ARBIOS SYSTEMS INC
Form 10QSB
May 17, 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 THREE MONTH PERIOD ENDED MARCH 31, 2004

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	91-19553323
(State or other jurisdiction of incorporation organization)	(IRS Employer Identification No.)
8797 Beverly Blvd., Los Angeles, California (Address of principal executive offices)	90048 (Zip Code)

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

110 North George Burns Road, Suite D-4018 Los Angeles, CA 90048
(Former address, if changed since last report)

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 May 14, 2004, there were 13,198,097 shares of common stock, $.001 par value, issued and outstanding.

ARBIOS SYSTEMS, INC. AND SUBSIDIARY

FORM 10-QSB

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

PART I

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ASSETS	March 31, 2004 (Unaudited)	December 3 (Audit
Current assets		
Cash	$ 3,147,084	$ 3,507
Prepaid expenses	145,823	155
Total current assets	$ 3,292,907	$ 3,663

Net property and equipment	42,541	45
Patent rights, net of accumulated amortization of $83,256	316,744	324
Other assets	12,421	7
Total assets	$ 3,664,613	$ 4,040
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 75,227	$ 148
Current portion of capitalized lease obligation	7,988	8
Total current liabilities	$ 83,215	$ 156
Long-term liabilities		
Capital lease obligation, less current portion	4,591	6
Other liabilities	5,556	5
Total Long-term liabilities	10,147	12
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; 13,198,098 shares issued and outstanding	13,199	13
Additional paid-in capital	5,532,950	5,485
Deficit accumulated during the development stage	(1,974,898)	(1,627
Total stockholders' equity	3,571,251	3,871
Total liabilities and stockholders' equity	$ 3,664,613	$ 4,040

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,		Inception to
	2004	2003	March 31, 2004
Revenues	$ --	$ 20,375	$ 248,936
Operating expenses:			
General and administrative	229,215	36,354	846,454
Research and development	120,667	85,391	1,130,341

Total operating expenses	349,882	121,745	1,976,795
Loss before other income (expense)	(349,882)	(101,370)	(1,727,859)
Other income (expense):			
Interest	5,060	(400)	(238,097)
Total other income (expense)	5,060	(400)	(238,097)
Loss before tax provision	(344,822)	(101,770)	(1,965,956)
Provision for taxes	2,575	1,122	8,942
Net loss	$ (347,397)	$ (102,892)	$ (1,974,898)
Net earnings per share:			
Basic	$ (0.03)	$ (0.02)	$ (0.30)
Diluted	$ (0.03)	$ (0.02)	$ (0.30)
Weighted-average shares used to compute net earnings per share:			
Basic	13,191,422	6,719,047	6,582,070
Diluted	13,191,422	6,719,047	6,582,070

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,		Inc
	2004	2003	Marc
Cash flows from operating activities:			
Net loss	$ (347,397)	$ (102,892)	$(1
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of debt discount	--	--	
Depreciation and amortization	10,493	9,463	
Issuance of common stock for compensation	--	--	

Issuance of common stock for payable	47,500	--	
Settlement of accrued expense	--	--	
Deferred compensation costs	--		
Research and Development	--	42,945	
Changes in operating assets and liabilities:			
Prepaid expenses	10,163	1,194	
Other Assets	(4,987)		
Accrued liabilities	(73,002)	(16,687)	
Other	--		
Net cash used in operating activities	(357,230)	(65,977)	(1
Cash flows from investing activities:			
Additions of property and equipment	--	(5,746)	
Net cash used in investing activities	--	(5,746)	
Cash flows from financing activities:			
Proceeds from issuance of convertible debt	--	--	
Proceeds from issuance of common stock	--	250,200	4
Proceeds from issuance of preferred stock	--	--	
Payments on capital lease obligation, net	(2,772)	(1,936)	
Cost of issuance of preferred stock	--	--	
Cost of issuance of common stock	--	(2,957)	
Net cash provided by (used for) financing activities	(2,772)	245,307	4
Net increase (decrease) in cash	(360,002)	173,584	3
Cash:			
At beginning of period	3,507,086	27,849	
At end of period	$ 3,147,084	$ 201,433	$ 3

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)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

(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 March 31, 2004 and the results of operation and cash flows for the three month period ended March 31, 2004 and 2003.

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 periods ended March 31, 2003 and March 31, 2004 are not necessarily indicative of the results to be expected for any subsequent quarter or for the entire fiscal year.

(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 services on the date of grant.

If the Company had elected to recognize compensation cost for its stock options and warrants 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 March	
	2004	2003
Net loss as reported	$(347,397)	$(102,892)
Compensation recognized under APB 25	--	--
Compensation recognized under SFAS 123	(18,146)	$ (1,760)
Proforma	$(365,543)	$(104,652)
Basic and diluted loss per common share:		
As reported	$ (0.03)	$ (0.02)
Proforma	$ (0.03)	$ (0.02)

The fair value of each option is estimated on the date of grant using the Black Scholes option-pricing model. The following weighted-average assumptions were used in the Black Scholes option-pricing model; dividend yield nil, expected volatility 0.05%, risk free interest rate 3.0% and expected life ranging from 5 to 7 years.

(3) SUBSEQUENT EVENTS:

On April 1, 2004, the Company entered into a two-year agreement to lease an additional 1,700 square feet of office space for administrative purposes. The rent is approximately $60,000 per year including taxes and other fees.

On April 19, 2004, the Company purchased certain assets of Circe Biomedical,

Inc. including Circe's patent portfolio, rights to a bioartificial liver (HepatAssist)(TM), a Phase III Investigational New 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 deferred 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 will expense 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 its 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 organization. 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 $249,000) 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. However, based on our current estimates, we believe that we have sufficient financial resources to conduct our planned operations beyond the next 12 months.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States require management to make estimates and assumptions that affect the reported assets, liabilities, sales and expenses in the accompanying financial statements. Critical accounting policies are those that require the most subjective and complex judgments, often employing the use of estimates about the effect of matters that are inherently uncertain. Certain critical accounting policies, including the assumptions and judgements underlying them, are disclosed in the Note 1 to the Consolidated Financial Statements included in our Annual Report on Form 10-KSB. However, we do not believe that there are any alternative methods of accounting for our operations that would have a material affect on our financial statements.

RESULTS OF OPERATIONS

COMPARISON OF THREE-MONTH PERIOD ENDED MARCH 31, 2004 TO THREE-MONTH PERIOD ENDED MARCH 31, 2003.

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 for the three-month period ended March 31, 2003 ($20,000) represent revenues recognized from a government research grant that we have received.

General and administrative expenses consist primarily of salaries (including salaries indirectly paid under our existing loan-out agreement with Cedars-Sinai Medical Center), office and equipment lease expenses, and professional fees and expenses. All office expenses for the three months ended March 31, 2004 and 2003 consisted solely of the expenses of our research offices located in the Cedars-Sinai Medical Center. General and administrative expenses for the three-month period ended March 31, 2004 increased by $193,000 to $229,000 over the three month period ended March 31, 2003 due to an increase in the number of employees and consultants employed and an increase in professional fees. On March 31, 2003, we had only four employees and consultants, which number increased to ten on March 31, 2004. In addition, professional fees increased during the three month period ended March 31, 2004 as compared to the same period in fiscal 2003 due to the legal and accounting fees and expenses related to our status as a public company and legal expenses associated with the acquisition of certain assets from Circe Biomedical, Inc., which transaction closed in April 2004. During the 2004 quarter, 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 consisted primarily of salaries for our scientists and technicians, laboratory costs, and the cost of scientific supplies. Research and development expenses for the three-month period ended March 31, 2004 increased by $35,000 to $121,000, over the three-month period ended March 31, 2003 because of 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.

During the three-month period ended March 31, 2004 we earned $5,000 in interest, compared to $400 of interest expense during the three-month period ended March 31, 2003, as a result of the cash balances that we maintained during the current fiscal quarter. In September and October 2003, we raised $4,400,000 in the private placement of our securities. As a result, during the current fiscal quarter, we maintained cash balances of over $3 million. In addition, we used a portion of the foregoing offering proceeds to repay all outstanding indebtedness, thereby eliminating our interest expense.

Our net loss increased by $245,000 to $347,000 during the three-month period ended March 31, 2004 due to the increased operating expenses incurred in the fiscal 2004 period as compared to the same period in 2003. 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, 2004, we had cash of $3,147,000 and only $93,000 of total indebtedness (both long-term and current liabilities). We do not have any bank credit lines. To date, we have funded our operations primarily from the sale of debt and equity securities and 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. The 4.4 million warrant shares issued in September and October, 2003 are exercisable at $2.50 per share and are callable by us 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)(TM), a Phase III Investigational New Drug application, selected equipment, clinical and marketing data, and over 400 standard operating procedures and clinical 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, gross proceeds of $4 million from the issuance of debt or equity securities. The purchase of these assets reduced our available cash funds by $200,000, and will further reduce our available cash by $250,000 when the second payment is made. However, we believe that these assets will significantly expedite the development of LIVERAID, our bioartificial liver, and will lead to future cost savings in excess of the amount paid to acquire the assets. Many of the standard operating procedures and clinical 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 governmental research grants during the next twelve months. Although we have applied for an additional SBIR research grant, no assurance can be given that the grant application will be approved. Even if the grant is approved, it is unlikely that we would receive any grant funds by the end of 2004.

Based on our current plan of operations, we believe that our current cash balances will be sufficient to fund our foreseeable expenses for at least the next twelve months. 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. As a result, we will have to obtain significant additional funds during the next 12 months in order to fund our operations after that period. We currently expect to attempt to obtain additional financing through the sale of additional equity and possibly through strategic alliances with larger pharmaceutical or biomedical companies. We cannot be sure that we will be able to obtain additional funding from either of these sources, or that the terms under which we obtain such funding will be beneficial to this company.

The following is a summary of our contractual cash obligations at March 31, 2004 for the balance of this fiscal year and for the following fiscal years:

CONTRACTUAL OBLIGATIONS	TOTAL	2004	2005	2006
Long-Term Office Leases (1)	$428,000	$137,000	$137,000	$77,000

(1) Assumes that the current lease at Cedars-Sinai Medical Center will be renewed in June 2004 for a three-year period on substantially the same terms as currently in effect.

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 A DEVELOPMENT STAGE COMPANY SUBJECT TO ALL OF THE RISKS AND UNCERTAINTIES OF A NEW BUSINESS.

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, Inc., 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.

WE MUST OBTAIN GOVERNMENTAL APPROVAL FOR EACH OF OUR PRODUCTS, THE RECEIPT OF WHICH IS 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., LIVERAID(TM) and SEPET(TM) will require FDA approval prior to 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(TM) or LIVERAID(TM) 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 LIVERAID(TM), SEPET(TM), and related 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. Japan's health regulatory authority has, and other countries regulatory authorities could potentially object to the marketing of any therapy that uses pig liver cells (which LIVERAID(TM) is expected to utilize) due to safety concerns. 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.

OUR PRODUCTS ARE AT AN EARLY STAGE OF DEVELOPMENT AND HAVE NEVER BEEN COMPLETED OR MARKETED.

Before obtaining regulatory approvals for the commercial sale of SEPET(TM) and LIVERAID(TM), significant and potentially very costly preclinical and clinical work will be necessary. We have completed only preclinical testing of the LIVERAID(TM) utilizing sorbents. There can be no assurance that we will be able to successfully complete preclinical testing of SEPET(TM) and LIVERAID(TM) combining liver cell therapy with selective plasma exchange (which will take an extended period of time). Therefore, proofs of concept and feasibility for both SEPET(TM) and LIVERAID(TM) utilizing selective plasma exchange are still lacking and there can be no assurance that we will be able to provide such proofs for these two products. We have not independently confirmed any of the claims made by the licensors of any of our products and technologies concerning the potential safety or efficacy of these products and technologies. We will need to file an IND for LIVERAID(TM) and an IDE for SEPET(TM) 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 commenced preparation of either IND or IDE 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 result in the FDA's approval of any application that we may file.

OUR LIVERAIDTM PRODUCT UTILIZES A BIOLOGICAL COMPONENT OBTAINED FROM PIGS THAT COULD PREVENT OR RESTRICT THE RELEASE AND USE OF THAT PRODUCT.

Use of liver cells harvested from pig livers carries a risk of transmitting viruses harmless to pigs but deadly to humans. For instance, all pigs carry porcine endogenous retrovirus ("PERV"), but its potential effects on people are 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 LIVERAID(TM)-treated patients and cause potentially serious disease. This may result in the FDA or other health regulatory agencies not approving LIVERAID(TM) 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 LIVERAID(TM) product. Litigation instituted by any of these organizations, and negative publicity regarding our use of pig liver cells in LIVERAID(TM), could have a material adverse effect on our business, operating results and financial condition.

UNCERTAIN DEVELOPMENT PATHS AND MARKETS FOR OUR PRODUCTS.

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

WE WILL NEED SIGNIFICANT ADDITIONAL CAPITAL, WITHOUT WHICH WE WILL HAVE TO

CURTAIL OR CEASE OPERATIONS.

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 for approximately 12 months. Furthermore, the clinical development expenses for each of our products will be very substantial, i.e., well in excess of the amount of cash that we currently still have. Accordingly, we will have to either (i) obtain additional debt or equity financing during the next 12-month period in order to fund the further development of our products and working capital needs, 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 two current 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 additional equity funding that we obtain will reduce the percentage ownership held by our existing security holders.

WE ARE SUBJECT TO SIGNIFICANT COMPETITION FROM NUMEROUS LARGE, WELL FUNDED COMPANIES.

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 under development. 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(TM) modules by Spectrum Laboratories, Inc.) 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(TM) and/or LIVERAID(TM). 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, obtaining FDA approval of our products could be delayed or the marketing of our products could be suspended or otherwise adversely affected.

WE ARE DEPENDENT ON SPECTRUM LABORATORIES, INC. AS THE MANUFACTURER OF LIVERAIDTM AND SEPET(TM).

We have an exclusive manufacturing arrangement for LIVERAID(TM) devices with Spectrum Laboratories, Inc., which also has been providing us with cartridges for prototypes of the SEPET(TM). We have encountered certain delays in the delivery of the LIVERAID(TM) and SEPET(TM) cartridges from Spectrum Laboratories, Inc. In addition, the current model of the SEPET(TM) cartridge is made of the semi-permeable membrane which needs to be modified to improve sieving of protein-bound toxins. 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(TM) and/or SEPET(TM). There can be no assurance that the SEPET(TM) cartridge allowing unrestricted passage of albumin-bound toxins while retaining blood components with molecular weight higher than 100 kDa will be developed. Although Spectrum Labs has agreed to transfer their know-how to another manufacturer for us if they are unable to meet their contractual obligations to us, we may have difficulty in finding a replacement manufacturer or may be required to alter the design of LIVERAID (TM) if we are unable to effectively transfer the Spectrum Labs know-how to another manufacturer.

WE HAVE LIMITED PATENT PROTECTION AND MAY NOT BE ABLE TO PROTECT OUR PATENTS AND PROPRIETARY RIGHTS.

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 right of others. We have relied substantially on the patent legal work that was performed for our assignors and licensors and have not, in some cases, 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. 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, and on several key members of our management, including, John Vierling, MD, FACP, Chairman of the Board, Kristin P. Demetriou, Marvin S. Hausman, MD, Richard W. Bank, MD, and Roy Eddleman who are members of our Board of Directors. Each of these individuals, except Dr. Rozga, works for us only on a part-time, very limited basis. We are also dependent upon Achilles A. Demetriou, MD, PhD, FACS, the other co-founder of Arbios Technologies, Inc. and the Chairman of our Scientific Advisory Board. We do not have long-term employment contracts with Drs. Jacek Rozga and Achilles A. Demetriou, and the loss of the services of either of them 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.

THE MARKET SUCCESS OF OUR PRODUCTS WILL BE DEPENDENT IN PART UPON THIRD-PARTY REIMBURSEMENT POLICIES.

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 SEPETTM or LIVERAIDTM, 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.

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)) within 45 days of the filing date of this Quarterly Report on Form 10-QSB. 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:

Our Board of Directors has adopted a Code of Ethics for its Chief Executive Officer and Chief Financial Officer, as well as a Code of Ethics for its employees. These Codes are intended to ensure compliance with rules and regulations, promote honest and ethical behavior and to prevent wrongdoing.

Based on his evaluation as of March 31, 2004, the chief executive officer/chief financial officer has concluded that there were no significant changes in the company's internal controls over financial reporting or in any other areas that could significantly affect the company's internal controls subsequent to the date of his most recent evaluation, including corrective actions with regard to significant deficiencies and material weaknesses.

PART II. OTHER INFORMATION

ITEM 5. OTHER INFORMATION

We recently engaged a regulatory consultant and an attorney to counsel us with respect to the availability of a FDA Section 510 (k) Pre-Market Notification for SEPET. These consultants have advised us that we should submit a notification filing under Section 510 (k), and we currently expect to do so. In pursuing the 510(k) with the FDA, we will have to, among other requirements, establish that SEPET is "substantially equivalent" to at least one other legally-marketed product that has been cleared for marketing by the FDA via a 510(k) submission. We believe that we have identified products that we can demonstrate are "substantially equivalent" to SEPET. We are in the process of compiling information to submit to the FDA prior to our commencement of a small clinical trial for SEPET. No assurance can be given that we will, in fact, submit a Section 510 (k) Pre-Market Notification for SEPET or that the FDA will agree with us that this notification filing is available to us.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

31.1 Certification of Chief Executive Officer and Chief Financial Officer

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 March 31, 2004, to be signed on its behalf by the undersigned, thereunto duly authorized the 14th day of May, 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