ARBIOS SYSTEMS INC
Form SB-2
June 14, 2004

As filed with the Securities and Exchange Commission on June 14, 2004 Reg. No. _____

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM SB-2

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

Arbios Systems, Inc.

(Name of Small Business Issuer in its Charter)

Nevada	**3841**	**91-19553323**
(State of jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

8797 Beverly Blvd.,
Los Angeles, California 90048
(310) 657-4898

(Address and telephone number of principal executive offices and principal place of business)

Jacek Rozga, M.D., Ph. D
President
8797 Beverly Blvd.,
Los Angeles, California 90048
(310) 657-4898

(Name, address and telephone number of agent for service)

Copy to:

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Approximate date of proposed sale to the public: From time to time after the date this registration statement becomes effective.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box. [ ]

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered	Proposed maximum offering price per unit[(1)]	Proposed maximum aggregate offering price[(1)]	Amount of registration fee[(1)]
Common stock, par value $0.001	12,740,597(2)	$ 3.375	$ 42,999,515	$ 5,448.04

(1) The price is estimated in accordance with Rule 457(c) under the Securities Act of 1933, as amended, solely for the purpose of calculating the registration fee and represents the average of the high and the low prices of the Common Stock on June 7, 2004, as reported on the OTC Bulletin Board.

(2) Of these shares, 7,143,097 are currently outstanding shares to be offered for resale by selling stockholders and 5,597,500 shares are currently unissued shares to be offered for resale by selling stockholders following issuance upon exercise of outstanding warrants. In addition to the shares set forth in the table, the amount to be registered includes an indeterminate number of shares issuable upon exercise of the warrants, as such number may be adjusted as a result of stock splits, stock dividends and similar transactions in accordance with Rule 416.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

[ARBIOS SYSTEMS LOGO]

ARBIOS SYSTEMS, INC.

12,740,597 Shares of Common Stock

This prospectus relates to the sale of up to 7,143,097 shares of our currently outstanding shares of common stock that are owned by some of our stockholders, and 5,597,500 shares of our common stock issuable upon the exercise of currently outstanding common stock purchase warrants held by some of our stockholders. For a list of the selling stockholders, please see "Selling Stockholders." We are not selling any shares of common stock in this offering and therefore will not receive any proceeds from this offering. We will, however, receive the exercise price of the warrants if and when those warrants are exercised by the selling stockholders. None of the warrants has been exercised as of the date of this prospectus. We will pay the expenses of registering these shares.

Our common stock is traded in the over-the-counter market and is quoted on the OTC Bulletin Board under the symbol ABOS. On June 10, 2004, the closing price of our common stock was $3.50 per share.

The shares included in this prospectus may be offered and sold directly by the selling stockholders in the open market at prevailing prices or in individually negotiated transactions, through agents designated from time to time or thorough underwriters or dealers. We will not control or determine the price at which a selling stockholder decides to sell its shares. Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under applicable state law or that an exemption from registration is available.

You should understand the risks associated with investing in our common stock. Before making an investment, read the Risk Factors, which begin on page 4 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2004.

TABLE OF CONTENTS

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus; it does not contain all of the information you should consider before investing in our common stock. Read the entire prospectus before making an investment decision.

Throughout this prospectus, the terms we, us, our, and our company refer to Arbios Systems, Inc., a Nevada corporation formerly known as Historical Autographs U.S.A., Inc., and, unless the context indicates otherwise, also includes our wholly-owned subsidiary, Arbios Technologies, Inc., a Delaware corporation.

A glossary of certain terms used in this prospectus is contained on page 51 under Glossary of Terms.

Company Overview

Arbios Systems, Inc. is a Nevada corporation based in Los Angeles, California. Through our wholly owned subsidiary, Arbios Technologies, Inc. (ATI), a Delaware corporation, we seek to develop, manufacture and market liver assist devices to meet the urgent need for therapy of liver failure.

Products Under Development. We currently have two products in development for the treatment of acute and chronic liver failure; a novel blood purification therapy called selective plasma filtration therapy (SEPET) and an extracorporeal, bioartificial liver (BAL) device that incorporates porcine hepatocytes (pig liver cells).

Our SEPET product consists of a single-use cartridge that is designed to remove toxins in the patient s blood. The SEPET cartridge is placed on a blood perfusion apparatus (such as a standard kidney dialysis machine) that is attached to the patient's blood circulation system. At the end of the selective plasma filtration treatment, the SEPET disposable cartridges is discarded, and a new cartridge is used for the next therapy.

We currently have two BAL systems in development that are based on similar technologies and that depend upon our proprietary method of procuring, cryopreserving (freezing), storing and handling the porcine hepatocytes (pig liver cells) used in both BALs to provide essential liver functions.

LIVERAID . In 2000 we commenced the development of LIVERAID , a bioartificial liver cartridge that incorporates several proprietary components and technologies, including a single-use dual hollow-fiber cartridge with fiber-within-fiber geometry. The module is attached to a base instrument which facilitates perfusion of the LIVERAID with a patient s plasma. LIVERAID currently is in pre-clinical development.

BAL 2004. In April 2004 we purchased a BAL system from Circe Biomedical, Inc., known as the HepatAssist system. This system includes a standard hollow fiber single-use cartridge designed to contain approximately 7 billion pig cells, and a proprietary perfusion apparatus. We believe that the original HepatAssist system can be enhanced by, among other things, doubling the number of pig cells in the cartridge and by using the perfusion platform contemplated for LIVERAID . We currently refer to this enhanced version of the HepatAssist system as our BAL 2004.

We purchased the Circe Biomedical assets in order to facilitate and accelerate the development of LIVERAID . However, since the original HepatAssist system has already been tested on over 100 patients in FDA-approved clinical studies, we are currently evaluating the possibility of conducting clinical studies of the BAL 2004 system under a modified version of the FDA- approved Phase III IND protocol that we acquired. The timing and allocation of resources to the development of LIVERAID and/or BAL 2004 will depend upon various factors, including FDA regulatory requirements and our future financial resources.

We currently own 11 U.S. patents applicable to our liver support technologies, one U.S. patent application, and three foreign patent applications. In addition, we are the licensee of seven patents.

Company History. Arbios Systems, Inc. was originally incorporated in February 1999 as Historical Autographs U.S.A., Inc. (HAUSA). Until October 2003, HAUSA was an e-commerce based company engaged in the business of acquiring and marketing historical documents. On October 30, 2003, HAUSA completed a reorganization (the Reorganization) in which HAUSA, through its wholly-owned subsidiary, acquired all of the outstanding shares of ATI in exchange for 11,930,598 shares of our common stock. As a result of the Reorganization, ATI became the wholly-owned subsidiary of HAUSA. After the Reorganization, HAUSA changed its name to Arbios Systems, Inc., replaced its officers and directors with those of ATI, closed its offices, ceased its e-commerce business, and moved its offices to Los Angeles, California. We currently do not plan to conduct any business other than the business of developing liver assisted devices as heretofore conducted by ATI.

	The Offering
Common stock offered by the selling stockholders	12,740,597 shares, consisting of 7,143,097 outstanding shares owned by selling stockholders and 5,597,500 shares issuable to selling stockholders upon exercise of outstanding warrants.
Common stock currently outstanding	13,198,097 shares (1)
Common stock to be outstanding after the offering, assuming no exercise of the warrants	13,198,097 shares (1)
Common stock to be outstanding after the offering, assuming the exercise of all warrants	18,795,598 shares (1)
OTC Bulletin Board Trading Symbol	ABOS
Risk Factors	An investment in our common stock involves significant risks. See Risk Factors beginning on page 4

(1) In addition to these outstanding shares of common stock, as of May 31, 2004, there were outstanding options to purchase 644,000 shares of our common stock (with exercise prices ranging from $0.15 per share to $2.60 per share).

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information contained in this prospectus and in the documents incorporated by reference before deciding to invest in our company. If any of the following risks actually occur, our business, financial condition or operating results and the trading price or value of our securities could be materially adversely affected.

RISKS RELATED TO OUR BUSINESS

We are an early-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 ATI, 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., SEPET and our BAL systems will require approval from the FDA prior to clinical testing and commercialization. The process for obtaining FDA approval to market therapeutic products is both time-consuming and costly, with no certainty of a successful outcome. This process includes the conduct of extensive pre-clinical and clinical testing, which may take longer or cost more than we currently anticipate due to numerous factors, including without limitation, difficulty in securing centers to conduct trials, difficulty in enrolling patients in conformity with required protocols and/or projected timelines, unexpected adverse reactions by patients in the trials to our products, temporary suspension and/or complete ban on trials of our products due to the risk of transmitting pathogens from the xenogeneic biologic component, and changes in the FDA s requirements for our testing during the course of that testing. We have not yet established with the FDA the nature and number of clinical trials that the FDA will require in connection with its review and approval of either SEPET or our BAL 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. 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 our BAL systems are 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 marketed.

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 BAL systems (which will take an extended period of time). We have not independently confirmed any of the third party claims made with respect to patents, licenses or technologies we have acquired concerning the potential safety or efficacy of these products and technologies. We will need to file an investigational new drug application (IND) for LIVERAID and an investigational drug exemption for SEPET with the FDA and have these applications cleared by the FDA before we can begin clinical testing of these two products, and the FDA may require significant revisions to our clinical testing plans or require us to demonstrate efficacy endpoints that are more time-consuming or difficult to achieve than what we currently anticipate. We have not yet completed preparation of either the IND or the investigational drug exemption application, and there can be no assurance that we will have sufficient experimental data to justify the submission of said applications. Because of the early stage of development of each of our products, we do not know if we will be able to generate clinical data that will support the filing of the FDA applications for these products or the FDA s approval of any product marketing approval application or IND that we do file.

We need FDA approval before conducting clinical studies of BAL 2004 and need to obtain additional funding to conduct such studies.

We are currently considering requesting FDA approval for a Phase III clinical study of the BAL 2004 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 BAL 2004 is based. The preparation of a modified or supplemented Phase III IND will be expensive and difficult to prepare. 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 BAL 2004, we will not be able to conduct any clinical trials until we raise substantial amounts of additional financing

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Our BAL systems utilize 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 pig cells carry genetic material of the porcine endogenous retrovirus (PERV), but its ability to infect people is unknown. Repeated testing, including a 1999 study of 160 xenotransplant (transplantation from animals to humans) patients and recently completed Phase II/III testing of the HepatAssist system by Circe Biomedical, Inc., has turned up no sign of the transmission of PERV to humans. Still, no one can prove that PERV or another virus would not infect BAL-treated patients and cause potentially serious disease. This may result in the FDA or other health regulatory agencies not approving our BAL 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 BAL system. Litigation instituted by any of these organizations, and negative publicity regarding our use of pig liver cells in a BAL, 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. 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 from the date of this prospectus. Furthermore, the clinical development expenses 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 (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, 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.

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. Furthermore, many companies are engaged in the development of medical devices or products that are or will be competitive with our proposed products. Most of the companies with which we compete have substantially greater financial, technical, manufacturing, marketing, distribution and other resources than us.

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

Our business model calls for the outsourcing of the clinical development, manufacturing and marketing of our products in order to reduce our capital and infrastructure costs as a means of potentially improving the profitability of these products for us. We have not yet entered into any strategic alliances or other licensing or contract manufacturing arrangements (except for the contractual manufacturing of LIVERAID modules by Spectrum Labs) and there can be no assurance that we will be able to enter into satisfactory arrangements for these services or the manufacture or marketing of our products. We will be required to expend substantial amounts to retain and continue to utilize the services of one or more clinical research management organizations without any assurance that the products covered by the clinical trials conducted under their management ultimately will generate any revenues for SEPET and/or our BAL 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.

We are dependent on Spectrum Laboratories, Inc. as the manufacturer of our LIVERAID™ cartridges and have no manufacturing agreements of BAL 2004.

We have an exclusive manufacturing arrangement with Spectrum Laboratories, Inc. for the fiber-within-fiber LIVERAID cartridges. Although we have no agreement with Spectrum Laboratories, Inc. for the manufacture of the SEPET cartridges, Spectrum Laboratories has also been providing us with cartridges for prototypes of the SEPET . We have encountered certain delays in the delivery of the LIVERAID and SEPET cartridges from Spectrum Laboratories, Inc. There can be no assurance that we will not encounter delays or other manufacturing problems with Spectrum Labs with respect to our clinical or commercial supplies of LIVERAID (and/or our SEPET cartridges if we agree to have Spectrum Laboratories manufacture the SEPET cartridges). Although Spectrum Labs has agreed to transfer all of the know-how related to these products to any other manufacturer of our products if Spectrum Laboratories is unable to meet its contractual obligations to us, we may have difficulty in finding a replacement manufacturer or may be required to alter the design of the LIVERAID cartridges if we are unable to effectively transfer the Spectrum Labs know-how to another manufacturer.

We currently do not have a manufacturing arrangement for the cartridges used in the BAL 2004 system. While we believe there are several potential contract manufactures who can produce these cartridges, there can be no assurance that we will be able to enter into such an arrangement on commercially favorable terms, or at all.

We have uncertain 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 rights of others. We currently own 11 U.S. patents on our liver support products, three foreign patents, have one patent application pending, and are the licensee of seven additional liver support patents. We have relied substantially on the patent legal work that was performed for our assignors and licensors with respect to all of these patents, application and licenses, and have not independently verified the validity or any other aspects of the patents or patent applications covering our products with our own patent counsel.

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

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

The development of our products is dependent upon Dr. Rozga and certain other persons. 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 M. 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 ATI 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 eit her 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 our products, and we cannot predict whether levels of reimbursement for our products, if any, will be high enough to allow us to charge a reasonable profit margin. Even with FDA approval, third-party payers may deny reimbursement if the payer determines that our particular new products are unnecessary, inappropriate or not cost effective. If patients are not entitled to receive reimbursement similar to reimbursement for competing products, they may be unwilling to use our products since they will have to pay for the unreimbursed amounts, which may well be substantial. The reimbursement status of newly approved health care products is highly uncertain. If levels of reimbursement are decreased in the future, the demand for our products could diminish or our ability to sell our products on a profitable basis could be adversely affected.

We may be subject to product liability claims.

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 BAL 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..

RISKS RELATED TO OUR COMMON STOCK

Our Stock Is Thinly Traded, So You May Be Unable To Sell At Or Near Ask Prices Or At All If You Need To Sell Your Shares To Raise Money Or Otherwise Desire To Liquidate Your Shares

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

If Securities Or Industry Analysts Do Not Publish Research Reports About Our Business, Our Stock Price And Trading Volume Could Decline.

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

You May Have Difficulty Selling Our Shares Because They Are Deemed Penny Stocks,

Since our common stock is not listed on the Nasdaq Stock Market, if the trading price of our common stock remains 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.

Anti-Takeover Provisions In Our Articles Of Incorporation Could Affect The Value Of Our Stock

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

Potential Issuance of Additional Common and Preferred Stock Could Dilute Existing Stockholders

We are authorized to issue up to 25,000,000 shares of common stock. To the extent of such authorization, our board of directors has the ability, without seeking stockholder approval, to issue additional shares of common stock in the future for such consideration as the board of directors may consider sufficient. The issuance of additional common stock in the future will reduce the proportionate ownership and voting power of the common stock offered hereby. We are also authorized to issue up to 5,000,000 shares of preferred stock, the rights and preferences of which may be designated in series by the board of directors. Such designation of new series of preferred stock may be made without stockholder approval, and could create additional securities which would have dividend and liquidation preferences over the common stock offered hereby. Preferred stockholders could adversely affect the rights of holders of common stock by:

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

Substantial Sales Of Common Stock Could Cause Stock Price To Fall

As of June 8, 2004, we had outstanding 13,198,097 shares of common stock, of which approximately 11,930,597 shares were restricted securities (as that term is defined under Rule 144 promulgated under the Securities Act of 1933, as amended). Other than the shares registered for resale by this prospectus, only approximately 1,220,000 shares are currently freely tradable shares. However, as a result of the registration of the shares included in this prospectus, an additional 7,143,097 shares of our currently outstanding common stock will be able to be freely sold on the market, which number will increase to 12,740,597 shares if the warrants owned by the selling stockholders are exercised and the underlying 5,597,500 shares that are included in this prospectus are purchased. Because there currently are only 1,220,000 shares freely tradable shares, the sudden release of 12,740,597 additional freely trading shares included in this prospectus onto the market, or the perception that such shares will come onto the market, could have an adverse affect on the trading price of the stock. In addition to the shares that may be registered for re-sale under this prospectus, an additional 4,835,000 shares of restricted stock will become eligible for public resale under Rule 144 commencing in November 2004. Although Rule 144 restricts the number of shares that any one holder can sell during any three-month period under Rule 144, because more than one stockholder holds these restricted shares, a significant number of shares could legally be sold commencing in November 2004. No prediction can be made as to the effect, if any, that sales of the shares included in this prospectus or subject to Rule 144 sales commencing in November 2004, or the availability of such shares for sale, will have on the market prices prevailing from time to time. Nevertheless, the possibility that substantial amounts of common stock may be sold in the public market may adversely affect prevailing market prices for our common stock and could impair our ability to raise capital through the sale of our equity securities.

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

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

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

FORWARD-LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements. This document contains forward-looking statements, which reflect the views of our management with respect to future events and financial performance. These forward-looking statements are subject to a number of uncertainties and other factors that could cause actual results to differ materially from such statements. Forward-looking statements are identified by words such as anticipates, believes, estimates, expects, plans, projects, ta similar expressions. Readers are cautioned not to place undue reliance on these forward-looking statements, which are based on the information available to management at this time and which speak only as of this date. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. For a discussion of some of the factors that may cause actual results to differ materially from those suggested by the forward-looking statements, please read carefully the information under "Risk Factors" beginning on page 4.

The identification in this document of factors that may affect future performance and the accuracy of forward-looking statements is meant to be illustrative and by no means exhaustive. All forward-looking statements should be evaluated with the understanding of their inherent uncertainty. You may rely only on the information contained in this prospectus.

We have not authorized anyone to provide information different from that contained in this prospectus. Neither the delivery of this prospectus nor the sale of common stock means that information contained in this prospectus is correct after the date of this prospectus. This prospectus is not an offer to sell or solicitation of an offer to buy these securities in any circumstances under which the offer or solicitation is unlawful.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the common stock by the selling stockholders pursuant to this prospectus. However, we may receive the sale price of any common stock we sell to the selling stockholders upon exercise of the warrants. If all warrants are exercised for cash (including those that contain cash-less exercise provisions), the total amount of proceeds we would receive is $12,628,750. Other than the warrants to purchase 150,000 shares at an exercise price of $3.40 per share that contain cash-less exercise provisions, all other warrants must be exercised by the payment of the cash exercise price. We expect to use the proceeds we receive from the exercise of warrants, if any, for general working capital purposes. We will pay the expenses of registration of these shares, including legal and accounting fees.

12

MARKET PRICE OF COMMON STOCK AND OTHER SHAREHOLDER MATTERS

Market Information

Our common stock has been traded on the OTC Bulletin Board over-the-counter market since March 18, 2004 under the symbol ABOS. From the Reorganization until March 18, 2004, our common stock was listed on the Pink Sheets over-the-counter electronic trading system under the symbol ABOS. Before to the Reorganization on October 30, 2003, our common stock was listed on the Pink Sheets under the symbol HIAU, but there was virtually no trading in the common stock.

Our common stock will be offered in amounts, at prices, and on terms to be determined in light of market conditions at the time of sale. The shares may be sold directly by the selling stockholders in the open market at prevailing prices or in individually negotiated transactions, through agents, underwriters, or dealers. We will not control or determine the price at which the shares are sold.

To our knowledge, there was no trading in our common stock until shortly before the Reorganization on October 30, 2003, and any trading was not based on our company s current operations or prospects. Accordingly, the following table only sets forth the high and low bid information for our common stock for the periods indicated since the Reorganization. The following price information reflects inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions:

Quarter Ending	High	Low
December 31, 2003[(1)]	$3.26	$3.00
March 31, 2004	$3.50	$3.40

(1) Reflects initial trading activity commencing on November 1, 2003 through the end of the calendar quarter ended December 31, 2003.

Holders

As of May 31, 2004, there were approximately 138 holders of record of our common stock.

Dividends

We have not paid any dividends on our common stock to date and do not anticipate that we will be paying dividends in the foreseeable future. Any payment of cash dividends on our common stock in the future will be dependent upon the amount of funds legally available, our earnings, if any, our financial condition, our anticipated capital requirements and other factors that the Board of Directors may think are relevant. However, we currently intend for the foreseeable future to follow a policy of retaining all of our earnings, if any, to finance the development and expansion of our business and, therefore, do not expect to pay any dividends on our common stock in the foreseeable future.

MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

Overview

On October 30, 2003, we completed a reorganization (the Reorganization) in which Arbios Technologies, Inc. (ATI), 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 business of developing liver assist devices that Arbios Technologies, Inc. has conducted since its organization.

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

Since the formation of ATI 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.

In April 2004 we purchased certain assets of Circe Biomedical, Inc. including a portfolio of patents, rights to a bioartificial liver (HepatAssist), a Phase III IND, 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.

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 judgments underlying them, are disclosed in the Note 1 to the Consolidated Financial Statements included in this prospectus. 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 first quarter of 2004, we also incurred additional consulting fees in connection with our investigation of the suitability and advisability of submitting a Section 510(k) Pre-Market Notification with the 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 .