

ARBIOS SYSTEMS INC  
Form SB-2  
February 09, 2005

As filed with the Securities and Exchange Commission on February 9, 2005

Reg. No. 333-\_\_\_\_

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

**FORM SB-2**

**REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933**

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**Arbios Systems, Inc.**  
(Name of Small Business Issuer in its Charter)

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**Nevada**  
(State of jurisdiction of  
incorporation or organization)

**3841**  
(Primary Standard Industrial  
Classification Code Number)

**91-1955323**  
(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)

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**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:**

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

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

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

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

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

**CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered	Amount to be registered	Proposed maximum offering price per unit <sup>(1)</sup>	Proposed maximum aggregate offering price <sup>(1)</sup>	Amount of registration fee <sup>(1)</sup>
Common stock, par value \$0.001	4,602,122 (2)	\$2.95	\$13,576,259	\$1,597.93

(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](http://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.





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 hereby 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

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(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.

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*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.



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 or 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 expressions. Readers are cautioned not to place undue reliance on these forward-looking statements, which are based on the information available to management at this time and which speak only as of this date. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. For a discussion of some of the factors that may cause actual results to differ materially from those suggested by the forward-looking statements, please read carefully the information under “Risk Factors” beginning on page 4.



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

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

### **USE OF PROCEEDS**

We will not receive any proceeds from the sale 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:

<b>Quarter Ending</b>	<b>High</b>	<b>Low</b>
December 31, 2003 <sup>(1)</sup>	\$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.”

## **Holder**

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 SEPE<sup>TM</sup> 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)<sup>™</sup>, 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<sup>™</sup> 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<sup>™</sup> to the further development of the HepatAssist<sup>™</sup> bioartificial liver (we refer to the enhanced version of this bioartificial liver as our HepatAssist-2<sup>™</sup> 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<sup>™</sup> will be between \$3 million and \$4 million. The cost of developing HepatAssist-2<sup>™</sup> will be between \$15 million and \$20 million, and the cost of developing LIVERAID<sup>™</sup> 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:

<b>Contractual Obligations</b>	<b>Total</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007 and thereafter</b>
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/subfulminant 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 HeparAssist-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 HeparAssist-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.



Currently, there is no direct treatment for liver failure, except for a successful liver transplant. There is, however, a current scarcity of donor livers, and approximately two thousand patients on the waiting list for donor livers die annually before receiving liver transplants. Treatments with currently available technologies (e.g., blood purification methods) are, at best, short-term measures, and none of them has achieved wide clinical use or ability to arrest or reverse liver failure and improve survival. As a consequence, liver failure patients must still either undergo liver transplantation or endure prolonged hospitalization with low probability of survival. In addition, many patients do not qualify for transplantation. Still others do not recover after transplantation because of irreversible brain damage caused by liver failure. Although the liver has a remarkable capacity for regeneration, the repair process after massive liver damage is markedly impaired.

There is a need to develop artificial means of liver replacement and/or assistance with the aim of either supporting patients with borderline functional liver cell mass until their liver regenerates or until a donor liver becomes available for transplantation. Such an “artificial liver” should also support patients during recovery after transplantation with marginal livers and after extended liver resections for trauma or cancer. To achieve these effects, an effective liver support system should be able to lower blood levels of substances toxic to the brain and liver and to provide whole liver functions, which are impaired or lost.

It is generally believed that liver support at this level of complexity requires utilization of viable isolated liver cells (hepatocytes). The founders of this company as well as investigators not associated with this company have demonstrated *in vitro* and in animal models of liver failure that cell-based bioartificial livers can provide whole liver functions. However, only a few bioartificial livers were tested in humans and it remains to be seen whether systems utilizing hepatocytes as the only means of liver support are effective. We believe that in order to provide the maximum support for the failing liver, porcine hepatocyte therapy should be combined with blood detoxification.

Each of our bioartificial liver systems (LIVERAID™ and HepatAssist-2™) was designed to become an advanced effective application of the basic bioartificial liver concept. In these bioartificial liver systems, liver cell therapy (porcine hepatocytes) is combined with blood detoxification (sorbent based plasma therapy). Depending on the cause of liver disease, severity of illness and deficiency of specific liver functions, these bioartificial liver modes of therapy can be provided individually, simultaneously or sequentially. Because of these features, we believe our bioartificial liver technology is well suited to treat patients with liver failure of all causes and severity, including those requiring maximum liver support. While the original HepatAssist Phase II/III clinical trial demonstrated an increase in patient survival in patients with viral and drug-induced fulminant/subfulminant hepatic failure, a new Phase III clinical trial will be needed before our HepatAssist-2™ system (which is an enhanced version of the original HepatAssist system) can be used by human patients. Pre-clinical data for our LIVERAID™ system has indicated that, as with HepatAssist, this novel bioartificial liver system can improve heart rate and blood pressure, clearance of ammonia and ICG (a liver function test) and prolonged survival time of pigs with terminal liver failure. The pre-clinical data provide evidence of feasibility and efficacy in laboratory testing and in animal studies. However, the efficacy of the LIVERAID™ system still needs to be demonstrated in FDA-approved clinical trials before it can be used by human patients.

In liver failure patients, there is a need for an effective blood purification therapy that will clear the blood of toxins. SEPET™ (selective plasma filtration therapy) is a novel form of such therapy. During selective plasma filtration therapy, the plasma fraction containing substances that are toxic to the brain, the liver and other internal organs and tissues would be removed from patient blood and replaced with normal human plasma.

### **The Products We Are Developing**

We currently are developing two novel treatments for acute and chronic liver failure. We believe that both our SEPET™ and either of our bioartificial liver systems may:

- Help keep liver failure patients alive and neurologically intact before, during and immediately after transplantation.
  - Allow, in selected cases, survival without a transplant (a “bridge” to liver regeneration).
- Support patients during periods of functional recovery and regeneration after extensive removal due to liver trauma and/or cancer.
  - Accelerate recovery from acute exacerbation of chronic liver disease.
    - Shorten length of stay in intensive care units.
      - Shorten hospital stay.
      - Reduce the cost of care.
    - Reduce intractable itching associated with severe jaundice.

We believe that SEPET™ and our bioartificial liver systems can achieve these effects because it can lower blood levels of substances that are toxic to both the brain and liver. However, proof of feasibility is lacking at this time, and the clinical utility of this product still needs to be demonstrated in patients with acute liver failure.

We own certain technologies and rights related to our products, and have licensed certain other technologies. See “Patents and Proprietary Rights” below, for a description of the rights that we own and have licensed.

### **SEPET™**

We are developing SEPET™ (selective plasma filtration therapy) as a blood purification measure to provide temporary liver support during acute liver failure and acute exacerbation of chronic liver disease. Selective plasma filtration therapy will be provided through our single-use, disposable cartridge that contains a bundle of hollow fibers made of bio- and hemo-compatible material and being capable of sieving substances with molecular weight of up to 100 kDa. The importance of using fibers with this sieving characteristics is that most hepatic failure toxins have a molecular weight that is less than 100 kDa, while all "good" blood components have molecular weight greater than 100 kDa. At present, Spectrum Labs is the manufacturer of these disposable cartridges. See “Business—Manufacturing,” below. The SEPET™ system is designed for use with any commercially available kidney dialysis unit or other similar machines that utilize hollow-fiber cartridges. Accordingly, no apparatus needs to be developed or manufactured for SEPET™. Accessory components for the SEPET™ system (e.g., tubings, connectors, pressure gauges, etc.), will consist of standard components that are currently used in renal dialysis. We expect that these accessory components will be manufactured for us by third-party vendors.



During therapy, an ultrafiltrate containing toxins and mediators of inflammation with molecular weight of 100 kDa or less will be recovered from the side port of the cartridge, while at the same time, commercially available (e.g., blood bank) fresh frozen plasma and/or its synthetic substitute will be administered to the patient.

We believe that as a result of these two processes, the levels of pathological and normal blood components present in the patient's circulation will move toward normal ranges, thereby facilitating recovery from liver failure. Based on published medical literature, rapid and efficient blood detoxification is expected to protect the liver, brain and other organs against further injury, accelerate healing of the native liver and improve its residual functions.

### **LIVERAID™ And HepatAssist-2™ Bioartificial Liver Systems**

We currently have two bioartificial liver systems under development that have been designed to function similarly. Although there are distinctions between the two systems as described below, both systems are designed to (i) provide liver cell functions by utilizing viable pig liver cells that are housed in specially designed cartridges and (ii) detoxify blood. Since it has been scientifically established that pig liver cells perform liver functions when maintained in specially designed cartridges outside of the human body, our bioartificial liver cartridges are designed to bring human plasma into contact with viable pig liver cells in a manner similar to that observed in the normal human liver inside the body in order to provide liver functions to the patient. In addition, both of our bioartificial liver systems are designed to lower the levels of pathological blood components (through charcoal and other purification sorbents).

We have designed and intend to demonstrate that our HepatAssist-2™ and LIVERAID™ products can provide temporary liver support during acute liver failure and acute exacerbation of chronic liver disease. The LIVERAID™ utilizes a proprietary multi-compartment hollow fiber module incorporating viable pig liver cells and a blood detoxification circuit. The module is attached to a base instrument pumps the patient's plasma through the LIVERAID™ cartridge. The hollow fibers are made of a polyethersulfone membrane or a similar material and assembled using our proprietary fiber-within-a-fiber geometry. This geometry allows for the integration of two different functions within a single module. Depending on the causes of liver disease, severity of illness and deficiency of specific liver functions, LIVERAID™ is designed to offer liver cell therapy, blood detoxification or a combination thereof. During treatment, individual modes of therapy may be added or removed.

The HepatAssist-2™ system also incorporates several proprietary components and technologies into an integrated liver assist system, including a hollow fiber cartridge with porcine hepatocytes and a plasma re-circulation circuit that incorporates sorbents. However, since the HepatAssist-2™ is based on the HepatAssist system, its cartridge does not contain our proprietary fiber-within-a-fiber geometry

At present, most bioartificial liver systems (including the original HepatAssist system) are filled with plasma rather than blood. Both the LIVERAID™ and HepatAssist-2™ systems are designed to be perfused with a patient's plasma to prevent leakage of pig cells and cell debris into patient blood circulation. The platform for our bioartificial liver systems will utilize an oxygenator, sorbent column(s), and a disposable tubing kit. These components are available from third party vendors.

A critical aspect of both the LIVERAID™ and HepatAssist-2™ technology include the source and method of procurement of liver cells, the cryopreservation (freezing) of the liver cells, the storage of the liver cells, the proprietary plasma re-circulation loop incorporating the cell cartridge and sorbents, and the standard operating procedure protocols and quality control and programs related to the foregoing. We currently own or have licensed numerous proprietary technologies and methods for sourcing and using hepatocytes, which technologies and methods apply to both our LIVERAID™ and HepatAssist-2™ systems. The following addresses our current plans and procedures regarding viable liver cells (hepatocytes).

**Hepatocyte donors.** Ideally, human hepatocytes should be used in a bioartificial liver. However, there is a shortage of organ donors and published data demonstrated that pig liver cells outperform animal and human liver cell lines, including those derived from liver cancers. In addition, use of human cancer-derived cells raises safety concerns. At this time, we intend to utilize normal pig liver cells.

**Hepatocyte harvest.** The founders of our ATI subsidiary and Circe Biomedical, Inc. developed certain semi-automated methods for large-scale harvest of pig hepatocytes. The methods of harvesting and collecting liver cells are covered by four patents, which patents we either have acquired from Circe and now own or have licensed from Cedars-Sinai Medical Center.

**Hepatocyte storage.** Hepatocyte storage, quality control and shipment of cells to treatment sites are best achieved by use of cell freezing (i.e., cryopreservation). Cryopreservation also provides greater protection from bacterial and viral contamination because frozen cells can be stored until microbiologic testing is completed and cells are then released for clinical use. Prior to use, cells are rapidly thawed and their viability is tested. The patented hepatocyte cryopreservation technology is now owned by us and by Cedars-Sinai Medical Center, who has licensed this technology to us.

The pig liver cells will be harvested from young purpose-bred, pathogen-free, vaccinated pigs raised in an United States Department of Agriculture (“USDA”) certified facility specifically for biomedical research purposes. Each batch of cryopreserved pig liver cells will be released for clinical use only after proper verification of biosafety and viability/functionality of the cells. We acquired all of the required laboratory and quality assurance protocols from Circe Biomedical, which protocols were previously reviewed by the FDA and deemed to be in compliance with FDA requirements.

HepatAssist-2™ and LIVERAID™ are designed to be used in the same manner as any other plasma therapy device. In a typical clinical procedure, the operator will install bioartificial liver components (cell cartridge, oxygenator, sorbent detoxification column(s), tubing kit) into the blood/plasmaperfusion platform. Approximately 15 billion viable pig hepatocytes will be seeded into the extra-fiber space through the cell module side ports. At the start of treatment, the platform will be attached to the patient and the bioartificial liver system will be perfused with the patient’s oxygenated plasma. In the LIVERAID™ system, in addition to the foregoing, fresh frozen plasma will be recirculated through the sorbent columns in the diafiltration circuit. At the end of treatment, the disposables will be discarded in the normal manner that all other biohazardous waste products (such as syringes and bandages) are handled and disposed of. No special governmental regulations have been required, or are expected, to dispose of the used cartridges and disposable products.

We expect to demonstrate that during LIVERAID™ or HepatAssist-2™ therapy, substances normally metabolized by the liver and accumulated in the blood during liver failure will diffuse freely across the porous membrane into the compartment containing pig liver cells. At the same time, products of pig liver cell metabolism will diffuse back into the plasma compartment and then into the blood circuit. It is anticipated that as a result of these two processes, the levels of pathological and normal blood components present in the patient’s circulation will move toward normal ranges, thereby facilitating recovery from liver failure. Additional therapeutic benefits may be provided by blood purification (detoxification) therapy. In this mode of therapy, small and large protein-bound toxins, which accumulate in the blood during liver failure are expected to be removed by sorbents. Blood detoxification is believed to protect the liver, brain and other organs against further injury, accelerate healing of the native liver and improve its residual functions. Decreased blood toxicity is also expected to prolong the life and metabolic activity of pig hepatocytes in the bioartificial liver modules.

## Product Advantages

We believe that SEPET™ as a blood purification therapy will be more effective than sorbent-based devices (e.g., charcoal, resin, silica, etc.) and whole plasma exchange therapy because only the plasma fraction containing known toxins of hepatic failure is being removed and discarded during SEPET™ therapy. In contrast, sorbent-based blood purification is not toxin-specific, and in the case of charcoal sorption is limited because of the protective coating of the charcoal particles. Once development of SEPET™ is completed and its use is approved, we believe that it will be able to be used with currently available hospital kidney dialysis systems to provide selective plasma filtration therapy, which may offer the following advantages:

- Ease of use. The systems bring user friendliness (e.g., pump integration, automation and an intuitive user interface) to traditionally complex liver support procedures.
- Simplicity. Kidney dialysis systems are routinely used and, therefore, there may be no need for extensive personnel training for use of these similar systems in the SEPET™.
- Low cost. The cost of therapy is expected to be lower than with any other liver assist device that is currently under development because the machine to which the SEPET™ cartridge can be attached to a standard machine (such as a kidney dialysis machine) with commercially available tubing. Therefore, unlike other devices, no special equipment is required.
- No Intensive Care Unit needed to provide treatment. SEPET™ may become available for treatment of patients with lower degree of liver failure outside of intensive care unit settings. We do not believe that any changes will have to be made to SEPET™ or the dialysis system in order for SEPET™ to become available outside of intensive care unit settings.

To our knowledge, LIVERAID™ and HepatAssist-2™ are the only liver assist devices under development that are capable of providing both liver cell functions and blood purification either simultaneously or sequentially in a versatile and customized manner depending on the cause and severity of liver failure.

Drs. Demetriou and Rozga, the founders of ATI and the principal stockholders of this company, have previously demonstrated that cryopreserved pig hepatocytes remain alive (>80% viability) after thawing. Moreover, they quickly aggregate, forming liver-like 3-D units, and resume basic functions (e.g., drug metabolism) at levels comparable to those seen in intact livers. Drs. Demetriou and Rozga have also reported that treatment of animals and patients with fulminant hepatic failure with a bioartificial liver loaded with freshly thawed pig hepatocytes prolonged life, alleviated intracranial hypertension and improved blood chemistry. In addition, in experimental animals bioartificial liver therapy improved native liver function and triggered mechanisms regulating liver regeneration. In addition, treatment with either of our two bioartificial liver systems can be commenced with 2-3 hours of patient preparation, thereby making bioartificial liver therapy available on demand. In contrast, we believe other liver assist devices under development require longer time for preparation prior to patient treatment (up to several days in some instances).

## Clinical Utility

The clinical performance of the SEPET™ and LIVERAID™ has not been assessed yet. However, *in vivo* large animal studies have provided proofs of feasibility and clinical efficacy for LIVERAID™. Additionally, virtually all basic aspects of these new technologies (effect of blood purification, liver cell function, utility of hollow-fiber membranes, performance of a design incorporating both pig liver cells and sorbent) have been validated in the past by Drs. Demetriou and Rozga, the founders of ATI, and other investigators. Furthermore, the animal and clinical data generated and published to date on the first-generation bioartificial liver, indicate that the basic concept of a

bioartificial liver utilizing cryopreserved pig liver cells and blood detoxification, is valid and that repeated 6-hour bioartificial liver treatments are safe and yield measurable therapeutic benefits. Accordingly, we believe that our novel, next-generation products will represent improvements and/or enhancements of earlier technologies.

Our HepatAssist-2™ system is an enhanced version of the original HepatAssist system. The safety and efficacy of the original HepatAssist were evaluated in a prospective, randomized, controlled, multi-center FDA-approved clinical trial. A total of 171 patients, 86 in the control group, and 85 bioartificial liver group, were enrolled. Patients with fulminant/subfulminant hepatic failure and primary non-function following liver transplantation were included. Data were analyzed with and without accounting for the following confounding factors: liver transplantation, time to transplant, cause of the disease or condition, disease severity, and treatment site. For the entire patient population, survival at 30 days was 71% for bioartificial liver vs. 62% for the control group. When survival was analyzed accounting for confounding factors (e.g., liver transplantation, survival prior to transplantation), in the entire patient population, there was no difference between the two groups. However, survival in 147 fulminant/subfulminant hepatic failure patients was significantly higher in the bioartificial liver compared to the control group. Thus, this was the first prospective, randomized, controlled trial of an extracorporeal liver support system that demonstrated safety and improved survival in patients with fulminant/subfulminant hepatic failure.

### **Market Opportunity**

There is an urgent need for artificial means of liver replacement and/or assistance to facilitate recovery from liver failure without a transplant. An effective liver assist device could also help maintain liver failure patients alive until an organ becomes available for transplantation. The SEPET™ and LIVERAID™/HepatAssist-2™ systems are designed to treat patients with liver failure of all causes and severity, including acute exacerbation of chronic liver disease.

The patient and market opportunity is substantial and underserved. According to the American Liver Foundation, 25,000,000 Americans - one in every 10 - are or have been suffering from liver and biliary diseases. According to the National Center For Health Statistics published for 2000, there were 360,000 hospital discharges for patients with chronic liver disease or cirrhosis. Of those, 27,035 died (10<sup>th</sup> leading cause of death in males and 12<sup>th</sup> in females; 4<sup>th</sup> cause of death in persons aged 45 - 54 years) because no donor liver was found or because they had contraindications to transplantation. During 2001 alone, 12,207 people died in the United States due to alcoholic liver disease and 5,652 individuals died as a consequence of other diseases of liver (inflammatory, drug-induced, acute hepatitis, unspecified, etc.). Approximately 3.9 million Americans are chronically infected with the hepatitis C virus and an estimated 25,000 people each year are infected with the hepatitis C virus. At the same time, 10,000 - 12,000 deaths occur annually due to hepatitis C virus infection. Hepatic decompensation, as a result of chronic hepatitis C virus infection, is the leading cause of liver transplantation. In 2002, there were only 4,200 liver donations in the United States versus 6,900 additions to the waiting list. As of September 1, 2004, the liver transplant waiting list contained 17,485 individuals. According to National Institutes of Health and the American Association for the Study of Liver Diseases, 5,000 deaths occur annually as a consequence of hepatitis B virus infection.

Based on these data, we estimate that more than 200,000 extracorporeal liver support treatments may be needed annually in the United States alone to help keep liver failure patients alive until either an organ becomes available for transplantation or the native liver recovers from injury. We believe that SEPET™ and our bioartificial liver systems may address this demand.

At present no direct treatment for liver failure is available and such patients must receive a liver transplant or endure prolonged hospitalization with significant mortality. Moreover, no prognostic test is available that would help predict which liver failure patient is likely to survive on medical therapy alone. Due to the critical nature of liver failure and the resulting adverse effects on other organs, the hospitalization costs can be as high as \$20,000 per day. In fact, it is estimated that the in-patient cost of liver failure treatment can reach \$200,000 per episode without a transplant. While liver transplants have significantly increased the chances of survival for patients with liver failure, due to a severe shortage of donor livers, less than 10% of liver failure patients received a transplant. Further, many liver failure patients were excluded from the waiting list because of alcohol or drug abuse, cancer, cardiovascular disease or inadequate post-operative support by family or others.

At this time, based on the preliminary information available to us, we estimate that the cost of a single treatment with the SEPET™ therapy could be within a \$2,000 - \$4,000 range and that cost of the bioartificial liver therapy could be approximately \$20,000. We anticipate that SEPET™ and/or bioartificial liver therapy will have to be repeated up to 5-7 times before a satisfactory clinical outcome is obtained. Based on these estimates and the above mentioned projections, the potential U.S. market for SEPET™ and bioartificial liver is significant, with similar opportunities in countries outside the U.S. However, we have not confirmed the potential size of these markets through an independent marketing study.

If we are successful in demonstrating the clinical utility of one or both of our products, liver failure patients treated with our products may be spared liver transplantation and the need for life long immune-suppression. In addition, these patients can be treated outside of the intensive care unit and could be discharged from the hospital after shorter stays, all of which would reduce costs for healthcare providers and generate a demand for the use of these products.

In addition to the U.S., the potential market for our products includes Europe and Asia. According to World Health Organization, globally, an estimated 170 million persons are chronically infected with the hepatitis C virus (8.9 million in Europe, 32.3 million in South-East Asia, 62.2 million in Western Pacific). At the same time, an estimated 3 to 4 million persons are newly infected each year. Hepatitis B virus infection causes nearly 1,000,000 deaths annually. It is most common in Asia, Africa and Middle East. Of the 2 billion people who have been infected with the hepatitis B virus, more than 350 million have chronic (lifelong) infections. These chronically infected persons are at high risk of death from cirrhosis of the liver and liver cancer. In China, liver disease represents a pressing health problem and the need for an effective liver support therapy is more urgent than in most other markets. Although epidemiological data on hepatitis C virus and hepatitis B virus infection in China are not publicly available, we believe there are approximately 200 million carriers of the hepatitis virus B or C in China, and primary liver cancer is a common malignancy.

### **Sales, Marketing & Distribution**

We currently do not have any agreements in place to market any of our products if and when those products are commercially released, and we do not currently expect to establish an in-house marketing and sales program to distribute our products. We currently expect to outsource the sales, marketing and distribution of our products to third parties who specialize in the sales, marketing and distribution of medical products. Alternatively, we may enter into strategic alliances with larger medical companies or license the rights to our products to such larger companies. We currently expect that our products will be marketed in the U.S., Europe and Asia.





## Manufacturing

In December 2001 we entered into a manufacturing and supply agreement with Spectrum Laboratories, Inc. for the future manufacture of our LIVERAID™ cartridges. Under that agreement, we agreed that Spectrum Labs will manufacture the hollow fiber cartridges with fiber-in-fiber geometry that we will need for the LIVERAID™ bioartificial liver. The agreement provides that the price of the hollow fiber-in-fiber cartridges to be sold by Spectrum Labs to us will be determined by good faith negotiations between the parties. We have agreed that we will not purchase cartridges with fiber-in-fiber geometry from any other manufacturer unless Spectrum Labs is either unable or unwilling to manufacture the cartridges. To date, Spectrum Labs has manufactured all of the LIVERAID™ cartridges that we have been using in the development of that bioartificial liver device. Currently, the final step in manufacturing the LIVERAID™ cartridges is completed manually, which has resulted in a high incidence of rejected cartridges and a lengthy manufacturing period. These 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 acquire or develop an automated manufacturing process for the LIVERAID™ cartridges. However, since such an automated 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 an automated 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. While we have identified other possible manufacturers of the LIVERAID™ cartridges, it is uncertain if any of those other companies would want to manufacture the cartridges for us, and if so, on what terms.

We currently do not have a manufacturing arrangement for the cartridges used in the HepatAssist-2™ system. However, the HepatAssist-2™ cartridge is based on a conventional single-bundle hollow-fiber technology and a number of third party manufacturers, including Spectrum Laboratories, Inc. can produce these cartridges.

With respect to cartridges that we expect will be needed for SEPET™, we anticipate that such cartridges will be commercially manufactured by either Spectrum Labs or a manufacturer of clinical hemodialyzers. Additional disposable components (tubing kits) may also be manufactured by third party subcontractors.

The kidney dialysis unit that will be used as a platform for SEPET™ therapy is not expected to require any technical adjustments. Since pressure monitors and hemoglobin detectors are standard in kidney dialysis systems, additional safety features may not be required. Since the existing kidney dialysis units will not be affected, only the kidney dialysis cartridge will be replaced by a SEPET™ cartridge, no consents will have to be obtained from the manufacturers of those units, and no additional insurance is expected to be required to use those units. Blood oxygenator/heat exchangers are available from third party vendors who sell these products.

The platform we currently expect to use for LIVERAID™ will be an existing instrument manufactured and marketed by an unaffiliated medical device manufacturer. The instrument we expect to use has been certified and approved in Europe for bioartificial liver use. However, in order to use this existing platform for bioartificial liver therapy, the instrument must be outfitted with customized software and with hook-ups and components (tubing set) that are specifically designed for use with LIVERAID™ and HepatAssist-2™.

The pig liver cells will be harvested from young purpose-bred, pathogen-free, vaccinated pigs raised in an USDA certified facility specifically for biomedical research purposes. We have identified a facility that currently breeds pigs that meet the FDA's requirements. The liver cells will be harvested and cryopreserved under aseptic conditions using our proprietary technology as well as commercially available equipment.

As regards to cell procurement/cryopreservation for bioartificial liver use, we do not yet own our own specialized and certified bio-secure porcine liver cell manufacturing plant. Currently, we expect to subcontract the manufacture of the bioartificial liver porcine liver cells needed to conduct clinical trials and during early stages of commercialization from one or more third parties who already manufacture such cells. At the conclusion of Phase II/III clinical testing of the LIVERAID™ or Phase III clinical testing of HepatAssist-2™ (if we obtain FDA approval to conduct such studies under a modified version of the FDA-approved Phase III IND protocol), we will have to determine whether to build a cell procurement facility to meet the expected requirements for commercial sales, which will require a substantial capital investment, or to continue to purchase such cells from third parties. This decision will be based on technical evaluation of the project as well as an economic evaluation of company performance.

### **Patents and Proprietary Rights**

Bioartificial Liver Rights. Our subsidiary, ATI, has obtained exclusive, worldwide rights from Cedars-Sinai Medical Center and Spectrum Labs to seven issued U.S. patents protecting LIVERAID™ and accompanying cell procurement/cryopreservation technologies. The founders of ATI (Dr. Rozga and Dr. Demetriou) are co-inventors of both the semi-automated methods for large-scale production of isolated pig/human hepatocytes and cryopreservation of isolated pig/human hepatocytes. Our key proprietary LIVERAID™ technologies include the following licensed patents:

- (1) A hollow fiber module with unique fiber-in-fiber geometry (US Patent #5,015,585 "Method and Apparatus for Culturing and Diffusively Oxygenating Cells on Isotropic Membranes" issued on May 14, 1991). We have licensed this patent from Spectrum Labs.
- (2) A bioartificial liver system in which liver cell therapy and blood detoxification are integrated in a single fiber-in-fiber module (US Patent # 6,582,955 B2 for "Bioreactor With Application as Blood Therapy Device" issued in June 2003). We have licensed this patent from Spectrum Labs.
- (3) Semi-automated large-scale liver cell procurement technology (US Patent #5,888,409 for "Methods for Cell Isolation and Collection" issued on March 30, 1999). We licensed this patent from Cedars-Sinai Medical Center.
- (4) Liver cell procurement technology (US Patent #5,968,356 for "System for Hepatocyte Cell Isolation and Collection" issued on October 19, 1999, and related European Patent #0 830 099 for "Apparatus and Method for Cell Isolation and Collection"). We licensed this patent from Cedars-Sinai Medical Center.
- (5) Liver cell cryopreservation technology (US Patent #6,140,123 for "Method for Conditioning and Cryopreserving Cells" issued on October 31, 2000). We licensed this patent from Cedars-Sinai Medical Center.

(6) A bioartificial liver device with integrated tubes (“Bioreactor and Related Method” US Patent #6,242,248 B1 issued on June 5, 2001). We licensed this patent from Cedars-Sinai Medical Center.

(7) A bioartificial liver device (“Bioreactor and Related Method” US Patent #6,207,448 B1 issued on March 27, 2001). We licensed this patent from Cedars-Sinai Medical Center.

*Cedars-Sinai Medical Center Licenses.* On June 19, 2001, ATI entered into an agreement with Cedars-Sinai Medical Center pursuant to which Cedars-Sinai granted to ATI exclusive and worldwide rights to the foregoing five patents and to certain other technical information. These rights are and remain exclusive over the legal life of the various patents and include, subject to limitations, the right to sublicense the patent rights to third parties. In order to maintain its rights under the license, ATI is required to expend an aggregate amount of \$1,760,000 in research and development expenses toward the development and promotion of products derived from the patents. ATI’s research and development commitment remains in full force and effect until June 30, 2008. Under the terms of the license, ATI is obligated to meet expenditure milestones per annum through 2008 in order to reach the required \$1,760,000. If ATI expenditures exceed a given year’s milestone, however, such excess may be carried over to the following year. To date, we have spent approximately \$1,010,000 towards the fulfillment of this obligation. Additionally, Cedars-Sinai Medical Center will have nonexclusive rights to any products derived from the patents. We will have to pay Cedars-Sinai Medical Center royalty fees equal to 1.5% of the gross sales price of royalty bearing products. From the third to tenth years of the license, the royalty fee percent will phase out evenly to 0%. Cedars-Sinai Medical Center is a stockholder of this company. See “Certain Relationships and Related Transactions.”

*Spectrum Labs License Agreement.* On December 26, 2001, ATI entered into a license agreement with Spectrum Labs, pursuant to which Spectrum Labs granted to ATI an exclusive, worldwide license to develop, make, use and distribute products based on Spectrum Labs’ hollow fiber-in-fiber technology, solely for applications in ATI’s liver assist devices. The license includes the rights to the two issued patents referred to above. Provided that ATI purchases the hollow fiber cartridges that it expects that it will need for its products from Spectrum Labs, ATI will not have to pay a royalty for the license. In the event that Spectrum Labs is not the manufacturer of the hollow fiber cartridges, ATI will have to pay Spectrum Labs a royalty for the license (see, “Business--Manufacturing,” above). Unless the Spectrum Labs license agreement is terminated sooner due to a breach of the license, the term of the license will continue until the expiration of the two patents. Spectrum Labs also agreed to grant ATI a right of first refusal to obtain a license to make, use, develop or distribute products based on Spectrum Labs’ technology other than in liver assisted products, provided that such other products are in the fields of artificial blood therapy and bioprocessing and therapeutic devices. See “Certain Relationships and Related Transactions.”

In addition, in April 2004, we acquired from Circe Biomedical, Inc., a portfolio of intellectual properties, including certain U.S. and foreign patents, applicable to (i) the HepatAssist bioartificial liver that Circe was developing, including various patents related to the harvesting and handling of cells to be used in the bioartificial liver, and (ii) Circe’s artificial pancreas system. We do not intend to use or maintain certain of the bioartificial liver patents or any of the artificial pancreas patents. The following is a list of the patents and patent applications that we acquired from Circe Biomedical and that we expect to maintain and use with our bioartificial liver system:

- (1) Process for preparing isotropic microporous polysulfone membranes.US Patent #4970034 (issued on November 13, 1990).

- (2) Continuous Spinning of Hollow-Fiber Membranes Using Solvent Mixture as Precipitation Medium. US Patent #5151227 (issued on September 29, 1992).
- (3) Method and Apparatus for Casting Hollow Fiber Membranes. US Patent #5298206 (issued on March 29, 1994).
- (4) Apparatus for Bioprocessing a Circulating Fluid. US Patent #5643794 (issued on July 1, 1997).
- (5) Dual Fiber Bioreactor. US Patent #5712154 (issued on January 27, 1998).
- (6) Cryopreserved Hepatocytes and High Viability and Metabolic Activity. US Patent #5795711 (issued on August 18, 1998).
- (7) Closed System for Processing Cells. US Patent #5858642 (issued on January 12, 1999).
- (8) Method of Thawing Cryopreserved Cells. US Patent #5895745 (issued on April 20, 1999).
- (9) High Flow Technique for Harvesting Mammalian Cells. US Patent #5912163 (issued on June 15, 1999).
- (10) Removal of Agent From Cell Suspension. US Patent #6068775 (issued on May 30, 2000).
- (11) Method for Cryopreserving Hepatocytes. US Patent #6136525 (issued on October 24, 2000).

Patent Applications

<u>Patent No.</u>	<u>Country</u>	<u>Title of Patent Application</u>
2216203	CA	Method of Thawing Cryopreserved Cells
9-256534	JP	Method of Thawing Cryopreserved Cells
99106212.6-2113	EU	Removal of Agent From Cell Suspension

In addition to the foregoing Circe Biomedical patents, we also acquired other rights to Circe's HepatAssist bioartificial liver and related technologies, such as clinical and marketing data and over 400 manufacturing and quality assurance/control standard operation protocols that the FDA had previously reviewed. In addition to being necessary for the HepatAssist system, the manufacturing standard operating procedures for harvesting and cryopreservation of hepatocytes are directly applicable to, and important to the development of our LIVERAID™ and HepatAssist-2™ systems. The Phase I - III clinical data that we acquired is expected to be useful in the preparation of future FDA submissions, since the data is based on pig liver cells from the same source that we currently intend to use for our bioartificial liver systems. We also acquired an FDA Phase III IND for an enhanced version of the HepatAssist system. 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 various protocols may also offer us an opportunity to expedite an IND submission for our LIVERAID™ system and to shorten the regulatory timeline for FDA approval of our two bioartificial liver systems.

In connection with our acquisition of the foregoing patents, we also assumed Circe Biomedical's obligations to make the following royalty payments:

(a) Pursuant to that certain Royalty Agreement, dated as of January 29, 1999, between Circe Biomedical, Inc. (as a wholly-owned subsidiary of W.R. Grace & Co.) and Circe Acquisition Corp., we assumed the obligation to pay a royalty of 2% of "net sales" any product that utilizes or incorporates the bioartificial liver patents, technology, inventions, and technical or scientific data that Circe Biomedical acquired from W.R. Grace & Co. Since the assets that we acquired from Circe are expected to be used in either the LIVERAID™ or the HepatAssist-2™ systems, it is likely that we will have to pay this royalty with respect of sales of those parts of our bioartificial liver systems that incorporate the W.R. Grace & Co. technology. Net sales includes revenues received from by us or our licensees and sublicensees from third parties. The obligation to pay royalties on the net sales of certain parts of our bioartificial liver systems will continue for at least 10 years after the date on which we have obtained all required regulatory approvals and have received \$100,000 of net sales.

(b) Pursuant to that certain Restated License Agreement dated as of August 1, 1999 between Circe Biomedical, Inc. and Cedars-Sinai Medical Center, we are obligated to make royalty payments equal to 1% of the "net sales" price for that portion of a liver assist system sold by us or any of our sublicensees that comprises or incorporates a cartridge having a combination of porcine hepatocytes with hollow fiber membranes. Since both of our bioartificial liver systems will utilize this type of cartridge, we will have to pay this royalty with respect of sales of all cartridges used in either of our bioartificial liver systems. Our obligation to pay these royalties will begin with the first commercial sale of a bioartificial liver and continue thereafter for ten years.

Under U.S. law, utility patents filed before June 8, 1995 are valid for 20 years from the filing date, or 17 years from date of issuance, whichever period is longer. Patents filed on or after June 8, 1995 are good for 20 years from the date of filing.

SEPET™ Rights. Our intellectual property rights to SEPET™ consist of patent application and certain related trade secrets. Our patent application regarding our selective plasma filtration therapy (SEPET™) technology was filed in August 2002.

We have not filed for any copyright or trademark protection to date.

## **Research and Development**

ATI and Spectrum Labs also entered into a four-year research agreement pursuant to which ATI and Spectrum Labs agreed to combine their expertise and their respective technologies to enable ATI to (i) develop liver assist systems, (ii) conduct pre-clinical and Phase I-III clinical testing, (iii) obtain regulatory approvals and (iv) commercialize such liver assist systems. Under the terms of the agreement, Spectrum Labs agreed to perform certain research on liver assist devices for ATI during product development, pre-clinical and clinical testing at no cost to ATI. Spectrum Labs also agreed to pay for all costs and expenses in connection with the research program and agreed to allocate a total of \$550,000 to the program during the research term. ATI and Spectrum Labs have recently agreed that Spectrum Labs has now satisfied its obligations to develop and manufacture clinical-grade, second-generation liver assist devices and that we will pay Spectrum Labs an additional \$54,960 over an 18-month period. Spectrum Labs has agreed to perform additional research and development work as may we may request, which additional future work will be provided by Spectrum Labs on terms that we may in the future agree to.

We have spent a total of \$437,000 on research and development during the fiscal year ended December 31, 2003 and \$431,000 for the fiscal year ended December 31, 2002. In addition, pursuant to our research agreement with Spectrum Labs, that company provided research and development services valued at approximately \$117,379 in 2002 and \$17,260 in 2003 for our liver assist systems. See, "Certain Relationships and Related Transactions - Research Agreement."



## Competition

Our products will compete with numerous other products and technologies that are currently used or are being developed by companies, academic medical centers and research institutions. These competitors consist of both large established companies as well as small, single product development stage companies. We expect substantial competition from these companies as they develop different and/or novel approaches to the treatment of liver disease. Some of these approaches may directly compete with the products that we are currently developing.

Other therapies currently available include whole plasma exchange therapy, a procedure involving massive plasma transfusions that is being used primarily for correction of coagulopathy in patients with severe acute liver failure. In addition, two extracorporeal blood detoxification systems are currently available in the U.S. for treatment of liver failure: (1) the Adsorba column (Gambro, Hechingen, Germany) which contains activated charcoal and (2) the BioLogic-DT system (HemoCleanse, West Lafayette, Indiana) utilizing a mixture of charcoal, silica and exchange resins. Published data indicate that in limited, uncontrolled clinical trials utilizing these systems, only a transient improvement in neurological status was observed with no effect on patients survival.

Other technologies offered by competing companies include the following:

Teraklin's MARS system (molecular adsorbents recirculating system) combines the specific removal of the toxins of liver failure (albumin bound toxins) using a hollow-fiber cartridge impregnated with albumin, which is also added to the dialysate solution. Albumin in the dialysate is "regenerated" during continuous recirculation in the closed loop system through adsorbents (charcoal, resin). In addition, standard hemodialysis is performed during MARS treatment. In Europe, initial results in patients with acute liver failure were encouraging. In September 2004 Gambro GmbH (Lund, Sweden) announced that it had acquired assets of Teraklin. In November 2004, Teraklin and Gambro announced that in a recently completed Phase II controlled study, which was conducted in 79 patients with acute exacerbation of chronic liver disease, MARS treatment improved hepatic encephalopathy and lowered blood levels of certain toxins implicated in the pathophysiology of liver failure.

Fresenius's PROMETHEUS system is a variant of Teraklin's MARS system and also combines albumin dialysis with sorbent based plasma detoxification and hemodialysis. In Europe, initial results in a small group of patients with acute exacerbation of chronic liver failure appeared encouraging. Controlled clinical trials are needed to establish if the technology has any therapeutic value.

Vital Therapies, Inc. uses technology developed and marketed by Hepatix and VitaGen, Inc. Its bioartificial liver (ELAD) utilizes a cell line derived from human liver cancer tissue and a conventional hollow fiber bioreactor. A Phase I clinical study of the newest ELAD version was recently reported at the annual meeting of the American Association for the Study of Liver Disease. (November 2004, Boston). In patients with acute liver failure, treatment with ELAD had no effect on survival when compared to patients receiving standard therapy.

Several other technologies could potentially compete with our bioartificial liver systems. These include xenotransplantation (use of pig organs in humans), transplantation of isolated hepatocytes and *ex vivo* whole liver perfusions. While major progress has been made in the area of xenotransplantation and transgenic pigs are now available, attempts at xenotransplantation have resulted only in short-term survival of grafted organs. *Ex vivo* whole liver perfusion is impractical because it is cumbersome and requires maintenance of multiple pathogen-free pig colonies due to direct cell-cell contact between pig liver and human blood cells. Although transplantation of hepatocytes showed great promise in animal models of liver failure, there is no adequate supply source of human cells due to shortage of organ donors.





## Government Regulation

In order to clinically test, manufacture, and market products for therapeutic use, we will have to satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. In the United States, the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, labeling, storage, record keeping, approval, advertising, and promotion of our products. Product development and approval within this regulatory framework takes a number of years and involves the expenditure of substantial resources. After laboratory analysis and preclinical testing in animals, an investigational new drug application is filed with the FDA to begin human testing. Typically, a three-phase clinical testing program is then undertaken. In phase 1, small clinical trials are conducted to determine the safety of the product. In phase 2, clinical trials are conducted to assess safety and gain preliminary evidence of the efficacy of the product. In phase 3, clinical trials are conducted to provide sufficient data for the statistically valid proof of safety and efficacy. The time and expense required to perform this clinical testing can vary and is substantial. No action can be taken to market any new drug or biologic product in the United States until an appropriate marketing application has been approved by the FDA. Even after initial FDA approval has been obtained, further clinical trials may be required to provide additional data on safety and effectiveness and are required to gain clearance for the use of a product as a treatment for indications other than those initially approved. In addition, side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product's use and, potentially, withdrawal of the product from the market. Any adverse event, either before or after marketing approval, can result in product liability claims against us.

In addition to regulating and auditing clinical trials, the FDA regulates and inspects equipment, facilities, and processes used in the manufacturing and testing of such products prior to providing approval to market a product. If after receiving clearance from the FDA, a material change is made in manufacturing equipment, location, or process, additional regulatory review may be required. We will also have to adhere to current Good Manufacturing Practice and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, laboratories, and processes following the initial approval. If, as a result of these inspections, the FDA determines that any equipment, facilities, laboratories, or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal, or administrative sanctions and/or remedies against us, including the suspension of the manufacturing operations.

The FDA has separate review procedures for medical devices before such products may be commercially marketed in the United States. There are two basic review procedures for medical devices in the United States. Certain products may qualify for a Section 510(k) procedure, under which the manufacturer gives the FDA a Pre-Market Notification, or 510(k) Notification, of the manufacturer's intention to commence marketing of the product at least 90 days before the product will be introduced into interstate commerce. The manufacturer must obtain written clearance from the FDA before it can commence marketing the product. Among other requirements, the manufacturer must establish in the 510(k) Notification that the product to be marketed is "substantially equivalent" to another legally-marketed, previously existing product. If a device does not qualify for the 510(k) Notification procedure, the manufacturer must file a Pre-Market Approval Application. The Pre-Market Approval Application requires more extensive pre-filing testing than the 510(k) Notification procedure and involves a significantly longer FDA review process. We are currently in the process of designing clinical trials to demonstrate the safety and efficacy of SEPET™ in treating patients with chronic liver failure. We have submitted to the FDA a draft clinical study protocol and are preparing an IDE for SEPET™ for submission to the FDA.



HepatAssist-2™ and LIVERAID™ are classified by the FDA as biological therapeutics and Class III medical devices. Accordingly, they are subject to a two-step approval process starting with a submission of an investigational new drug application (an “IND”) to conduct human studies followed by the submission of a Product Marketing Approval and a new drug application. The steps required before a product such as HepatAssist-2™ or LIVERAID™ may be approved by the FDA for marketing in the United States generally include (i) preclinical laboratory and animal tests; (ii) the submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may commence; (iii) adequate and well- controlled human clinical trials to establish the safety and efficacy of the product; and (iv) the submission to the FDA of either a product application. Preclinical tests include laboratory evaluation of the product, as well as animal studies to assess the potential safety and efficacy of the product. The results of the preclinical tests, together with analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may be commenced. The sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. Human clinical trials typically involve three sequential phases. Each trial must be reviewed and approved by the FDA before it can begin. Phase I involves the initial introduction of the experimental product into human subjects to evaluate its safety and, if possible, to gain early indications of efficacy. Phase II usually involves a trial in a limited patient population to (i) evaluate preliminarily the efficacy of the product for specific, targeted indications; (ii) determine dosage tolerance and optimal dosage; and (iii) identify possible adverse effects and safety risks. Phase III typically involves further evaluation of clinical efficacy and testing of product safety of a product in final form within an expanded patient population. The results of preclinical testing and clinical trials, together with detailed information on the manufacture and composition of the product, are submitted to the FDA in the form of an application requesting approval to market the product. In the case of HepatAssist2™, the product will be available for Phase III testing once the new platform to provide therapy (which we currently believe will be the PERFORMER) is found to be equivalent as a plasma perfusion apparatus to the original platform used in previous Phase I/II/III studies, and the FDA agrees to amend the previous IND to use the PERFORMER in a new Phase III clinical study. No assurance can be given that the results of the equivalency studies will show that the PERFORMER is a suitable platform for the HepatAssist-2™ bioartificial liver. In the case of LIVERAID™, only preclinical efficacy study has been completed and an IND application to conduct Phase I clinical study needs to be prepared and submitted to the FDA. Finally, we will also have to re-establish an approved cell manufacturing capability or engage an approved third party provider of pig cells.

In addition to obtaining FDA approval, we will have to obtain the approval of the various foreign health regulatory agencies of the foreign countries in which we may wish to market our products. Certain health regulatory authority (including those of Japan, France and the United Kingdom) have 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 expected to utilize) due to safety concerns. If we are unable to obtain the approval of the health regulatory authorities in any country, the potential market for our products will be reduced.

## **Employees**

We currently employ six full-time employees, one part-time employee, and six independent contractors who provide services to us on a part-time basis. Of the foregoing employees and contractors, five are primarily engaged in administration/management, and remaining seven persons are involved in scientific research, product development and/or regulatory compliance matters. Our employees are not represented by a labor organization or covered by a collective bargaining agreement. We have not experienced work stoppages and we believe that our relationship with our employees is good.

## **Property**

We currently maintain our laboratory and office space at Cedars-Sinai Medical Center in Los Angeles, California, which facilities we lease under a three-year lease that expires on June 30, 2007. We currently pay rent of \$6,441 per month for the 1,008 square foot facility under the lease. Cedars-Sinai Medical Center is a stockholder of our company and was one of the initial stockholders of ATI. See "Certain Relationships and Related Transactions."

Since April 1, 2004, we have been leasing 1,700 square feet of additional administrative office space in a building across the street from our laboratories that are located at Cedars-Sinai Medical Center. Our new offices are located at 8797 Beverly Blvd., Suite 206, Los Angeles, California 90048 and are our new executive offices. The new office lease requires us to pay rent of \$5,000 per month and has a term of two years.

## **Legal Proceeding**

We are not a party to any material legal proceedings.

We may occasionally become subject to legal proceedings and claims that arise in the ordinary course of our business. It is impossible for us to predict with any certainty the outcome of pending disputes, and we cannot predict whether any liability arising from pending claims and litigation will be material in relation to our consolidated financial position or results of operations.

**DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS****Directors and Executive Officers of Arbios Systems, Inc.**

The following table sets forth the name, age and position held by each of our executive officers and directors as of December 31, 2004. Directors are elected at each annual meeting and thereafter serve until the next annual meeting (currently expected to be held during the first calendar quarter of 2005) at which their successors are duly elected by the stockholders.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Jacek Rozga, M.D., Ph.D.	55	President, Chief Financial Officer, and Director
Roy Eddleman	64	Director
Marvin S. Hausman M.D. (2)	63	Director
John M. Vierling, M.D. (1) (2)	58	Chairman of the Board and Director
Jack E. Stover (1) (2)	51	Director
Scott L. Hayashi	33	Vice President of Administration and Secretary
David J. Zeffren	48	Vice President of Operations

(1) Member of our Audit Committee.

(2) Member of Nominating Committee and Compensation Committee.

**Business Experience and Directorships**

The following describes the backgrounds of current directors and the key members of the management team. All of our officers and directors also currently hold the same offices with ATI.

**Jacek Rozga, MD, PhD.** Dr. Rozga is a co-founder of ATI and has been a director and the President of that company since its organization in August 2000. Dr. Rozga has been a director, the President, the Chief Financial Officer and the Chief Scientific Officer of this company since October 30, 2003. Since 1992, Dr. Rozga has been a professor of Surgery at UCLA School of Medicine. Dr. Rozga has also been a research scientist at Cedars-Sinai Medical Center since 1992.

**Roy Eddleman.** Mr. Eddleman has been the Chairman of the Board and Chief Executive Officer of Spectrum Laboratories, Inc. since July 1982. Spectrum Laboratories, Inc. is a public company in the business of developing and commercializing proprietary tubular membranes and membrane devices for existing and emerging life sciences applications. Mr. Eddleman also has been the founder and/or principal and Director of each of (i) Spectrum Separations, Inc., now a part of UOP/Hitachi, (ii) ICM, Inc., now a part of Perstorff/Perbio, (iii) Facilichem, Inc., a joint venture with SRI International, (iv) Nuclepore, Inc., now a part of Corning and Whatman, and (v) Inneraction Chemical, Inc., now a part of Merck Darmstadt. He is the founder and a benefactor of the Roy Eddleman Research Museum of Chemistry and the Chemical Heritage Foundation in Philadelphia.

**Marvin S. Hausman, MD.** Dr. Hausman has, since January 1997, been the President and Chief Executive Officer of Axonyx, Inc., a public company engaged in the business of acquiring and developing novel post-discovery central nervous system drug candidates, primarily in areas of memory and cognition. Dr. Hausman has 30 years of drug development and clinical care experience at various pharmaceutical companies, including working in conjunction with Bristol-Meyers International, Mead-Johnson Pharmaceutical Co., and E.R. Squibb. He was a co-founder of Medco Research Inc., a NYSE-traded biopharmaceutical company which was acquired by King Pharmaceuticals, Inc.

Dr. Hausman has been the President of Northwest Medical Research Partners, Inc. since 1995 and previously served as a member of the Board of Directors of Regent Assisted Living, Inc. from 1996 through 2001.

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**John M. Vierling, MD, FACP.** Dr. Vierling has been a Professor of Medicine at the David Geffen School of Medicine at UCLA since 1996 and was the Director of Hepatology and Medical Director of Multi-Organ Transplantation Program at Cedars-Sinai Medical Center from 1990-2004. He is also currently the President Elect of the American Association for the Study of Liver Diseases. Dr. Vierling was the Chairman of the Board of the American Liver Foundation from 1994 to 2000, and the President of the Southern California Society for Gastroenterology from 1994 to 1995. Dr. Vierling has also been a member of numerous National Institutes of Health study sections and advisory committees, including the NIDDK Liver Tissue Procurement and Distribution Program. He is currently Chairman of the Data Safety Monitoring Board for the National Institute of Health, NIDDK ViraHep C Multicenter Trial. Dr. Vierling's research has focused on the immunological mechanisms of liver injury caused by hepatitis B and C viruses and autoimmune and alloimmune diseases.

**Jack E. Stover** Mr. Stover was elected as a director of this company in November 2004. Mr. Stover has been the President and Chief Operating Officer of Antares Pharma, Inc., an emerging public pharmaceutical company since July 2004. In September 2004, he was named Chief Executive Officer and President of that company. Prior thereto, for approximately two years Mr. Stover was Executive Vice President, Chief Financial Officer and Treasurer of SICOR, Inc., a public injectable pharmaceutical company that was acquired by Teva Pharmaceutical Industries. Prior to that, Mr. Stover was Executive Vice President and Director for Gynetics, Inc., a proprietary women's drug company, and the Senior Vice President, Chief Financial Officer, Chief Information Officer and Director for B. Braun Medical, Inc., a private global medical device and product company. For over 16 years, Mr. Stover was an employee and then a partner with PricewaterhouseCoopers, working in their bioscience industry division in New Jersey.

**Scott Hayashi** Mr. Hayashi joined the company as its Chief Administrative Officer in February 2004, became the Secretary of the company in July 2004 and was appointed as the Vice President of Administration in November 2004. Prior to joining Arbios, Mr. Hayashi was a Manager of Overseas Development for Syncor International, Inc. a subsidiary of Cardinal Health, Inc. for three years. Before joining Syncor International, Mr. Hayashi worked in finance, mergers and acquisitions for Litton Industries, Inc., now a part of Northrop Grumman Corporation and AlliedSignal, Inc., now a part of Honeywell, Inc.

**David J. Zeffren** Mr. Zeffren was first employed by us as a consultant in February, 2004, before being appointed Vice President of Operations in November 2004. Prior to joining Arbios, Mr. Zeffren had been the Chief Operating Officer of Skilled Health Systems, L.C., a healthcare technology and clinical research organization from 1999 to 2004. Mr. Zeffren was also Chief Operating Officer of Physician Care Management from 1996 to 1999. Mr. Zeffren was a Corporate Director, Business Development & Division Manager at INFUSX, Inc., a subsidiary of Salick Health Care, Inc. from 1993-1996. Mr. Zeffren has over 15 years of experience working in the healthcare and medical device industries.

There are no family relationships between any of the officers and directors.

## Committees

In February 2004, our Board of Directors established an Audit Committee. The Board of Directors has instructed the Audit Committee to meet periodically with the company's management and independent accountants to, among other things, review the results of the annual audit and quarterly reviews and discuss the financial statements, recommend to the Board the independent accountants to be retained, and receive and consider the accountants' comments as to controls, adequacy of staff and management performance and procedures in connection with audit and financial controls. The Audit Committee is also authorized to review related party transactions for potential conflicts of interest. The Audit Committee consisted of two persons and is currently composed of Dr. Vierling and Mr. Stover. Each of these individuals is a non-employee director and, in the opinion of our Board, is independent as defined under the Nasdaq Stock Market's listing standards. Mr. Stover is our "audit committee financial expert" as defined under Item 401(e) of Regulation S-B of the Securities Exchange Act of 1934, as amended. The Audit Committee operates under a formal charter that governs its duties and conduct.

In November 2004, we established a Compensation Committee and a Nomination Committee. The Compensation Committee is authorized to review and make recommendations to the full Board of Directors relating to the annual salaries and bonuses of our senior executive officers. The Nomination Committee assists the Board in identifying qualified director candidates, selecting nominees for election as directors at meetings of stockholders and selecting candidates to fill vacancies on our Board, and developing criteria to be used in making such recommendations.

## EXECUTIVE COMPENSATION

The following tables set forth certain information concerning the annual and long-term compensation for services rendered to us (and ATI) in all capacities for the fiscal years ended December 31, 2004, 2003, and 2002 of (i) all persons who served as the Chief Executive Officer of this company during the fiscal year ended December 31, 2004 and (ii) each of the other person who was an executive officers on December 31, 2004 and whose total annual salary and bonus during the fiscal year ended December 31, 2004 exceeded \$100,000. (The Chief Executive Officer and the other named officers are collectively referred to as the "Named Executive Officers.") The information set forth below includes all compensation paid to the Named Executive Officers by ATI before the Reorganization by ATI, and all compensation paid to him by both this company and ATI since the Reorganization.

### Summary Compensation Table

Name and Principal Position	Year	Annual Compensation			Other Annual Compensation	Long-Term Compensation
		Salary	Bonus			Awards Securities Underlying Options
Jacek Rozga, M.D., Ph.D Chief Executive Officer, Chief Financial Officer, and Chief Scientific Officer	2004 <sup>(1)</sup>	\$ 198,909	—	—	—	30,000 <sup>(2)</sup>
	2003	\$ 143,125	\$ 15,000	—	—	18,000 <sup>(2)</sup>
	2002	\$ 85,000	\$ 5,000	—	—	18,000
Scott L. Hayashi	2004 <sup>(3)</sup>	\$ 80,000	\$ 12,000	\$	8,000 <sup>(4)</sup>	10,000



David J. Zeffren	2004 <sup>(5)</sup>	\$	120,000	10,000
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- (1) The compensation set forth for 2003 includes amounts paid to Jacek Rozga, M.D., Ph.D by both ATI and Arbios Systems, Inc.
  - (2) Represents options granted to Jacek Rozga, M.D., Ph.D by ATI, which options were assumed by this company in the Reorganization.
  - (3) Mr. Hayashi joined Arbios Systems, Inc. in February 2004.
  - (4) Represents cash payments made to Mr. Hayashi for health and other benefits.

- (5) Mr. Zeffren joined Arbios Systems, Inc. in February 2004 as a consultant before becoming an executive officer of this company in November 2004. The compensation shown includes amounts paid both as a consultant and as an officer of the company.

During the three years prior to the Reorganization, Raymond H. Kuh was the President of HAUSA. During the last three years, HAUSA did not pay Mr. Kuh, or any other executive officer, any salary or bonus, and Mr. Kuh was not granted any options. Accordingly, no information is provided regarding Mr. Kuh or any other former executive officer of HAUSA.

### Stock Option Grants

The following table contains information concerning grants of stock options during the fiscal year ended December 31, 2004 by us (including ATI) to the Named Executive Officers (HAUSA did not grant any options). In the Reorganization, all of the option granted by ATI were assumed by HAUSA and now represent options to purchase shares of our common stock. We have not granted any stock appreciation rights.

#### Option Grants in Fiscal Year Ended December 31, 2004

##### Individual Grants

Name	Number of Shares Underlying Options Granted	% of Total Options Granted to Employees In Fiscal Year	Exercise Price	Market Price on Date of Grant	Expiration Date
Jacek Rozga, M.D., Ph.D	30,000(1)	60%	\$2.25	\$2.25	February 2, 2011
Scott L. Hayashi	10,000(2)	20%	\$2.25	\$2.25	February 2, 2009
David J. Zeffren	10,000(3)	20%	\$2.00	\$2.25	February 2, 2009

- (1) One half of these options vested six months after the date of grant, and the balance will vest twelve months following the date of grant.
- (2) The options vest in monthly increments over the first twelve months following the date of grant.
- (3) The options vest in monthly increments over the first six months following the date of grant.

### Aggregate Options

The following table sets forth the number and value of unexercised options held by the Named Executive Officers as of December 31, 2004. There were no exercises of options by the Named Executive Officers in fiscal year 2004.

**Aggregated Option Exercises in Fiscal Year Ended December 31, 2004  
and FY-End Option Values**

Name	Shares Acquired in Exercise	Value Realized	Number of Securities Underlying Unexercised Options at FY-End (#) Exercisable/ Unexercisable	Value of Unexercised In-the-Money Options at FY-End (#) Exercisable/ Unexercisable <sup>(1)</sup>
Jacek Rozga, M.D., Ph.D	—	—	51,000/15,000	\$82,230/\$6,450
Scott Hayashi	—	—	8,333/1,667	\$3,583/\$717
David J. Zeffren	—	—	10,000/0	\$6,800/0

(1) Dollar amounts reflect the net values of outstanding stock options computed as the difference between \$2.68 (the last reported sale on December 31, 2004) and the exercise price of the options.

### Employment Agreements

Dr. Rozga, receives compensation from us in his capacity as the President and Chief Financial Officer of this company and in his capacity as President and Chief Financial Officer of ATI, our operating subsidiary. In his capacity as the President and Chief Financial Officer of this company, Dr. Rozga earns an annual salary of \$65,000. In addition, Dr. Rozga and three of ATI's other employees provide services to ATI pursuant to that certain Employee Loan-Out Agreement, dated July 1, 2001, as amended, between ATI and Cedars-Sinai Medical Center. Dr. Rozga and the other employees are technically employed and paid by Cedars-Sinai Medical Center. Under the terms of the Loan-Out Agreement, the medical center permits Dr. Rozga to provide services to ATI, and ATI pays Cedars-Sinai Medical Center an amount equal to Dr. Rozga's salary plus an amount equal to the cost of fringe benefits and Cedars-Sinai Medical Center pays to Dr. Rozga. Through this arrangement, Dr. Rozga earns an annual salary of \$135,000 (which amount is paid through Cedar-Sinai but funded by ATI). The Loan-Out Agreement expires on June 30, 2005, and may be terminated by either party upon notice of breach of the agreement, for cause, or breach of the facilities agreement pursuant to which the Company leases its laboratories from Cedars-Sinai, provided that the parties have an opportunity to cure the breach. Dr. Rozga has no obligations to Cedars-Sinai other than the services he is providing to this company. Other than the Loan-Out Agreement, Dr. Rozga does not have an employment contract with Cedar Sinai Medical Center.

### Compensation of Board of Directors

During the fiscal year ended December 31, 2004, each of our directors was granted stock options to purchase 30,000 shares of common stock at an exercise price of \$2.25 per share. All director options are granted at the market price on the date of grant and have a term of seven years. Providing that the directors still are on the board at that time, one half of the options vest six months after the date of grant, and the remaining options vest on the first anniversary of the grant. We currently also reimburse all directors for any expenses incurred by them in attending meetings of the board of directors.

In 2004 the Board of Directors also established a special investor relations committee and appointed Dr. Richard Bank as the chairman of that committee. In consideration for his services as committee chairman, Dr. Bank was granted a seven-year stock option to purchase 100,000 shares of our common stock at a price of \$2.97 per share (the market price on the date of grant). The option provided that it will expire 30 days after Dr. Bank ceases to be a director.

Effective January 15, 2005, Dr. Bank resigned from our Board of Directors. Upon his resignation, the Board has extended the exercise period of Dr. Bank's options to January 15, 2006.

## Stock Option Plan

In 2001, we adopted our “2001 Stock Option Plan,” pursuant to which the Board of Directors has the authority to grant options to purchase up to a total of 1,000,000 shares of our common stock to our directors, officers, consultants and employees. Awards under the plan may be either non-qualified options or options intended to qualify as “Incentive Stock Options” under Section 422 of the Internal Revenue Code of 1986, as amended.

The exercise price of options granted under the plan may not be less than 100% of the fair market value of the common stock on the day of grant. If options are granted to a person who controls more than 10% of our stock, then the exercise price may not be less than 110% of the fair market value on the day of the grant. The purchase price and method of exercise of each nonqualified option granted to officers and other key employees shall be determined by the Board of Directors. The purchase price is payable in full by cash. However, the Board of Directors may accept payment for the purchase price of the shares of common stock acquired upon exercise of an option, by optionee’s tendering outstanding shares of our common stock owned by the optionee, or by other so-called cashless exercises as permitted by law, or any combination of cash, check, shares and cashless exercises.

Options granted under the stock option plan become exercisable and shall expire on such dates as determined by the Board of Directors, provided, however, that no term may exceed ten years from the date of grant, or five years from the date of grant in the case of any optionee holding more than 10 percent of the combined voting power of all classes of our capital stock as of the date of grant. After options become exercisable they may be exercised at any time or from time to time as to any part thereof.

Options are not transferable except by will or by the laws of descent and distribution; during the life of the person to whom the option is granted, that person alone may exercise them. All rights to exercise options terminate 90 days after the date a grantee ceases to be an employee of this company or any subsidiary for any reason other than death or disability.

### SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of our common stock as of January 31, 2005 (a) by each person known by us to own beneficially 5% or more of any class of our common stock, (b) by each of our Named Executive Officers and our directors and (c) by all executive officers and directors of this company as a group. As of January 31, 2005 there were 16,207,909 shares of our common stock issued and outstanding. Unless otherwise noted, we believe that all persons named in the table have sole voting and investment power with respect to all the shares beneficially owned by them. Except as otherwise indicated, the address of each stockholder is c/o the company at 8797 Beverly Blvd., Los Angeles, California, 90048.

Name and Address of Beneficial Owner	Shares Beneficially Owned (1)	Percentage of Class
Jacek Rozga, M.D., Ph.D.	2,331,000(2)	14.3%
Achilles A. Demetriou, M.D., Ph.D and Kristin P. Demetriou	2,536,000(3)	15.4%

John M. Vierling, MD	91,000(4)	*
Roy Eddleman	428,669 (5)	2.6%
Marvin S. Hausman MD	629,500(6)	3.8%
Gary Ballen (7) 140 Burlingame, Los Angeles, California 90049	1,139,222(7)	6.8%
Neuberger Berman LLC 111 River Street - Suite 1000 Hoboken, NJ 07030-5776(8)	2,440,199(8)	14.4%
LibertyView Special Opportunities Fund, LP 111 River Street - Suite 1000 Hoboken, NJ 07030-5776(9)	1,357,466(9)	8.1%
All executive officers and directors as a group (5 persons)	3,480,169) (10)	20.8%

\* Less than 1%.

- (1) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Shares of common stock subject to options, warrants and convertible securities currently exercisable or convertible, or exercisable or convertible within 60 days, are deemed outstanding, including for purposes of computing the percentage ownership of the person holding such option, warrant or convertible security, but not for purposes of computing the percentage of any other holder.
- (2) Includes currently exercisable options to purchase 66,000 shares of common stock.
- (3) Consists of (i) 2,500,000 shares owned by the A & K Demetriou Family Trust, of which Achilles A. Demetriou, M.D., Ph.D. and Kristin P. Demetriou each are co-trustees with the right to vote or dispose of the trust's shares, and (ii) currently exercisable options to purchase 36,000 shares of common stock issued to Kristin P. Demetriou.
- (4) Consists of currently exercisable options to purchase 91,000 shares of common stock.
- (5) Consists of currently exercisable options to purchase 66,000 shares of common stock, and 362,669 shares of common stock owned by Spectrum Laboratories, Inc. Mr. Eddleman is the Chairman of the Board and Chief Executive Officer of Spectrum Laboratories, Inc.
- (6) Consists of (i) currently exercisable options to purchase 98,000 shares of common stock, (ii) currently exercisable warrants to purchase 187,500 shares of common stock, (iii) 100,000 shares owned by the Marvin Hausman Revocable Trust, and (iv) 244,000 shares owned by Northwest Medical Research, Inc. Dr. Hausman is the trustee of the Marvin Hausman Revocable Trust and the Chief Executive Officer and principal stockholder of Northwest Medical Research, Inc.
- (7) Includes (i) 417,000 shares of common stock registered in Mr. Ballen's name, (ii) currently exercisable warrants to purchase 600,000 shares of common stock owned by Mr. Ballen, and (iii) 122,222 shares registered in the name of American Charter & Marketing LLC, over which Mr. Ballen has voting and investment control.
- (8) Neuberger Berman LLC is the investment adviser to, and Neuberger Berman Asset Management, LLC, is the general partner of LibertyView Special Opportunities Fund, LP, LibertyView Funds, LP and LibertyView Health Sciences Fund, LP, which collectively own 1,661,466 shares of common stock and warrants to purchase

778,733 additional shares of common stock.

- (9) Consists of (i) 904,977 shares of common stock, and (ii) currently exercisable warrants to purchase 452,489 shares of common stock.
- (10) Includes currently exercisable options and warrants to purchase 508,500 shares of common stock.

## SELLING STOCKHOLDERS

### Selling Stockholder Table

The shares to be offered by the selling stockholders are "restricted" securities under applicable federal and state securities laws and are being registered under the Securities Act of 1933, as amended (the "Securities Act"), to give the selling stockholders the opportunity to publicly sell or otherwise dispose of those shares. The registration of these shares does not require that any of the shares be offered or sold by the selling stockholders. The shares included in this prospectus may be disposed of by the selling stockholders or their transferees 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 dispose of its shares.

No estimate can be given as to the amount or percentage of our common stock that will be held by the selling stockholders after any sales or other dispositions made pursuant to this prospectus because the selling stockholders are not required to sell any of the shares being registered under this prospectus. The following table assumes that the selling stockholders will sell all of the shares listed in this prospectus.

The following table sets forth the beneficial ownership of the selling stockholders:

Selling stockholder	Beneficial Ownership Before Offering <sup>(1)</sup>		Number of Shares Being Offered	Beneficial Ownership After Offering <sup>(1)</sup>	
	Number of Shares	Percent		Number of Shares	Percent
4 P Management Partners, S.A.(2)	37,500(3)	*	37,500	*	
Bristol Investment Fund, Ltd.(4)	169,683(5)	1.04%	169,683	*	
Brookstone Biotech Ventures, LP(6)	135,747(7)	*	135,747	*	
Cranshire Capital, L.P.(8)	112,500(9)	*	112,500	*	
Crescent International Ltd.(10)	150,000(11)	*	150,000	*	
Dr. Susanne Schoen	15,000(12)	*	15,000	*	
Heinz Hoefliger	37,500(13)	*	37,500	*	
Arnd Wolpers	15,000(14)	*	15,000	*	
Hilary Lea Shane	152,500(15)	*	112,500	40,000	*
LibertyView Funds, LP(16)	678,733(17)	4.13%	678,733	*	
LibertyView Special Opportunities Fund, LP(18)	1,357,466(19)	8.15%	1,357,466	*	
Lindsey A. Rosenwald	169,683(20)	1.04%	169,683	*	
Nite Capital LP(21)	101,811(22)	*	101,811	*	
Omicron Master Trust(23)	169,683(24)	1.04%	169,683	*	
Prolate LLC(25)	101,811(26)	*	101,811	*	
	339,368(28)	2.08%	339,368	*	



Portside Growth and Opportunity  
Fund(27)

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SIBEX Capital Fund Inc.(29)	339,366(30)	2.08%	339,366	*
TCMP3 Partners(31)	105,000(32)	*	105,000	*
Truk International Fund, LP(33)	6,108(34)	*	6,108	*
Truk Opportunity Fund, LLC(35)	95,703(36)	*	95,703	*
Vicis Capital Master Fund(37)	67,873(38)	*	67,873	*
Whalehaven Capital Fund Limited(39)	169,683(40)	1.04%	169,683	*
Rodman & Renshaw, LLC(41)	114,404(42)	*	114,404	*

\* Less than 1%

- (1) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Shares of common stock subject to options, warrants and convertible securities currently exercisable or convertible, or exercisable or convertible within 60 days, are deemed outstanding, including for purposes of computing the percentage ownership of the person holding the option, warrant or convertible security, but not for purposes of computing the percentage of any other holder.
- (2) Konrad Meyer has voting and investment control of the securities held by 4 P Management Partners, S.A.
- (3) Includes currently exercisable warrants to purchase 12,500 shares of common stock.
- (4) Paul Kessler, manager of Bristol Capital Advisors LLC, the investment advisor to Bristol Investment Fund, Ltd., has voting and investment control of the securities held by Bristol Investment Fund, Ltd. Paul Kessler disclaims beneficial ownership of these securities.
- (5) Includes currently exercisable warrants to purchase 56,561 shares of common stock.
- (6) Robert L. Carver, President of Brookstone Capital, Inc., General Partner of Brookstone Biotech Ventures, LP, has voting and investment control of the securities held by Brookstone Biotech Ventures, LP.
- (7) Includes currently exercisable warrants to purchase 45,249 shares of common stock.
- (8) Mitchell Koein, President of Downsvew Capital, Inc., the General Partner of Cranshire Capital, L.P., has voting and investment control of the securities held by Cranshire Capital, L.P.
- (9) Includes currently exercisable warrants to purchase 37,500 shares of common stock.
- (10) Mel Craw and Maxi Brezzi, managers of GreenLight (Switzerland) SA, the investment advisor to Crescent International Ltd., have voting and investment control of the securities held by Crescent International Ltd. Mel Craw and Maxi Brezzi disclaim beneficial ownership of these securities.
- (11) Includes currently exercisable warrants to purchase 50,000 shares of common stock.
- (12) Includes currently exercisable warrants to purchase 5,000 shares of common stock.
- (13) Includes currently exercisable warrants to purchase 12,500 shares of common stock.
- (14) Includes currently exercisable warrants to purchase 5,000 shares of common stock.
- (15) Includes currently exercisable warrants to purchase 37,500 shares of common stock.
- (16) Neuberger Berman Asset Management, LLC is the general partner of LibertyView Funds, LP. Neuberger Berman LLC is the investment adviser to Neuberger Berman Asset Management, LLC and is responsible for the selection, acquisition and disposition of the portfolio securities by this fund. LibertyView Funds, LP is an affiliate of a registered broker-dealer. We have been informed by LibertyView Funds, LP that it acquired the securities offered by this prospectus for its own account in the ordinary course of business, and that, at the time it acquired such securities, it had no agreement or understanding, direct or indirect, with any person to distribute such securities.
- (17) Includes currently exercisable warrants to purchase 226,244 shares of common stock.
- (18) Neuberger Berman Asset Management, LLC is the general partner of LibertyView Special Opportunities Fund, L.P. Neuberger Berman LLC is the investment adviser to Neuberger Berman Asset Management, LLC and is responsible for the selection, acquisition and disposition of the portfolio securities by this fund. LibertyView Special Opportunities Fund, LP is an affiliate of a registered broker-dealer. We have been informed by LibertyView Special Opportunities Fund, LP that it acquired the securities offered by this prospectus for its own

account in the ordinary course of business, and that, at the time it acquired such securities, it had no agreement or understanding, direct or indirect, with any person to distribute such securities.

- (19) Includes currently exercisable warrants to purchase 452,489 shares of common stock.
- (20) Includes currently exercisable warrants to purchase 56,561 shares of common stock.
- (21) Keith Goodman has voting and investment control of the securities held by Nite Capital LP.

- (22) Includes currently exercisable warrants to purchase 33,937 shares of common stock.
- (23) Omicron Capital, L.P., a Delaware limited partnership (“Omicron Capital”), serves as investment manager to Omicron Master Trust, a trust formed under the laws of Bermuda (“Omicron”), Omicron Capital, Inc., a Delaware corporation (“OCI”), serves as general partner of Omicron Capital, and Winchester Global Trust Company Limited (“Winchester”) serves as the trustee of Omicron. By reason of such relationships, Omicron Capital and OCI may be deemed to share dispositive power over the shares of our common stock owned by Omicron, and Winchester may be deemed to share voting and dispositive power over the shares of our common stock owned by Omicron. Omicron Capital, OCI and Winchester disclaim beneficial ownership of such shares of our common stock. Omicron Capital has delegated authority from the board of directors of Winchester regarding the portfolio management decisions with respect to the shares of common stock owned by Omicron and, as of the date of this prospectus, Mr. Olivier H. Morali and Mr. Bruce T. Bernstein, officers of OCI, have delegated authority from the board of directors of OCI regarding the portfolio management decisions of Omicron Capital with respect to the shares of common stock owned by Omicron. By reason of such delegated authority, Messrs. Morali and Bernstein may be deemed to share dispositive power over the shares of our common stock owned by Omicron. Messrs. Morali and Bernstein disclaim beneficial ownership of such shares of our common stock and neither of such persons has any legal right to maintain such delegated authority. No other person has sole or shared voting or dispositive power with respect to the shares of our common stock being offered by Omicron, as those terms are used for purposes under Regulation 13D-G of the Securities Exchange Act of 1934, as amended. Omicron and Winchester are not “affiliates” of one another, as that term is used for purposes of the Securities Exchange Act of 1934, as amended, or of any other person named in this prospectus as a selling stockholder. No person or “group” (as that term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, or the SEC’s Regulation 13D-G) controls Omicron and Winchester.
- (24) Includes currently exercisable warrants to purchase 56,561 shares of common stock.
- (25) S. Donald Sussman has voting and investment control of the securities held by Prolate LLC.
- (26) Includes currently exercisable warrants to purchase 33,937 shares of common stock.
- (27) Peter A. Cohen, Morgan B. Stark, Thomas W. Strauss and Jeffrey M. Solomon, the managing members of C4S & Co., LLC, the managing member of Ramius Capital Group, LLC, the investment adviser of Portside Growth and Opportunity Fund, have voting and investment control of the securities held by Portside Growth and Opportunity Fund. Peter A. Cohen, Morgan B. Stark, Thomas W. Strauss and Jeffrey M. Solomon disclaim beneficial ownership of these securities.
- (28) Includes currently exercisable warrants to purchase 113,123 shares of common stock.
- (29) Viacheslav Chebotarevich and Oleg S. Krasnoshchek share voting and investment control of the securities held by SIBEX Capital Fund Inc.
- (30) Includes currently exercisable warrants to purchase 113,122 shares of common stock.
- (31) Steven Slawson and Walter Schecter have voting and investment control of the securities held by TCMP3 Partners.
- (32) Includes currently exercisable warrants to purchase 35,000 shares of common stock.
- (33) Michael E. Fein and Stephen E. Saltzstein, as principals of Atoll Asset Management, LLC, the managing member of Truk International Fund, LP, have voting and investment control of the securities held by Truk International Fund, LP. Michael E. Fein and Stephen E. Saltzstein disclaim beneficial ownership of these securities.
- (34) Includes currently exercisable warrants to purchase 2,036 shares of common stock.
- (35) Michael E. Fein and Stephen E. Saltzstein, as principals of Atoll Asset Management, LLC, the managing member of Truk Opportunity Fund, LLC, have voting and investment control of the securities held by Truk Opportunity Fund, LLC. Michael E. Fein and Stephen E. Saltzstein disclaim beneficial ownership of these securities.
- (36) Includes currently exercisable warrants to purchase 31,901 shares of common stock.
- (37) Richard Han has voting and investment control of the securities held by Vicis Capital Master Fund.
- (38) Includes currently exercisable warrants to purchase 22,624 shares of common stock.
- (39)

Evan Schemenaur, Arthur Jones and Jennifer Kelly have voting and investment control of the securities held by Whalehaven Capital Fund Limited.

- (40) Includes currently exercisable warrants to purchase 56,561 shares of common stock.
- (41) Thomas G. Pinou, Chief Financial Officer of Rodman & Renshaw, LLC has voting and investment control of the securities held by Rodman & Renshaw, LLC.

- (42) Consists of shares issuable upon the exercise of currently exercisable warrants to purchase shares of common stock.

### **Relationships with Selling Stockholders**

Other than Rodman & Renshaw LLC, all of the selling stockholders are investors who purchased their securities from us in the \$6,611,905 private placement that was completed on January 11, 2005. Except as set forth below, none of the selling stockholders has held any position or office with us or any of our affiliates, or has had any other material relationship (other than as purchasers of securities) with us or any of our affiliates, within the past three years.

Dr. Richard Bank was a member of this company's Board of Directors from December 2003 through January 15, 2005. Dr. Bank is a Senior Vice President of Neuberger Berman, LLC, the parent company of the LibertyView funds, including LibertyView Special Opportunities Fund, LP and LibertyView Funds, LP, and is the portfolio manager of LibertyView Health Sciences Fund, LP.

Rodman & Renshaw to act as our placement agent in the January 11, 2005 private placement. We paid Rodman & Renshaw a cash fee of \$252,833 at the closing and issued to Rodman & Renshaw warrants to purchase 114,404 shares of our common stock, which shares are included in this prospectus. The warrants issued to Rodman & Renshaw have the same terms and conditions as the warrants issued to the investors in the private placement. In addition, we paid Rodman & Renshaw \$25,000 as a reimbursement the out-of-pocket expenses it incurred in the offering.

4P Management Partners S.A. of Zurich, Switzerland has been our investor relations service company in Europe since July, 2004. In connection with retaining 4P Management, we issued two warrants to 4P Management Partners S.A. to purchase an aggregate of 100,000 shares of common stock. The securities of 4P Management included in this prospectus were purchased for cash by 4P Management in the January 11, 2005 private placement.

The information in the above table is as of the date of this prospectus. Information concerning the selling stockholders may change from time to time and any such changed information will be described if and when necessary in supplements to this prospectus or, if appropriate, a post-effective amendment to the registration statement of which this prospectus is a part.

## PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock 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.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales effected after the date the registration statement of which this prospectus is a part is declared effective by the SEC;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to

broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).



The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be "underwriters" within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or (2) the date on which the shares may be sold pursuant to Rule 144(k) of the Securities Act.

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

### Transactions Between Us and Our Affiliates

On December 26, 2001, ATI entered into various agreements with Spectrum Laboratories, Inc. (“Spectrum Labs”). Concurrently with these agreements, Spectrum Labs also purchased 362,669 shares of ATI’s common stock. Mr. Eddleman, one of the members of our Board of Directors, is the Chairman and CEO of Spectrum Labs. The three principal agreements entered into by ATI and Spectrum Labs in December 2001 are the following:

A. License Agreement. Spectrum Labs granted to ATI an exclusive, worldwide license to develop, make, use and distribute products based on two Spectrum Labs patents. Provided that ATI purchases the hollow fiber cartridges that it expects that it will need for its products from Spectrum Labs, ATI will not have to pay a royalty for the license. In the event that Spectrum Labs is not the manufacturer of the hollow fiber cartridges, ATI will have to pay Spectrum Labs a royalty for the license (see, “Business--Manufacturing and Supply Agreement”). Spectrum Labs also agreed to grant ATI a right of first refusal to obtain a license to make, use, develop or distribute products based on Spectrum Labs’ technology other than in liver assisted products, provided that such other products are in the fields of artificial blood therapy and bioprocessing and therapeutic devices.

B. Research Agreement. ATI and Spectrum Labs also entered into a four-year research agreement pursuant to which ATI and Spectrum Labs agreed to combine their expertise and their respective technologies to enable ATI to (i) develop liver assist systems, (ii) conduct pre-clinical and Phase I-III clinical testing, (iii) obtain regulatory approvals and (iv) commercialize such liver assist systems. Under the terms of the agreement, Spectrum Labs agreed to perform certain research toward the development of hollow fiber-in-fiber modules for ATI’s liver assist systems during product development, pre-clinical and clinical testing at no cost to ATI. Spectrum Labs also agreed to pay for all costs and expenses in connection with the research program and agreed to allocate a total of \$550,000 to the program during the research term. In October 2002, ATI and Spectrum Labs agreed that Spectrum Labs has now satisfied its research and development obligations, that ATI owed Spectrum Labs an additional \$54,960 for services provided by Spectrum Labs (which amount has been paid in full), and that the 362,669 shares of ATI common stock previously issued to Spectrum Labs are now fully vested. Spectrum Labs has agreed to perform additional research and development work as may be requested by ATI on such terms as the parties may agree to in good faith negotiations.

C. Manufacturing and Supply Agreement. ATI and Spectrum Labs have also entered into an agreement pursuant to which the parties have agreed that Spectrum Labs will manufacture for ATI the hollow fiber cartridges with fiber-in-fiber geometry that ATI intends to use for its LIVERAID™ device. The agreement provides that the price of the hollow fiber-in-fiber cartridges to be sold by Spectrum Labs to ATI will be determined by good faith negotiations between the parties. ATI has agreed that it will not purchase cartridges with fiber-in-fiber geometry from any other manufacturer unless Spectrum Labs is either unable or unwilling to manufacture the cartridges. In the event that Spectrum Labs is unwilling to manufacture the fiber-in-fiber cartridges for ATI, ATI shall have the right to have a third party manufacture the cartridges for it, in which case ATI will pay Spectrum Labs a royalty for the license granted to ATI by Spectrum Labs under the License Agreement. The royalty shall be equal to 3% of the net sales (total sales less taxes, returns, transportation, insurance, and handling charges) attributed solely to the fiber-in-fiber cartridges.

In July 2003, ATI granted Dr. Marvin Hausman a five-year warrant to purchase 50,000 shares of common stock, at an exercise price of \$1.00 per share, in consideration for Dr. Hausman's efforts in introducing ATI to an investor who made a \$250,000 investment in ATI. Dr. Hausman is a member of this company's Board of Directors and a member of ATI's Board of Directors.

Dr. Richard Bank received a warrant to purchase 40,000 shares of our common stock as a fee for introducing certain investors to this company in September 2003. The warrant is exercisable at any time until January 5, 2007 at an exercise price of \$2.50 per share. At the time of the warrant issuance, Dr. Bank was a director of this company.

## DESCRIPTION OF SECURITIES

We are presently authorized to issue 25,000,000 shares of \$.001 par value common stock and 5,000,000 shares of \$.001 par value preferred stock. As of the date of this prospectus, we had 16,207,909 shares of common stock issued and outstanding and no preferred stock issued and outstanding.

### Common Stock

The holders of our common stock are entitled to equal dividends and distributions per share with respect to the common stock when, as and if declared by the board of directors from funds legally available therefore. No holder of any shares of common stock has a preemptive right to subscribe for any of our securities, nor are any common shares subject to redemption or convertible into other securities. Upon liquidation, dissolution or winding-up of our company, and after payment of creditors and preferred stockholders, if any, the assets will be divided pro rata on a share-for-share basis among the holders of the shares of common stock. All shares of common stock now outstanding are fully paid, validly issued and non-assessable. Each share of our common stock is entitled to one vote with respect to the election of any director or any other matter upon which stockholders are required or permitted to vote.

### Preferred Stock

Under our articles of incorporation, the board of directors has the power, without further action by the holders of the common stock, to designate the relative rights and preferences of the preferred stock, and to issue the preferred stock in one or more series as designated by the board of directors. The designation of rights and preferences could include preferences as to liquidation, redemption and conversion rights, voting rights, dividends or other preferences, any of which may be dilutive of the interest of the holders of the common stock or the preferred stock of any other series. The issuance of preferred stock may have the effect of delaying or preventing a change in control of the company without further stockholder action and may adversely affect the rights and powers, including voting rights, of the holders of the common stock.

### Registration Rights

In 2003 we entered into registration rights agreements with the investors who, in the aggregate, purchased 4,400,000 units. Each unit consisted of one share our common stock and one common stock purchase warrant. In those registration rights agreements, we agreed to file a registration statement, at our expense, to register the resale of the 4,400,000 shares of our common stock that are issuable upon the exercise of the warrants held by those investors. Our Board of Directors has also approved the registration of the 4,400,000 shares that were included in the units. The registration statement is required to be filed after January 31, 2004 if (i) requested in writing by the holders of a majority of the then outstanding warrants (including any shares previously issued upon the exercise of the warrants), and (ii) the closing price of our common stock has exceeded \$2.50 for 20 consecutive trading days. The shares that we are obligated to register under the foregoing registration rights agreements have been registered in a prior registration statement.



The warrant that we issued to Wolfe Axelrod Weinberger Associates LLC for the purchase of 75,000 shares of our common stock granted the holder of that warrant “piggyback registration” rights. Under the piggyback registration provisions, we are required, subject to certain limited exceptions, to register the 75,000 shares of our common stock in any registration statement that we file. All of the shares issuable to Wolfe Axelrod Weinberger Associates LLC have already been included in a prior registration statement. Accordingly, unless that prior registration statement is withdrawn prior to the time that Wolfe Axelrod Weinberger Associates LLC sells its warrant shares under that registration statement, we will have no further obligation to register and of these warrant shares under the registration rights provision of the warrant.

In connection with the organization and initial capitalization of ATI, we also granted certain “piggy-back” registration rights to The A & K Demetriou Family Trust, Jacek Rozga, and Cedars-Sinai Medical Center, our initial three stockholders. Under these agreements, subject to certain customary conditions and exceptions, the foregoing three stockholders have the right to include in any future registration statement filed by this company some or all of their shares of the common stock. The shares of common stock owned by Cedars-Sinai Medical Center have been included in a prior, currently effective, registration statement. Accordingly, unless that prior registration statement is withdrawn a before Cedars-Sinai its shares under that registration statement, we will have no further obligation to register the shares of Cedars-Sinai. The A & K Demetriou Family Trust, Jacek Rozga have waived their rights to have their shares included in this prospectus.

On January 11, 2005, we sold 2,991,812 shares of our common stock and issued warrants to purchase 1,495,906 shares of our common stock. In connection with the sale of these securities, we entered into a registration rights agreement with the investors pursuant to which we agreed to file a registration statement, at our expense, to register the resale of the foregoing 2,991,812 shares of our common stock as well as the 1,495,906 shares of our common stock that are issuable upon exercise of the stock purchase warrants. The registration statement is required to be prepared and filed no later than the 30th day immediately following the closing date of private placement.

This prospectus includes 4,488,718 shares that we are obligated to register under the foregoing registration rights agreement. We are required to use commercially reasonable efforts to have the registration statement declared effective by the SEC as soon as practicable. If the registration statement is not declared effective within 90 days of the closing date of the private placement (or 120 days if the registration statement is subjected to a full review by the SEC), we will be subject to the payment of liquidated damages to the investors as described in the registration rights agreement. In addition, if after the registration statement has been declared effective by the SEC, sales cannot be made by the investors under this prospectus for any reason (including without limitation by reason of a stop order, or our failure to update the prospectus) for 20 consecutive days (or 45 days during any 12-month period), then we will be required to pay each investor, as liquidated damages and not as a penalty, an amount equal to 1.5% of the aggregate purchase price paid by such investor for his shares for each 30-day period or a pro rata payment for any portion thereof following the date by which this prospectus should have been effective

## Shares Eligible For Future Sale

As of the date of this prospectus, we had 16,207,909 shares of common stock outstanding. That number does not include (i) the 743,000 shares that are reserved for issuance under outstanding options and that may be issued if and when the options are exercised, or (ii) 7,282,810 shares that may be issued upon the exercise of currently outstanding warrants (including the warrants to purchase 1,810,310 shares that are owned by the selling stockholders listed in this prospectus).

Freely Tradeable Shares After Offering. As of the date of this prospectus, excluding the shares that are covered by this prospectus, 8,363,097 shares of our 16,207,909 currently outstanding shares can be publicly resold. Upon the re-sale of the 2,991,812 currently outstanding shares covered by this prospectus, and the exercise and sale of the 1,610,310 warrant shares included in this prospectus, all of these 4,602,122 shares will also be freely tradable without restriction or limitation under the Securities Act. As a result, after the completion of this offering, there will be a total of 12,765,219 shares of our common stock that will be tradable without restriction under the Securities Act. In addition, we have also previously registered 5,597,500 additional shares of our common stock that can be issued upon the exercise of outstanding warrants and can also be immediately resold pursuant to that prior registration statement..

Rule 144. In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who has beneficially owned restricted securities shares for at least one year, including persons who may be deemed our “affiliates,” as that term is defined under the Securities Act, would be entitled to sell within any three month period a number of shares that does not exceed the greater of 1% of the then outstanding shares (approximately 162,079 shares if the currently outstanding warrants and options are not exercised, or 180,182 shares if all outstanding options and warrants are exercised) or the average weekly trading volume of shares during the four calendar weeks preceding such sale. Sales under Rule 144 are subject to certain manner-of-sale provisions, notice requirements and the availability of current public information about the company. A person who has not been our affiliate at any time during the three months preceding a sale, and who has beneficially owned his shares for at least two years, would be entitled under Rule 144(k) to sell such shares without regard to any volume limitations under Rule 144.

Currently, there are 4,900,500 unregistered shares outstanding, of which 4,835,000 are currently eligible for public resale under Rule 144. The remaining 65,500 shares will become eligible for public resale under Rule 144 at various times in 2005. The future availability of Rule 144 to our holders of restricted securities would be conditioned on, among other factors, the availability of certain public information concerning the company.

Form S-8 Registration of Options. We intend to file a registration statement on Form S-8 covering the shares of common stock that have been reserved for issuance under our stock option plan, which would permit the resale of such shares in the public marketplace.

## Transfer Agent

Our transfer agent currently is The Nevada Agency and Trust Company, 50 West Liberty Street, Suite 880, Reno, Nevada 89501.

## CHANGE OF ACCOUNTANTS

On January 27, 2004, our board of directors approved, by unanimous written consent, resolutions to dismiss our former independent accountants, Williams and Webster, P.S. (“Williams”). Williams’ report on our financial statements for the prior two years did not contain an adverse opinion or disclaimer of opinion, and was not modified as to uncertainty, audit scope, or accounting principles, except that there was an explanatory paragraph relating to our ability to continue as a going concern.



During the two prior fiscal years, we had no disagreements with Williams, whether or not resolved, on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which, if not resolved to Williams' satisfaction, would have caused it to make reference to the subject matter of the disagreement in connection with its report. Williams did not advise us of any of the events requiring reporting under the Commission's rules.

On January 27, 2004, our board also approved, by unanimous written consent, resolutions to engage Stonefield Josephson, Inc. as our independent accountants to audit our financial statements for the year ending December 31, 2003, and for quarterly statements during 2004. Stonefield Josephson, Inc. audited the financial statements of our Arbios Technologies, Inc. subsidiary for the fiscal year ended December 31, 2002. We did not consult with Stonefield Josephson, Inc. regarding the application of accounting principles to a specific, completed or contemplated transaction, or the type of audit opinion that might be rendered on our financial statements prior to the engagement.

#### **INTERESTS OF NAMED EXPERTS AND COUNSEL**

No expert or counsel was hired on a contingent basis that will receive a direct or indirect interest in our business that is valued at greater than \$50,000.

The financial statements for the years ended December 31, 2003 and 2002 included in this prospectus have been audited by Stonefield Josephson, Inc. to the extent and for the periods indicated in their report thereon. Such financial statements have been included in this prospectus and registration statement in reliance upon the report of Stonefield Josephson, Inc. and upon the authority of such firm as experts in auditing and accounting.

#### **DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Our Articles of Incorporation provide that no officer or director shall be personally liable to this corporation or its stockholders for monetary damages except as provided pursuant to Nevada Revised Statutes. Our bylaws and Articles of Incorporation also provide that we shall indemnify and hold harmless each person who serves at any time as a director or officer of Arbios Systems, Inc. from and against any and all claims, judgments and liabilities to which such person shall become subject by reason of the fact that he is or was a director or officer of Arbios Systems, Inc., and shall reimburse such person for all legal and other expenses reasonably incurred by him or her in connection with any such claim or liability. We also have the power to defend such person from all suits or claims in accord with the Nevada Revised Statutes. The rights accruing to any person under our bylaws and Articles of Incorporation do not exclude any other right to which any such person may lawfully be entitled, and we may indemnify or reimburse such person in any proper case, even though not specifically provided for by the bylaws and Articles of Incorporation.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.



## LEGAL MATTERS

Troy & Gould Professional Corporation, Los Angeles, California, has rendered an opinion with respect to the validity of the shares of common stock covered by this prospectus. Attorneys at Troy & Gould Professional Corporation collectively own 75,000 shares of our common stock.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form SB-2 under the Securities Act for the common stock offered under this prospectus. We are subject to the informational requirements of the Exchange Act, and file annual reports, quarterly reports, special reports, proxy statements and other information with the Commission. These reports, proxy statements and other information filed by Arbios Systems, Inc. can be inspected and copied at the public reference facilities of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of these materials can be obtained from the Public Reference Section of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549, at prescribed rates. The Commission also maintains a Web site that contains reports, proxy statements, information statements and other information concerning Arbios Systems, Inc. at the site located at <http://www.sec.gov>. This prospectus does not contain all the information in the registration statement and its exhibits, which we have filed with the Commission under the Securities Act and to which reference is made.

## GLOSSARY OF TERMS

“**Dialysate**” is a cleansing liquid used in the two forms of dialysis—hemodialysis and peritoneal dialysis.

“**Dialysis**” is the process of cleaning wastes from the blood artificially. This job is normally done by the kidney and liver.

“**Extracorporeal**” means situated or occurring outside the body.

“**Ex vivo**” pertains to a biological process or reaction taking place outside of a living cell or organism.

“**Fulminant**” means occurring suddenly, rapidly, and with great severity or intensity.

“**Hemodialysis**” pertains to the use of a machine to clean wastes from blood after the kidneys have failed. The blood flows through a device called a dialyzer, which removes the wastes. The cleaned blood then flows back into the body.

“**Hemofiltration/ Hemofiltrate**” “Hemofiltration” is a continuous dialysis therapy in which blood is pumped through a hollow-fiber cartridge and the liquid portion of blood containing substances are removed into the sink compartment. The liquid portion of the blood (“hemofiltrate”) is discarded.

“**Hepatitis**” is an inflammation of the liver caused by infectious or toxic agents.

“**Hepatocytes**” are the organ tissue cells of the liver.

“**kDa**” is a measure of molecular weight using “Daltons” (abbreviated as “Da”). One “Da” is 1/12 of the weight of an atom carbon <sup>12</sup>C. “kDa” is a kilodalton, or a 1,000 Daltons.

“**IND**” means Investigational New Drug application.

“***In vitro***” pertains to a biochemical process or reaction taking place in a test-tube (or more broadly, in a laboratory) as opposed to taking place in a living cell or organism.

“***In vivo***” pertains to a biological process or reaction taking place in a living cell or organism.

“**PERV**” means the porcine endogenous retrovirus.

“**Plasma**” is the clear, yellowish fluid portion of blood. Plasma differs from serum in that it contains fibrin and other soluble clotting elements.

“**Porcine**” means of or pertaining to swine; characteristic of the hog.

“**Regeneration**” means regrowth of lost or destroyed parts or organs.

“**Sorbent**” means to take in and adsorb or absorb.

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FINANCIAL STATEMENTS FOR  
ARBIOS SYSTEMS, INC.

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**AUDITED  
FINANCIAL  
STATEMENTS**

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors  
Arbios Systems, Inc. and Subsidiary  
Beverly Hills, California

We have audited the accompanying consolidated balance sheet of Arbios Systems, Inc. and Subsidiary as of December 31, 2003 and the related consolidated statements of operations, stockholders' equity and cash flows for the years ended December 31, 2003 and 2002, and from August 23, 2000 (inception) to December 31, 2003. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Arbios Systems, Inc. and Subsidiary as of December 31, 2003 and the results of their operations and cash flows for the years ended December 31, 2003 and 2002, and from August 23, 2000 (inception) to December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

/s/ STONEFIELD JOSEPHSON, INC.

CERTIFIED PUBLIC ACCOUNTANTS  
Santa Monica, California  
March 9, 2004

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**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)

**CONSOLIDATED BALANCE SHEET - DECEMBER 31, 2003**

## ASSETS

## CURRENT ASSETS:

Cash	\$ 3,507,086
Prepaid expenses	155,986
	<u>                    </u>

Total current assets	\$ 3,663,072
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PROPERTY AND EQUIPMENT, net	45,633
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PATENT RIGHTS, net	324,145
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DEPOSITS	7,434
	<u>                    </u>

	\$ 4,040,284
	<u>                    </u>

**LIABILITIES AND STOCKHOLDERS' EQUITY**

## CURRENT LIABILITIES:

Accounts payable and accrued expenses	\$ 148,229
Current maturities of capital lease obligation	8,526
	<u>                    </u>

Total current liabilities	\$ 156,755
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## LONG-TERM LIABILITIES:

Capital lease obligation, less current maturities	6,826
Other liabilities	5,555
	<u>                    </u>

Total long-term liabilities	12,381
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## STOCKHOLDERS' EQUITY:

Preferred stock, \$.001 par value, 5,000,000 shares authorized none issued and outstanding	-
Common stock, \$.001 par value; 25,000,000 shares authorized; 13,150,598 shares issued and outstanding	13,151
Additional paid-in capital	5,485,498
Deficit accumulated during the development stage	(1,627,501)
	<u>                    </u>

Total stockholders' equity	3,871,148
	<u>                    </u>

	\$ 4,040,284
	<u>                    </u>

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

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**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year ended December 31, 2003	Year ended December 31, 2002	August 23, 2000 (Inception) to Period Ended December 31, 2003
<b>REVENUES</b>	\$ 137,828	\$ 111,108	\$ 248,936
<b>OPERATING EXPENSES:</b>			
General and administrative	340,067	172,737	617,239
Research and development	436,849	431,199	1,009,674
<b>Total operating expenses</b>	<b>776,916</b>	<b>603,936</b>	<b>1,626,913</b>
<b>LOSS BEFORE OTHER EXPENSE</b>	<b>(639,088)</b>	<b>(492,828)</b>	<b>(1,377,977)</b>
	(243,230)	(830)	(243,157)
<b>INTEREST EXPENSE, NET</b>			
<b>LOSS BEFORE PROVISION FOR INCOME TAXES</b>	<b>(882,318)</b>	<b>(493,658)</b>	<b>(1,621,134)</b>
<b>PROVISION FOR INCOME TAXES</b>	<b>3,375</b>	<b>1,122</b>	<b>6,367</b>
<b>NET LOSS</b>	<b>\$ (885,693 )</b>	<b>\$ (494,780)</b>	<b>\$ (1,627,501)</b>
<b>BASIC AND DILUTED LOSS PER SHARE</b>	<b>\$ (0.11)</b>	<b>\$ (0.08)</b>	<b>\$ (0.27)</b>
<b>BASIC AND DILUTED WEIGHTED AVERAGE COMMON SHARES OUTSTANDING</b>	<b>7,887,237</b>	<b>5,897,225</b>	<b>6,091,089</b>

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



**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A Development Stage Company)

**CONSOLIDATED STATEMENT OF STOCKHOLDER'S EQUITY**

**PERIOD FROM AUGUST 23, 2000 (INCEPTION) TO DECEMBER 31, 2003**

	Preferred Stock		Common Stock		Additional
	Shares	Amount	Shares	Amount	Capital
Balance, August 23, 2000 (inception) restated for effect of reverse merger with Historical Autographs U.S.A., Inc.			—	\$ —	\$ —
Stock issuance in exchange for cash			5,000,000	50	4,950
<b>Net loss</b>					
Balance, December 31, 2000, as restated	—	—	5,000,000	50	4,950
Issuance of junior preferred stock for cash of \$ 250,000 and in exchange for patent rights, research and development costs, and employee loan-out costs less issuance expenses of \$11,268, June 29, 2001	681,818	7			958,278
				Deficit Accumulated During the Development Stage	
		Deferred Costs			Total
Balance, August 23, 2000 (inception) restated for effect of reverse merger with Historical Autographs U.S.A., Inc.					\$ —
Stock issuance in exchange for cash					5,000
<b>Net loss</b>				(9,454)	(9,454)
Balance, December 31, 2000, as restated			—	(9,454)	(4,454)
Issuance of junior preferred stock for cash of \$250,000 and in exchange for patent rights, research and development costs, and employee loan-out costs less issuance expenses of \$11,268, June 29, 2001		(343,553)			614,732

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

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)

**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**

**PERIOD FROM AUGUST 23, 2000 (INCEPTION) TO DECEMBER 31, 2003**

	Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Costs	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount				
Issuance of common stock in exchange for patent rights and deferred research and development costs			362,669	4	547,284			547,288
Services receivable						(550,000)		550,000
Deferred employee loan-out costs								
receivable earned						82,888		82,888
Net loss							(237,574)	(237,574)
Balance December 31, 2001	681,818	7	5,362,669	54	1,510,512	(810,665)	(247,028)	452,880
Amendment of December 31, 2001 agreement for the issuance of common stock agreement in exchange for research and development services					(495,599)	550,000		54,401
Deferred employee loan-out costs								
receivable earned						171,776		171,776
Issuance of common stock for compensation			70,000	1	10,499			10,500
Issuance of common stock for cash			999,111	9	149,857			149,866

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)

**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**

**PERIOD FROM AUGUST 23, 2000 (INCEPTION) TO DECEMBER 31, 2003**

	Preferred Stock		Common Stock		Additional	Deferred	Deficit	
	Shares	Amount	Shares	Amount	Paid-In	Costs	Accumulated	Total
					Capital		During the	
							Development	
							Stage	
Net loss							(494,780)	(494,780)
Balance, December 31, 2002	681,818	\$ 7	6,431,780	\$ 64	\$ 1,175,269	\$ (88,889)	\$ (741,808)	\$ 344,643
Issuance of common stock for cash less issuance expense of \$2,956			417,000	417	246,827			247,244
Issuance of common stock for convertible debenture less issuance expense of \$519,230			4,000,000	4,000	3,476,770			3,480,770
Issuance of common stock for convertible debenture less issuance expense of \$49,500			400,000	400	350,100			350,500
Shares issued in connection with acquisition of Historical Autographs U.S.A., Inc. on October 30, 2003			1,220,000	8,263	(8,263)			—
Value of warrants and beneficial conversion feature of bridge loan					244,795			244,795
Deferred employee loan-out costs receivable earned						88,889		88,889
Preferred Stock converted to Common Stock	(681,818)	(7)	681,818	7				
Net loss							(885,693)	(885,693)
Balance, December 31, 2003	—	\$ —	13,150,598	\$ 13,151	\$ 5,485,498	—	\$ (1,627,501)	\$ 3,871,148



**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A Development Stage Company)

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year ended December 31, 2003	Year ended December 31, 2002	Period from August 23, 2000 (Inception) to Period Ended December 31, 2003
<b>CASH FLOWS USED FOR OPERATING ACTIVITIES:</b>			
Net loss	\$ (885,693)	\$ (494,780)	\$ (1,627,501)
<b>ADJUSTMENTS TO RECONCILE NET INCOME (LOSS) TO NET CASH PROVIDED BY (USED FOR) OPERATING ACTIVITIES:</b>			
Amortization of debt discount	244,795	—	244,795
Depreciation and amortization	40,243	33,774	92,337
Issuance of common stock for compensation	—	10,500	10,500
Settlement of accrued expense	—	54,401	54,401
Deferred compensation costs	88,889	171,776	319,553
<b>CHANGES IN ASSETS AND LIABILITIES:</b>			
<b>(INCREASE) DECREASE IN ASSETS:</b>			
Prepaid expenses	(135,177)	8,798	(155,988)
Deposit	—	—	(7,434)
<b>INCREASE (DECREASE) IN LIABILITIES:</b>			
Accrued liabilities	78,411	53,817	148,230
Other	—	5,556	5,556
<b>Total adjustments</b>	<b>317,161</b>	<b>338,622</b>	<b>711,950</b>
Net cash used for operating activities	(568,532)	(156,158)	(915,551)
<b>CASH FLOWS USED FOR INVESTING ACTIVITIES -</b>			
purchase of property and equipment	(23,470)	(6,340)	(37,115)
<b>CASH FLOWS PROVIDED BY (USED FOR) FINANCING ACTIVITIES:</b>			
Proceeds from convertible promissory note	400,000	—	400,000
Proceeds from issuance of preferred stock	—	—	250,000
Proceeds from issuance of common stock	4,250,200	149,866	4,405,066
Payments on capital lease obligations, net	(7,275)	(2,373)	(9,648)
Cost of issuance of preferred stock	—	—	(11,268)
Cost of issuance of common stock	(571,686)	—	(574,398)
Net cash provided by financing activities	4,071,239	147,493	4,459,752
<b>NET INCREASE (DECREASE) IN CASH</b>	<b>3,479,237</b>	<b>(15,005)</b>	<b>3,507,086</b>
CASH, beginning of period	27,849	42,854	—
<b>CASH, end of year</b>	<b>\$ 3,507,086</b>	<b>\$ 27,849</b>	<b>\$ 3,507,086</b>

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SUPPLEMENTAL DISCLOSURES OF CASH FLOW  
INFORMATION:

Interest paid	\$	—\$	—\$	—
Income taxes paid	\$	—\$	800	\$ 2,992

SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING  
INFORMATION:

During the year ended December 31, 2003, \$400,000 of convertible promissory notes were converted into 400,000 shares of common stock and 681,818 shares of preferred stock were converted into common shares.

See Note (1) regarding the transaction with Historical Autographs, U.S.A. Inc. The accompanying notes form an integral part of these consolidated financial statements.

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**FOR THE YEARS ENDED DECEMBER 31, 2003 AND 2002**

**(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

**GENERAL**

Arbios Systems, Inc. and its wholly owned subsidiary (collectively, the "Company") are engaged in developing and marketing liver-assist devices to meet the urgent need for therapy that facilitates recovery from liver failure. The Company's products in development are called SEPET(TM), which is a blood purification therapy device for patients with liver failure, and LIVERAID(TM), which is a bioartificial liver.

On October 30, 2003, Historical Autographs U.S.A., Inc. and Arbios Technologies, Inc. consummated a reverse merger, in which Arbios Technologies, Inc. became the wholly owned subsidiary of Historical Autographs U.S.A., Inc. Concurrently with the merger, Historical Autographs U.S.A., Inc. changed its name to Arbios Systems, Inc. and is herein referred to as "Systems". The shareholders of Arbios Technologies, Inc. transferred ownership of one hundred percent of all the issued and outstanding shares of their capital stock of Arbios Technologies, Inc. in exchange for 11,930,598 newly issued shares, or approximately 91%, of the common stock, \$0.001 par value, of Systems. At that time, the former management of Systems resigned and was replaced by the same persons who serve as officers and directors of Arbios Technologies, Inc. Inasmuch as the former owners of Arbios Technologies, Inc. controlled the combined entity after the merger, the combination was accounted for as a purchase by Arbios Technologies, Inc. as acquirer, for accounting purposes in accordance with Statement of Financial Accounting Standards No. 141 using reverse merger accounting, and no adjustments to the carrying values of the assets or liabilities of the acquired entity were required. Proforma operating results, as if the acquisition had taken place at the beginning of the period, have not been presented as the operations of the acquiree were negligible. The financial position and results of operations of Systems is included in the consolidated statements of the Company from the date of acquisition.

**DEVELOPMENT STAGE ENTERPRISE:**

The Company is a development stage enterprise as defined in Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises." The Company is devoting substantially all of its present efforts to establish a new business. Its planned principal operations have not yet commenced, with the exception of research and development, which were initiated in 2000 and are being vigorously pursued. All losses accumulated since inception have been considered as part of the Company's development stage activities. Payments received under contracts to fund certain research activities are recognized in the period on which the research activities are performed. Payments received in advance that are related to future performance will be deferred and recognized as revenue when the research projects are performed.

**PRINCIPLES OF CONSOLIDATION:**

The accompanying consolidated financial statements include the accounts of the Systems and its wholly owned subsidiary, Arbios Technologies, Inc. All material intercompany accounts have been eliminated in consolidation.

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

**(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, CONTINUED:**

**USE OF ESTIMATES:**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**FEDERAL GOVERNMENT GRANTS:**

The Company is partially funded by certain governmental grants. Payments received under contracts to fund certain research activities are recognized as revenue in the period in which the research activities are performed. Payments received in advance that are related to future performance will be deferred and recognized as revenue when the research project are performed. Reimbursements recorded under these grants are subject to governmental audit. Management believes that material adjustments will not result from subsequent audits, if any, of costs reflected in the accompanying financial statements.

**COMPREHENSIVE INCOME:**

SFAS No. 130, "Reporting Comprehensive Income", establishes standards for the reporting and display of comprehensive income and its components in the financial statements. As of December 31, 2003 and 2002, the Company has no items that represent comprehensive income and therefore, the Company has not included a schedule of comprehensive income in the financial statements.

**PROPERTY AND EQUIPMENT:**

Property and equipment are stated at cost. Depreciation is provided using the straight-line method over estimated useful lives of the assets of five years.

**PATENT RIGHTS:**

The Company purchased the exclusive right to certain patents (see Note 3). These patents are recorded at fair market value as of the date of purchase. They are amortized over the estimated useful life or remaining legal life at the date of purchase, whichever is shorter.

**DEFERRED EMPLOYEE LOAN-OUT COSTS RECEIVABLE:**

The Company purchased the loan-out of certain employees in exchange for junior preferred stock (see Note 4). These loan-out costs are expensed as the employee services are performed.



**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, CONTINUED:

**FAIR VALUE OF FINANCIAL INSTRUMENTS:**

The Company's financial instruments, none of which are held for trading purposes, include cash and accounts payable and accrued expenses, have carrying amounts which approximate fair value due to their short maturities.

**INCOME TAXES:**

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reported amounts at each period end, based on enacted tax laws and statutory tax rates applicable to the period in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The provision for income taxes represents the tax payable for the period, if any, and the change during the period in deferred tax assets and liabilities.

**STOCK-BASED COMPENSATION:**

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

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, CONTINUED:

**STOCK-BASED COMPENSATION, CONTINUED:**

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

	December 31, 2003	December 31, 2002
Net loss as reported	\$ (885,693)	\$ (494,780)
Compensation recognized under APB 25	—	—
Compensation recognized under SFAS 123	(12,710)	(18,042)
	\$ (898,403)	\$ (512,822)
<b>Basic and diluted loss per common share:</b>		
As reported	\$ (0.11)	\$ (0.08)
Proforma	\$ (0.11)	\$ (0.09)

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

**LOSS PER SHARE:**

The Company utilizes SFAS No. 128, "Earning per Share." Basic loss per share is computed by dividing loss available to common shareholders by the weighted-average number of common shares outstanding. Diluted loss per share is computed similar to basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. The computation of diluted loss per share does not assume conversion, exercise or contingent exercise of securities that would have an anti-dilutive effect on losses.

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, CONTINUED:

**RECENT ACCOUNTING PRONOUNCEMENTS:**

During April 2003, the FASB issued SFAS 149 - "Amendment of Statement 133 on Derivative Instruments and Hedging Activities", effective for contracts entered into or modified after June 30, 2003, except as stated below and for hedging relationships designated after June 30, 2003. In addition, except as stated below, all provisions of this Statement should be applied prospectively. The provisions of this Statement that relate to Statement 133 Implementation Issues that have been effective for fiscal quarters that began prior to June 15, 2003, should continue to be applied in accordance with their respective effective dates. In addition, paragraphs 7(a) and 23(a), which relate to forward purchases or sales of when-issued securities or other securities that do not yet exist, should be applied to both existing contracts and new contracts entered into after June 30, 2003. The Company does not participate in such transactions, however, is evaluating the effect of this new pronouncement, if any.

During May 2003, the FASB issued SFAS 150 - "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity", effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. This Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a freestanding financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. Some of the provisions of this Statement are consistent with the current definition of liabilities in FASB Concepts Statement No. 6, Elements of Financial Statements. The Company has implemented this pronouncement and has concluded that the adoption has no material impact to the financial statements.

In December 2003, the FASB issued a revised SFAS No. 132, "Employers' Disclosures about Pensions and Other Postretirement Benefits" which replaces the previously issued Statement. The revised Statement increases the existing disclosures for defined benefit pension plans and other defined benefit postretirement plans. However, it does not change the measurement or recognition of those plans as required under SFAS No. 87, "Employers' Accounting for Pensions," SFAS No. 88, "Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits," and SFAS No. 106, "Employers' Accounting for Postretirement Benefits Other Than Pensions." Specifically, the revised Statement requires companies to provide additional disclosures about pension plan assets, benefit obligations, cash flows, and benefit costs of defined benefit pension plans and other defined benefit postretirement plans. Also, companies are required to provide a breakdown of plan assets by category, such as debt, equity and real estate, and to provide certain expected rates of return and target allocation percentages for these asset categories. The Company has implemented this pronouncement and has concluded that the adoption has no material impact to the financial statements.

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

## (1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, CONTINUED:

**RECENT ACCOUNTING PRONOUNCEMENTS, CONTINUED:**

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities." Interpretation 46 changes the criteria by which one company includes another entity in its consolidated financial statements. Previously, the criteria were based on control through voting interest. Interpretation 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. A company that consolidates a variable interest entity is called the primary beneficiary of that entity. In December 2003 the FASB concluded to revise certain elements of FIN 46, which will be issued shortly. The FASB also modified the effective date of FIN 46. For all entities that were previously considered special purpose entities, FIN 46 should be applied in periods ending after December 15, 2003. Otherwise, FIN 46 is to be applied for registrants who file under Regulation S-X in periods ending after March 15, 2004, and for registrants who file under Regulation SB, in periods ending after December 15, 2003. The Company does not expect the adoption to have a material impact on the Company's financial position or results of operations. (2) PROPERTY AND EQUIPMENT: Property and equipment consisted of the following:

	December 31, 2003
Office equipment	\$ 866
Computer equipment	23,277
Medical equipment	37,971
	62,114
Less accumulated depreciation	16,481
	\$ 45,633

Depreciation expense was \$10,641, \$4,172, and \$16,481 for the year ended December 31, 2003 and 2002, and the period from August 23, 2000 (inception) to December 31, 2003, respectively.

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

**(3) PATENT RIGHTS:**

In June 2001, the Company received exclusive rights to four existing patents and one pending patent. At the date of exchange, the aggregate value of these rights was \$400,000. At December 31, 2003 and 2002, the accumulated amortization of these rights was \$75,856 and \$46,253, and the estimated remaining life was 8 years. Amortization expense was \$29,602, \$29,602, and \$75,856 for the years ended December 31, 2003 and 2002 and the period from August 23, 2000 (inception) to December 31, 2003, respectively. Future estimated amortization expense is as follows:

Year ending December 31,		
2004	\$	29,602
2005		29,602
2006		29,602
2007		29,602
2008		29,602
Thereafter		176,135
		<hr/>
	\$	324,145
		<hr/>

In conjunction with the patents rights described above, the Company committed to the licensor to spend a total of \$1,760,000 in research and development expenses toward the development and promotion of products, commencing from the acquisition date until June 30, 2008. Future remaining minimum payments under this agreement were as follows:

Year ending December 31,		
2004	\$	150,000
2005		200,000
2006		300,000
2007		400,000
2008		500,000
		<hr/>
	\$	1,550,000
		<hr/>

In the event the Company expends more than the minimum annual amount in any year, the excess may be carried over to the subsequent year. For the years ended December 31, 2003 and 2002, and the period from August 23, 2000 (inception) to December 31, 2003, the research and development costs incurred were \$436,849, \$431,199, and \$1,009,674, respectively. As of December 31, 2003, the Company had a \$799,674 as carryforward to apply to future years.

The Company is subject to paying royalty fees to the licensor, who is a shareholder, equal to 1.5% of the gross sales price of royalty bearing products. From year three to the tenth year of the license the royalty fee percent will phase out evenly to 0%. As of December 31, 2003 and 2002, the Company had not paid any royalty fees since it did not have any sales of royalty bearing products.



**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

(4) DEFERRED EMPLOYEE LOAN-OUT COSTS:

In June 2001, the Company received a commitment for the loan-out of certain employees over a two-year period in exchange for junior preferred stock (see note 8). The Company has deferred the estimated loan-out costs over the two-year period. The loan-out costs are expensed as the services are performed. At the date of the exchange, the cost of the employee loan-out over the two-year period was \$319,553.

In December 2001, the Company paid \$24,000 to purchase additional employee loan-out costs. For the years ended December 31, 2003 and 2002, and the period from August 23, 2000 (inception) to December 31, 2003, the amortized employee loan-out costs were \$88,889, \$171,776, and \$343,553, respectively.

(5) CONVERTIBLE PROMISSORY NOTES:

In September 2003, the Company issued units of convertible subordinated notes and warrants, consisting of convertible promissory notes (the "Notes") for an aggregate principal amount of \$400,000 and warrants for the purchase 300,000 shares of the Company's common stock at \$1 per share. The Notes bore interest at 7% per annum and were due on the earlier of March 31, 2004 or upon the occurrence of various other events or conditions set forth in the Notes. Under the terms of the Notes, the holders retained the right, subject to certain exceptions, to convert all or any part of the principal outstanding under the Notes into (i) shares of the Company's Common Stock at a conversion price per share equal to \$1 and (ii) warrants for the purchase of Company's common stock at \$2.50 per share.

The conversion price was subject to adjustment in the event of a stock split, combination or like transaction. The warrant price was subject to adjustment in the event of a stock split, combination or like transaction. The Company recorded the Notes net of a discount equal to the fair value allocated to the warrants issued of \$122,390. The Notes also contained a beneficial conversion feature, which resulted in additional debt discount of \$122,390. The beneficial conversion amount was measured using the accounting intrinsic value, i.e. the excess of the aggregate fair value of the common stock into which the debt is convertible over the proceeds allocated to the security.

In October 2003, the Notes were converted into 400,000 shares of common stock at \$1 per share. The Company recognized interest expense totaling \$224,401 for the unamortized warrants and beneficial conversion feature discount in accordance with Emerging Issues Task Force 00-27.

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

(6) COMMITMENTS AND CONTINGENCIES:

**Commitments**

The Company leases office facilities and equipment under noncancellable operating leases, which require monthly payments of \$6,441 and expire in June 2004. The Company is required to pay for taxes, insurance, and maintenance. The Company is subleasing lab space for \$2,777 per month. Rent expense was \$77,202, \$71,736, and \$187,080 for the years ended December 31, 2003 and 2002, and the period from August 23, 2000 (inception) to December 31, 2003, respectively.

**Agreements**

On December 26, 2001, the Company received the exclusive worldwide rights and license to use certain proprietary rights from Spectrum Laboratories, Inc. ("Spectrum") partially in exchange for 362,669 shares of common stock (see note 8). The license grants the Company the right to use Spectrum's technology and to exploit such rights to develop and distribute products solely for use in the Company's liver-assist devices. In addition, the Company entered into a manufacturing and supply agreement with Spectrum. The agreement stipulates that the Company must contract with Spectrum for the manufacture and supply of certain products used in the liver-assist devices.

(7) STOCKHOLDERS' EQUITY:

**Preferred Stock**

The Company has 5,000,000 shares of preferred stock authorized. There are no shares of preferred stock issued or outstanding. The board of directors has the authority to set by resolution the particular designation, preferences and other special rights and qualification of preferred stock.

**Junior Preferred Stock**

In June 2001, Arbios Technologies, Inc. issued 681,818 shares of junior preferred stock, in exchange for \$250,000 in cash, exclusive rights to certain patents and one pending patent valued at \$400,000 (see Note 3), and future services of certain employees valued at \$319,553 (see Note 4).



**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
(A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

(7) STOCKHOLDERS' EQUITY, CONTINUED:

**Junior Preferred Stock (Continued)**

In October 2003, all issued and outstanding shares of the junior preferred stock were converted into 681,818 shares of common stock.

**Common Stock**

In August 2000, Arbios Technologies, Inc. issued 5,000,000 shares of common stock, \$0.001 par value, to the Company's two officers in exchange for \$5,000 in cash.

In December 2001, Arbios Technologies, Inc. issued 362,669 shares of common stock in exchange for future research costs valued at \$550,000, an exclusive license (see Note 8), a manufacturing and supply agreement (see Note 8), and exclusive rights to one patent and one pending patent.

In June 2002, Arbios Technologies, Inc. issued 70,000 shares of common stock to a Board member as compensation for services rendered valued at \$10,500.

In July 2002, Arbios Technologies, Inc. issued 999,111 shares of common stock to investors in exchange for \$149,866 in cash, or \$.15 per share.

In July 2002, Arbios Technologies, Inc. issued options to purchase 18,000 shares of common stock to each of its five Board members for services rendered. The options are exercisable at \$0.15 per share. The options vest 50% in six months and 50% in 12 months from the beginning date of service provided by the respective Board members.

In July 2002, Arbios Technologies, Inc. issued a warrant to purchase 100,000 shares of common stock to a Board member for services rendered to the Company. The warrant is exercisable at \$0.15 per share and has a 7-year life. The warrant also has conversion rights in lieu of payment of the exercise price and is not transferable.

In January 2003, Arbios Technologies, Inc. issued 417,000 shares of common stock and warrants to purchase 600,000 shares of common stock at an exercise price of \$1.00 per share to an investor in exchange for \$250,200 in cash. The Company recognized \$2,956 in stock issuance expense.

In September and October 2003, Arbios Technologies, Inc. issued 4,000,000 shares of common stock and warrants to purchase 4,000,000 shares of common stock at an exercise price of \$2.50 in exchange for \$4,000,000 in cash. The Company recognized \$519,230 in stock issuance expense.

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

**(7) STOCKHOLDERS' EQUITY, CONTINUED:****Common Stock (Continued)**

In September 2003, convertible promissory notes totaling \$400,000 were converted into 400,000 shares of Company's common stock.

In October 2003, Arbios Technologies, Inc. entered into a reorganization transaction wherein the shareholders of Systems retained 1,220,000 shares of the reorganized entity after the transaction. Since Systems was treated as the acquiree for accounting purposes, those shares were accounted for as being issued as of that date. Stock Option Plan

In 2001, Systems adopted the 2001 Stock Option Plan (the "Company Plan") for the purpose of granting incentive stock options and/or non-statutory stock options to employees, consultants, directors and others. Under the Company Plan, the Company is authorized to grant options to purchase up to 1,000,000 shares. The Company Plan is administered by the Board of Directors of the Company or by a committee of the Board. However, in connection with the reorganization transaction between Systems and Arbios Technologies, Inc. in October 2003, Systems assumed all of the 314,000 outstanding options granted by Arbios Technologies, Inc. under its existing stock option plan and the options previously issued under that plan were cancelled. None of the terms of the assumed options were changed, the options assumed under the Company Plan are identical to the options that were previously granted under the Technologies Plan.

Transactions under the Plan during the year ended December 31, 2003 and 2002 are summarized as follows:

	Stock Option Plan	Weighted Average Exercise Price
Balance, December 31, 2001	—	\$ —
Granted	90,000	\$ 0.15
Canceled	—	\$ —
Balance, December 31, 2002	90,000	\$ 0.15
Granted	233,000	\$ 1.00
Canceled	9,000	\$ 0.15
Balance, December 31, 2003	<u>314,000</u>	<u>\$ 0.78</u>
Options exercisable, December 31, 2003	<u>194,000</u>	<u>\$ 0.61</u>

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

**(7) STOCKHOLDERS' EQUITY, CONTINUED:****Warrants:**

As of December 31, 2003, warrants to purchase 5,050,000 shares of common stock at prices ranging from \$0.15 to \$2.50 were outstanding. All warrants are exercisable as of December 31, 2003 and expire at various dates through 2008.

**(8) RESEARCH COSTS:**

On December 26, 2001, the Company received a commitment for research costs in the amount of \$550,000 from Spectrum Laboratories, Inc. ("Spectrum") partially in exchange for 362,669 shares of common stock (See Note 6). Spectrum was required to expend at least \$137,500 per year toward the development of the Company's liver-assist devices. The original agreement was to expire on November 30, 2005 and stipulated the following yearly minimum research costs expenditures by Spectrum:

Year ending December 31,		
2002	\$	148,958
2003		137,500
2004		137,500
2005		126,042
	\$	550,000

In the event Spectrum expended more than the minimum annual amount in any year, the excess was carried over to the subsequent year. For the years ended December 31, 2003 and 2002, and the period from August 23, 2000 (inception) to December 31, 2003, the research and development costs incurred by Spectrum was \$0, respectively. The Company may repurchase a portion of the foregoing shares for nominal consideration if less than the specified amounts are expended by Spectrum.

In July 2002, the original agreement was amended. The Company and Spectrum agreed that, since the prototype system had been delivered early, all 362,669 shares issued to Spectrum on December 26, 2001, were deemed fully vested and any future obligations of \$550,000 research cost commitment was deemed fulfilled. In addition, any additional research and development work requested from Spectrum by the Company and the cost of such work will be negotiated in good faith before the work is initiated and that the Company will pay for such work in 36 monthly cash installments. Furthermore, the Company agreed that billings of \$109,360, through September 29, 2002, were due for research costs already provided, in lieu of the original \$550,000 obligation. This amount was reduced by \$54,400 in payment for the 362,669 shares previously received, and the Company shall pay the balance of \$54,960 to Spectrum in cash in monthly payments over an 18-month period starting November 1, 2002.

**ARBIOS SYSTEMS, INC. AND SUBSIDIARY**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**  
**YEARS ENDED DECEMBER 31, 2003 AND 2002**

**(9) INCOME TAXES:**

The actual tax benefits differ from the expected tax benefit computed by applying the United States federal corporate tax rate of 34% to loss before income taxes as follows for the years ended December 31, 2003 and 2002, and the period from August 23, 2000 (inception) to December 31, 2003:

	Year Ended December 31, 2003	Year Ended December 31, 2002	Period from August 23, 2000 (inception) to December 31, 2003
Expected tax benefit	\$ (301,136)	\$ (168,226)	\$ (553,562)
State income taxes, net of federal benefit	(49,767)	(28,867)	(76,191)
Other	—	(20,979)	(20,979)
Changes in valuation allowance	\$ 350,903	\$ 218,072	650,732
	\$ —	\$ —	\$ —

The following table summarizes the significant components of the Company's deferred tax asset at December 31, 2003:

	December 31, 2003
Deferred tax asset arising from net operating loss carryforward	\$ 650,732
Less valuation allowance	(650,732)
Net deferred tax asset	\$ —

The Company recorded a valuation allowance of 100% for its net operating loss carryforward due to the uncertainty of its realization.

For the year ended December 31, 2003, the Company had an operating loss carryforward of approximately \$1,627,000, which begins expiring in 2016.

**(10) RELATED PARTY TRANSACTION:**

In 2003, the son of a director received 7,500 shares of common stock valued at \$1 per share as a finder's fee.



**UNAUDITED**  
**FINANCIAL**  
**STATEMENTS**

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

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

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

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

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

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



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

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

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



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

**(1) BASIS OF PRESENTATION:**

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

The unaudited condensed consolidated financial statements and notes are presented pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures, normally included in financial statements prepared in accordance with generally accepted accounting principles, have been omitted pursuant to such SEC rules and regulations. These financial statements should be read in conjunction with the Company's audited financial statements and the accompanying notes for the year ended December 31, 2003 included in this prospectus. The results of operations for the three month and nine month periods ended September 30, 2004 are not necessarily indicative of the results to be expected for any subsequent quarter or for the entire fiscal year.

**(2) Stock-Based Compensation:**

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

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

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

### (3) Contract Commitment

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

**PART II - INFORMATION NOT REQUIRED IN PROSPECTUS****ITEM 24. INDEMNIFICATION OF DIRECTORS AND OFFICERS**

Nevada law provides that Nevada corporations may include within their articles of incorporation provisions eliminating or limiting the personal liability of their directors and officers in shareholder actions brought to obtain damages for alleged breaches of fiduciary duties, as long as the alleged acts or omissions did not involve intentional misconduct, fraud, a knowing violation of law or payment of dividends in violation of the Nevada statutes. Nevada law also allows Nevada corporations to include in their articles of incorporation or bylaws provisions to the effect that expenses of officers and directors incurred in defending a civil or criminal action must be paid by the corporation as they are incurred, subject to an undertaking on behalf of the officer or director that he or she will repay such expenses if it is ultimately determined by a court of competent jurisdiction that such officer or director is not entitled to be indemnified by the corporation because such officer or director did not act in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the corporation.

Nevada law also provides that Nevada corporations may eliminate or limit the personal liability of its directors and officers.

Our Articles of Incorporation provide that no officer or director shall be personally liable to this corporation or its shareholders for monetary damages for breach of fiduciary duty as a director or officer of this corporation. Our bylaws and Articles of Incorporation also provide that we shall, to the maximum extent and in the manner permitted by the Nevada Revised Statutes, indemnify each person who serves at any time as a director or officer of Arbios Systems, Inc. from and against any and all expenses, judgments, fines, settlements and other amounts actually and reasonable incurred in connection with any proceeding arising by reason of the fact that he is or was an agent of Arbios Systems, Inc.. We also have the power to defend such person from all suits or claims in accord with the Nevada Revised Statutes. The rights accruing to any person under our bylaws and Articles of Incorporation do not exclude any other right to which any such person may lawfully be entitled, and we may indemnify or reimburse such person in any proper case, even though not specifically provided for by the bylaws and Articles of Incorporation.

Insofar as indemnification for liabilities for damages arising under the Securities Act of 1933, (the "Act") may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provision, or otherwise, we have been advised that in the opinion of the Security and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

**ITEM 25. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION**

We estimate that expenses in connection with the distribution described in this registration statement (other than brokerage commissions, discounts or other expenses relating to the sale of the shares by the selling stockholders) will be as set forth below. We will pay all of the expenses with respect to the distribution, and such amounts, with the exception of the Securities and Exchange Commission registration fee, are estimates.

SEC registration fee	\$ 1,597.93
Accounting fees and expenses	\$ 2,000
Legal fees and expenses	\$ 25,000
Printing and related expenses	1,000
Transfer agent fees and expenses	-0-
Miscellaneous	\$ 3,402.07
<b>Total</b>	<b>\$ 33,000</b>

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## ITEM 26. RECENT SALES OF UNREGISTERED SECURITIES

In June 2001, Arbios Technologies, Inc. sold 681,818 shares of its Junior Preferred Stock to Cedars-Sinai Medical Center for \$250,000. Concurrently and in connection with the foregoing issuance of Junior Preferred Stock, Cedars-Sinai Medical Center granted to Arbios Technologies, Inc. an exclusive, worldwide license to five patents and other technical information. The foregoing shares were sold pursuant to an exemption available under Section 4(2) of the Securities Act of 1933 (the "Securities Act") because the issuance did not involve any public offering.

In December 2001, Arbios Technologies, Inc. sold 362,669 shares of common stock to Spectrum Laboratories, Inc. In connection with the sale of the 362,669 shares of common stock, Arbios Technologies, Inc. and Spectrum Laboratories, Inc. entered into a License Agreement, a Research Agreement, and a Manufacturing and Supply Agreement. In addition, the total amount of cash consideration paid by Spectrum Laboratories, Inc. for the shares is \$54,400. The foregoing shares were sold to Spectrum Laboratories, Inc. pursuant to an exemption available under Section 4(2) of the Securities Act.

In August 2002, Arbios Technologies, Inc. sold 999,111 shares of common stock at a price of \$0.15 per share to six accredited investors. The foregoing securities were sold pursuant to an exemption available under Section 4(2) of the Securities Act.

In August 2002, Arbios Technologies, Inc. issued a warrant to purchase 100,000 shares of common stock to Technomedics Management and Systems, Inc. for services rendered to Arbios Technologies, Inc. The warrant enables the holder to purchase up to 100,000 shares of common stock at an exercise price of \$0.15 per share until August 18, 2009. The foregoing warrant was issued pursuant to an exemption available under Section 4(2) of the Securities Act.

In January 2003, Arbios Technologies, Inc. sold (i) 417,000 shares of common stock, and (ii) warrants to purchase 600,000 shares of common stock to one accredited investor for an aggregate purchase price of \$250,000. The warrants are exercisable through January 28, 2007 at a price of \$1.00 per share. The foregoing securities were sold pursuant to an exemption available under Section 4(2) of the Securities Act.

In September 2003, Arbios Technologies, Inc., sold 2,310,000 Units, at a price of \$1.00 per Unit, to a total of 41 investors. All investors were accredited investors. Each unit consisted of one share of Arbios Technologies, Inc.'s common stock and one common stock purchase warrant, that is exercisable at \$2.50 per share for a period of three years. The offering was effected pursuant to an exemption available under Section 4(2) of the Securities Act and Rule 506 promulgated thereunder. No underwriters were involved in the offering, although Arbios Technologies, Inc. did pay a placement agent fee to Spencer Edwards, Inc..

In October 2003, Arbios Technologies, Inc., sold 1,690,000 Units, at a price of \$1.00 per Unit, to a total of 24 investors. All investors were accredited investors. Each unit consisted of one share of Arbios Technologies, Inc.'s common stock and one common stock purchase warrant, that is exercisable at \$2.50 per share for a period of three years. The offering was effected pursuant to an exemption available under Section 4(2) of the Securities Act and Rule 506 promulgated thereunder.

In December, 2003, we issued to (i) Richard W. Bank 40,000 shares of common stock, and a warrant to purchase 40,000 additional shares of common stock at an exercise price of \$2.50 per share, and (ii) Adam Hausman 7,500 shares of common stock, and a warrant to purchase 7,500 additional shares of common stock at an exercise price of \$2.50 per share. The foregoing shares and warrants were issued as consideration for the services rendered by Dr. Bank and Mr. Hausman to Arbios Systems, Inc. Dr. Bank is a member of the Board of Directors of Arbios Systems, Inc., and Mr. Hausman is the son of Marvin S. Hausman, a member of the Board of Directors of Arbios Systems, Inc. The foregoing securities were sold pursuant to an exemption available under Section 4(2) of the Securities Act.

In connection with our acquisition of Arbios Technologies, Inc. by merger on October 30, 2003, Arbios Systems, Inc. issued 11,930,598 shares of our common stock to the 72 former stockholders of Arbios Technologies, Inc. in exchange for all of their shares of Arbios Technologies, Inc. All of the 72 former Arbios Technologies, Inc. stockholders were “accredited investors.” The shares were issued pursuant to an exemption available under Section 4(2) of the Securities Act.

In September 2003, we sold 16 units of convertible promissory notes and warrants (the “Bridge Units”), at a price of \$25,000 per Bridge Unit, to ten accredited investors. Each Bridge Unit consisted of (i) a \$25,000 principal amount convertible, subordinated promissory note of Arbios Technologies, Inc. and (ii) three-year warrants to purchase 18,750 shares of Arbios Technologies, Inc.’s common stock at an exercise price of \$1.00 per share. The notes bore interest at 7% per annum and, unless converted, were payable on March 31, 2004. In 2004, all ten holders of outstanding convertible promissory notes of Arbios Technologies, Inc. converted their notes, in accordance with the terms of those notes, into 400,000 shares of common stock, and warrants to purchase an additional 400,000 shares at an exercise price of \$2.50 per share.. The Bridge Units were issued pursuant to an exemption available under Section 4(2) of the Securities Act, and the issuance of the common stock and additional warrants upon the conversion of the notes was exempt pursuant to Section 3(a)(9) of the Securities Act. No commissions were paid, and no underwriter was involved in the sale of the Bridge Units or the conversion of the promissory notes.

Since the acquisition of Arbios Technologies, Inc., Arbios Systems, Inc. has issued options to purchase shares of common stock from time to time under the 2003 Stock Option Plan. The stock option grants were exempt from registration pursuant to Section 4(2) of the Securities Act, since they were made to a small number of informed executive officers of the company or consultants who had access to all information relevant to their investment decisions. In addition, pursuant to the acquisition of Arbios Technologies, Inc., Arbios Systems, Inc. assumed all outstanding options under Arbios Technologies, Inc.'s Stock Option Plan (on the same terms and conditions as in effect prior to the merger), which were granted by Arbios Technologies, Inc. without registration pursuant to the exemption from registration available under Rule 701 under the Securities Act. Arbios Systems, Inc. plans to register under the Securities Act the offering of common stock pursuant to all options granted or which may be granted in the future under the 2003 Stock Option Plan (including the Arbios Technologies, Inc. options assumed in the acquisition).

On March 30, 2004, Arbios Systems, Inc. entered into a retainer agreement with Wolfe Axelrod Weinberger Associates LLC, an investor relations firm. Pursuant to that agreement, we granted to Wolfe Axelrod Weinberger Associates LLC a warrant to purchase 150,000 shares of our common stock at a price of \$3.40 per share. The warrant expires on April 1, 2009. Pursuant to the terms of that warrant, the number of shares that can be purchased under that warrant was reduced in December 2004 to 75,000 shares. The warrant was issued pursuant to an exemption available under Section 4(2) of the Securities Act.



In July, 2004, the Company entered into an agreement with 4P Management Partners S.A. of Zurich, Switzerland, to perform investor relations services for the Company in Europe. The Company issued two warrants to 4P Management Partners S.A. to purchase an aggregate of 100,000 shares of common stock. The first warrant for 50,000 shares vests immediately with an exercise price of \$1.50 per share and a five year expiration term. The second warrant for 50,000 shares vests ratably each month over one year with an exercise price of \$3.50 per share and a five year expiration term. The shares were issued pursuant to an exemption available under Section 4(2) of the Securities Act.

In October 2004, an option holder exercised his option to purchase 18,000 shares of our common stock at an exercise price of \$1.00 per share. The shares were issued pursuant to an exemption available under Section 4(2) of the Securities Act.

On January 11, 2005, the Company sold to 16 institutional investors, two U.S. accredited persons, and four foreign accredited persons 2,991,812 shares of its common stock and warrants to purchase 1,495,906 shares of common stock. The aggregate purchase price of the securities sold in the private placement was \$6,611,905.65. The shares were sold at a price of \$2.21 per share. The warrants are exercisable at an initial cash exercise price of \$2.90 per share (subject to adjustment), and expire on January 11, 2010. The shares and warrants were sold in reliance upon the exemption from registration contained in Section 4(2) of the Securities Act and Regulation D promulgated thereunder because, among other things, the transaction did not involve a public offering, all of the investors were accredited individuals or institutional buyers, the investors had access to information about the Company, the investors represented that they are purchasing the securities for investment and not resale, and the Company has taken appropriate measures to restrict the transfer of the securities.

On February 1, 2005 we issued a warrant to purchase 200,000 shares of our common stock to AFO Advisors LLC, an advisor to the Company, as additional compensation for services rendered to the Company during the past 15 months. The warrants have a term of five years and have an exercise price of \$2.90 per share (the closing trading price of our common stock on the OTC Bulletin Board on the date of grant). The warrant was issued pursuant to an exemption available under Section 4(2) of the Securities Act.

## ITEM 27. EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
2.1	Agreement and Plan of Reorganization, dated October 20, 2003, between the Registrant, Arbios Technologies, Inc., HAUSA Acquisition, Inc., Cindy Swank and Raymond Kuh (1)
3.1	Articles of Incorporation of Historical Autographs U.S.A., Inc.(2)
3.2	Certificate of Amendment of Articles of Incorporation (1)
3.3	Bylaws (2)
4.1	Revised form of Common Stock certificate(4)
4.2	Form of Warrant for the Purchase of Shares of Common Stock issued by the Registrant upon the assumption of the Arbios Technologies, Inc. outstanding Warrant(4)
4.3	Common Stock Purchase Warrant, dated April 1, 2004, issued to Wolfe Axelrod Weinberger Associates LLC(5)

- 4.4 Form of Warrant to Purchase Common Stock of Arbios Systems, Inc. , dated January 11, 2005, issued to investors and placement agent (6)
- 5.1 Opinion of counsel as to legality of securities being registered.

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10.1	Form of 2001 Stock Option Plan (2)
10.2	Facilities Lease, entered into as of June 30, 2001, by and between Cedars-Sinai Medical Center and Arbios Technologies(4)
10.3	Standard Multi-Tenant Office Lease, dated as of February 13, 2004, by and between Beverly Robertson Design Plaza and Arbios Systems, Inc.(4)
10.4	Employee Loan-Out Agreement, entered into effective as of July 1, 2001, by and between Cedars-Sinai Medical Center and Arbios Technologies, Inc.(4)
10.5	Second Amendment to Employee Loan-Out Agreement, entered into effective as of May 7, 2003, by and between Cedars-Sinai Medical Center and Arbios Technologies, Inc.(4)
10.6	License Agreement, entered into as of June 2001, by and between Cedars-Sinai Medical Center and Arbios Technologies, Inc.(4)
10.7	Spectrum Labs License Agreement(4)
10.8	Third Amendment to Employee Loan-Out Agreement, entered into effective as of June 21, 2004, by and between Cedars-Sinai Medical Center and Arbios Systems, Inc. (5)
10.9	Asset Purchase Agreement among Circe Biomedical, Inc., a Delaware corporation, Arbios Technologies, Inc., and Arbios Systems, Inc., dated as of April 7, 2004(5)
10.10	Manufacturing and Supply Agreement, dated as of December 26, 2001, between Spectrum Laboratories, Inc. and Arbios Technologies, Inc. (5)
10.11	Research Agreement, dated as of December 26, 2001, between Spectrum Laboratories, Inc. and Arbios Technologies, Inc. (5)
10.12	First Amendment to Research Agreement, dated as of October 14, 2002, between Spectrum Laboratories, Inc. and Arbios Technologies, Inc. (5)
10.13	Third Amendment to Facilities Lease, entered into effective as of June __, 2004, by and between Cedars-Sinai Medical Center and Arbios Technologies, Inc. (5)
10.14	Form of Purchase Agreement, dated as of January 11, 2005, by and among Arbios Systems, Inc. and the Investors named therein. (6)
10.15	Form of Registration Rights Agreement, dated as of January 11, 2005, by and among Arbios Systems, Inc. and the Investors named therein.(6)
14.1	Arbios Systems, Inc. Code of Business Conduct and Ethics Adopted by the Board of Directors on January 15, 2004(4)
16.1	Letter on Change in Certifying Accountant (3)
21.1	List of Subsidiaries(4)
23.1	Consent of Stonefield Josephson, Inc., independent auditors

23.2 Consent of Troy & Gould Professional Corporation (reference is made to Exhibit 5.1)

24.1 Power of Attorney (reference is made to the signature page)

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- (1) Previously filed as an exhibit to the Company's Current Report on Form 8-K on October 14, 2003, which exhibit is hereby incorporated herein by reference.
- (2) Previously filed as an exhibit to the Company's Registration Statement Form 10-SB filed April 26, 2001, which exhibit is hereby incorporated herein by reference.
- (3) Previously filed as an exhibit to the Company's Current Report on Form 8-K on January 30, 2004, which exhibit is hereby incorporated herein by reference.
- (4) Previously filed as an exhibit to the Company's Annual Report on Form 10-KSB on March 30, 2004, which exhibit is hereby incorporated herein by reference.
- (5) Previously filed as an exhibit to the Company's Registration Statement on Form SB-2 filed on June 14, 2004, as amended, which exhibit is hereby incorporated herein by reference.
- (6) Previously filed as an exhibit to the Company's Current Report on Form 8-K on January 14, 2004, which exhibit is hereby incorporated herein by reference.

## **ITEM 28. UNDERTAKINGS**

### **A. Rule 415 Offering**

We hereby undertake:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933.
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.
  - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that paragraphs (1)(i) and (1)(ii) do not apply if the registration statement is on Form S-3 or Form S-8, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the Company pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

**B. Request for Acceleration of Effective Date**

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Company pursuant to the foregoing provisions, or otherwise, the Company has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Company of expenses incurred or paid by a director, officer or controlling person of the Company in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Company will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

**SIGNATURES**

In accordance with the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form SB-2 and authorized this registration statement to be signed on its behalf by the undersigned, in Los Angeles, California, on February 7, 2005.

**ARBIOS SYSTEMS, INC.**

Date: February 7, 2005

By: /s/ JACEK ROZGA, M.D., PH.D

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

**POWER OF ATTORNEY**

The officers and directors of Arbios Systems, Inc., whose signatures appear below, hereby constitute and appoint Jacek Rozga, M.D., Ph.D and Scott Hayashi and each of them, their true and lawful attorneys and agents, each with power to act alone, to sign, execute and cause to be filed on behalf of the undersigned any amendment or amendments, including post-effective amendments, to this registration statement of Arbios Systems, Inc. on Form SB-2. Each of the undersigned does hereby ratify and confirm all that said attorneys and agents shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ JACEK ROZGA Jacek Rozga, M.D., Ph.D	President (principal executive officer) and Chief Financial Officer (principal financial officer and principal accounting officer)	February 7, 2005
/s/ JOHN M. VIERLING John M. Vierling, MD	Chairman of the Board, and Director	February 7, 2005
/s/ ROY EDDLEMAN Roy Eddleman	Director	February 7, 2005
/s/ MARVIN S. HAUSMAN Marvin S. Hausman MD	Director	February 7, 2005

/s/ JACK E. STOVER  
Jack E. Stover

Director

February 7, 2005

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21.1	List of Subsidiaries(4)

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- 24.1 Power of Attorney (reference is made to the signature page)

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