ARBIOS SYSTEMS INC
Form 10QSB
November 15, 2004

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

FORM 10-QSB

(MARK ONE)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2004

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934

COMMISSION FILE NUMBER: 000-32603

ARBIOS SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Nevada	91-1955323
(State or other jurisdiction of incorporation organization)	(IRS Employer Identification No.)
8797 Beverly Blvd., Los Angeles, California	90048
(Address of principal executive offices)	(Zip Code)

(310) 657-4898
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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 x No o.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. On November 14, 2004, there were 13,198,097 shares of common stock, $.001 par value, issued and outstanding.

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ARBIOS SYSTEMS, INC.
FORM 10-QSB

PART I

ITEM 1. Condensed Consolidated Financial Statements

ARBIOS SYSTEMS, INC. AND SUBSIDIARY
(A development stage company)
CONDENSED CONSOLIDATED BALANCE SHEET

ASSETS	September 30, 2004 (Unaudited)	December 31, 2003 (Audited)
Current assets		
Cash and cash equivalents	$ 2,005,557	$ 3,507,086
Prepaid expenses	87,359	155,986
Total current assets	$ 2,092,916	$ 3,663,072
Net property and equipment	110,625	45,633
Patent rights, net of accumulated amortization of $98,057	301,943	324,145
Other assets	12,421	7,434
Total assets	$ 2,517,905	$ 4,040,284
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 69,644	$ 148,229
Accrued expenses	251,416	
Current portion of capitalized lease obligation	8,291	8,526
Total current liabilities	329,351	156,755
Long-term liabilities		
Contract commitment	250,000	
Capital lease obligation, less current portion		6,826
Other liabilities		5,555
Total long-term liabilities	250,000	12,381
Stockholders' equity		
Preferred stock, $.001 par value; 5,000,000 shares authorized: none issued and outstanding		
Common stock, $.001 par value; 25,000,000 shares authorized; 13,198,097 and 13,150,598 shares issued and outstanding in 2004 and 2003, respectively	13,199	13,151
Additional paid-in capital	6,333,900	5,485,498
Deficit accumulated during the development stage	(4,408,545)	(1,627,501)
Total stockholders' equity	1,938,554	3,871,148
Total liabilities and stockholders' equity	$ 2,517,905	$ 4,040,284

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

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

	For the three months ended Sept. 30,		For the nine months ended Sept. 30,		Inception to
	2004	2003	2004	2003	Sept. 30, 2004
Revenues	$ 38,220	$ 84,810	$ 72,030	$ 127,828	$ 320,966
Operating expenses:					
General and administrative	774,062	17,449	1,679,832	93,619	2,328,576
Research and development	302,860	129,582	1,183,366	310,658	2,161,535
Total operating expenses	1,076,922	147,031	2,863,198	404,277	4,490,111
Loss before other income (expense)	(1,038,702)	(62,221)	(2,791,168)	(276,449)	(4,169,145)
Other income (expense):					
Interest income	3,660		13,367		15,923
Interest expense	(183)	(20,710)	(668)	(21,073)	(246,381)
Total other income (expense)	3,477	(20,710)	12,699	(21,073)	(230,458)
Loss before tax provision	(1,035,225)	(82,931)	(2,778,469)	(297,522)	(4,399,603)
Provision for taxes			2,575	1,122	8,942
Net loss	$ (1,035,225)	$ (82,931)	$ (2,781,044)	$ (298,644)	$ (4,408,545)
Net earnings per share:					
Basic and diluted	$ (0.08)	$ (0.01)	$ (0.21)	$ (0.04)	$ (0.60)
Weighted-average shares:					
Basic and diluted	13,198,097	6,848,780	13,195,881	6,806,011	7,389,764

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

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

	For the nine months ended September 30,		Inception to September 30,
	2004	2003	2004
Cash flows from operating activities:			
Net loss	$ (2,781,044)	$ (298,644)	$ (4,408,545)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of debt discount		20,400	244,795
Depreciation and amortization	36,098	29,686	128,435
Issuance of securities for compensation	1,026,668		1,037,168
Settlement of accrued expense			54,401
Deferred compensation costs		88,889	319,553
Research and development			
Changes in operating assets and liabilities:			
Prepaid expenses	68,627	(103,791)	(87,360)
Other assets	(4,987)		(12,421)
Accounts payable and accrued expenses	(5,387)	(19,567)	142,843
Other liabilities	(5,555)	30,000	
Contract obligation	250,000		250,000
Net cash used in operating activities	(1,415,580)	(253,027)	(2,331,131)
Cash flows from investing activities:			
Additions of property and equipment	(78,888)	(18,717)	(116,003)
Net cash used in investing activities	(78,888)	(18,717)	(116,003)
Cash flows from financing activities:			
Proceeds from issuance of convertible debt		400,000	400,000
Advance payments from stock subscription		2,310,000	
Proceeds from issuance of common stock		250,200	4,405,066
Proceeds from issuance of preferred stock			250,000
Payments on capital lease obligation, net	(7,061)	(5,242)	(16,709)
Cost of issuance of preferred stock			(11,268)
Cost of issuance of common stock		(2,961)	(574,398)
Net cash provided by (used for) financing activities	(7,061)	2,951,997	4,452,691
Net (decrease) increase in cash	(1,501,529)	2,680,253	2,005,557
Cash:			
At beginning of period	3,507,086	27,849	
At end of period	$ 2,005,557	$ 2,708,102	$ 2,005,557
Supplemental disclosures of non-cash financing activity			
Issuance of securities for payable	$ 47,500		$ 47,500

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

Arbios Systems, Inc. and Subsidiary (A Development Stage Company)
Notes to Condensed Consolidated Financial Statements (Unaudited)
Nine Months Ended September 30, 2004

(1) Basis of Presentation:

In the opinion of the management of Arbios Systems, Inc. (the "Company"), the accompanying unaudited condensed consolidated financial statements include all normal adjustments considered necessary to present fairly the financial position as of September 30, 2004, and the results of operations for the periods presented.

The unaudited condensed consolidated financial statements and notes are presented as permitted by Form 10-QSB. These 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. These 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, 2003, filed with the SEC. The results of operations for the three month and nine month periods ended September 30, 2004 are not necessarily indicative of the results to be expected for any subsequent quarter or for the entire fiscal year.

Certain prior year amounts have been reclassified to conform with current year presentation.

(2) Stock-Based Compensation:

SFAS No. 123, "Accounting for Stock-Based Compensation," establishes and encourages the use of the fair value based method of accounting for stock-based compensation arrangements under which compensation cost is determined using the fair value of stock-based compensation determined as of the date of grant and is recognized over the periods in which the related services are rendered. The statement also permits companies to elect to continue using the current intrinsic value accounting method specified in Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," to account for stock-based compensation. The Company has elected to use the intrinsic value based method and has disclosed the pro forma effect of using the fair value based method to account for its stock-based compensation issued to employees. For non-employee stock based compensation the Company recognizes an expense in accordance with SFAS No. 123 and values the equity securities based on the fair value of the security on the date of grant with subsequent adjustments based on the fair value of the equity security as it vests.

If the Company had elected to recognize compensation cost for its stock options and warrants for employees based on the fair value at the grant dates, in accordance with SFAS 123, net earnings and earnings per share would have been as follows:

	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
	2004	2003	2004	2003
Net loss as reported	$ (1,035,225)	$ (82,931)	$ (2,781,044)	$ (298,644)
Compensation recognized under:				
APB 25				
SFAS 123	(52,384)	(5,191)	(214,203)	(12,142)
Proforma net loss	$ (1,087,609)	$ (88,122)	$ (2,995,247)	$ (310,786)
Basic and diluted loss per common share:				
As reported	$ (0.08)	$ (0.01)	$ (0.21)	$ (0.04)
Proforma	$ (0.08)	$ (0.01)	$ (0.23)	$ (0.05)

(3) Contract Commitment

On April 19, 2004, the Company purchased certain assets of Circe Biomedical, Inc. including Circe's patent portfolio, rights to a bioartificial liver (HepatAssist) , a Phase III Investigational Drug application, selected equipment, clinical and marketing data, and over 400 standard operating procedures and clinical protocols previously reviewed by the Food and Drug Administration. In exchange for these assets, the Company paid a $200,000 upfront payment and is committed to make a $250,000 deferrred payment due the earlier of April 12, 2006 or when the Company has raised accumulated gross proceeds of $4 million from the issuance of debt or equity securities. The Company expensed the cost of the acquisition in the fiscal quarter ended June 30, 2004 as part of acquired research and development costs, as the underlying rights have not yet reached the stage at which their commercial feasibility can be established.

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 develop 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

On October 30, 2003, we completed a reorganization (the Reorganization) in which Arbios Technologies, Inc., our operating company, became our wholly-owned subsidiary. At the time of the Reorganization, we had virtually no assets and virtually no liabilities (prior to the Reorganization we were an e-commerce based company engaged in the business of acquiring and marketing historical documents). Shortly after the Reorganization, we changed our name to Arbios Systems, Inc. In the Reorganization, we also replaced our officers and directors with those of Arbios Technologies, Inc. Following the Reorganization, we ceased our e-commerce business, closed our former offices, and moved our offices to Los Angeles, California. We currently do not plan to conduct any business other than the operations Arbios Technologies, Inc. has conducted since its formation. Accordingly, since our prior operating results as an e-commerce business are not indicative of, and have no relevance to, our current or future operations or to our financial statement, all financial information contained in the enclosed interim financial statements for periods prior to the Reorganization are those of Arbios Technologies, Inc.

Although we acquired Arbios Technologies, Inc. in the Reorganization, for accounting purposes, the Reorganization was accounted for as a reverse merger since the stockholders of Arbios Technologies, Inc. acquired a majority of the issued and outstanding shares of our common stock, and the directors and executive officers of Arbios Technologies, Inc. became our directors and executive officers. Accordingly, the financial statements attached as Item 1 in Part I above, and the description of our results of operations and financial condition, reflect (i) the operations of Arbios Technologies, Inc. alone prior to the Reorganization, and (ii) the combined results of this company and Arbios Technologies, Inc. since the Reorganization. No goodwill was recorded as a result of the Reorganization.

Since the formation of Arbios Technologies, Inc. in 2000, our efforts have been principally devoted to research and development activities, raising capital, and recruiting additional scientific and management personnel and advisors. To date, we have not marketed or sold any product and have not generated any revenues from commercial activities, and we do not expect to generate any revenues from commercial activities during the next 12 months. Substantially all of the revenues that we have recognized to date have been Small Business Innovation Research grants (in an aggregate amount of $321,000) that we received from 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 at least one of our two potential products, and the preparation and submission of applications to the FDA. 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 research and development programs, the results of clinical studies, and the timing and cost of regulatory submissions.

Critical Accounting Policies

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

Our significant accounting policies are summarized in Note 1 to our audited financial statements for the year ended December 31, 2003. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Development Stage Enterprise

We are a development stage enterprise as defined by the Financial Accounting Standards Board's ("FASB") Statement of Financial Accounting Standards ("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.

Patents

The Company capitalizes certain patent rights that are believed to have future economic benefit. 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

SFAS No. 123, "Accounting for Stock-Based Compensation," establishes and encourages the use of the fair value based method of accounting for stock-based compensation arrangements under which compensation cost is determined using the fair value of stock-based compensation determined as of the date of grant and is recognized over the periods in which the related services are rendered. The statement also permits companies to elect to continue using the current intrinsic value accounting method specified in Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," to account for stock-based compensation. We have elected to use the intrinsic value based method and have disclosed the pro forma effect of using the fair value based method to account for our stock-based compensation. For non-employee stock based compensation, we recognize an expense in accordance with SFAS No. 123 and value the equity securities based on the fair value of the security on the date of grant.

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 revenues from sales. Revenues of $38,220 and $84,810 for the three-months ended September 30, 2004 and 2003, and revenues of $72,030 and $127,828 for the nine month periods ended September 30, 2004 and 2003 represent revenues recognized from a government research grant.

General and administrative expenses of $774,062 and $17,449 were incurred for the three months ended September 30, 2004 and 2003. General and administrative expenses of $1,679,832 and $93,619 were incurred for the nine months ended September 30, 2004 and 2003. For the nine months ended September 30, 2004, the expenses include $929,000 in non-cash option and warrant charges for grants awarded to consultants, $447,000 in fees incurred to outside consultants and professionals, and $110,000 in salaries and other administrative expenses. The 2003 expenses consist primarily of legal fees, audit fees and travel expenses incurred. Professional fees increased in the 2004 periods due to legal and accounting fees related to our status as a public company and legal expenses associated with the acquisition of certain assets from Circe Biomedical Inc. in April 2004. In 2004 we also incurred additional consulting fees in connection with our investigation of the suitability and advisability of submitting a Section 510(k) Pre-Market Notification with the United States Food and Drug Administration (FDA) for our SEPET™ product. General and administrative expenses are expected to remain at a significantly higher level than in past periods due to the lease of additional office space (effective as of April 1, 2004), the addition of more employees and consultants (primarily to assist with our financial controls and investor relations strategies and to evaluate and prepare submissions to the FDA), and additional professional and other fees related to being a public company.

Research and development expenses of $302,860 and $129,582 were incurred for the three months ended September 30, 2004 and 2003. Research and development expenses of $1,183,366 and $310,658 were incurred for the nine months ended September 30, 2004 and 2003. Research and development expenses for the nine months ended September 30, 2004 increased by $872,708 over prior year levels primarily due to $450,000 of purchased research and development from Circe Biomedical, Inc., $197,000 incurred for various research and development consultants regarding manufacturing, regulatory and product management, $97,000 non cash option grant charges for options awarded to scientific consultants, $52,000 in higher salary costs for scientists and technicians, and $88,000 increase in preclinical testing of SEPET™ and LIVERAID™. We expect our research and development activities and expenses specifically related to regulatory and clinical trial costs for SEPET™ to increase during the balance of the current fiscal year ending December 31, 2004.

Interest income of $3,660 and $13,367 was earned for the three and nine months ended September 30, 2004. There was no interest income for the corresponding 2003 periods. In September and October 2003, we raised gross proceeds of $4,400,000 in the private placement of our securities. As a result, during the three and nine month periods ended September 30, 2004, we maintained cash balances of over $2.0 million. In addition, we used a portion of the foregoing offering proceeds to repay all outstanding indebtedness, thereby substantially decreasing our interest expense.

Our net loss was $1,035,225 and $82,931 for the three months ended September 30, 2004 and 2003. The net loss was $2,781,044 and $298,644 for the nine months ended September 30, 2004 and 2003. The increase in net loss is attributed to an increase in operating expenses incurred in the fiscal 2004 periods as compared to the same periods in 2003 as explained above without an increase in revenues. Operating expenses are expected to further increase in the current fiscal year compared to last year as we increase our operations, while revenues are not currently anticipated.

Liquidity and Capital Resources

As of September 30, 2004, we had cash of $2,006,000 and $354,000 of total indebtedness (both long-term and current liabilities reduced by non-cash unvested option expense of $225,000). 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 an SBIR government grant. During fiscal 2003, sales of our securities consisted of the following: (i) $250,000 obtained in January 2003 from the sale of our common stock sold at a price of $0.60 per share; (ii) $400,000 raised from the sale of subordinated convertible promissory notes (which notes were converted in October 2003 into common stock and warrants at $1.00 per share immediately prior to the Reorganization); (iii) $2,310,000 raised in a private offering of common stock and warrants sold at a price of $1.00 per share; and (iv) $1,690,000 obtained immediately prior to the Reorganization in an offering of common stock and warrants sold at a price of $1.00 per share. We have not, however, raised any capital from financings since the end of the fiscal year ended December 31, 2003. Of the 4.4 million warrant shares issued in September and October, 2003 are exercisable at $2.50 per share and are callable by the Company if the common stock trades at an average price of $4 per share for 20 consecutive trading days.

In April 2004 we purchased certain assets of Circe Biomedical, Inc. including Circe s patent portfolio, rights to a bioartificial liver (HepatAssist) , a Phase III Investigational New Drug application, selected equipment, clinical and marketing data, and over 400 standard operating procedures and technical validation protocols that have previously been reviewed by the FDA. The purchase price paid for these assets consisted of $200,000 paid at the closing and our agreement to make a second payment, in the amount of $250,000, on the earlier of April 12, 2006 or when we have raised, on a cumulative basis from April 12, 2004, gross proceeds of $4 million from the issuance of debt or equity securities. We believe that the original HepatAssist bioartificial liver that we acquired can be enhanced by, among other things, increasing the number of pig cells used in the device and by using a different perfusion platform. As a result, we have recently shifted our emphasis from the development of LIVERAID to the further development of the HepatAssist bioartificial liver (we refer to the enhanced version of this bioartificial liver as our HepatAssist-2 bioartificial liver system). Many of the standard operating procedures and technical protocols that we acquired will be usable by us and will eliminate the need for us to independently develop these procedures and protocols.

We do not currently anticipate that we will derive any revenues from either product sales or from additional governmental research grants during the next twelve months.

Based on our current plan of operations, we believe that our current cash balances will be sufficient to fund our current level of operations, including all of our development activities, only until approximately the middle of 2005. However, the estimated 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. For example, based on our current assumptions, we estimate that the cost of developing SEPET will be approximately $3 million. The cost of developing HepatAssist-2 will be between $15 million and $20 million, and the cost of developing LIVERAID will be between $20 million and $25 million. In addition, the development of these products will last beyond the middle of 2005. As a result, we will have to obtain additional funds by the middle of 2005 in order to fund our future operations and the continued development of our products. 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 currently do not have any banking facilities and are dependent upon obtaining additional funding from the sale of additional equity securities. We do not have any funding commitments and cannot be sure that we will be able to obtain additional funding, or that the terms under which we obtain such funding will be beneficial to this company. In the event that we do not obtain additional funding, we will have to curtail our product development activities and take other steps to reduce our costs. Excluding development expenses, we currently have sufficient funds available to us to fund our overhead and personnel expenses for the next twelve months.

The following is a summary of our contractual cash obligations at September 30, 2004 for the balance of this fiscal year and for the following fiscal years:

Contractual Obligations	Total	2004	2005	2006	2007 and thereafter
Purchased Research &Development	$250,000			$250,000	
Long-Term Office Leases	$325,000	$34,000	$137,000	$77,000	$77,000

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

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

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.

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 a start-up company that has not generated any operating revenues to date (our only revenues were two government research grants). Accordingly, while we have been in existence since November 1999, and Arbios Technologies, our operating subsidiary, has been in existence since 2000, we should be evaluated as a new, start-up company, subject to all of the risks and uncertainties normally associated with a new, start-up company. As a start-up 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 significant revenues from the sale of any of our products for at least the next few 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 U.S., SEPET and our bioartificial liver systems will require approval from the FDA prior to clinical testing and commercialization. The process for obtaining FDA approval to market therapeutic products is both time-consuming and costly, with no certainty of a successful outcome. This process includes the conduct of extensive pre-clinical and clinical testing, which may take longer or cost more than we currently anticipate due to numerous factors, including without limitation, difficulty in securing centers to conduct trials, difficulty in enrolling patients in conformity with required protocols and/or projected timelines, unexpected adverse reactions by patients in the trials to our products, temporary suspension and/or complete ban on trials of our products due to the risk of transmitting pathogens from the xenogeneic biologic component, and changes in the FDA s requirements for our testing during the course of that testing. We have not yet established with the FDA the nature and number of clinical trials that the FDA will require in connection with its review and approval of either SEPET or our bioartificial liver systems 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 bioartificial liver systems are designed to utilize) due to safety concerns that pig cells may transmit viruses or diseases to humans. If the health regulatory agencies of other countries impose a ban on the use of therapies that incorporate pig cells, such as our bioartificial liver systems, we would be prevented from marketing our products in those countries. If we are unable to obtain the approval of the health regulatory authorities in Japan, France, the United Kingdom or other countries, the potential market for our products will be reduced.

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

Before obtaining regulatory approvals for the commercial sale of our products, significant and potentially very costly preclinical and clinical work will be necessary. There can be no assurance that we will be able to successfully complete all required testing of SEPET or our bioartificial liver systems. 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 one to three years to obtain approval for SEPET , approximately five years for LIVERAID , and two to three years for HepatAssist-2 . 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. We will need to file an investigational new drug application (IND) for LIVERAID and an investigational drug exemption for SEPET with the FDA and have these applications cleared by the FDA before we can begin clinical testing of these two products, and 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. We have not yet completed preparation of either the IND or the investigational drug exemption application, and there can be no assurance that we will have sufficient experimental data to justify the submission of said applications. 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.

We need FDA approval before conducting clinical studies of HepatAssist-2 , the cost of which exceeds our current financial resources. Accordingly, we will not be able to conduct such studies until we obtain additional funding.

We are currently considering requesting FDA approval for a Phase III clinical study of the HepatAssist-2 system. Such a request will require that we supplement and/or amend the existing Phase III IND that was approved by the FDA for the original HepatAssist system on which the HepatAssist-2 is based. The preparation of a modified or supplemented Phase III IND will be expensive and difficult to prepare. Although the cost of completing the Phase III study in the manner that we currently contemplate is uncertain and could vary significantly, if that Phase III clinical study is authorized by the FDA, we currently estimate that the cost of conducting that study would be between $15 million and $20 million. 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 IND. The clinical tests that we would conduct under any FDA-approved protocol are very expensive to conduct and will cost much more than our current financial resources. Accordingly, even if the FDA approves the modified Phase III IND that we submit for HepatAssist-2 , we will not be able to conduct any clinical trials until we raise substantial amounts of additional financing.

Our bioartificial liver systems utilize 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 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 xenotransplant (transplantation from animals to humans) patients and recently completed Phase II/III testing of the HepatAssist system by Circe Biomedical, Inc., has turned up 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 bioartificial liver systems 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.

Since we only have sufficient capital to conduct our operations through the middle of 2005, we will need to obtain significant additional capital, which additional funding may dilute our existing stockholders.

Based on our current proposed plans and assumptions, we anticipate that our existing funds will only be sufficient to fund our operations and capital requirements through the middle of 2005. Furthermore, the clinical development expenses of our products will be very substantial. Based on our current assumptions, we estimate that the cost of developing SEPET will be approximately $3 million, the cost of developing HepatAssist-2 will be between $15 million and $20 million, and the cost of developing LIVERAID will be between $20 million and $25 million. 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 have to (i) obtain additional debt or equity financing during the next year 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 Labs) 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 SEPET and/or our bioartificial liver systems. 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 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 dependent on Spectrum Laboratories, Inc. as the manufacturer of our LIVERAID™ 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, Inc. for the fiber-within-fiber LIVERAID cartridges. Although we have no agreement with Spectrum Laboratories, Inc. for the manufacture of the SEPET cartridges, Spectrum Laboratories has also been providing us with cartridges for prototypes of the SEPET and has expressed an interest in manufacturing the HepatAssist-2 cartridge. Spectrum Laboratories, Inc. has encountered problems manufacturing the LIVERAID cartridges for us, which problems, if not remedied, may limit the amount and timeliness of cartridges that can be manufactured. There can be no assurance that we will not encounter delays or

other manufacturing problems with Spectrum Labs with respect to our clinical or commercial supplies of LIVERAID (and/or our SEPET cartridges if we agree to have Spectrum Laboratories manufacture the SEPET cartridges). Although Spectrum Labs 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 or may be required to alter the design of the LIVERAID cartridges if we are unable to effectively transfer the Spectrum Labs know-how to another manufacturer.

We currently do not have a manufacturing arrangement for the cartridges used in the HepatAssist-2 system. While we believe there are several potential contract manufactures 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.

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 11 U.S. patents on our liver support products, three foreign patents, have one patent application pending, and are the licensee of seven 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.

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 of disclosure of such information.

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

We are highly dependent on Jacek Rozga, MD, PhD, our President and Chief Scientific Officer. To a lesser extent, we also depend upon the medical and scientific advisory services that we receive from the members of our Board of Directors, all of whom have extensive backgrounds in medicine. However, each of these individuals, except Dr. Rozga, works for us as an unpaid advisor only on a part-time, very limited basis. We are also dependent upon the voluntary advisory services of Achilles A. Demetriou, MD, PhD, FACS, the other co-founder of Arbios Technologies and the Chairman of our Scientific Advisory Board. We do not have a long-term employment contract with Dr. Jacek Rozga, and the loss of the services of either of the foregoing persons would have a material adverse effect on our business, operations and on the development of our products. We do not carry key man life insurance on either of these individuals.

As we expand the scope of our operations by preparing FDA submissions, conducting multiple clinical trials, and potentially acquiring related technologies, we will need to obtain the full-time 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 full-time senior personnel, our overhead expenses for salaries and related items will increase substantially from current levels.

ITEM 3. Controls And Procedures

Evaluation of Disclosure Controls and Procedures:

Our management, under the supervision and with the participation of our chief executive officer/ chief financial officer, conducted an evaluation of our "disclosure controls and procedures" (as defined in the Securities Exchange Act of 1934 Rules 13a-14(c)) as of the end of the September 30, 2004 fiscal quarter. Based on their evaluation, our chief executive officer/chief financial officer concluded that as of the evaluation date, our disclosure controls and procedures are effective to ensure that all material information required to be filed in this Quarterly Report on Form 10-QSB has been made known to him.

Changes in Internal Controls:

Based on his evaluation as of September 30, 2004, the chief executive officer/chief financial officer has concluded that there were no material changes in the company's internal controls over financial reporting or in any other areas that is reasonably likely to materially affect the company's internal controls over financial reporting subsequent to the date of his most recent evaluation.

PART II. OTHER INFORMATION

ITEM 5. Other Information

On June 14, 2004, we filed a registration statement on Form SB-2 with the Securities and Exchange Commission to register 12,740,597 shares of our common stock, consisting of 7,143,097 outstanding shares owned by certain existing stockholders and 5,597,500 shares issuable to the selling stockholders upon exercise of outstanding warrants. On October 19, 2004, that registration statement was declared effective by the Securities and Exchange Commission.

ITEM 6. Exhibits And Reports On Form 8-K

(a)	Exhibits
31.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act

(b) Reports on Form 8-K

None

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report on Form 10-QSB for the fiscal quarter ended September 30, 2004, to be signed on its behalf by the undersigned, thereunto duly authorized the 14th day of November, 2004.

ARBIOS SYSTEMS, INC.

By: /S/ Jacek Rozga, M.D., Ph. D

Jacek Rozga, M.D., Ph. D
Chief Executive Officer and Chief Financial Officer