ARBIOS SYSTEMS INC
Form SB-2
February 09, 2005

As filed with the Securities and Exchange Commission on February 9, 2005 **Reg. No. 333-___**

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**	**91-1955323**
(State of jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

8797 Beverly Blvd., Suite 206
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., Suite 206
Los Angeles, California 90048
(310) 657-4898
(Name, address and telephone number of agent for service)

Copy to:

Istvan Benko, Esq.
Troy & Gould Professional Corporation
1801 Century Park East, Suite 1600
Los Angeles, California 90067
(310) 553-4441

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. o

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. o

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. o

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

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	4,602,122 (2)	$2.95	$13,576,259	$1,597.93

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(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 February 8, 2005, as reported on the OTC Bulletin Board.

(2) Of these shares, 2,991,812 are currently outstanding shares to be offered for resale by selling stockholders and 1,610,310 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, INC.

4,602,122 Shares of Common Stock

This prospectus relates to the sale or other disposition of up to 2,991,812 shares of our currently outstanding shares of common stock that are owned by some of our stockholders, and 1,610,310 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 February 8, 2005, the closing price of our common stock was $2.95 per share.

The shares included in this prospectus may be disposed of on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. We will not control or determine the price at which a selling stockholder decides to sell or otherwise dispose of 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 February __, 2005.

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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 58 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 types of products in development for the treatment of acute and chronic liver failure; a novel extracorporeal (outside of the human body) blood purification therapy called selective plasma filtration therapy ("SEPET™") and an extracorporeal, bioartificial liver device that contains biologic components (in this case, pig liver cells).

Our SEPET™ product consists of a single-use cartridge that is designed to remove toxins and mediators of inflammation 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 cartridge is discarded, and a new cartridge is used for the next therapy.

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

HepatAssist-2™. In April 2004 we purchased a bioartificial liver system from Circe Biomedical, Inc., known as the "HepatAssist" system. The HepatAssist system we purchased included a standard hollow fiber single-use cartridge designed to contain approximately 5 billion viable pig cells, a charcoal column and a proprietary perfusion apparatus. We believe that the original HepatAssist system can be enhanced by, among other things, increasing the number of viable pig cells in the cartridge to 15 billion and by using the perfusion platform we plan to use for LIVERAID™. We refer to our enhanced version of the HepatAssist system as our "HepatAssist-2™." We are currently testing, and expect to use the PERFORMER as the perfusion platform for our HepatAssist-2™ system. RanD S.r.l., the manufacturer of the PERFORMER, has equipped the PERFORMER with proprietary software and a tubing set specifically designed for use with our HepatAssist-2™ system.

LIVERAID™. In 2000 we commenced the development of LIVERAID™, a bioartificial liver that incorporates several proprietary components and technologies, including a single-use dual hollow-fiber cartridge with fiber-within-fiber geometry and a blood purification circuit utilizing sorbents. The cell 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.

We purchased the HepatAssist system and other assets from Circe Biomedical 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 and we acquired an FDA- approved Phase III IND protocol for that system, we currently intend to focus our resources first on the development of our HepatAssist-2™ system and then on the development of LIVERAID™. As a result, we are currently evaluating the possibility of conducting clinical studies of the HepatAssist-2™ 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 the HepatAssist-2™ and/or LIVERAID™ systems will depend upon various factors, including FDA regulatory requirements and our future financial resources.

Certain countries, including Japan, France and the United Kingdom, have in the past objected to transplantation of animal cells in humans because of the risk of transmitting viruses from the animals (including pigs) to humans. Since both of our bioartificial liver systems use pig liver cells to provide essential liver functions, these regulatory objections may prevent our bioartificial liver products, if developed and approved by the FDA, from being marketed in those other countries. The original HepatAssist system was used in FDA-approved clinical studies using pig cells without any signs of transmission of viruses of disease from the pigs to humans, and the FDA has approved a new IND protocol that also contemplates the use of pig cells.

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 HAUSA 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.

Our principal operations and executive offices are located at 8797 Beverly Blvd., Suite 206, Los Angeles, California 90048 and our telephone number is (310) 657-4898. We also maintain a web site at www.arbios.com. The information on our web site is not, and you must not consider such information to be, a part of this prospectus.

Recent Developments

On January 11, 2005, we completed a $6,611,905 private equity financing to a group of institutional investors and accredited investors. In the offering, we sold 2,991,812 shares of our common stock at a price of $2.21 per share to the investors and issued to them warrants to purchase an additional 1,495,906 shares of our common stock at an exercise price of $2.90 per share. The warrants are exercisable for five years and can be redeemed by us after January 11, 2007 if the average trading price of our common stock for 20 consecutive trading days is equal to or greater than $5.80 and the average trading volume of the common stock is at least 100,000 shares during those 20 days. The proceeds of the private equity financing will be used to fund our general working capital needs and the further development of our products. This prospectus is part of the registration statement that we filed as a result of our agreement to register for resale under the Securities Act both the shares of common stock sold in that offering and the shares of common stock issuable upon exercise of the warrants sold in the financing. Rodman & Renshaw acted as our placement agent in the offering, and we issued to Rodman & Renshaw warrants to purchase 114,404 shares of common stock, which warrant shares are also included in this prospectus.

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The Offering

Common stock covered hereby	4,602,122 shares, consisting of 2,991,812 outstanding shares owned by selling stockholders and 1,610,310 shares issuable to selling stockholders upon exercise of outstanding warrants.
Common stock currently outstanding	16,207,909 shares (1)
Common stock to be outstanding assuming the sale of all shares covered hereby and assuming no exercise of the warrants for the shares covered by this prospectus	16,207,909 shares (1)
Common stock to be outstanding assuming the sale of all shares covered herby and assuming the exercise of all warrants for the shares covered by this prospectus	17,818,219 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 February 1, 2005, there were outstanding (i) options to purchase 743,000 shares of our common stock (with exercise prices ranging from $0.15 per share to $3.40 per share), and (ii) warrants (other than the warrants owned by the selling stockholders) to purchase 5,672,500 shares of our common stock (with exercise prices ranging from $0.15 per share to $3.50 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, including the risk that we may never market any products or generate revenues.

We are an early-stage company that has not generated any operating revenues to date (our only revenues were two government research grants). Accordingly, while we have been in existence since February 1999, and ATI, our operating subsidiary, has been in existence since 2000, we should be evaluated as an early-stage company, subject to all of the risks and uncertainties normally associated with an early-stage company. As an early-stage, we expect to incur significant operating losses for the foreseeable future, and there can be no assurance that we will be able to validate and market products in the future that will generate revenues or that any revenues generated will be sufficient for us to become profitable or thereafter maintain profitability.

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

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

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

The development, production and marketing of our products are subject to extensive regulation by government authorities in the United States and other countries. In the U.S., SEPET™ and our bioartificial liver systems will require approval from the 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 liver assist systems, temporary suspension and/or complete ban on trials of our products due to the risk of transmitting pathogens from the xenogeneic biologic component, and changes in the FDA's requirements for our testing during the course of that testing. We have not yet established with the FDA the nature and number of clinical trials that the FDA will require in connection with its review and approval of either SEPET™ or our bioartificial liver systems and these requirements may be more costly or time-consuming than we currently anticipate.

Each of our products in development is novel both in terms of its composition and function. Thus, we may encounter unexpected safety, efficacy or manufacturing issues as we seek to obtain marketing approval for products from the FDA, and there can be no assurance that we will be able to obtain approval from the FDA or any foreign governmental agencies for marketing of any of our products. The failure to receive, or any significant delay in receiving, FDA approval, or the imposition of significant limitations on the indicated uses of our products, would have a material adverse effect on our business, operating results and financial condition. The health regulatory authorities of certain countries, including those of Japan, France and the United Kingdom, have previously objected, and other countries' regulatory authorities could potentially object to the marketing of any therapy that uses pig liver cells (which our bioartificial liver systems are designed to utilize) due to safety concerns that pig cells may transmit viruses or diseases to humans. If the health regulatory agencies of other countries impose a ban on the use of therapies that incorporate pig cells, such as our bioartificial liver systems, we would be prevented from marketing our products in those countries. If we are unable to obtain the approval of the health regulatory authorities in Japan, France, the United Kingdom or other countries, the potential market for our products will be reduced.

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

Before obtaining regulatory approvals for the commercial sale of our products, significant and potentially very costly preclinical and clinical work will be necessary. There can be no assurance that we will be able to successfully complete all required testing of SEPET™ or our bioartificial liver systems. While the time periods for testing our products and obtaining the FDA's approval are dependent upon many future variable and unpredictable events, we estimate that it could take between two to three years to obtain approval for SEPET™, approximately five years for LIVERAID™, and three to four years for HepatAssist-2™. We have not independently confirmed any of the third party claims made with respect to patents, licenses or technologies we have acquired concerning the potential safety or efficacy of these products and technologies. Before we can begin clinical testing of these products, we will need to file an investigational new drug application ("IND") for LIVERAID™, amend a Phase III IND to resume clinical testing of our HepatAssist-2™ bioartificial liver, and file an investigational drug exemption for SEPET™ with the FDA, which applications will have to be cleared by the FDA. The FDA may require significant revisions to our clinical testing plans or require us to demonstrate efficacy endpoints that are more time-consuming or difficult to achieve than what we currently anticipate. We have not yet completed preparation of either the INDs or the investigational drug exemption application, and there can be no assurance that we will have sufficient experimental and technology validation data to justify the submission of said applications. Because of the early stage of development of each of our products, we do not know if we will be able to generate clinical data that will support the filing of the FDA applications for these products or the FDA's approval of any product marketing approval application or IND that we do file.

The cost of conducting clinical studies of HepatAssist-2™ exceeds our current financial resources. Accordingly, we will not be able to conduct such studies until we obtain additional funding.

We are currently considering requesting FDA approval for a Phase III clinical study of the HepatAssist-2™ system. Such a request will require that we supplement and/or amend the existing Phase III IND that was approved by the FDA for the original HepatAssist system on which the HepatAssist-2™ is based. The preparation of a modified or supplemented Phase III IND will be expensive and difficult to prepare. Although the cost of completing the Phase III study in the manner that we currently contemplate is uncertain and could vary significantly, if that Phase III clinical study is authorized by the FDA, we currently estimate that the cost of conducting that study would be between $15 million and $20 million. We currently do not have sufficient funds to conduct this study and have not identified any sources for obtaining the required funds. In addition, no assurance can be given that the FDA will accept our proposed changes to the previously approved Phase III IND. The clinical tests that we would conduct under any FDA-approved protocol are very expensive to conduct and will cost much more than our current financial resources. Accordingly,

even if the FDA approves the modified Phase III IND that we submit for HepatAssist-2™, we will not be able to conduct any clinical trials until we raise substantial amounts of additional financing.

Our bioartificial liver systems utilize a biological component obtained from pigs that could prevent or restrict the release and use of those products.

Use of liver cells harvested from pig livers carries a risk of transmitting viruses harmless to pigs but deadly to humans. For instance, all pig cells carry genetic material of the porcine endogenous retrovirus ("PERV"), but its ability to infect people is unknown. Repeated testing, including a 1999 study of 160 xenotransplant (transplantation from animals to humans) patients and the Phase II/III testing of the HepatAssist system by Circe Biomedical, Inc., has turned up no sign of the transmission of PERV to humans. Still, no one can prove that PERV or another virus would not infect bioartificial liver-treated patients and cause potentially serious disease. This may result in the FDA or other health regulatory agencies not approving our bioartificial liver systems or subsequently banning any further use of our product should health concerns arise after the product has been approved. At this time, it is unclear whether we will be able to obtain clinical and product liability insurance that covers the PERV risk.

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

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

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

Despite our recent $6.6 million private equity financing, we still need to obtain significant additional capital to complete the development of our liver assist devices, which additional funding may dilute our existing stockholders.

Based on our current proposed plans and assumptions, we anticipate that our existing funds will be sufficient to fund our operations and capital requirements for at least the 12-month period following the date of this prospectus. However, the clinical development expenses of our products will be very substantial. Based on our current assumptions, we estimate that the cost of developing SEPET™ into a commercial product will approximately $3 million to $4 million, the cost of developing HepatAssist-2™ into a commercial product will be between $15 million and $20 million, and the cost of developing LIVERAID™ into a commercial product will be between $20 million and $25 million. These amounts, which could vary substantially if our assumptions are not correct, are well in excess of the amount of cash that we currently have available to us. Accordingly, we will have to (i) obtain additional debt or equity financing in order to fund the further development of our products and working capital needs, and/or (ii) enter into a strategic alliance with a larger pharmaceutical or biomedical company to provide its required funding. The amount of funding needed to complete the development of one or both of our products will be very substantial and may be in excess of our ability to raise capital.

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

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

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

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

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

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

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

We have an exclusive manufacturing arrangement with Spectrum Laboratories, Inc. ("Spectrum Labs")for the fiber-within-fiber LIVERAID™ cartridges. Although we have no agreement with Spectrum Labs for the manufacture of the SEPET™ cartridges, Spectrum Labs has also been providing us with cartridges for prototypes of the SEPET™ and has expressed an interest in manufacturing the HepatAssist-2™ cartridge. Spectrum Labs has encountered problems manufacturing the LIVERAID™ cartridges for us, which problems, if not remedied, may limit the amount and timeliness of cartridges that can be manufactured. Spectrum Labs has informed us that it can, and is willing to develop a manufacturing process for large-scale manufacturing of the LIVERAID™ cartridges that will reduce or eliminate these problems and shorten the manufacturing period. However, since such manufacturing process is expensive, Spectrum Labs has not yet undertaken to acquire or develop the necessary equipment and technology. No assurance can be given that Spectrum Labs will, in fact, be able to acquire or develop a large-scale manufacturing process or that Spectrum Labs will otherwise be able to satisfy our needs for the LIVERAID™ cartridges. In the event that Spectrum Labs is either unable or unwilling to manufacture the amount of LIVERAID™ cartridges that we need, we will have to find one or more alternative manufacturers for the 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 Labs is unable to meet its contractual obligations to us, we may have difficulty in finding a replacement manufacturer or may be required to alter the design of the LIVERAID™ cartridges if we are unable to effectively transfer the Spectrum Labs know-how to another manufacturer.

We currently do not have a manufacturing arrangement for the cartridges used in the HepatAssist-2™ system. While we believe there are several potential contract manufactures who can produce these cartridges, there can be no assurance that we will be able to enter into such an arrangement on commercially favorable terms, or at all.

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

Our ability to compete successfully will depend, in part, on our ability to defend patents that have issued, obtain new patents, protect trade secrets and operate without infringing the proprietary rights of others. We currently own 11 U.S. patents on our liver support products, three foreign patents, have one patent application pending, and are the licensee of seven additional liver support patents. We have relied substantially on the patent legal work that was performed for our assignors and licensors with respect to all of these patents, application and licenses, and have not independently verified the validity or any other aspects of the patents or patent applications covering our products with our own patent counsel.

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

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

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

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

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

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

Our ability to successfully penetrate the market for our products may depend significantly on the availability of reimbursement for our products from third-party payers, such as governmental programs, private insurance and private health plans. We have not yet established with Medicare or any third-party payers what level of reimbursement, if any, will be available for our products, and we cannot predict whether levels of reimbursement for our products, if any, will be high enough to allow us to charge a reasonable profit margin. Even with FDA approval, third-party payers may deny reimbursement if the payer determines that our particular new products are unnecessary, inappropriate or not

cost effective. If patients are not entitled to receive reimbursement similar to reimbursement for competing products, they may be unwilling to use our products since they will have to pay for the unreimbursed amounts, which may well be substantial. The reimbursement status of newly approved health care products is highly uncertain. If levels of reimbursement are decreased in the future, the demand for our products could diminish or our ability to sell our products on a profitable basis could be adversely affected.

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

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

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

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

RISKS RELATED TO OUR COMMON STOCK

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

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

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

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

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

Since our common stock is not listed on the Nasdaq Stock Market, if the trading price of our common stock is below $5.00 per share, trading in our common stock will be subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a penny stock (generally, any non-Nasdaq equity security that has a market price of less than $5.00 per share, subject to certain exceptions). 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 number of shares of common stock may be released onto the market at any time, and the sales of such additional shares of common stock could cause stock price to fall

As of the date of this prospectus, we had outstanding 16,207,909 shares of common stock, of which approximately 8,363,000 are currently freely tradable shares or are registered for re-sale pursuant to another outstanding prospectus. However, in the past year, the average daily trading volume of our shares has only been a few thousand shares, and there have been many days in which no shares were traded at all. As a result of the registration of the shares included in this prospectus, 2,991,812 additional shares of our currently outstanding common stock will be able to be freely sold on the market, which number will increase to 4,602,122 shares if the warrants owned by the selling stockholders are exercised and the underlying 1,610,310 shares that are included in this prospectus are purchased. Because of the limited trading volume, the sudden release of 4,602,122 additional freely trading shares that are 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, we have also previously registered 5,597,500 additional currently unissued shares of our common stock that can be issued upon the exercise of outstanding warrants and can be immediately resold pursuant to that prior registration statement. If these other warrants are exercised and the underlying 5,597,500 registered shares are released for sale on the market, the market price could further be adversely affected. Finally, there are currently 4,900,500 shares of unregistered, restricted stock that are currently eligible for public resale under Rule 144 promulgated under the Securities Act, some of which shares also may be offered and sold on the market from time to time. No prediction can be made as to the effect, if any, that sales of the 4,602,122 shares included in this prospectus, the sales of the

5,597,000 previously registered warrant shares, or the sale of any of the 4,900,500 shares subject to Rule 144 sales will have on the market prices prevailing from time to time. Nevertheless, the possibility that substantial amounts of common stock may be sold in the public market may adversely affect prevailing market prices for our common stock and could impair our ability to raise capital through the sale of our equity securities.

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

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

· announcements of the results of clinical trials by us or our competitors,

· developments with respect to patents or proprietary rights,

· announcements of technological innovations by us or our competitors,

· announcements of new products or new contracts by us or our competitors,

· actual or anticipated variations in our operating results due to the level of development expenses and other factors,

· changes in financial estimates by securities analysts and whether our earnings meet or exceed such estimates,

· conditions and trends in the pharmaceutical and other industries,

· new accounting standards,

· general economic, political and market conditions and other factors, and

· the occurrence of any of the risks described in this prospectus.

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," "targets" and similar expressi 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 or other disposition of the common stock covered hereby 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 included in this prospectus are exercised for cash, the total amount of proceeds we would receive is $4,670,000. 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.

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
June 30, 2004	$4.25	$2.75
September 30, 2004	$5.15	$4.00
December 31, 2004	$5.15	$2.65

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

Our common stock is also listed on the Frankfurt Stock Exchange in Germany. The trading symbol of our common stock on the Frankfurt Stock Exchange is "NNV."

Holders

As of February 1, 2005, there were 164 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 $321,000) that we received from the United States Small Business Administration.

Our current plan of operations for the next 12 months primarily involves research and development activities, including clinical trials for at least one of our potential products, and the preparation and submission of applications to the FDA. We currently intend to submit an investigational new drug exemption application and to commence conducting clinical studies for SEPET™ in the first quarter of 2005. We also intend to reactivate work on the HepatAssist bioartificial liver system by modifying the FDA-approved Phase III IND protocol. Because the anticipated cost of conducting clinical studies for the HepatAssist-2™ system exceeds our current financial resources, we will not, however, be able to commence clinical studies for the HepatAssist-2™ system until we raise additional capital. As a result of our intention to focus our attention and financial resources on conducting studies on SEPET™, submitting FDA filings for SEPET™, and further developing our strategy for revising and activating our HepatAssist-2™ system's FDA applications, we do not currently anticipate that we will devote substantial resources to the development of LIVERAID™ in the near term. The actual amounts we may expend on research and development and related activities during the next 12 months may vary significantly depending on numerous factors, including the results of our clinical studies and the timing and cost of regulatory submissions. However, based on our current estimates, we believe that we have sufficient financial resources to conduct our planned operations for at least the 12-month period following the date of this prospectus.

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 was $450,000, which amount has now been fully paid.

Critical Accounting Policies

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

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

Development Stage Enterprise

We are a development stage enterprise as defined by the Financial Accounting Standards Board's ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises." We are devoting substantially all of our present efforts to research and development. All losses accumulated since inception have been considered as part of our development stage activities.

Patents

We capitalize certain patent rights that are believed to have future economic benefit. These patent rights are amortized using the straight-line method over the remaining life of the patent. Certain patent rights received in conjunction with purchased research and development costs have been expensed. Legal costs incurred in obtaining, recording and defending patents are expensed as incurred.

Stock-Based Compensation

SFAS No. 123, "Accounting for Stock-Based Compensation," as in effect prior to December 2004, established and encouraged the use of the fair value based method of accounting for stock-based compensation arrangements under which compensation cost is determined using the fair value of stock-based compensation determined as of the date of grant and is recognized over the periods in which the related services are rendered. The statement also permitted companies to elect to continue using the current intrinsic value accounting method specified in Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," to account for stock-based compensation. To date, we have used the intrinsic value based method and have disclosed the pro forma effect of using the fair value based method to account for our stock-based compensation. For non-employee stock based compensation, we recognized an expense in accordance with SFAS No. 123 and value the equity securities based on the fair value of the security on the date of grant. In December 2004, the FASB issued SFAS No.123 (revised 2004), "Share-Based Payment". Statement 123(R) requires that the compensation cost relating to a wide range of share-based payment transactions (including stock options) be recognized in financial statements. That cost will be measured based on the fair value of the equity instruments issued. Statement 123(R) replaces FASB Statement No. 123 and supersedes APB Opinion No. 25. As a small business issuer, we will be required to apply Statement 123(R) to our first interim or annual reporting period that begins after December 15, 2005.

Results of Operations

Comparison of Nine-Month Period ended September 30, 2004 to Nine-month Period ended September 30, 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 of $72,030 and $127,828 for the nine month periods ended September 30, 2004 and 2003 represent revenues recognized from a government research grant.

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

Research and development expenses of $1,183,366 and $310,658 were incurred for the nine months ended September 30, 2004 and 2003, respectively. Research and development expenses for the nine months ended September 30, 2004

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

Interest income of $13,367 was earned for the nine months ended September 30, 2004. There was no interest income for the corresponding 2003 period. In September and October 2003, we raised $4,400,000 in the private placement of our securities. As a result, during the nine-month period ended September 30, 2004, we maintained cash balances of over $2.5 million. In addition, we used a portion of the foregoing offering proceeds to repay all outstanding indebtedness, thereby substantially decreasing our interest expense.

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

Comparison of Fiscal Year ended December 31, 2003 to Year ended December 31, 2002.

Revenues for fiscal year 2003 ($138,000) and fiscal year 2002 ($111,000) represented revenues recognized during those periods from two government research grants that we have received. The total amount of the two grants is $304,000, of which we have received $249,000. We anticipate that the balance of the foregoing grants, a total of $55,000, will be recognized as revenues and paid to us during 2004.

General and administrative expenses consist primarily of salaries, office and equipment lease expenses, and professional fees and expenses. General and administrative doubled from $173,000 in fiscal 2002 to $340,000 in fiscal 2003 due to an increase in the number of employees and consultants employed by us in fiscal 2003, and increased professional fees. In addition, professional fees increased during 2003 due to the legal and accounting fees and expenses related to the Reorganization and the additional legal, consulting and accounting fees and expenses related to our status as an active public company. General and administrative expenses are expected to significantly increase during the current fiscal year ending December 31, 2004 due to the lease of additional office space (which new lease went into effect on April 1, 2004), the addition of more employees and consultants (primarily to assist with our financial controls 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 scientific supplies. Research and development expenses remained substantially unchanged from fiscal 2002 to fiscal 2003 because of the limited amount of capital available to us during most of fiscal 2003 and because of our focus on completing the studies sponsored and funded by the SBIR. However, we expect our research and development activities and expenses to increase significantly in the current fiscal year ending December 31, 2004.

Interest expense increased from $1,000 in fiscal 2002 to $243,000 in fiscal 2003 due to the accounting treatment of the $400,000 we borrowed from certain investors during fiscal 2003. The $400,000 aggregate amount of loans were represented by convertible notes that were issued to the investors. In addition to the convertible loans, the investors also received, in the aggregate, warrants to purchase 300,000 shares of our common stock at an exercise price of $1.00 per share. All of the loans were converted by the investors in October 2003 into 400,000 shares of common stock and warrants to purchase an additional 400,000 shares at a price of $2.50 per share. Most of the $243,000 interest expense in fiscal 2003 represented a non-cash expense recognized under accounting rules based on the value of conversion feature of the convertible notes and the value attributed to the warrants. Since the convertible notes have all been converted, no additional interest will be accrued under these notes during the current fiscal year.

Our net loss increased to $886,000 in fiscal 2003 from $495,000 in fiscal 2002 due to the increased operating and other expenses incurred in fiscal 2003. Operating expenses are expected to further increase in the current fiscal year as we increase our operations, while revenues are expected to remain insignificant.

Liquidity and Capital Resources

As of September 30, 2004, we had cash of $2,006,000 and $354,000 of total indebtedness (both long-term and current liabilities reduced by non-cash unvested option expense of $225,000). We do not have any bank credit lines. To date, we have funded our operations primarily from the sale of debt and equity securities and an SBIR government grant. On January 11, 2005. we completed a private placement in which we raised a total of $6,611,905 from the sale of 2,991,812 shares of our common stock and the issuance of warrants to purchase an additional 1,495,906 shares at an exercise price of $2.90 per share. In addition to our own legal and related offering expenses, we paid our placement agent commissions of $253,000 and reimbursed the placement agent and the investors for approximately $55,000 of their expenses and legal fees. The remaining net proceeds of the private placement will be used for working capital purposes.

In April 2004 we purchased certain assets of Circe Biomedical, Inc. including Circe's patent portfolio, rights to a bioartificial liver (HepatAssist)™, a Phase III Investigational New Drug application, selected equipment, clinical and marketing data, and over 400 standard operating procedures and technical validation protocols that have previously been reviewed by the FDA. The purchase price paid for these assets consisted of $200,000 paid at the closing and our agreement to make a second payment, in the amount of $250,000, on the earlier of April 12, 2006 or when we raised gross proceeds of $4 million from the issuance of debt or equity securities. Since the January 11, 2005 private placement satisfied this condition, we paid the remaining unpaid portion of the purchase price for the Circe assets ($250,000) in January 2005. We believe that the original HepatAssist™ bioartificial liver that we acquired can be enhanced by, among other things, increasing the number of pig cells used in the device and by using a different perfusion platform. As a result, we have recently shifted our emphasis from the development of LIVERAID™ to the further development of the HepatAssist™ bioartificial liver (we refer to the enhanced version of this bioartificial liver as our HepatAssist-2™ system). Many of the standard operating procedures and technical protocols that we acquired will be usable by us and will eliminate the need for us to independently develop these procedures and protocols.

We do not currently anticipate that we will derive any revenues from either product sales or from additional governmental research grants during the next twelve months (other than a $38,200 final payment from the prior research grant expected to be received later this year).

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 12 months from the date of this prospectus. However, the estimated cost of completing the development of our products and of obtaining all required regulatory approvals to market our products is substantially greater than the amount of funds we currently have available and substantially greater than the amount we could possibly receive under any governmental grant program. For example, based on our current assumptions, we estimate that the cost of developing SEPET™ will be between $3 million and $4 million. The cost of developing HepatAssist-2™ will be between $15 million and $20 million, and the cost of developing LIVERAID™ will be between $20 million and $25 million. 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 September 30, 2004 for the balance of this fiscal year and for the following fiscal years:

Contractual Obligations	Total	2004	2005	2006	2007 and thereafter
Purchased Research &Development	$ 250,000(1)	—	—	$ 250,000(1)	—
Long-Term Office Leases	$ 325,000	$ 34,000	$ 137,000	$ 77,000	$ 77,000

(1) This amount was paid in January 2005.

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

BUSINESS

We conduct all of our operations through our wholly owned subsidiary, Arbios Technologies, Inc. (“ATI”). We currently have three products in development; a novel extracorporeal blood purification therapy called selective plasma filtration therapy (“SEPET™”) and two extracorporeal, bioartificial liver systems ("HepatAssist-2™" and "LIVERAID™") that incorporate porcine hepatocytes (pig liver cells).

Product Overview

We currently own the rights to two bioartificial liver systems. The system that we have been developing is known as LIVERAID™. This system was developed by this company’s founders, Drs. A. A. Demetriou and J. Rozga. In April 2004, we acquired from Circe Biomedical, Inc., an unaffiliated biomedical company, the rights to another bioartificial liver, known as the HepatAssist system. Certain technologies included in the HepatAssist bioartificial liver were designed and tested in pre-clinical and clinical studies by Drs. A. A. Demetriou and J. Rozga. Both of our bioartificial liver systems are based on substantially similar underlying medical technologies, and both utilize a single-use cartridge that contains pig liver cells and a column that contains certain sorbents. When a patient’s blood is pumped through either the bioartificial liver cartridges, substances normally metabolized by the liver and accumulated in the blood during liver failure move across the porous tubes into two plasma compartments, one of which is filled with pig liver cells and the other that incorporates columns that contain chemical particles (sorbents). The exposure of the viable pig liver cells to plasma will cause toxic substances contained in plasma to be metabolized, thereby reducing their level. In addition, the sorbents also lower the level of pathological blood components, such as ammonia. At the same time, substances produced by pig liver cells move across the porous wall back into the blood compartment. As a result of these two processes (provision of whole liver functions by the pig liver cells and removal of toxins by the sorbents), we believe the levels of pathological and normal blood components will move toward normal ranges. Our belief is confirmed by the results of tests performed using the HepatAssist bioartificial liver system that we acquired and now own, which system is an earlier version of our LIVERAID™ system.

Our HepatAssist-2™ system effectively is the HepatAssist system that has been enhanced by using more pig cells. HepatAssist-2™ is based on a single-use hollow-fiber cartridge that contains pig liver cells and a single-use blood detoxification column that contains charcoal particles. However, we do not expect that the HepatAssist-2™ will use the proprietary perfusion platform that was designed and developed for the HepatAssist system. Instead, we are testing a perfusion platform known as the PERFORMER for use as the platform to provide bioartificial liver therapy. The PERFORMER is a multi-function integrated system capable of supporting extracorporeal blood/plasma/fluid circulation therapies that is manufactured by RanD S.r.l. (Italy). The PERFORMER has been equipped with proprietary software and a tubing set for use with our HepatAssist-2™ system.

LIVERAID™ is based on a single-use cartridge that contains our proprietary designed porous tubes. In addition, the LIVERAID™ cartridge contains approximately three times more pig cells than the cartridge that was originally used in the HepatAssist system. We anticipate that LIVERAID™ cartridge will be attached to a perfusion platform (a machine--such as a kidney dialysis machine-- through which the patient's blood is circulated) that has been customized to operate with this system. At this time, we anticipate that the PERFORMER will be used as the platform to provide LIVERAID™ therapy.

SEPET™ is a single-use cartridge that contains specially designed porous tubes. When a patient's blood is pumped through these tubes, substances normally metabolized by the liver and accumulated in the blood during liver failure move across the porous wall and are discarded. As a result of this blood purification (detoxification) process, we believe that the levels of pathological blood components will move toward normal ranges.

SEPET™, LIVERAID™ and HepatAssist-2™ all rely on single-use cartridges that are placed on a blood perfusion apparatus that is attached to the patient's blood circulation system. For SEPET™ the blood perfusion apparatus is a standard kidney dialysis machine. At the end of the treatments with any of our products, the disposable cartridges are discarded, and new cartridges are used for the next therapy.

Background of our company

Arbios Technologies, Inc., our operating subsidiary, was formed in August of 2000 by Drs. A. A. Demetriou and J. Rozga, two leaders in the field of artificial liver therapy, to develop extracorporeal devices for the treatment of liver failure. As employees of Cedars-Sinai Medical Center, Drs. A. A. Demetriou and J. Rozga previously were involved in the development of a first generation bioartificial liver (known as HepatAssist) that was licensed by Cedars-Sinai Medical Center in 1994 to W.R. Grace & Co. and then subsequently transferred to other entities, including Circe Biomedical, Inc. The prior owners of this technology, including in particular W.R. Grace & Co. and Circe Biomedical, Inc., spent many millions of dollars on the research and development of the original HepatAssist system, the perfusion platform and on the related technologies and operating procedures necessary to bring the product to market. The original HepatAssist system was tested in Phase II/III clinical trials approved by the FDA in patients with fulminant/subfulminant liver failure and primary non-function following liver transplantation. These trials of the original HepatAssist system were the first large (171 patients) prospective, randomized, controlled multi-center trial demonstrating a survival advantage for an extracorporeal liver assist system utilizing pig liver cells. Although treated fulminant/subfuliminat hepatic failure patients with viral and drug-induced liver injury had improved survival compared to controls when adjusted for the effect of confounding factors (such as liver transplantation), the primary clinical end point in the overall study population (survival at 30 days post-transplantation) was not achieved. Accordingly, the HepatAssist system was not approved for marketing, and the FDA requested that a new Phase III clinical study be performed. A new Phase III protocol was prepared and approved by the FDA. However, before these new studies could be undertaken, in 2003 Circe Biomedical, Inc. ceased its operations. In April 2004, we purchased most of the remaining assets of Circe Biomedical, Inc. that related to its bioartificial liver operations, including rights to the original HepatAssist system, the new Phase III protocol that was approved by the FDA, and over 400 manufacturing and quality control and quality assurance standard operation protocols previously reviewed by the

FDA.

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To date, we have funded our operations from funds we raised from the sale of over $12,000,000 of our equity securities and $321,000 of Small Business Innovation Research (SBIR) grants that have been awarded by the United States Small Business Administration. We intend to apply for additional SBIR grants to fund a portion of our research expenditures. However, whether or not we receive additional SBIR grants, we will have to raise substantial additional proceeds to fund our future clinical development expenses and our on-going working capital needs.

Our research offices and laboratories are located at Cedars-Sinai Medical Center, Los Angeles, California. Under our lease agreement and other arrangements with Cedars-Sinai, we have access to all of the key development resources of that leading medical center (e.g., animal facility, surgical core facility, clinical laboratory and others). Cedars-Sinai Medical Center will be considered as one of the clinical testing sites.

We have also entered into various agreements with Spectrum Laboratories, Inc. (“Spectrum Labs”), including research and development agreements and manufacturing agreements. Spectrum is expected to be the manufacturer of the cartridges to be used in both liver assist devices. Spectrum Labs is a company that specializes in the development and manufacture of innovative molecular separation products for the research community and is a supplier of dialysis and ultrafiltration membranes used for biomedical research, molecular biology and clinical diagnostics throughout the world.

Strategy

We have established collaborations with Cedars-Sinai Medical Center and Spectrum Labs that are expected to facilitate the development of SEPET™ and our bioartificial liver systems and could potentially accelerate the clinical testing, regulatory approval and commercialization of those products in the United States and other markets. In addition, in April 2004 we purchased certain assets (including a bioartificial liver system that is the predecessor of our HepatAssist-2™) that we intend to utilize to reduce our development costs and expedite the testing and regulatory process for our bioartificial liver systems. We currently do not intend to engage in the manufacture of either of our products or of the pig cells that would be used in the bioartificial liver systems and intend to rely on third parties for these functions.

We believe that the testing and regulatory approval periods for SEPET™ will be shorter than for either of our bioartificial liver systems because SEPET™ will be evaluated as a medical device that does not contain biological components (such as pig cells that are an integral part of our two bioartificial liver systems). Accordingly, because of the shorter regulatory period and the ability of SEPET™ to operate through the use of a standard, currently available kidney dialysis unit, we expect that the development of SEPET™ will be completed before the development of either LIVERAID™ or HepatAssist-2™ is completed.

We have engaged regulatory consultants and an FDA attorney to counsel us with respect to regulatory approval of our products and are currently in the process of designing clinical trials to demonstrate the safety and efficacy of SEPET™ in treating patients with acute exacerbation of chronic liver failure. We are also preparing an investigational device exemption for SEPET™ for submission to the FDA. See, "Governmental Regulation," below.

We have already performed *in vitro* and *in vivo* testing of the SEPET™ and LIVERAID™ prototype devices and currently plan to commence clinical testing of SEPET™ during 2005. We anticipate that we will be able to file an application requesting market approval of the SEPET™ in late 2006. We are currently evaluating the possibility of conducting clinical studies of the HepatAssist-2™ system under a modified version of the FDA- approved Phase III IND protocol that we recently acquired. Since we are still currently developing our clinical and regulatory strategies for our two bioartificial liver systems, we cannot estimate when an application requesting marketing approval of either systems will be filed with the FDA.

The April 2004 acquisition of the assets of Circe Biomedical has potentially provided us with new opportunities for the development of a bioartificial liver. The Circe bioartificial liver device that we acquired consisted of the following four distinct components that will be useful to the development of our bioartificial liver products: (1) *FDA-approved standard operating procedures*. These are standard operating procedures for production of porcine cells including harvesting, freezing, and thawing of the cells (we expect that the cells used in our bioartificial liver systems will be derived from the same herd of pigs previously used by Circe in its Phase III trial of HepatAssist.). Because these procedures and protocols have already been approved by the FDA, we will not have to establish our own similar protocols and obtain the FDA's approval for those protocols, thereby saving time and money. In addition, the herd of pigs that Circe used has already been tested and approved by the FDA for health status, safety, biological compatibility and functionality in human patients. By using cells from the same herd of pigs that the FDA had previously approved, we do not expect to have to apply for, and obtain, the FDA's approval for the safety of these pigs, thereby eliminating another time consuming and expensive process to obtaining approval for our bioartificial liver systems. (2) *The cartridge used in the Phase III trial of HepatAssist*. While we could use this existing, FDA-approved cartridge, we intend to request the FDA's approval to increase the number of pig cells that the cartridge could contain, which increase we believe will improve the functionality of the system. (3) *An FDA approved Phase III protocol*. We intend to modify this protocol and submit the modified protocol to the FDA for approval. (4) *The HepatAssist perfusion platform.* The HepatAssist perfusion platform is Circe's specially designed machine that pumped the patient's plasma through the HepatAssist cartridge. This machine was used in the Phase III trial of HepatAssist. We believe that there currently are other existing machines that are more efficient and easier to use than Circe's machine. Accordingly, we are testing a machine called The PERFORMER that has been equipped with proprietary software and our tubing to enable the machine to work with our bioartificial liver products. We expect that the PERFORMER will become the platform for both our HepatAssist-2™ and LIVERAID™ systems.

Based on our current assumptions, we estimate that the cost of developing SEPET™ into a commercial product will be between $3 million to $4 million. The cost of developing HepatAssist-2™ into a commercial product will be between $15 million and $20 million, and the cost of developing LIVERAID™ into a commercial product will be between $20 million and $25 million. These amounts, which could vary substantially if our assumptions are not correct, and are well in excess of the amount of cash that we currently have available to us. See, "Risk Factors."

Liver Function Background

The liver controls, or affects, almost every aspect of metabolism and most physiologic regulatory processes, including protein synthesis, sugar and fat metabolism, blood clotting, the immune system, detoxification (alcohol, chemical toxins, drugs) and waste removal. Loss of liver function is a devastating and life threatening condition. Liver failure affects all age groups and may be due to many causes, including viral infection (hepatitis), ingestion of common medications, alcohol, and surgical liver removal for trauma and cancer.

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