

ARBIOS SYSTEMS INC  
Form 10QSB  
November 14, 2006

**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, 2006

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  
(IRS Employer Identification No.)

8797 Beverly Blvd., #304, Los Angeles, California  
(Address of principal executive offices)

90048  
(Zip Code)

(310) 657-4898  
(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 November 2, 2006, there were 17,460,181 shares of common stock, \$.001 par value per share, issued and outstanding.

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



ARBIOS SYSTEMS, INC.

## FORM 10-QSB

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**PART I - FINANCIAL INFORMATION****ITEM 1. Financial Statements**

**ARBIOS SYSTEMS, INC.**  
(A development stage company)  
**CONDENSED BALANCE SHEETS**

	September 30, 2006 (Unaudited)	December 31, 2005 (Audited)
<b><u>ASSETS</u></b>		
Current assets		
Cash and cash equivalents	\$ 934,435	\$ 2,379,738
Short term investments	1,993,000	\$ 1,996,000
Prepaid expenses	115,993	195,841
Total current assets	3,043,428	4,571,579
Net property and equipment	82,476	101,629
Patent rights, net of accumulated amortization of \$108,774 and \$93,418, respectively	157,893	173,249
Other assets	47,826	55,773
Total assets	\$ 3,331,623	\$ 4,902,230
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
Current liabilities		
Accounts payable	\$ 140,064	\$ 160,649
Accrued expenses	110,186	152,362
Total current liabilities	250,250	313,011
Accrued warrant liability	524,172	-
Stockholders' equity		
Preferred stock, \$.001 par value; 5,000,000 shares authorized: none issued and outstanding		
Common stock, \$.001 par value; 60,000,000 shares authorized; 17,460,181 and 16,232,909 shares issued and outstanding at September 30, 2006 and December 31, 2005 respectively	17,460	16,233
Additional paid-in capital	14,307,052	13,352,217
Deficit accumulated during the development stage	(11,767,311)	(8,779,231)
Total stockholders' equity	2,557,201	4,589,219
Total liabilities and stockholders' equity	\$ 3,331,623	\$ 4,902,230

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, 2006
	2006	2005	2006	2005	
Revenues	\$ -	\$ -	\$ -	\$ -	\$ 320,966
<b>Operating expenses:</b>					
General and administrative	753,604	470,505	2,210,018	1,810,552	7,216,933
Research and development	469,316	386,517	1,280,869	1,005,712	5,271,431
Total operating expenses	1,222,920	857,022	3,490,887	2,816,264	12,488,364
Loss before other income (expense)	(1,222,920)	(857,022)	(3,490,887)	(2,816,264)	(12,167,398)
<b>Other income (expense):</b>					
Change in fair value of warrant liability	102,546		375,670		375,670
Interest income	38,964	44,934	127,137	84,351	268,555
Interest expense	-	(5)	-	(134)	(244,138)
Total other income (expense)	141,510	44,929	502,807	84,217	400,087
Net loss	\$ (1,081,410)	\$ (812,093)	\$ (2,988,080)	\$ (2,732,047)	\$ (11,767,311)
<b>Net loss per share:</b>					
Basic and diluted	\$ (0.06)	\$ (0.05)	\$ (0.17)	\$ (0.17)	
<b>Weighted-average shares:</b>					
Basic and diluted	17,460,181	16,232,909	17,172,469	16,105,583	

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, 2006
	2006	2005	
<b>Cash flows from operating activities:</b>			
Net loss	\$ (2,988,080)	\$ (2,732,047)	\$ (11,767,311)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of debt discount			244,795
Depreciation and amortization	37,957	44,082	237,734
Change in fair value of warrant liability	(375,670)		(375,670)
Patent rights impairment			91,694
Interest earned on discounted short term investments	(86)	(37,500)	(8,738)
Issuance of common stock, options & warrants for compensation	595,114	483,159	2,208,245
Settlement of accrued expense			54,401
Deferred compensation costs			319,553
Changes in operating assets and liabilities:			
Prepaid expenses	79,848	16,938	(115,995)
Other assets	7,947	(4,616)	(47,826)
Accounts payable and accrued expenses	(56,960)	(13,580)	162,549
Other liabilities		70,737	64,695
Contract obligation		(250,000)	-
Net cash used in operating activities	(2,699,930)	(2,422,827)	(8,931,874)
<b>Cash flows from investing activities:</b>			
Additions of property and equipment	(3,447)	(7,715)	(144,796)
Purchase of short term investments	(10,904,894)	(3,995,518)	(19,882,608)
Maturities of short term investments	10,907,980		17,898,346
Net cash used in investing activities	(361)	(4,003,233)	(2,129,058)
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of convertible debt			400,000
Proceeds from common stock option/warrant exercise		62,500	65,200
Net proceeds from issuance of common stock and warrants	1,254,988	6,227,594	11,313,250
Net proceeds from issuance of preferred stock			238,732
Payments on capital lease obligation, net		(5,341)	(21,815)
Net cash provided by financing activities	1,254,988	6,284,753	11,995,367
Net (decrease) increase in cash	(1,445,303)	(141,307)	934,435
Cash at beginning of period	2,379,738	1,501,905	
Cash at end of period	\$ 934,435	\$ 1,360,598	\$ 934,435

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

Issuance of securities for obligation related to finder's fees		\$	47,500	\$	47,500
Accrued warrant liability	\$	524,172			

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, 2006**

**(1) Basis of Presentation:**

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

On October 30, 2003, Historical Autographs U.S.A., Inc. and Arbios Technologies, Inc. consummated a reverse merger, in which Arbios Technologies, Inc. became the wholly owned subsidiary of Historical Autographs U.S.A., Inc. Concurrently with the merger, Historical Autographs U.S.A., Inc. changed its name to Arbios Systems, Inc. and is herein referred to as "Arbios Systems". The stockholders of Arbios Technologies, Inc. transferred ownership of one hundred percent of all the issued and outstanding shares of their capital stock of Arbios Technologies, Inc. in exchange for 11,930,598 newly issued shares, or approximately 91%, of the common stock, \$.001 par value, of Arbios Systems. At that time, the former management of Arbios Systems resigned and was replaced by the same persons who served as officers and directors of Arbios Technologies, Inc. The former owners of Arbios Technologies, Inc. controlled the combined entity after the merger, and the combination was accounted for as a purchase by Arbios Technologies, Inc. as the acquirer, for accounting purposes in accordance with Statement of Financial Accounting Standards No. 141 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 is included in the condensed 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, 2006, and the results of operations for the period presented. These condensed financial statements should be read in conjunction with the Company's audited financial statements and the accompanying notes included in the Company's Form 10-KSB for the year ended December 31, 2005 filed with the SEC. The Company's operating results will fluctuate for the foreseeable future. Therefore, period-to-period comparisons should not be relied upon as predictive of the results in future periods. The results of operations for the period ended September 30, 2006 are not necessarily indicative of the results to be expected for any subsequent periods or for the entire fiscal year. As of the date of the filing of the Company's Form 10-QSB for the quarter ended September 30, 2006, which includes these Condensed Financial Statements and Notes, the Company estimates that it has cash to operate through the second quarter of calendar year 2007; and therefore will need to obtain significant additional funds during the first half of 2007. The accompanying Condensed Financial Statements and Notes are prepared assuming the Company will continue as an operating entity.

**(2) Recent Accounting Pronouncements**



In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation Number 48, *Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109*, ("FIN48"). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken in a tax return. The Company must determine whether it is "more-likely-than-not" that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. Once it is determined that a position meets the more-likely-than-not recognition threshold, the position is measured to determine the amount of benefit to recognize in the financial statements. FIN 48 applies to all tax positions related to income taxes subject to FASB Statement No. 109, *Accounting for Income Taxes*. The interpretation clearly scopes out income tax positions related to FASB Statement No. 5, *Accounting for Contingencies*. We do not anticipate that the adoption of this statement will have a material effect on our financial position or results of operations.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements ("SFAS No. 157"). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 with earlier application encouraged. We are evaluating the impact of adopting SFAS No. 157 on our financial statements.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements ("SAB 108"), to address diversity in practice in quantifying financial statement misstatements. SAB 108 requires that we quantify misstatements based on their impact on each of our financial statements and related disclosures. SAB 108 is effective as of the end of our 2006 fiscal year, allowing a one-time transitional cumulative effect adjustment to retained earnings as of January 1, 2006 for errors that were not previously deemed material, but are material under the guidance in SAB 108. We believe that SAB 108 will not have a material impact on our financial statements.

### **(3) Short Term Investments**

Short-term investments generally mature between three and twelve months. Short term investments consist of U.S. Government Agency Notes purchased at a discount with interest accruing to the notes full value at maturity. All of the Company's short-term investments are classified as available-for-sale and are carried at fair market value which approximates cost plus accrued interest.

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

In 2001, Arbios Systems, Inc. adopted the 2001 Stock Option Plan (the "2001 Plan") for the purpose of granting incentive stock options and/or non-statutory stock options to employees, consultants, directors and others. Under the 2001 Plan, the Company is authorized to grant options to purchase up to 1,000,000 shares. The 2001 Plan is administered by the Board of Directors of the Company or by a committee of the Board. However, in connection with the reorganization transaction between Arbios Systems and Arbios Technologies, Inc. in October 2003, Arbios Systems assumed all of the 314,000 outstanding options granted by Arbios Technologies, Inc. under its existing stock option plan and the options previously issued under the Arbios Technologies, Inc. plan were cancelled. None of the terms of the assumed options were changed. The options assumed under the Company Plan are identical to the options that were previously granted under the Arbios Technologies, Inc. Plan.

In 2005, Arbios Systems, Inc. adopted the 2005 Stock Incentive Plan (the "2005 Plan") for the purpose of granting incentive stock options and/or non-statutory stock options to employees, consultants, directors and others. Under the 2005 Plan, the Company is authorized to grant options to purchase up to 3,000,000 shares. The Company Plan is administered by the Board of Directors of the Company or by a committee of the Board.

Commencing January 1, 2006 the Company adopted Statement of Financial Accounting Standard ("SFAS") No. 123R, "Share Based Payment ("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, the Company accounted for stock-based employee compensation under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," as allowed by SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). The Company has applied the modified prospective method in adopting SFAS 123R. Accordingly, periods prior to adoption have not been restated.



The following table illustrates the effect on net income and earnings per share if the fair value method had been applied to the prior period.

	Three months ended September 30, 2005	Nine months ended September 30, 2005
Net loss as reported	\$ (812,093)	\$ (2,732,047)
Compensation recognized under:		
APB 25		4,375
SFAS 123	(193,723)	(697,496)
Pro forma net loss	\$ (1,005,816)	\$ (3,425,168)
Basic and diluted loss per common share:		
As reported	\$ (0.05)	\$ (0.17)
Pro forma	\$ (0.06)	\$ (0.21)

Under SFAS 123R, forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate. The Company utilized a 5% forfeiture rate based upon historical forfeitures. Under SFAS 123 and APB 25, the Company elected to account for forfeitures when awards were actually forfeited, at which time all previous pro forma expense was reversed to a reduced pro forma expense for the period in which the forfeiture occurred.

As of September 30, 2006, there was \$435,000 of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under existing stock option plans. This cost is expected to be recognized over a weighted average period of 1.33 years. The total fair value of shares vested and unvested during the nine months ended September 30, 2006 was \$497,000, of which \$457,000 is attributed to employee options.

The fair value of options granted to employees was estimated using the Black Scholes option-pricing model. These same assumptions are also used in applying the Black Scholes option-pricing model for any stock based option and warrant compensation paid to non-employees. The fair value of options and warrants at the date of grant and the assumptions utilized are indicated in the following table:

	Nine Months Ended September 30 ,	
	2006	2005
Weighted average of fair value at date of grant for options granted during the period	\$ 0.92	\$ 1.44
Risk-free interest rates	4.35% - 5.04%	3.77% - 4.45%
Expected option life in years	7	5-7
Expected stock price volatility	.72 - .76	.76 - .83
Expected dividend yield	-	-

The following summarizes the activity of the Company's stock options for the nine months ended September 30, 2006.

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2005	1,887,000	\$ 1.93		
Granted	375,000	1.30		
Exercised	-			
Canceled or expired	-			
Outstanding at September 30, 2006	2,262,000	\$ 1.82	4.49	\$ 32,400
Exercisable at September 30, 2006	1,548,000	\$ 1.91	4.34	\$ 32,400

The following summarizes the activity of the Company's non-vested stock options for the nine months ended September 30, 2006.

	Shares	Weighted Average Exercise Price
Non vested at December 31, 2005	668,000	\$ 1.89
Granted	375,000	1.30
Vested	(329,000)	1.80
Non vested at September 30, 2006	714,000	\$ 1.62

##### (5) Accrued Warrant Liability

In accordance with "EITF 00-19: Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" ("EITF 00-19") and other authoritative literature, it was determined that the warrants issued in the January 2005 and March 2006 private placements and the related registration rights agreements, discussed below, are free standing derivative financial instruments as defined in EITF 00-19. In accordance with EITF 00-19, the value and balance sheet classification of the warrants are reviewed each reporting period and, while the warrants are classified as a liability, any changes in the value of the warrants on a re-measurement date will be recorded in the statement of operations.

On March 6, 2006, the Company completed a \$1,350,000 private equity financing to a group of institutional investors and an accredited investor. In the offering, the Company sold 1,227,272 shares of its common stock at a price of \$1.10 per share to the investors and issued to them warrants to purchase an additional 613,634 shares of its common stock at an exercise price of \$1.50 per share. The Company also entered into a Registration Rights Agreement with the investors in the March 2006 private placement pursuant to which the Company agreed to register and to maintain an effective registration statement for the shares of common stock issued in the private placement and for the common stock to be issued upon the exercise of warrants issued in the transaction. The Registration Rights Agreement provides for liquidated damages of 1.5% of the aggregate purchase price for each 30 day period, with a maximum of eight 30 day periods (12% maximum liquidating damages), if the Company fails to maintain the effectiveness of such registration statement. As of the date the warrants were issued and as of June 30, 2006, 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. As of September 30, 2006, due primarily to a reduction

in the fair market value of the Company's common stock share price, the potential liquidated damages exceeded the reasonable discount between registered and unregistered shares thereby making the settlement alternative uneconomic, and the warrants were reclassified from equity to accrued warrant liability in the amount of \$219,000, based on the fair value of the warrants on September 30, 2006. The quarter end closing common stock price was \$1.15, \$0.90 and \$0.75 as of March 31, June 30 and September 30, 2006, respectively. The warrants were valued using the Black Scholes option-pricing model utilizing the same assumptions used to value the Company's common stock options outstanding (see footnote 4).

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

The registration rights agreement associated with the January 2005 private placement mentioned provides 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 failed to register such shares, or fails to warrant shares or 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, due primarily to a reduction in the fair market value of the Company's common stock share price, the potential liquidated damages exceeded the reasonable discount between registered and unregistered shares thereby making the settlement alternative uneconomic, and the warrants, valued at \$681,000 were reclassified from equity to accrued warrant liability, based on the fair value of the warrants on March 31, 2006. The warrants were valued using the Black Scholes option-pricing model utilizing the same assumptions used to value the Company's common stock options outstanding. As of September 30, 2006, the potential liquidated damages continues to exceed a reasonable discount between the fair value of the registered and unregistered shares, thereby making net share settlement an uneconomic alternative. Due to a decline in the market value of the Company's common stock, the accrued warrant liability has been reduced by \$376,000 based on the change in the fair value of the warrant liability.

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

On September 28, 2006 the Company amended outstanding warrants to purchase an aggregate of 1,300,000 shares of common stock of the Company at exercise prices ranging from \$1.00 to \$2.50 (the "Warrants"). The Warrants were originally issued to investors in 2003 in connection with certain financing transactions and were scheduled to expire on either September 30, 2006 or October 23, 2006. The amendment extends the expiration date of the Warrants until February 15, 2007. The extension of the warrants was calculated using a Black Scholes valuation and resulted in a charge of \$103,000 which was booked to our income statement during the third quarter of FY 2006.

#### **(7) Subsequent Event**

On October 29, 2006 the Company amended outstanding warrants to purchase an aggregate of 4,400,000 shares of common stock of the Company, each of which has an exercise price of \$2.50 (the "Warrants"). The Warrants were originally issued to investors in 2003 in connection with certain financing transactions. 4,000,000 of the Warrants were scheduled to expire on October 29, 2006 and 400,000 of the Warrants are scheduled to expire on February 15, 2007. The amendment extends the expiration date of the Warrants until October 29, 2008. The extension of the warrants was calculated using a Black Scholes valuation and is estimated to result in a charge of approximately \$432,000, which will be booked to our income statement during the fourth quarter of FY 2006

In addition, the Warrants contain a call provision whereby the Company can require the holders of the Warrant to exercise them 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.



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

### SAFE HARBOR STATEMENT

*In addition to historical information, the information included in this Form 10-QSB contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), such as those pertaining to our capital resources, our ability to complete the research and development of our products, and our ability to obtain regulatory approval for our products. Forward-looking statements involve numerous risks and uncertainties and should not be relied upon as predictions of future events. Certain such forward-looking statements can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," "seeks," "approximately," "intends," "plans," "pro forma," "estimates," or "anticipates" or other variations thereof or comparable terminology, or by discussions of strategy, plans or intentions. Such forward-looking statements are necessarily dependent on assumptions, data or methods that may be incorrect or imprecise and may be incapable of being realized. The following factors, among others, could cause actual results and future events to differ materially from those set forth or contemplated in the forward-looking statements: need for a significant amount of additional capital, lack of revenue, uncertainty of product development, ability to obtain regulatory approvals in the United States and other countries, and competition. Readers are cautioned not to place undue reliance on forward-looking statements, which reflect our management's analysis only. We assume no obligation to update forward-looking statements.*

### Overview

To date, we have been principally engaged in research and development of our products, management of clinical trials, raising capital, and recruitment of additional scientific and management personnel and advisors. We have not marketed or sold any products and have not generated any revenues from commercial activities; however, from inception we have recorded revenues of approximately \$321,000 of Small Business Innovation Research (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 FDA. We submitted an investigational device exemption, or IDE, application for SEPET™ in March 2005 and commenced clinical studies for SEPET™ in the third quarter of 2005. We also intend to reactivate work on the HepatAssist™ cell-based liver support system by modifying the FDA-reviewed Phase III IND protocol. Because the anticipated cost of conducting clinical studies for the HepatAssist™ cell-based liver support system exceeds our current financial resources, we will not, however, be able to commence clinical studies for the HepatAssist™ cell-based liver support system until we raise significant additional capital. The actual amounts we may expend on research and development and related activities during the next 12 months may vary significantly depending on numerous factors, including the results of our clinical studies and the timing and cost of regulatory submissions. Based on our current estimates, we believe that we may have sufficient financial resources to conduct our planned operations through the second quarter of calendar year 2007 following the date of this Quarterly Report. We will need to obtain significant additional funds during the first half of 2007 to support our clinical trial activities and working capital needs. We do not expect to make any significant purchases or sales of plant or equipment during the next twelve months, nor do we expect to hire a significant number of employees during that period unless additional funds are raised.

Our research offices and laboratories are located at Cedars-Sinai Medical Center, Los Angeles, California. In April 2005, we leased an additional 1,680 square foot facility in Woodstock, Connecticut to be used for swine housing and tissue procurement. We maintain our administrative offices in Los Angeles, California and Waltham, Massachusetts.



## **Critical Accounting Policies**

Management's discussion and analysis of our financial condition and results of operations are 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 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 condensed financial statements for the year ended December 31, 2005. 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 ("FASB") SFAS No. 7, "Accounting and Reporting by Development Stage Enterprises." We are devoting substantially all of our present efforts to research and development. All losses accumulated since inception have been considered as part of our development stage activities.

### *Short Term Investments*

Short-term investments generally mature between three and twelve months. Short term investments consist of U.S. government agency notes purchased at a discount with interest accruing to the notes full value at maturity. All of our short-term investments are classified as available-for-sale and are carried at fair market value which approximates cost plus accrued interest.

### *Patents*

In accordance with FASB No. 2, the costs of intangibles that are 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 Statement of Financial Accounting Standard No. 123R, "Share Based Payment ("SFAS 123R"), which requires all share based payments, including grants of stock options, to be recognized in the income statement as an operating expense, based on fair values.



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

## Results of Operations

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

General and administrative expenses of \$754,000 and \$471,000 were incurred for the three months ended September 30, 2006 and 2005, respectively. General and administrative expenses of \$2,210,000 and \$1,811,000 were incurred for the nine months ended September 30, 2006 and 2005, respectively. General and administrative expenses for the three months ended September 30, 2006 increased by \$283,000 over the prior year level. The increase is primarily attributed to a \$213,000 increase in non-cash option and warrant charges, and increases in various administrative expenses, including investor relations, insurance, employee travel and rent. General and administrative expenses for the nine months ended September 30, 2006 increased by \$399,000 over the prior year level. The increase is primarily attributed to increases in investor relation fees, payroll costs, non-cash option and warrant charges, employee travel costs, insurance, rent, professional fees and board of director fees. The increases in payroll costs and other administrative expenses are a result of an increase in the number of employees.

Research and development expenses of \$469,000 and \$387,000 were incurred for the three months ended September 30, 2006 and 2005, respectively. Research and development expenses of \$1,281,000 and \$1,006,000 were incurred for the nine months ended September 30, 2006 and 2005, respectively. The research and development expenses for the three months ended September 30, 2006 increased by \$82,000 over the comparable prior year's levels primarily as a result of increased payroll costs and consultant fees. The staffing increases include hiring a Clinical Research Manager. Consulting costs include outside services for manufacturing, regulatory, and clinical trial coordinators. The research and development expenses for the nine months ended September 30, 2006 increased by \$275,000 over the comparable prior year's levels primarily as a result of increased payroll costs, costs related to the SEPET™ and HepatAssist™ programs, consultant fees and non-cash option charges. These costs are offset in part by a decline in employee loan-out costs of \$141,000 from Cedars-Sinai Medical Center. The staffing increases include hiring a Vice President of Operations and increased staff which replaced the discontinued employee loan out costs from Cedars-Sinai Medical Center. Consulting costs include outside services for manufacturing, regulatory, and clinical trial coordinators.

The change in fair value of warrant liabilities of \$103,000 and \$376,000 for the quarter and nine months ended September 30, 2006, reflect the decline in the warrant liability based upon the Black Scholes valuation model. The decline is primarily due to a decline in the value of the Company's common stock.

Interest income of \$39,000 and \$45,000 was earned for the three months ended September 30, 2006 and 2005, respectively. Interest income of \$127,000 and \$84,000 was earned for the nine months ended September 30, 2006 and 2005, respectively. The increase in interest income primarily reflects increase in short term interest rates over prior year levels and the investment of available funds in short term investments.

Our net loss was \$1,081,000 and \$812,000 for the three months ended September 30, 2006 and 2005, respectively. Our net loss was \$2,988,000 and \$2,732,000 for the nine months ended September 30, 2006 and 2005, respectively. The increase in net loss for the three and nine month periods ended September 30, 2006 compared to the comparable period in 2005 is attributable to increases in general and administrative expenses, research and development expenses and the change in fair value of warrant liabilities.

**Liquidity and Capital Resources**

As of September 30, 2006, we had cash of \$934,000, short term investments of \$1,993,000 and \$250,000 of current liabilities. We do not have any bank credit lines. To date, we have funded our operations primarily from the sale of debt and equity securities and to a lesser extent, SBIR government grants.

On March 6, 2006, we completed a \$1,350,000 private equity financing to a group of institutional investors and an accredited investor. In the offering, we sold 1,227,272 shares of our common stock at a price of \$1.10 per share to the investors and issued to them 5-year warrants to purchase an additional 613,634 shares of our common stock at an exercise price of \$1.50 per share.

Based on our current plan of operations, we believe that our current cash balances will only be sufficient to fund our operations through the second quarter of 2007 from the date of this report and that we will need to raise additional funds during the first half of 2007.

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

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

<b>Contractual Obligations</b>	<b>Total</b>	<b>2006</b>	<b>2007</b>	<b>2008 and thereafter</b>
Long-Term Leases	\$ 176,000	\$ 67,000	\$ 109,000	\$ —

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 contained in this Quarterly Report on Form 10-QSB.

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

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

We are an early-stage company that has not generated any operating revenues to date (our only revenues were from two government research grants). Accordingly, while we have been in existence for over five years, we should be evaluated as an early-stage company, subject to all of the risks and uncertainties normally associated with an early-stage company. As an early-stage company, we expect to incur significant operating losses for the foreseeable

future, and there can be no assurance that we will be able to validate and market products in the future that will generate revenues or that any revenues generated will be sufficient for us to become profitable or thereafter maintain profitability.



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

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

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

The development, production and marketing of our products are subject to extensive regulation by government authorities in the United States and other countries. In the United States, SEPET™ and our bioartificial HepatAssist™ liver system will require approval from the United States Food and Drug Administration (“FDA”) prior to clinical testing and commercialization. The process for obtaining FDA approval to both conduct the required trials and 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. For example, last year, the FDA granted us permission to commence a feasibility clinical trial for the SEPET™ liver assist device for 15 patients at two sites. In March 2006, the FDA allowed us to expand the number of clinical testing sites from two sites to up to four sites, and expand the patient enrollment of up to 20 patients for the SEPET™ feasibility clinical trial. Based on our estimates of the time it would take to obtain all required approvals at the three medical centers at which the Phase I feasibility clinical trial is being conducted, and based on the estimated time it would take to enroll patients in the trial, we had hoped to finish the study by the end of the current year. However, obtaining all medical center approvals took longer than anticipated, and patient accrual into this study has been slower than anticipated. Accordingly, while we still expect to complete the SEPET™ feasibility clinical trial in the near future, we no longer are certain that the study will be concluded by the end of the year. Assuming that the feasibility clinical trial is successful, we will have to obtain the FDA’s approval to conduct a pivotal trial. We have not yet established with the FDA the nature and number of these additional clinical trials that the FDA will require in connection with its review and approval of either the SEPET™ liver assist device or our HepatAssist™ cell-based liver support system, and these requirements may be more costly or time-consuming than we currently anticipate.

Each of our products in development is novel both in terms of its 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 HepatAssist™ cell-based liver support system is 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.

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

Before obtaining regulatory approvals for the commercial sale of our products, significant and potentially very costly preclinical and clinical work will be necessary. There can be no assurance that we will be able to successfully complete all required testing of the SEPET™ liver assist device or our HepatAssist™ cell-based liver support system. While the time periods for testing our products and obtaining the FDA's approval are dependent upon many future variable and unpredictable events, we estimate that it could take between two to three years to obtain approval for the SEPET™ liver assist device and three to four years for the HepatAssist™ cell-based liver support system. We have not independently confirmed any of the third-party claims made with respect to patents, licenses or technologies we have acquired concerning the potential safety or efficacy of these products and technologies. Before we can begin clinical testing of our HepatAssist™ cell-based liver support system, we will need to amend our active Phase III IND to resume clinical testing, which application will have to be cleared by the FDA. The FDA may require significant revisions to our clinical testing plans or require us to demonstrate efficacy endpoints that are more time-consuming or difficult to achieve than what we currently anticipate. Because of the early stage of development of each of our products, we do not know if we will be able to generate clinical data that will support the filing of the FDA applications for these products or the FDA's approval of any product marketing approval application or IND that we do file.

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

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

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

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

Use of liver cells harvested from pig livers carries a risk of transmitting viruses harmless to pigs but potentially deadly to humans. For instance, all pig cells carry genetic material of the porcine endogenous retrovirus ("PERV"), but its ability to infect people is unknown. Repeated testing, including a 1999 study of 160 xenotransplantation (transplantation from animals to humans) patients and the Phase II/III testing of the HepatAssist™ cell-based liver support system by

Circe Biomedical, Inc., has produced no sign of the transmission of PERV to humans. Still, no one can prove that PERV or another virus would not infect bioartificial liver-treated patients and cause potentially serious disease. This may result in the FDA or other health regulatory agencies not approving our HepatAssist™ cell-based liver support system or subsequently banning any further use of our product should health concerns arise after the product has been approved. At this time, it is unclear whether we will be able to obtain clinical and product liability insurance that covers the PERV risk.

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

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

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

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

Based on our current proposed plans and assumptions, the Company estimates that it has cash to operate through the second quarter of calendar year 2007, and therefore will need to obtain significant additional funds during the first half of 2007. The clinical development expenses of our products will be very substantial. Based on our current assumptions, we estimate that the clinical cost of developing the SEPET™ liver assist device will be approximately \$5 million to \$10 million, and the clinical cost of developing the HepatAssist™ cell-based liver support system will be between \$10 million and \$15 million, in excess of the cost of basic operations of the Company. These amounts, which could vary substantially if our assumptions are not correct, are well in excess of the amount of cash that we currently have available to us. Accordingly, we will be required to (i) obtain additional debt or equity financing in order to fund the further development of our products and working capital needs, and/or (ii) enter into a strategic alliance with a larger pharmaceutical or biomedical company to provide its required funding. The amount of funding needed to complete the development of one or both of our products will be very substantial and may be in excess of our ability to raise capital.

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

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

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

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

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

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

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

We have an exclusive manufacturing arrangement with Spectrum Laboratories for our fiber-within-fiber LIVERAID™ cartridges, the development of which we have placed on indefinite hold. Although we have no agreement with Spectrum Laboratories for the manufacture of the SEPET™ cartridges, Spectrum Laboratories has also been providing us with cartridges for prototypes of the SEPET™ liver assist device and has expressed an interest in manufacturing the

HepatAssist™ cartridge. Although Spectrum Laboratories has agreed to transfer all of the know-how related to these products to any other manufacturer of our products if Spectrum Laboratories is unable to meet its contractual obligations to us, we may have difficulty in finding a replacement manufacturer if we are unable to effectively transfer the Spectrum Laboratories know-how to another manufacturer. We have no control over Spectrum Laboratories or its suppliers, and if Spectrum Laboratories is unable to produce SEPET™ cartridges on a timely basis, our business may be adversely affected.

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

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

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

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

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

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

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





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

We are dependent upon our business and scientific personnel. We also depend upon the medical and scientific advisory services that we receive from the members of our Board of Directors and Scientific Advisory Board, many of whom have extensive backgrounds in the biomedical industry. We do not carry key man life insurance on any of these individuals. On November 9, 2006, our Chief Scientific Officer, Jacek Rozga, M.D., Ph.D., announced his resignation from the Company as a full-time employee. The Company has agreed to retain Dr. Rozga as a consultant and will draw upon Dr. Rozga's expertise from time-to-time as needed.

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

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

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

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

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



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

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

*Changes in stock option accounting rules may adversely affect our reported operating results, our stock price, and our ability to attract and retain employees.*

In December 2004, the Financial Accounting Standards Board published new rules that will require companies to record all stock-based employee compensation as an expense. Small business issuers such as this Company have to apply the new rules in their first reporting period beginning after December 15, 2005. The new rules apply to stock options grants, as well as a wide range of other share-based compensation arrangements including restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. As a small company with limited financial resources, we have depended upon compensating our officers, directors, employees and consultants with such stock based compensation awards in the past in order to limit our cash expenditures and to attract and retain officers, directors, employees and consultants. Accordingly, if we continue to grant stock options or other stock based compensation awards to our officers, directors, employees, and consultants after the new rules apply to us, our future earnings, if any, will be reduced (or our future losses will be increased) by the expenses recorded for those grants. These compensation expenses may be larger than the compensation expense that we would be required to record were we able to compensate these persons with cash in lieu of securities. Since we are a small company, the expenses we may have to record as a result of future options grants may be significant and may materially negatively affect our reported financial results. The adverse effects that the new accounting rules may have on our future financial statements should we continue to rely heavily on stock-based compensation may reduce our stock price and make it more difficult for us to attract new investors. In addition, reducing our use of stock plans to reward and incentivize our officers, directors and employees, could result in a competitive disadvantage to us in the employee marketplace.

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

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

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

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

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

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

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

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

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

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

Since our common stock is not listed on the Nasdaq Stock Market, if the trading price of our common stock is below \$5.00 per share, trading in our common stock will be subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a penny stock (generally, any non-Nasdaq equity security that has a market price of less than \$5.00 per share, subject to certain exceptions) and a two business day "cooling off period" before brokers and dealers can effect transactions in penny stocks. Such rules impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors (generally defined as an investor with a net worth in excess of \$1,000,000 or annual income exceeding \$200,000 individually or \$300,000 together with a spouse). For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to the sale. The broker-dealer also must disclose the commissions payable to the broker-dealer, current bid and offer quotations for the penny stock and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Such information must be provided to the customer orally or in writing before or with the written confirmation of trade sent to the customer. Monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. The additional burdens imposed upon broker-dealers by such requirements could discourage broker-dealers from effecting transactions in our common stock, which could severely limit the market liquidity of the common stock and the ability of holders of the common stock to sell their shares.



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

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

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

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

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

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

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

As of October 10, 2006, we had outstanding 17,460,181 shares of common stock. However, in the past year, the average daily trading volume of our shares has only been a few thousand shares, and there have been many days in which no shares were traded at all. In October 2004 and in February 2005, we registered a total of 7,207,810 shares of our common stock issuable upon the exercise of outstanding warrants. Of these shares, 25,000 have been issued upon the exercise of a warrant and a warrant for 75,000 of the shares has been cancelled without being registered. The remaining 7,107,810 shares underlying warrants have not yet been issued and will not be issued until the warrants are exercised. Since the shares underlying these warrants have been registered, they can be sold immediately following the exercise. Accordingly, 7,107,810 additional shares could be released onto the trading market at any time. Because of the limited trading volume, the sudden release of 7,107,810 additional freely trading shares onto the market, or the perception that such shares will come onto the market, could have an adverse affect on the trading price of the stock. In addition, there are currently 5,972,272 shares of unregistered, restricted stock that are currently eligible for public resale under Rule 144 promulgated under the Securities Act, some of which shares also may be offered and sold on the market from time to time. No prediction can be made as to the effect, if any, that sales of the 7,107,810 registered



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

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

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

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

### **ITEM 3. Controls and Procedures**

Our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e)) are effective to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 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. There was no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. However as this Company continues to expand its operations, we have implemented, and will continue to implement, additional disclosure and procedure controls, which encompass internal controls over financial reporting, that are appropriate for the Company's size and stage of development.

## **PART II. OTHER INFORMATION**

### **ITEM 1. Legal Proceedings**

None.

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

None.

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

None.

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

The Annual Meeting of Stockholders of the Company (the "Meeting") was held on July 31, 2006. The following matters were voted upon at the Meeting: (i) the election of directors of the Company to serve until the 2007 Annual Meeting of Stockholders, and (ii) the ratification of the appointment of Stonefield Josephson, Inc. as independent public accountants for the fiscal year ending December 31, 2006.

(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		Abstentions/Broker Non-Votes
		Against/Withheld		
Walter C. Ogier	11,617,463	101,000		-
Dennis Kogod	11,617,463	101,000		-
Thomas. C. Seoh	11,617,463	101,000		-
Jack E. Stover	11,617,463	101,000		-
Thomas M. Tully	11,617,463	101,000		-
John M. Vierling, M.D.	11,617,463	101,000		-

(ii) 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, 2006, were as follows:

Votes For	Votes		Abstentions/Broker Non-Votes
	Against/Withheld		
11,617,463	101,000		-

Following the distribution of the Company's Proxy Statement on Form 14A for the 2006 Annual Meeting, Dr. Demetriou, a nominee for election on the Board of Directors of the Company, informed the Company that, for personal reasons, he was removing himself from the nomination and election process and would be unable to join the Board of Directors for the upcoming year.

**ITEM 5. Other Information**

None

**ITEM 6. Exhibits**

- 31.1 Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 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, 2006

By: /S/ Walter C. Ogier

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

DATE: November 14, 2006

By: /S/ Scott L. Hayashi

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