued outstanding warrants. 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 Emerging Issues Task Force ("EITF") Issue No. 00-19: "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" ("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-dilution provision for the filed financial statements included in the Company's Quarterly Report on Form 10-QSB for the quarter ended September 30, 2006. Therefore, we restated the financial statements included in the Quarterly Report on Form 10-QSB for the quarter ended September 30, 2006 as follows: 1) for the nine month period ended September 30, 2006, additional paid in capital is decreased by \$385,000, other expense is increased by \$112,000 and the accrued warrant liability increased by \$497,000, and 2) for the three months ended September 30, 2006, additional paid in capital is decreased by \$114,000 and other expense is increased by \$49,000 with a corresponding increase in the accrued warrant liability of \$163,000. The cumulative effect of the restatement on retained earnings through September 30, 2006 is a decrease in retained earnings of \$112,000. See footnote 4 for the current accounting treatment of warrants.

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The following table shows the net effect of the restatement on net loss, accrued warrant liability and additional paid in capital for the three and nine months ended September 30, 2006.

	Three months ended September 30, 2006	Nine months ended September 30, 2006
<b>Net loss:</b>		
Originally reported	\$ (1,081,410)	\$ (2,988,080)
Adjustment	(49,000)	(112,000)
Restated	\$ (1,130,410)	\$ (3,100,080)
<b>Net loss per share:</b>		
Originally Reported	\$ (0.06)	\$ (0.17)
Adjustment	-	(0.01)
Restated	\$ (0.06)	\$ (0.18)
<b>Accrued warrant liability:</b>		
Originally reported		\$ 524,172
Adjustment		497,000
Restated		\$ 1,021,172
<b>Additional paid-in capital:</b>		
Originally reported		\$ 14,307,052
Adjustment		(385,000)
Restated		\$ 13,922,052

**(4) Cumulative Effect of a Change in Accounting Principle**

In accordance with FASB Statement No. 154: "Accounting Changes and Error Corrections, ("FASB 154") the Company is recording a change in accounting principal related to FASB'S EITF Issue No. 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 requires the registration rights agreement and any registration rights payments to be considered separately from the financial instruments. In accordance with EITF 00-19-2, the Company reversed the classification of the warrant liability associated with the warrants issued in the 2005 and 2006 financings from debt to equity during the period ended March 31, 2007. 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. The Company reviewed the instruments entered into in connection with the April 2007 financing discussed in Note 10 below and determined that the financing did not have any embedded derivatives requiring derivative accounting treatment. The Company recorded an accrual of \$180,000 to estimate a liability related to potential payments under contractual obligations associated with our 2005 and 2006 financings.

**(5) Recent Accounting Pronouncements**

In February 2007, the FASB issued FASB Statement No.159: "The Fair Value Option for Financial Assets and Financial Liabilities - including an amendment of FASB Statement No. 115" ("FAS 159"). This statement permits entities to choose to measure many financial instruments and certain other items at fair value and is expected to expand the use of fair value measurement. FASB 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the statement's impact on its financial statements.

On June 27, 2007, the FASB reached a final consensus on EITF Issue No. 07-03: "Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-03"). Currently, under FASB Statement No. 2: "Accounting for Research and Development Costs," nonrefundable advance payments for future research and development activities for materials, equipment, facilities and purchased intangible assets that have no alternative future use are expensed as incurred. EITF 07-03 addresses whether such non-refundable advance payments for goods or services that have no alternative future use and that will be used or rendered for research and development activities should be expensed when the advance payments are made or when the research and development activities have been performed. The consensus reached by the FASB requires companies involved in research and development activities to capitalize such non-refundable advance payments for goods and services pursuant to an executory contractual arrangement because the right to receive those services in the future represents a probable future economic benefit. Those advance payments will be capitalized until the goods have been delivered or the related services have been performed. Entities will be required to evaluate whether they expect the goods or services to be rendered. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment will be charged to expense. The consensus on EITF 07-03 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. Entities are required to recognize the effects of applying the guidance in EITF 07-03 prospectively for new contracts entered into after the effective date. The Company is in the process of evaluating the expected impact of EITF 07-03 on its financial position and results of operations following adoption.

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

On January 11, 2007, in accordance with the established Board of Director's compensation program, the Company granted 120,000 options to Board members with exercise prices of \$0.51 per share, the closing market price of the Company's common stock on the date of grant, valued at approximately \$46,000, which vest on a monthly pro-rata basis 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 issued 82,354 shares of restricted stock to consultants at a price of \$0.01 per share. The value of restricted shares issued, based on the closing price of the Company's common stock on the date of grant, was recorded as a consulting expense of approximately \$41,000 during the period the services were provided with a corresponding increase in additional paid in capital.

In March 2007, warrants to purchase 225,000 shares of common stock exercisable at \$1.50 per share were issued in conjunction with the acquisition of certain patents. The fair value of the warrants, which were expensed in March 2007, was determined to be approximately \$75,000 using the Black Scholes pricing model utilizing the following assumptions: risk free interest rate 4.48%, stock price volatility 0.79, expected life 6 years, dividend yield 0%.

In May 2007, the Company granted 410,000 options to employees and officers with exercise prices of \$0.82 per share which vest over four years fair valued at approximately \$254,000, and also granted 15,000 options with an exercise price of \$0.82 per share to an officer which vest on September 30, 2007 fair valued at approximately \$9,000. The Company also issued 15,244 shares of restricted stock to a director at a price of \$0.01 per share valued at approximately \$12,000 which fully vest six months after issuance. The fair value of the options was determined using

the Black Scholes pricing model utilizing the following assumptions: risk free interest rate 4.67%, stock price volatility 0.80, expected life 7 years, dividend yield 0%.

In July 2007, the Company granted 134,375 shares of restricted stock to Board members as compensation for services at a price of \$0.01 per share. The value of restricted shares issued, based on the closing price of the Company's common stock on the date of grant, was expensed for approximately \$111,000 with a corresponding increase in additional paid in capital. The Company also issued 200,000 shares of restricted stock to an investor relations consultant at a price of \$0.01 per share. The value of such restricted shares issued was approximately \$164,000. The Company also granted 200,000 performance-based options to purchase common stock with an exercise price of \$0.83 per share to an officer with a fair value of approximately \$130,000 of which \$39,000 is attributed to the milestones achieved to date; all the options vest according to achievement of Company milestones during FY 2007.

In September 2007, the Company granted 100,000 shares of restricted stock to a member of the Board of Directors as compensation for services at a price of \$0.01 per share. The value of these restricted shares issued, based on the closing price of the Company's common stock on the date of grant, was expensed for approximately \$48,000 with a corresponding increase in additional paid in capital. The Company also granted 300,000 performance-based options to purchase common stock to employees and officers with an exercise price of \$0.49 per share and a fair value of approximately \$114,000. In accordance with SFAS 123R, the recognition of the related option expense charges of the performance-based options was based on the evaluation of the estimated probabilities of achieving milestones and is being recognized ratably over the requisite service period. The estimations will be revised if subsequent information indicates that the actual number of instruments which will vest differs from their original estimates, with the change reflected in the related financial period. The fair value of the options was determined using the Black Scholes pricing model utilizing the following assumptions: risk free interest rate 4.20%-4.88%, stock price volatility .85, expected life 7 years, dividend yield 0%.

During the nine months ended September 30, 2007 and 2006, the Company recognized equity based compensation expense for stock options of \$346,081 and \$497,474, respectively, which was recognized in the Statement of Operations. As of September 30, 2007, the total compensation costs related to non-vested awards not yet recognized is \$400,217 which will be recognized over the next 1.38 years.

#### **(7) Accrued Warrant Liability**

During 2006, in accordance with EITF 00-19 and other authoritative literature, the Company determined that the warrants issued in the January 2005 and March 2006 private placements and the related registration rights agreements discussed below, were 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 were reviewed each reporting period and while the warrants were classified as a liability, any changes in the value of the warrants on a re-measurement date were 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 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 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 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 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, the anti-dilution provision discussed below 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 registration rights agreements entered into in connection 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, the potential liquidated damages exceeded the reasonable discount between registered and unregistered shares thereby making the settlement alternative uneconomic, and the warrants were reclassified from equity to accrued warrant liability, based on the fair value of the warrants using the Black Scholes pricing model. 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.



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 warrant 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 were 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%.

### **(8) 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 value of the extension of the warrants was calculated using the Black Scholes pricing model and resulted in a charge of approximately \$59,000, which was recorded in the statement of operations during the first quarter of 2007.

In addition, all of the extended 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.

### **(9) 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 six 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 four years with guaranteed cash payments of \$300,000 payable to the licensor over the next three years, of which \$50,000 is included in accrued expense and \$250,000 is recorded as a long-term contract obligation. The Company's 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 Statement No. 2: "Accounting for Research and Development Costs," the Company has expensed the patent acquisition costs of \$350,000 as they do not have any alternative future use.

In connection with this license agreement the Company issued a warrant to the licensor to acquire up to 225,000 shares of the Company's common stock at an exercise price per share of \$1.50. The warrant is immediately exercisable and expires on March 29, 2013. The warrant was valued at \$74,570 using the Black Scholes pricing model and expensed in the first quarter of 2007 as discussed in note 6.

#### **(10) April 2007 Private Equity Financing**

On April 23, 2007, the Company completed a private equity financing of \$4,861,000 to a group of current and new accredited investors which was reduced by \$377,000 in fund raising costs resulting in net proceeds of \$4,484,000 to the Company. 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: i) two shares of common stock, ii) one warrant to purchase one share of 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 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 common stock and warrants to purchase 7,478,462 shares of common stock. The warrants have no provision for cashless exercise and, subject to certain requirements, may be called by the Company provided that the Company's common stock trades above \$1.50 for the A Warrants and above \$2.80 for the B Warrants for a specified time period. The placement agent received: 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 with a Black Scholes valuation of \$275,845 utilizing the following assumptions: risk free interest rate 4.59%, stock price volatility 0.80, expected life 5 years, dividend yield 0%, 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 increased the number of shares issuable under the warrants issued in the 2005 and 2006 financing by approximately 702,000 shares.

#### **(11) Supply agreement with Membrana GmbH**

On September 14, 2007, Arbios Systems, Inc. (the "Company") entered into a Supply Agreement (the "Supply Agreement") with Membrana GmbH, a company organized under the laws of Germany ("Membrana"), for the provision of membranes for use in the Company's SEPET™ therapeutic blood filtration products for the treatment of liver failure and sepsis. The Supply Agreement provides that following the first commercial sale of the Company's product that contains Membrana membranes, Membrana will be the Company's exclusive supplier of certain identified membranes for use in products covered within a claim of an issued U.S. patent that is owned by or licensed exclusively to Arbios for the treatment of liver failure or sepsis anywhere in the world. In addition, the agreement provides that following the first commercial sale of the Company's product that contains Membrana membranes, Membrana shall not supply certain identified membranes for use in products covered within a claim of an issued U.S. patent that is owned by or licensed exclusively to Arbios for the treatment of liver failure or sepsis anywhere in the world to any third party that will incorporate such membranes into a product whose composition, method of manufacture or method of use falls within a claim of an issued U.S. patent that is owned by or licensed exclusively to Arbios. Such exclusivity may last for up to five years based upon the fulfillment of certain minimum purchase thresholds by the Company. The agreement also provides for pre-established per-unit pricing of Membrana membranes, including progressive quantity discounts.

The Supply Agreement will terminate following the six-year anniversary of the date of the first commercial sale of the Company's product that contains Membrana membranes. The Supply Agreement may be terminated by either party upon ninety days notice in the event of a material breach by the other party that remains uncured for ninety days, or upon sixty days notice if the other party becomes insolvent or becomes the subject of any voluntary or involuntary proceeding in bankruptcy, liquidation, dissolution, receivership, or general assignment for the benefit of creditors that is not dismissed within sixty days. In addition, upon sixty days notice, the Company may terminate the Supply Agreement or terminate the exclusivity of the Supply Agreement, upon Membrana's failure to meet certain delivery requirements.



## **(12) Separation Agreement with Former Chief Executive Officer**

On November 13, 2007, the Company entered into a Separation Agreement (the “Agreement”) with the former President and Chief Executive Officer of the Company, Walter C. Ogier. Pursuant to the terms of the Agreement, Mr. Ogier acknowledged that his employment and all positions held by him were terminated as of September 21, 2007 (the “Separation Date”). As consideration for Mr. Ogier performing consulting services for the Company for a period of 12 months following the Separation Date, the Company will pay Mr. Ogier monthly payments of \$25,000 and will allow Mr. Ogier to continue to utilize the Company’s health insurance plan for the lesser of 12 months following the Separation Date or the time that he becomes eligible to receive health insurance from another employer. In addition, certain of Mr. Ogier’s unvested options will become vested and exercisable and will remain exercisable for a period of 12 months following the Separation Date. Furthermore, Mr. Ogier agreed to release the Company from any and all legal claims or causes of action that he may have had arising from any event occurring prior to the Separation Date. The Company has accrued \$300,000 in the current period related to provisions of the Agreement.

## **(13) Subsequent Events**

On October 19, 2007, Arbios Systems, Inc. (the “Company”) entered into a Manufacturing & Supply Agreement (the “Supply Agreement”) with NxStage Medical, Inc. (“NxStage”) for the manufacture and supply of the Company’s SEPET™ Liver Assist Device for use in clinical trials and for commercial sale. The Supply Agreement provides that NxStage will be the Company’s exclusive manufacturer and supplier of the SEPET™ Liver Assist Device for commercial sale until the fifth anniversary of regulatory approval of the device. Under the Supply Agreement, NxStage will not manufacture, supply or sell the Company’s device to other parties and if NxStage manufactures, supplies or sells a competing product, as defined in the Supply Agreement, subject to certain exceptions, the Company may terminate the arrangement or convert it into a non-exclusive arrangement. In addition, if the Company purchases more than a certain number of devices in one calendar year, the Company will be subject to an annual minimum purchase requirement for the remainder of the agreement, which minimum will be subject to adjustment each year. The Supply Agreement provides for pre-established per-unit pricing, including quantity discounts and yearly adjustments.

The Supply Agreement will terminate upon the earlier of (i) the seventh anniversary of regulatory approval of the device or (ii) the seventh anniversary of the date of the Supply Agreement if regulatory approval of the device is not obtained by such date. The Supply Agreement may be terminated by either party (i) upon an extended prior notice period, (ii) upon a material breach by the other party that remains uncured, or (iii) upon notice if the other party becomes insolvent, files for bankruptcy, goes into liquidation or a receiver is appointed over all or a major part of the other parties’ assets. In addition, the Company may terminate the Supply Agreement or terminate the exclusivity of the Supply Agreement, upon the occurrence of certain events.

On November 8, 2007, the Company entered into a Consulting Agreement (the “Agreement”) with David Zeffren, the Company’s former Vice President of Product Development. Pursuant to the terms of the Agreement, the Company will pay Mr. Zeffren \$10,400 per month and Mr. Zeffren will advise and support the Company with its regulatory and clinical affairs. Mr. Zeffren will also be reimbursed for reasonable and customary expenses incurred by him on behalf of the Company. During the term of the Agreement and for a period of one year following the termination of the Agreement, Mr. Zeffren has agreed not to compete with the Company in the field the commercialization of medical devices or cell therapies for the treatment of liver disease, viral hepatitis or septic shock. Both the Company and Mr. Zeffren have the right to terminate the Agreement at anytime upon written notice.

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

### **SAFE HARBOR STATEMENT**

*In addition to historical information, the information included in this Quarterly Report on 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,” “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, including those risks set forth under “Factors That May Affect our Business And Our Future Results,” 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.

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 trials for SEPET™ in the third quarter of 2005. In the third quarter of 2007 we completed the Phase I feasibility clinical trial for SEPET™ and are in the process of preparing for the Phase II/III pivotal clinical trial which we anticipate to commence in mid-2008. The actual amounts we may expend on research and development and related clinical activities during the next 12 months may vary significantly depending on numerous factors, including how the results of our clinical trials and proposed trial designs are received by the FDA and the timing and cost of regulatory submissions. Based on our current estimates, we believe that we may not have sufficient financial resources to conduct our planned operations for the next twelve months. We do not expect to make any significant purchases or sales of plant or equipment during the next twelve months. We also intend to continue exploring options to reactivate our development of the HepatAssist™ Cell-Based Liver Support System; however we will need to obtain significant additional capital to fund this program or find a strategic partner who would be willing to assist in developing this product.

Our research offices and laboratories are located in Medford, Massachusetts where we lease 1,783 square feet at \$5,044 per month with a term of one year that was entered into on September 15, 2007. We maintain an administrative office in Pasadena, California and our headquarters is located in Waltham, Massachusetts, both of which are currently leased on a month-to-month basis for approximately \$1,500 and \$3,700 per month respectively.

On September 19, 2007, Walter C. Ogier, resigned from the Company as a Director and Chief Executive Officer of the Company. The Company's Board of Directors appointed Shawn P. Cain, previously the Vice President of Operations of the Company, as the interim President and Chief Executive Officer to serve until his successor is duly elected and qualified or until his removal or resignation.

## Critical Accounting Policies

This discussion is based on our unaudited condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these unaudited condensed 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 included in our Annual Report on Form 10-KSB as filed with the Securities and Exchange Commission. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our unaudited condensed 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 our 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 we 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, the predecessor to SFAS 123R, "Accounting for Stock-Based Compensation." Accordingly, we have applied the modified prospective method in adopting SFAS 123R whereby periods prior to adoption have not been restated.

### *Accounting for Uncertainty in Income Taxes*

In June 2006, the FASB issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes," or FIN 48. This Interpretation clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements and prescribes a recognition threshold of more-likely-than-not to be sustained upon examination. Measurement of the tax uncertainty occurs if the recognition threshold has been met. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. In the normal course of business we are subject to examination by taxing authorities. At present, there are no ongoing audits or unresolved disputes with the various tax authorities that we file with. Given our substantial net operating loss carryforwards as well as historical operating losses, the adoption of FIN 48 on January 1, 2007 did not have any effect on our financial position, results of operations or cash flows as of or for the periods ended September 30, 2007.

## **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 Small Business Innovation Research, SBIR grant.

General and administrative expenses of \$1,025,000 and \$754,000 were incurred for the three months ended September 30, 2007 and 2006, respectively. General and administrative expenses of \$2,651,000 and \$2,210,000 were incurred for the nine months ended September 30, 2007 and 2006, respectively. General and administrative expenses for the three

months ended September 30, 2007 increased by \$271,000 over the prior year level. The increase is primarily attributed to a \$300,000 severance obligation incurred to a former corporate officer offset by a decrease in investor relation costs of \$46,000. General and administrative expenses for the nine months ended September 30, 2007 increased by \$441,000 over the prior year level. The increase is primarily attributed to a \$300,000 severance obligation incurred to a former corporate officer, an increase of \$201,000 in corporate legal fees and a \$180,000 accrual for contractual obligations associated with our 2005 and 2006 financings offset by decreases in investor relation costs of \$142,000, Board of Director costs of \$98,000 and executive search fees of \$29,000. Legal costs have increased primarily due to greater activity related to patent registrations. The equity offerings contingency for \$180,000 was accrued for in the first quarter of 2007. Investor relations cost reductions are attributed to lower spending on fixed retainer costs. The decline in Board of Director costs reflects a temporary change in our compensation of board members with stock options and restricted stock instead of providing cash compensation.

Research and development expenses of \$423,000 and \$469,000 were incurred for the three months ended September 30, 2007 and 2006, respectively. The research and development expenses for the three months ended September 30, 2007 decreased by \$46,000 over the comparable prior year levels primarily from an decrease in HepatAssist program costs of \$43,000 due to the termination of the lease of the animal facility in Connecticut. Research and development expenses of \$1,983,000 and \$1,281,000 were incurred for the nine months ended September 30, 2007 and 2006, respectively. The research and development expenses for the nine months ended September 30, 2007 increased by \$702,000 over the comparable prior year levels primarily as a result of \$425,000 in costs related to the patent portfolio acquisition in March 2007 and an increase of \$347,000 in SEPET™ program costs which reflect the increased number of patients enrolled in the SEPET™ clinical trial. These increases are offset in part by a decline in HepatAssist costs of \$95,000.

Interest income of \$53,000 and \$39,000 was earned for the three months ended September 30, 2007 and 2006, respectively. Interest income of \$128,000 and \$127,000 was earned for the nine months ended September 30, 2007 and 2006, respectively. The change in interest income primarily reflects differences in cash and cash equivalent balances in 2007 from prior year levels and fluctuations in the interest rate in our cash account.

Our net loss was \$1,394,000 and \$1,130,000 for the three months ended September 30, 2007 and 2006, respectively. Our net loss was \$4,506,000 and \$3,100,000 for the nine months ended September 30, 2007 and 2006, respectively. The increase in net loss for the three and nine months ended September 30, 2007 compared to the comparable periods in 2006 is primarily attributable to the increase in research and development expenses and general and administrative employment severance payments incurred.

### **Liquidity and Capital Resources**

As of September 30, 2007, we had cash of approximately \$3,690,000 and current liabilities of approximately \$1,066,000. We have long term contract obligations of \$250,000 related to patent acquisitions and 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 grants.

As of the date of the filing of the Company's Quarterly Report on Form 10-QSB for the quarter ended September 30, 2007, we estimate that we do not have cash to operate for the next twelve months. We are continuing to pursue fund-raising possibilities through the sale of our equity securities. If we are unsuccessful in our efforts to raise additional funds through the sale of additional equity securities or if the level of cash and cash equivalents falls below anticipated levels, we will not have the ability to continue as a going concern after the second quarter of 2008. While we intend to pursue development of our product candidates, any continued development by us is contingent upon additional funding or a strategic partnership. The amount and timing of our future capital requirements will depend on numerous factors, including the number and characteristics of product candidates that we pursue, the conduct of preclinical tests and clinical studies, the status and timelines of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the ability to complete strategic collaborations and the availability of third-party funding, if any. We may also seek additional funding through corporate collaborations and other financing vehicles. If funds are obtained through arrangements with collaborative partners or others, we may be required to relinquish rights to our technologies or product candidates.

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 we will enter into strategic alliances, or that the terms

under which we obtain such funding or of any such strategic alliance will be beneficial to us or our shareholders.

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On April 23, 2007, we completed a private equity financing to a group of accredited investors for \$4,861,000 which was reduced by \$377,000 in fund raising costs resulting in net proceeds of \$4,484,000 to us. 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 common stock, ii) one warrant to purchase one share of 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 common stock and warrants to purchase 7,478,462 shares of 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. The placement agent received: 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 with a Black Scholes valuation of \$275,845 utilizing the following assumptions: risk free interest rate 4.59%, stock price volatility 0.80, expected life 5 years, dividend yield 0%, 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 our prior equity financings, we adjusted upwards the number of shares issuable under the warrants issued in the 2005 and 2006 financing by approximately 702,000 shares.

Based on our current plan, we believe that our current cash balances will not be sufficient to fund our operations for the next twelve months from the date of this report.

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	\$ 60,000	\$ 20,000	\$ 40,000	\$ -	\$ -
License Agreement	300,000		50,000	100,000	150,000
<b>Total</b>	<b>\$ 360,000</b>	<b>\$ 20,000</b>	<b>\$ 90,000</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 SBIR 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 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 does not have cash to operate for the next 12 months, and therefore we 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 our basic operations. 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 medical device 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.

As a result of a decrease in our available financial resources, we have significantly curtailed the research, product development, preclinical testing and clinical trials of our product candidates. The amount and timing of our future capital requirements will depend on numerous factors, including the timing of resuming of our research and development programs, if at all, the number and characteristics of product candidates that we pursue, the conduct of preclinical tests and clinical studies, the status and timelines of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the ability to complete strategic collaborations and the availability of third-party funding, if any.

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 studies 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.

*The cost of conducting pivotal clinical trials 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 trials until we obtain additional funding.*

Now that the feasibility clinical trial for the SEPET™ liver assist device has been completed, 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) but are attempting to identify 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 the trial would approximately be between \$10 million and \$15 million, excluding the manufacturing infrastructure. We currently do not have sufficient funds to conduct this trial 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 capital needs beyond 2007 will depend on many factors, including our research and development activities and the success thereof, the scope of our clinical trial program, the timing of regulatory approval for our products under development and the successful commercialization of our products. Our needs may also depend on the magnitude and scope of the activities, the progress and the level of success in our clinical trials, the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights, competing technological and market developments, changes in or terminations of existing collaboration and licensing arrangements, the establishment of new collaboration and licensing arrangements and the cost of manufacturing scale-up and development of marketing activities, if undertaken by us. We currently do not have committed external sources of funding and may not be able to secure additional funding on any terms or on terms that are favorable to us. If we raise additional funds by issuing additional stock, further dilution to our existing stockholders will result, and new investors may negotiate for rights superior to existing stockholders. If adequate funds are not available, we may be required to:

- delay, reduce the scope of or eliminate one or more of our development programs;
- obtain funds through arrangements with collaboration partners or others that may require us to relinquish rights to some or all of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves;
- license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available;
  - seek a buyer for all or a portion of our business; or
- wind down our operations and liquidate our assets on terms that are unfavorable to us.

*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 another year or longer.

*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 to allow clinical testing and ultimately 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 further clinical testing of our HepatAssist™ cell-based liver support system, we will need to amend our Phase III Investigational New Drug application, or 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.

*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, or PERV, but its ability to infect people is still 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.

*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, medical device and biotechnology industries are 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 and there can be no assurance that we will be able to enter into satisfactory arrangements for these services or the 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 trials 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 NxStage Medical, Inc. (“NxStage”) and Membrana, GmbH (“Membrana”) as the manufacturers of our SEPET™ cartridges, any failure or delay by either NxStage or Membrana to manufacture the cartridges will negatively affect our future operations.

We have exclusive manufacturing arrangements both with NxStage and Membrana. If NxStage or Membrana is unable to meet its contractual obligations to us, we may have difficulty in finding a replacement manufacturer/supplier if we are unable to effectively transfer the NxStage or Membrana know-how to another manufacturer. We have no control over NxStage, Membrana or their suppliers, and if NxStage or Membrana are unable to produce the SEPET™ cartridges or its components 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. In addition to the patents acquired on March 29, 2007, we currently own four United States 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 and investors with respect to all of these patents, application and licenses, and have not independently fully verified the validity or any other aspects of the patents or patent applications covering our products with our own patent counsel. For example, we had received from the European Patent Office an initial rejection of a patent filing citing references to certain issued patents that may represent prior art in the field of large-pore hemofiltration. This and potential other 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 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. If our products are approved, we intend to obtain coverage for them when they enter the marketplace (as well as requiring the manufacturers of our products to maintain insurance). We do not know if coverage will be available to us at acceptable costs or at all. We may encounter difficulty in obtaining clinical trial or commercial product liability insurance for our HepatAssist™ cell-based liver support system 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 by 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. Remediation of 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., and the recent patent acquisition in March 2007, we may 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 re-characterize 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 the provisions of our registration rights agreements, we may have to re-characterize some of our 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, or 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 100,000,000 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:



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- 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, 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 September 30, 2007, we had 25,578,461 outstanding 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. As of June 2006, the resale of a total of 8,015,480 shares of our common stock issuable upon the exercise of outstanding warrants were registered on a registration statement on Form SB-2. Since June 2006, a warrant to purchase 40,000 shares of our common stock has been cancelled. This warrant was issued to our former director, Richard Bank, as compensation for fundraising on our behalf and expired in January 2007. We have also registered an additional 746,602 shares of our common stock issuable upon exercise of outstanding warrants on the registration statement on Form SB-2 filed with the Securities and Exchange Commission (SEC) on June 1, 2007, and 8,055,077 shares of our common stock issuable upon exercise of outstanding warrants registered on the registration statement on Form SB-2 filed with the SEC on June 22, 2007. The shares underlying the 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, 16,777,159 additional shares could be released onto the trading market at any time. Because of the limited trading volume, the sudden release of 16,777,159 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 4,650,000 outstanding shares of unregistered restricted stock that are currently eligible for public resale under Rule 144 promulgated under the Securities Act of 1933, as amended, some of which shares also may be offered and sold on the market from time to time and an additional 3,256,674 shares that are issuable upon the exercise of outstanding options and other warrants. No prediction can be made as to the effect, if any, that sales of the 16,777,159 registered warrant shares, or the sale of any of the 4,650,000 shares subject to Rule 144 sales or the 3,256,674 shares issuable upon the exercise of outstanding options and other warrants 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.

*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 on Form 10-QSB.

### **ITEM 3 (A)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 Exchange Act, 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 Exchange Act, 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 September 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. However, as we continue to expand our 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 our size and stage of development. For example, as a result of our restatement of the financial statements, we will engage third party consultants to assist us in evaluating complex financial issues.

#### **(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.

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**PART II. OTHER INFORMATION****ITEM 1. Legal Proceedings.**

None.

**ITEM 2. Unregistered Sales 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.**

The 2007 Annual Meeting of Stockholders of the Company was held on July 12, 2007. The following matters were voted upon at the meeting: (i) the election of directors of the Company to serve until the 2008 Annual Meeting of Stockholders, (ii) to amend our Certificate of Incorporation to increase the number of authorized shares of common stock from 60,000,000 to 100,000,000, (iii) to amend our 2005 Stock Incentive Plan to increase the number of shares of common stock reserved for issuance from 3,000,000 to 4,000,000 shares, and (iv) the ratification of the appointment of Stonefield Josephson, Inc. as independent public accountants for the fiscal year ending December 31, 2007.

(i) The following table sets forth the names of the nominees who were elected to serve as directors and the number of votes cast for or withheld from the election of such nominee:

Name	Votes For	Votes Against	Abstentions/Broker Non-Votes
Walter C. Ogier	16,389,195	455,492	-
Dennis Kogod	14,267,495	2,577,192	-
Thomas. C. Seoh	14,242,495	2,602,192	-
Jack E. Stover	14,267,495	2,577,192	-
Thomas M. Tully	14,242,495	2,602,192	-
John M. Vierling, M.D.	16,417,495	427,192	-

(ii) The number of votes cast for, against and abstaining to amend our Certificate of Incorporation to increase the number or authorized shares of common stock from 60,000,000 to 100,000,000, were as follows:

Votes For	Votes Against	Abstain
16,793,495	51,191	0

(iii) The number of votes cast for, against and abstaining to amend our 2005 Stock Incentive Plan to increase the number of shares of common stock reserved for issuance from 3,000,000 to 4,000,000 shares, were as follows:

Votes For	Votes Against	Abstain
12,453,651	794,281	0

(iv) The number of votes cast for, against and abstaining from the ratification of the appointment of Stonefield Josephson, Inc. as our independent registered public accounting firm for the fiscal year ending December 31, 2007, were as follows:

Votes For	Votes Against	Abstain
14,662,995	31,191	2,150,000

**ITEM 5. Other Information.**

On September 15, 2007, the Company entered into a lease agreement with Cummings Properties, LLC to lease 1,783 square feet of laboratory space in Medford, Massachusetts at \$5,044 per month for a period of one year.

**ITEM 6. Exhibits.**

- 3.1 Certificate of Amendment to Certificate of Incorporation filed with the Secretary of State of the State of Delaware on July 13, 2007
- 10.1 Supply Agreement by and between Membrana GmbH and Company dated September 14, 2007
- 10.2 Lease Agreement by and between Cummings Properties, LLC and Company dated September 15, 2007
- 10.3 Consulting Agreement by and between David Zeffren and Company dated November 8, 2007
- 10.4 Separation Agreement by and between Walter C. Ogier and Company dated November 13, 2007
- 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 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 1350

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: November 14, 2007

By: /s/ Shawn P. Cain

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Shawn P. Cain  
Interim Chief Executive Officer (Principal Executive  
Officer)

Date: November 14, 2007

By: /s/ Scott L. Hayashi

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