ARBIOS SYSTEMS INC
Form 10QSB
May 16, 2005

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 MARCH 31, 2005

OR

[_] 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., #206, 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 [_].

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. On April 29, 2005, there were 16,232,909 shares of common stock, $.001 par value, issued and outstanding.

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 SHEETS

ASSETS	March 31, 2005 (Unaudited)	December 31, 2004 (Audited)
Current assets		
Cash and cash equivalents	$ 6,818,807	$ 1,501,905
Prepaid expenses	177,191	97,653
Total current assets	$ 6,995,998	$ 1,599,558
Net property and equipment	103,262	107,789
Patent rights, net of accumulated amortization of $112,857 for 2005 and $105,457 for 2004	287,143	294,543
Other assets	12,421	33,164
Total assets	$ 7,398,824	$ 2,035,054
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 98,358	$ 92,304
Accrued expenses	58,752	121,460
Contract commitment		250,000
Current portion of capitalized lease obligation	3,080	5,341
Total current liabilities	160,190	469,105
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; 16,232,909 and 13,216,097 shares issued and outstanding in 2005 and 2004, respectively		
	16,233	
	13,216	
Additional paid-in capital		
	13,300,215	
	6,508,061	

Deficit accumulated during the development stage		
	(6,077,814	)
	(4,955,328	)
Total stockholders' equity		
	7,238,634	
	1,565,949	
Total liabilities and stockholders' equity		
$	7,398,824	
$	2,035,054	

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 OPERATIONS
(Unaudited)

	For the three months ended March 31, 2005	2004	Inception to March 31, 2005
Revenues	$ -	$ -	$ 320,966
Operating expenses:			
General and administrative	874,464	200,285	3,486,833
Research and development	258,495	152,172	2,694,548
Total operating expenses	1,132,959	352,457	6,181,381
Loss before other income (expense)	(1,132,959)	(352,457)	(5,860,415)
Other income (expense):			
Interest income	10,559	5,060	26,691
Interest expense	(86)	-	(244,090)
Total other income (expense)	10,473	5,060	(217,399)
Net loss	$ (1,122,486)	$ (347,397)	$ (6,077,814)
Net loss per share:			
Basic and diluted	$ (0.07)	$ (0.03)	
Weighted-average shares:			
Basic and diluted	15,846,688	13,191,422	

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 three months ended March 31, 2005	2004	Inception to March 31, 2005
Cash flows from operating activities:			
Net loss	$ (1,122,486)	$ (347,397)	$ (6,077,814)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of debt discount			244,795
Depreciation and amortization			14,427
			10,493
			154,955
Issuance of common stock for compensation			464,198
			1,520,250
Settlement of accrued expense			54,401
Deferred compensation costs			319,553
Changes in operating assets and liabilities:			
Prepaid expenses			(79,538)
			10,163
			(177,193

)
Other assets

20,743

(4,987
)

(12,421
)
Accounts payable and accrued expenses

(15,775
)

(25,502
)

169,182

Contract obligation

(250,000
)

-

Net cash used in operating activities

(968,431
)

(357,230
)

(3,804,292
)

Cash flows from investing activities:

Additions of property and equipment

(2,500
)

(120,360
)
Net cash used in investing activities

(2,500
)

-

(120,360
)

Cash flows from financing activities:

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

6,227,594

10,058,262

Net proceeds from issuance of preferred stock

238,732

Payments on capital lease obligation, net

(2,261
)

(2,772
)

(18,735
)
Net cash provided by (used for) financing activities

6,287,833

(2,772
)

10,743,459

Net increase (decrease) in cash

5,316,902

	(360,002)
	6,818,807
Cash at beginning of period	
	1,501,905
	3,507,086
Cash at end of period	
$	6,818,807
$	3,147,084
$	6,818,807
Supplemental disclosures of non-cash financing activity	
Issuance of securities for obligation related to finder's fees	
$	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)
Three Months Ended March 31, 2005

(1) Basis of Presentation:

Arbios Systems, Inc., through its wholly owned subsidiary, Arbios Technologies, Inc., seeks to develop, manufacture and market liver assist devices to meet the urgent need for therapy of liver failure. Reference herein to “the Company” includes both Arbios Systems, Inc. and Arbios Technologies, Inc., unless the context indicates otherwise.

The unaudited condensed consolidated financial statements and notes are presented as permitted by Form 10-QSB. These unaudited condensed consolidated 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 consolidated financial statements include all normal adjustments considered necessary to present fairly the financial position as of March 31, 2005, and the results of operations for the period presented. 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, 2004, 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 three-month period ended March 31, 2005 are not necessarily indicative of the results to be expected for any subsequent quarters or for the entire fiscal year.

Certain prior year amounts have been reclassified to conform with the 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. The fair value of expensed options are estimated using the Black Scholes option-pricing model. In December 2004, the FASB issued SFAS No. 123 (revised 2004), “Share-Based Payment”. Statement 123(R) requires that the compensation cost relating to a wide range of share-based payment transactions (including stock options) be recognized in financial statements. That cost will be measured based on the fair value of the equity instruments issued. Statement 123(R) replaces FASB Statement No. 123 and supersedes APB Opinion No. 25. As a small business issuer, we will be required to apply Statement 123(R) to our first interim or annual reporting period that begins after December 15, 2005.

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 loss and losses per share would have been as follows:

	Three Months Ended March 31,	
	2005	2004
Net loss as reported	$ (1,122,486)	$ (347,397)
Compensation recognized under:		
APB 25	-	-
SFAS 123	(230,661)	(18,146)
Proforma net loss	$ (1,353,147)	$ (365,543)
Basic and diluted loss per common share:		
As reported	$ (0.07)	$ (0.03)
Proforma	$ (0.09)	$ (0.03)

(3) Contract Commitment

On January 15, 2005, the Company entered into a research and development agreement (the "Development Agreement") with Warsaw University of Technology (the "University") in Warsaw, Poland to develop a proprietary membrane for the SEPET™ product. During 2005, the Company is obligated to make scheduled milestone payments totaling up to $166,000 as specified progress is made. Payments of $67,000 have been paid through March 31, 2005 under this agreement.

(4) Subsequent Event

On April 1, 2005, Arbios Technologies, Inc., the wholly owned subsidiary of the Company, entered into a lease for a 1,680 square foot facility in Woodstock, Connecticut. The facilities were leased for the purpose of breeding livestock necessary for liver organ harvest. The lease has a term of two years and may be extended by the Company for a total of nine additional years. The monthly rent initially is $12,009 per month, and a security deposit equal to two months' rent was remitted to the landlord upon signing the lease.

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

Since the formation of our operating subsidiary in 2000, we have been principally engaged in the research and development of our products, in raising capital, and in 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; however 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.

In January 2005, we sold (i) 2,991,812 shares of our common stock and (ii) warrants to purchase 1,495,906 shares of our common stock (the “Warrants”) in a private placement for an aggregate purchase price of $6,611,905. The shares of common stock were sold at a price of $2.21 per share, and the Warrants are exercisable at an initial cash exercise price of $2.90 per share (subject to adjustment). In connection with the foregoing private placement, we paid our placement agent a cash fee of $252,833, reimbursed the placement agent $25,000 for administration expenses, and issued to the placement agent warrants to purchase 114,404 shares of our common stock. The warrants issued to the placement agent had the same terms and conditions as the Warrants. In addition, we also agreed to pay up to $30,000 of legal fees incurred by the investors in the private placement.

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.

Critical Accounting Policies

Management's discussion and analysis of our financial condition and results of operations are based on our unaudited condensed 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, 2004. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our unaudited condensed 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

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 valuation assigned to the capitalized patents is based upon a valuation report prepared by an independent intellectual property valuation company.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," as in effect prior to December 2004, established and encouraged 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 permitted 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. To date, we have used 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 recognized 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. The fair value of expensed options is estimated using the Black Scholes option-pricing model. In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment". Statement 123(R) requires that the compensation cost relating to a wide range of share-based payment transactions (including stock options) be recognized in financial statements. That cost will be measured based on the fair value of the equity instruments issued. Statement 123(R) replaces FASB Statement No. 123 and supersedes APB

Opinion No. 25. As a small business issuer, we will be required to apply Statement 123(R) to our first interim or annual reporting period that begins after December 15, 2005.

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. Accordingly, we did not recognize any revenues during the three month periods ended March 31, 2004 or March 31, 2005.

General and administrative expenses of $874,464 and $200,285 were incurred for the three months ended March 31, 2005 and 2004, respectively. General and administrative expenses for the three months ended March 31, 2005 increased by $674,179 over prior year levels primarily due to increases of $464,000 in non-cash option and warrant charges for grants awarded to consultants, $121,000 in fees incurred to consultants and professionals, $18,000 in investor relations costs and $17,000 in patent costs. General and administrative expenses are expected to increase as compared to the comparable periods in the prior year due to the addition of a Chief Executive Officer in March 2005 additional professional and other fees related to being a public company.

Research and development expenses of $258,495 and $152,172 were incurred for the three months ended March 31, 2005 and 2004. Research and development expenses for the three months ended March 31, 2005 increased by $106,323 over prior year levels primarily due to an increase of $63,000 in SEPET™ development costs, a $35,000 increase in consultant and salary expenses for regulatory and product management costs and an increase of $8,000 in rent. The Company recently received permission from the FDA to begin a feasibility study for SEPET™. It is anticipated that research and development expenses will increase for the remainder of 2005 as a result of funding for this trial, the establishment of cell manufacturing for our bioartificial liver product, and the hiring of a Vice President of Operations in April 2005.

Interest income of $10,559 and $5,060 was earned for the three months ended March 31, 2005 and 2004. The increase in interest income reflects the higher cash balances maintained in 2005 resulting from the gross proceeds of $6,611,905 on January 11, 2005, from a private equity financing and the increase in short term interest rates over prior year levels.

Our net loss was $1,122,486 and $347,397 for the three months ended March 31, 2005 and 2004. The increase in net loss is attributed to an increase in operating expenses in the fiscal 2005 period as compared to the same period in 2004. 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 March 31, 2005, we had cash of approximately $6,819,000 and $128,000 of total indebtedness (both long-term and current liabilities reduced by non-cash unvested option expense of $32,000). 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.

On January 11, 2005, we completed a $6,611,905 private equity financing to a group of institutional investors and accredited investors. In the offering, we sold 2,991,812 shares of our common stock at a price of $2.21 per share to the investors and issued to them warrants to purchase an additional 1,495,906 shares of our common stock at an exercise price of $2.90 per share. The warrants are exercisable for five years and can be redeemed by us after January 11, 2007 if the average trading price of our 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. We also issued warrants to purchase 114,404 shares of common stock to our placement agent in the offering.

Based on our current plan of operations and the private placement on January 11, 2005, we believe that our current cash balances will be sufficient to fund our foreseeable expenses for at least the next twelve months.

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We do not currently anticipate that we will derive any revenues from either product sales or from governmental research grants during the current fiscal year. 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 during the next 12 months. 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.

On March 31, 2005, we hired a Chief Executive Officer at a monthly salary of $25,000. In addition, on April 25, 2005, we also hired a new Vice President of Operations at a monthly salary of approximately $13,000. The additional salaries payable to the Chief Executive Officer, the Vice President of Operations, and the additional leasing costs for the Connecticut facility are expected to increase our monthly operating expenses by more than $55,000 from the operating expenses incurred during the fiscal quarter ended March 31, 2005.

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

Contractual Obligations	**Total**	**2005**	**2006**	**2007**	**2008 and thereafter**
Research agreement					
					$166,000
					$166,000
	-0-	-0-			
		-0-			
Long-term office leases					
					$270,000
					$139,000
					$93,000
					$38,000
		-0-			

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.

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 two government research grants). Accordingly, while we have been in existence since February 1999, and our operating subsidiary, has been in existence since 2000, 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 significant revenues from the sale of any of our products for at least the next 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 U.S., SEPET™ and our bioartificial liver systems will require approval from the United States Food and Drug Administration ("FDA") prior to clinical testing and commercialization. While we recently obtained permission from the FDA to conduct a feasibility clinical trial for SEPET™, the process for obtaining FDA approval for the remaining 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. The FDA recently authorized us to conduct a feasibility clinical trial for SEPET™ on 15 patients. However, assuming that the feasibility clinical trial is successful, we will still 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 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 two to three years to obtain approval for SEPET™, approximately five years for LIVERAID™, and three to four 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. Before we can begin clinical testing of these products, we will need to file an investigational new drug application ("IND") for LIVERAID™, amend a Phase III IND to resume clinical testing of our HepatAssist-2™ bioartificial liver, which applications 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. We have not yet completed preparation of either the INDs for our bioartificial liver products, or the investigational drug exemption application for the pivotal trial for SEPET™. There can be no assurance that we will have sufficient experimental and technology validation 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.

The cost of conducting clinical studies of HepatAssist-2™ 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, 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 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 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 xenotransplant (transplantation from animals to humans) patients and the 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.

Despite our recent $6.6 million private equity financing, we still 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, we anticipate that our existing funds will be sufficient to fund our operations and capital requirements for at least the 12-month period following the date of this Quarterly Report. However, the clinical development expenses of our products will be very substantial. Based on our current assumptions, we estimate that the clinical cost of developing SEPET™ will be approximately $3 million to $4 million, the clinical cost of developing HepatAssist-2™ will be between $15 million and $20 million, and the clinical 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 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) 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 third parties to manufacture the cartridges used in our products, any failure or delay by these third parties to manufacture the cartridges will negatively affect our future operations.

We currently do not have a manufacturing arrangement for the cartridges used in either the SEPET™ or the HepatAssist-2™ systems. These cartridges will be required both for the clinical trials that we need to complete and to market our products. 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. Any agreement that we may enter into with a third party manufacturer would be subject to all of the risks normally associated with third party manufacturing arrangements, including the ability of the manufacturer to produce and deliver to us the cartridges, or components thereof, in a timely fashion and in the quantities that are needed. Any interruption by the manufacturer to produce or deliver the products as required could materially affect our ability to complete our clinical trials and to market our products.

Because we are dependent on Medtronic, Inc. for the perfusion platform used in our bioartificial liver products, 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 both our HepatAssist-2™ and LIVERAID™ systems. The PERFORMER has been equipped with proprietary software and our tubing in order to enable the machine to work with our bioartificial liver products. 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 the PERFORMERS needed to ensure that HepatAssist-2™ and LIVERAID™ are commercially viable, we would not have an alternate platform immediately available for use, and the development and sales of such systems would cease until an alternate platform is 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 manufactures who can develop and manufacture perfusion platforms meeting the HepatAssist-2™ and LIVERAID™ 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 7 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 ATI 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.

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 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 secure such insurance for clinical trials for either of our two current products. 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 any 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.

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.

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 in 2005 to record all stock-based employee compensation as an expense. 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. Large public companies will have to apply the new financial accounting rules to the first interim or annual reporting period that begins after June 15, 2005, while small business issuers such as this company will have to apply the new rules in their first reporting period beginning after December 15, 2005. 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, we could result in a competitive disadvantage to us in the employee marketplace.

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.

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). Such rules require the delivery, prior to any penny stock transaction, of a disclosure schedule explaining the penny stock market and the risks associated therewith and 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.

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 March 31, 2005 that has materially

affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 6. Exhibits And Reports On Form 8-K

(a) Exhibits

10	Employment Agreement, entered into between Arbios Systems, Inc. and Amy Factor ("Factor"), effective as of March 31, 2005"
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act

(b) Reports on Form 8-K

None

SIGNATURES

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 March 31, 2005, to be signed on its behalf by the undersigned, thereunto duly authorized the 12th day of May, 2005.

ARBIOS SYSTEMS, INC.

By: /s/ Amy Factor

Amy Factor
Chief Executive Officer

By: /s/ Scott Hayashi

Scott Hayashi
Chief Financial Officer (Principal Financial Officer)