ARBIOS SYSTEMS INC
Form 10KSB
March 30, 2005

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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FORM 10-KSB

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2004

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

_____

Commission File Number: **000-32603**

ARBIOS SYSTEMS, INC.
(Name of small business issuer in its charter)

Nevada	**91-1955323**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
8797 Beverly Boulevard, #206 Los Angeles, CA 90048	**90048**
(Address of principal executive offices)	(Zip Code)

Issuer's Telephone Number**: 310-657-4898**

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $.001 par value

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes x No o

Check if disclosure of delinquent filers pursuant to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. o

Issuer's revenues for its most recent fiscal year: $ 72,000

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of March 15, 2005 was approximately $18,666,000 based on the closing sales price reported by the OTC Bulletin Board on such date.

There were 16,207,909 shares of the Company's common stock outstanding on March 15, 2005.

Transitional Small Business Disclosure Format (check one): YES o NO x

DOCUMENTS INCORPORATED BY REFERENCE: None.

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Introductory Comment

Throughout this Annual Report on Form 10-KSB, 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.

Forward Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a “safe harbor” for forward-looking statements. This annual report contains forward-looking statements within the meaning of the federal securities laws. These include statements about our expectations, beliefs, intentions or strategies for the future, which we indicate by words or phrases such as “anticipate,” “expect,” “intend,” “plan,” “will,” “we believe,” “the company believes,” “management belie similar language. The forward-looking statements are based on our current expectations and are subject to certain risks, uncertainties and assumptions, including those set forth in the discussion under “Description of Business” and “Management’s Discussion and Analysis or Plan of Operation – Factors that May Affect Future Results and Market Price of Our Stock.” Our actual results may differ materially from results anticipated in these forward-looking statements. We base our forward-looking statements on information currently available to us, and we assume no obligation to update them. 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 “Management’s Discussion and Analysis or Plan of Operation – Factors that May Affect Future Results and Market Price of Our Stock.”

PART I

ITEM 1. DESCRIPTION OF BUSINESS.

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.

We are a medical device company that is focusing on the development of products used for the treatment of liver failure. Our products under development currently consist of a novel extracorporeal blood purification therapy (“SEPET™”) and two extracorporeal, bioartificial liver systems ("HepatAssist-2™" and "LIVERAID™") that incorporat porcine hepatocytes (pig liver cells). Currently, our primary focus is on the development of SEPET™ and HepatAssist-2™. We currently own seven key U.S. patents and are the licensee of seven other U.S. patents, as well as the owner of a patent application and numerous related trade secrets.

In March 2005, we submitted an investigational new drug exemption application to the FDA to commence a pilot clinical study of our SEPET™ cartridge. Because our HepatAssist-2™ bioartificial liver system is an enhanced version of a system that was tested in Phase II/III clinical trials approved by the United States Food and Drug Administration (“FDA”), we have elected to initially focus on the development of HepatAssist-2™ before continuing the development of LIVERAID™.

A glossary of certain terms used in this Annual Report is contained on page 18 below.

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. We conduct all of our operations through ATI.

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

Product Overview

We currently have three products under development; a novel extracorporeal blood purification therapy ("SEPET™") and two extracorporeal, bioartificial liver systems ("HepatAssist-2™" and "LIVERAID™") that incorporate porcine hepatocytes (pig liver cells). The LIVERAID™ 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 or plasma is pumped through either of 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 patient's plasma causes 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.

Our HepatAssist-2™ system is the HepatAssist system that we acquired and then enhanced by using more pig cells. We do not expect that the HepatAssist-2™ will use the proprietary perfusion platform that was originally designed and developed for the HepatAssist system. Instead, we are testing a perfusion platform (a machine through which the patient's blood is circulated) known as the PERFORMER. 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) and distributed world-wide by Medtronic, Inc. 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 and its detoxification component utilizes two different sorbents (charcoal and resin). Because LIVERAID™ has as yet not been tested in clinical trials and the HepatAssist-2™ is an enhanced version of a system that was tested in Phase I/II/III clinical trials approved by the FDA, we have elected to initially focus on the development of HepatAssist-2™ before continuing the development of LIVERAID™.

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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™ was designed and qualified for use with the PRISMA hemodialysis system (manufactured by Gambro) and for use with other commercially available kidney dialysis units and/or plasma treatment systems that utilize hollow-fiber cartridges.

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. 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 Circe Biomedical, Inc. ("Circe Biomedical"). The prior owners of this technology spent 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 reviewed 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 reviewed by the FDA, and over 400 manufacturing and quality control and quality assurance standard operation protocols previously reviewed by the FDA.

To date, we have funded our operations from funds we raised from the sale of over $13,000,000 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 and development 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 is one of the clinical testing sites for our SEPET clinical testing program.

We have also entered into various agreements with Spectrum Laboratories, Inc. ("Spectrum Laboratories"), including research and development agreements and manufacturing agreements. Spectrum is expected to be a manufacturer of the cartridges to be used in our liver assist devices. Spectrum Laboratories 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 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 HepatAssist-2™ or LIVERAID™ is completed.

We have already performed *in vitro* and *in vivo* testing of 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 SEPET™ in late 2006 or early 2007. We are currently evaluating the possibility of conducting clinical studies of the HepatAssist-2™ system under a modified version of the FDA-reviewed Phase III IND protocol that we acquired in March 2004 from Circe Biomedical. 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 Biomedical assets 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, storing, shipping and processing by the end user (thawing, washing) of the cells. These procedures and protocols have been reviewed and approved by the FDA. (2) *The cartridge used in the Phase III trial of HepatAssist™*. We intend to use the existing, FDA-approved cartridge, and intend to seek 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 reviewed Phase III protocol acquired from Circe Biomedical*. 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 Biomedical's specially designed machine that pumped the patient's plasma through the HepatAssist cartridge. This machine was used in the Phase II/III trial of HepatAssist. Rather than using Circe Biomedical's specially designed machine, we intend to use the PERFORMER, a machine that is manufactured by RanD, S.r.l (Italy) and distributed by Medtronic, Inc. We are currently testing the PERFORMER that has been equipped with proprietary software and proprietary tubing set to enable the machine to work with HepatAssist-2™. We expect that the PERFORMER will become the platform for both our HepatAssist-2™ and LIVERAID™ systems.

We 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. In March 2005 we submitted an investigational device exemption for SEPET™ to the FDA. With respect to our bioartificial liver products, we have elected to initially focus on the development of HepatAssist-2™ before continuing the development of LIVERAID™ primarily because (i) the FDA has already reviewed a Phase III protocol that we own for HepatAssist, which protocol we intend to modify and submit to the FDA for approval, and (ii) the cost to complete LIVERAID™, and period for obtaining regulatory approval period for LIVERAID™ is expected to be substantially higher and longer than for HepatAssist-2™.

Based on our current assumptions, we estimate that the clinical cost of developing SEPET™ will be approximately $3 million to $4 million, the clinical cost of developing HepatAssist-2™ will be between $15 million and $20 million, and the clinical cost of developing LIVERAID™ will be between $20 million and $25 million. These amounts, which could vary substantially if our assumptions are not correct, are well in excess of the amount of cash that we currently have available to us. See, "Management's Discussion and Analysis or Plan of Operation – Factors that May Affect Future Results and Market Price of Our Stock."

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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 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. Management believes that treatments with currently available technologies (e.g., blood detoxification methods) are 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.

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 using viable isolated liver cells (hepatocytes) 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 purification or detoxification.

Each of our bioartificial liver systems (HepatAssist-2™ and LIVERAID™) 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 approved by the FDA. 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 prolong survival time of pigs with terminal liver failure. 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, mediators of inflammation and inhibitors of hepatic growth. SEPET™ is a novel form of such therapy in which the plasma fraction containing substances that are toxic to the brain, the liver and other internal organs and tissues are removed from patient blood and replaced with normal human plasma.

The Products We Are Developing

We currently are developing novel treatments for acute and chronic liver failure. We believe that our SEPET™ and 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 they 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 these products 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™ as a blood purification measure to provide temporary liver support during acute liver failure and acute exacerbation of chronic liver disease. SEPET™ 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 characteristic is that most hepatic failure toxins as well as mediators of inflammation and inhibitors of hepatic regeneration have a molecular weight that is less than 100 kDa, while "good" blood components, for the most part, 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, inhibitors of hepatic growth 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, intravenous electrolyte solutions, albumin solution, fresh frozen plasma, or a combination thereof 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.

HepatAssist2™ and LIVERAID™ 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 our HepatAssist-2™ and LIVERAID™ products to provide temporary liver support during acute liver failure and acute exacerbation of chronic liver disease. 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 that 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 (liver cell therapy and sorbent-based detoxification) 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 a cell cartridge and 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), a warmer, and a disposable tubing kit. These components are available from third party vendors.

Critical to both the LIVERAID™ and HepatAssist-2™ technologies are (i) the source and method of procurement of liver cells, (ii) the cryopreservation (freezing) of the liver cells, (iii) the storage of the liver cells, (iv) the proprietary plasma re-circulation loop incorporating the cell cartridge and sorbents, and (v) 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 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.

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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 are expected to 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. We are currently considering leasing facilities at which we will be able to breed and maintain pig liver donors, to harvest and cryopreserve (freeze) liver cells, and to assure that the pigs and cells remain free from infection and meet specific FDA requirements for use in our bioartificial liver systems. We believe that the facilities that we are currently evaluating will be suitable to meet our near-term goals for producing the number of cryopreserved pig liver cells that we expect to need until the commercial viability of our products is established.

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 HepatAssist-2™ therapy (and during LIVERAID™ therapy when this product is further developed), 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. Subject to the successful completion of clinical trials and FDA approval, we believe that SEPET™ will be able to be used with currently available hospital kidney dialysis systems, which may offer the following advantages:

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- 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 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, HepatAssist-2™ and LIVERAID™ 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, the hepatocytes 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

SEPET™ and LIVERAID™ have not been tested in patients. However, *in vivo* large animal studies have provided proofs of feasibility and clinical efficacy for the products. 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.

The animal and clinical data generated and published to date on HepatAssist, 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. To our knowledge, 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

Based on the number of patients with liver diseases, we believe that 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™, LIVERAID™ and 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 (10th leading cause of death in males and 12th in females; 4th 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 March 15, 2005, the liver transplant waiting list contained 17,680 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.

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 Laboratories 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 Laboratories 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 Laboratories is either unable or unwilling to manufacture the cartridges. To date, Spectrum Laboratories 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 Laboratories 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 Laboratories has not yet undertaken to acquire or develop the necessary equipment and technology. No assurance can be given that Spectrum Laboratories will, in fact, be able to acquire or develop an automated manufacturing process or that Spectrum Laboratories will otherwise be able to satisfy our needs for the LIVERAID™ cartridges. In the event that Spectrum Laboratories 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 Laboratories 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 HepatAssist-2™ and for LIVERAID™ bioartificial liver therapy will be a perfusion platform known as the PERFORMER. 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) and distributed by Medtronic, Inc. The PERFORMER has been equipped with proprietary software and a tubing set for use with our HepatAssist-2™ system.

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. 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 or lease our own specialized and certified bio-secure porcine liver cell manufacturing plant. At the conclusion of Phase III clinical testing of HepatAssist-2™ (if we obtain FDA approval to conduct such studies under a modified version of the FDA-reviewed Phase III IND protocol) or Phase II/III clinical testing of the LIVERAID™, 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 Laboratories 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 Laboratories.
(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 Laboratories.
(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.

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(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 five patents (see, "Patents and Proprietary Rights—Bioartificial Liver Rights") above 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. As of the end of the fiscal year ended December 31,2004, we had expended more than the minimum required $1,760,000 and have, therefore, fully satisfied the research and development expenditure requirement of this license. Additionally, Cedars-Sinai Medial Center will have nonexclusive rights to any products derived from the patents. We will have to initially 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 Laboratories License Agreement. On December 26, 2001, ATI entered into a license agreement with Spectrum Laboratories, pursuant to which Spectrum Laboratories granted to ATI an exclusive, worldwide license to develop, make, use and distribute products based on Spectrum Laboratories' hollow fiber-in-fiber technology, solely for applications in ATI's liver assist devices. The license includes the rights to 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 Laboratories, ATI will not have to pay a royalty for the license. In the event that Spectrum Laboratories is not the manufacturer of the hollow fiber cartridges, ATI will have to pay Spectrum Laboratories a royalty for the license (see, "Business–Manufacturing," above). Unless the Spectrum Laboratories 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 Laboratories also agreed to grant ATI a right of first refusal to obtain a license to make, use, develop or distribute products based on Spectrum Laboratories' 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 a portfolio of intellectual properties, including certain U.S. and foreign patents applicable to 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. We also acquired a number of other patents and rights related to Circe Biomedical's bioartificial liver program that we will not be using, as well as patents on other technologies that we do not intend to pursue (such as patents to Circe's artificial pancreas system and three patents for cholesterol removal membranes). 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 systems:

(1) Apparatus for Bioprocessing a Circulating Fluid. US Patent #5643794 (issued on July 1, 1997).
(2) Cryopreserved Hepatocytes and High Viability and Metabolic Activity. US Patent #5795711 (issued on August 18, 1998).
(3) Closed System for Processing Cells. US Patent #5858642 (issued on January 12, 1999).
(4) Method of Thawing Cryopreserved Cells. US Patent #5895745 (issued on April 20, 1999).
(5) High Flow Technique for Harvesting Mammalian Cells. US Patent #5912163 (issued on June 15, 1999).
(6) Removal of Agent From Cell Suspension. US Patent #6068775 (issued on May 30, 2000).
(7) Method for Cryopreserving Hepatocytes. US Patent #6136525 (issued on October 24, 2000).

Patent Applications

Patent No.	Country	Title of Patent Application
2216203	CA	Method of Thawing Cryopreserved Cells
9-256534	JP	Method of Thawing Cryopreserved Cells
97307459	EU	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 Biomedical'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. 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 technologytechnical or scientific data that Circe Biomedical acquired from W.R. Grace & Co. Since the assets that we acquired from Circe Biomedical 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. Net sales includes revenues received from 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 a patent application and certain related trade secrets. Our patent application regarding our selective plasma filtration therapy (SEPET™) technology was filed in August 2002 with the United States Patent and Trademark Office.

We have filed for trademark protection in the U.S. for both SEPET™ and HepatAssist-2™. We have not filed for any copyright or trademark protection for LIVERAID™.

Research and Development

In December 2001, ATI and Spectrum Laboratories entered into a four-year research agreement pursuant to which ATI and Spectrum Laboratories 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 Laboratories agreed to perform certain research on liver assist devices for ATI during product development, pre-clinical and clinical testing at no cost to ATI. Although all of the obligations of the parties under that research and development agreement were completed during the fiscal year ended December 31, 2004, Spectrum Laboratories has agreed to perform such additional research and development work as may we may request, which additional future work will be provided by Spectrum Laboratories on terms that we may in the future agree to.

We spent a total of $1,426,000 on research and development during the fiscal year ended December 31, 2004 and $437,000 on research and development during the fiscal year ended December 31, 2003. In addition, pursuant to our research agreement with Spectrum Laboratories, that company provided research and development services valued at $17,260 in 2003 for our liver assist systems. See, “Certain Relationships and Related Transactions–Research Agreement.”

In January 2005, we entered into a research and development agreement with the Faculty of Chemical and Process Engineering of the Warsaw University of Technology, in Warsaw, Poland. Pursuant to this agreement, Warsaw University agreed to provide research and develop services to us in connection with the development and manufacture of new membrane-based selective plasma filtration technologies and new selective plasma filtration devices to be used with our liver assist devices. Warsaw University also agreed to provide us with product development, pre-clinical and clinical testing and regulatory approval assistance. We will own all new technologies and procedures developed by the Warsaw University under the research and development agreement other than patentable technologies that Warsaw University develops without our assistance. In the event that any new products or technologies developed under the agreement use or rely on intellectual properties or technologies owned by the Warsaw University, or if the Warsaw University patents any technologies that it acquires while performing its services under the research agreement, the Warsaw University has granted to us a perpetual, royalty-free license to use such intellectual properties or technologies in our field of use, which includes liver assist systems, bioartificial kidney, hemodialysis and/or hemofiltration devices, and devices producing biologically active compounds. The research agreement has a term of one year, but may be extended by the parties. We believe that the cost of the research and development agreement to us during the first year will be approximately $166,000.

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:

Gambro'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, and sorbent columns placed in a dialysis circuit filled with 20% albumin solution. Albumin in the dialysate is "regenerated" during continuous recirculation in the closed loop system through sorbent columns (charcoal, resin). In addition, standard hemodialysis is performed during MARS treatment. In Europe, initial results in patients with acute liver failure were encouraging. In November 2004, 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 the MARS system and also combines albumin dialysis with sorbent based blood detoxification and dialysis. 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 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.

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 may 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.

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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

As of March 15, 2005, we employed 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.

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 ^{12}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.

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"**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.

ITEM 2. DESCRIPTION OF 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.

ITEM 3. LEGAL PROCEEDINGS.

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.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

No matters were submitted to a vote of security holders during the quarter ended December 31, 2004.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

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

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

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

Quarter Ending	High	Low
December 31, 2003[1]	$ 3.26	$ 3.00
March 31, 2004	$ 3.50	$ 3.40
June 30, 2004	$ 4.25	$ 2.75
September 30, 2004	$ 5.15	$ 4.00
December 31, 2004	$ 5.15	$ 2.65

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

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

Holders

As of March 15, 2005, there were 160 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.

Repurchase of Securities

We did not repurchase any of our common shares during fiscal year 2004.

Recent Sales of Unregistered 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 this company, as additional compensation for services rendered to us during the past 15 months. The warrant has a term of five years and 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 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

This annual report contains forward-looking statements within the meaning of the federal securities laws. These include statements about our expectations, beliefs, intentions or strategies for the future, which we indicate by words or phrases such as "anticipate," "expect," "intend," "plan," "will," "we believe," "the Company believes," "management beli similar language. The forward-looking statements are based on our current expectations and are subject to certain risks, uncertainties and assumptions, including those set forth in the discussion under "Description of Business," including the "Risk Factors" described in that section, and "Management's Discussion and Analysis or Plan of Operation." Our actual results may differ materially from results anticipated in these forward-looking statements. We base our forward-looking statements on information currently available to us, and we assume no obligation to update them.

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 Annual Report, 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 SEPET™, and the preparation and submission of applications to the FDA. In March 2005 we submitted an investigational new drug exemption ("IDE") application for SEPET™ and intend to commence conducting clinical studies for SEPET™ in the second quarter of 2005. We also intend to reactivate work on the HepatAssist bioartificial liver system by modifying the FDA-reviewed 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 next 12-month period following the date of this Annual Report.

In April 2004 we purchased certain assets of Circe Biomedical 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, 2004. 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 Fiscal Year ended December 31, 2004 to Year ended December 31, 2003.

Since we are still developing our products and do not have any products available for sale, we have not yet generated any revenues from sales. Revenues for fiscal year 2004 ($72,000) and fiscal year 2003 ($138,000) represent revenues recognized during those periods from two government research grants that we have received.

General and administrative expenses of $1,988,763 and $343,442 were incurred for years ended December 31, 2004 and 2003. For the year ended December 31, 2004, the expenses include $945,000 in non-cash option and warrant charges for grants awarded to consultants, $587,000 in fees incurred to outside consultants and professionals, and $179,000 in salaries and other administrative expenses. The 2003 expenses consist primarily of legal fees, audit fees and travel expenses. 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 FDA for our SEPET™ product. General and administrative expenses are expected to remain at a significantly higher level than in past periods due to the lease of additional office space (effective as of April 1, 2004), the addition of more employees and consultants (primarily to assist with our financial controls and investor relations strategies and to evaluate and prepare submissions to the FDA), and additional professional and other fees related to being a public company.

Research and development expenses of $1,426,379 and $436,849 were incurred for the years ended December 31, 2004 and 2003. Research and development expenses for the 2004 year increased by $989,530 over prior year levels primarily due to $450,000 of purchased research and development from Circe Biomedical, Inc., $242,000 incurred for various research and development consultants regarding manufacturing, regulatory and product management, $101,000 non cash option grant charges for options awarded to scientific consultants, $52,000 in higher salary costs for scientists and technicians, and $105,000 increase in preclinical testing of SEPET™ and LIVERAID™.

Interest income of $16,132 was earned for the years ended December 31, 2004. In September and October 2003, we raised gross proceeds of $4,400,000 in the private placement of our securities. As a result, during 2004, we maintained cash balances of between $3.5 million and $1.5 million. In addition, we used a portion of the foregoing offering proceeds to repay all outstanding indebtedness, thereby substantially decreasing our interest expense. Interest expense decreased to $847 in fiscal 2004 from $243,230 in fiscal 2003 due to 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. The $243,000 interest expense in fiscal 2003 represents 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 were converted in 2003, no additional interest accrued under these notes during 2004.

Our net loss increased to $3,327,827 in 2004 from $885,693 in 2003. The increase in net loss is attributed to an increase in operating expenses incurred in the fiscal 2004 periods as compared to the same periods in 2003, without an increase in revenues.

Liquidity and Capital Resources

As of December 31, 2004, we had cash of $1,501,905 and a total of $469,000 of total indebtedness. We do not have any bank credit lines. To date, we have funded our operations from the sale of debt and equity securities.

On January 11, 2005, we completed a $6,611,905 private equity financing to a group of institutional investors and accredited investors. In the offering, we sold 2,991,812 shares of our common stock at a price of $2.21 per share to the investors and issued to them warrants to purchase an additional 1,495,906 shares of our common stock at an exercise price of $2.90 per share. The warrants are exercisable for five years and can be redeemed by us after January 11, 2007 if the average trading price of our common stock for 20 consecutive trading days is equal to or greater than $5.80 and the average trading volume of the common stock is at least 100,000 shares during those 20 days. We also issued warrants to purchase 114,404 shares of common stock to our placement agent in the offering.

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

We do not currently anticipate that we will derive any revenues from either product sales or from governmental research grants during the current fiscal year. Although we are planning to submit an application for an additional SBIR research grant during 2004, no assurance can be given that the grant application will be approved. Even if the grant is approved, it is unlikely that we would receive any grant funds during the current fiscal year.

The cost of completing the development of our products and of obtaining all required regulatory approvals to market our products is substantially greater than the amount of funds we currently have available and substantially greater than the amount we could possibly receive under any governmental grant program. As a result, we will have to obtain significant additional funds during the next 12-15 months. We currently expect to attempt to obtain additional financing through the sale of additional equity and possibly through strategic alliances with larger pharmaceutical or biomedical companies. We cannot be sure that we will be able to obtain additional funding from either of these sources, or that the terms under which we obtain such funding will be beneficial to this company.

A summary of our contractual cash obligations at December 31, 2004 is as follows:

Contractual Obligations	Total	2005	2006	2007	2008 and thereafter

Long-Term Office Leases	$270,000
	$139,000
	$93,000
	$38,000
	$-0-

We do not believe that inflation has had a material impact on our business or operations.

We are not a party to any off-balance sheet arrangements, and we do not engage in trading activities involving non-exchange traded contracts. In addition, we have no financial guarantees, debt or lease agreements or other arrangements that could trigger a requirement for an early payment or that could change the value of our assets

Factors that May Affect Future Results and Market Price of Our Stock

We face a number of substantial risks. Our business, financial condition or results of operations could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and they should be considered in connection with the other information contained in this Annual Report on Form 10-KSB.

RISKS RELATED TO OUR BUSINESS

We are an early-stage company subject to all of the risks and uncertainties of a new business, including the risk that we may never market any products or generate revenues.

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

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

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

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

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

currently anticipate.

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

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

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

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

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

conduct any clinical trials until we raise substantial amounts of additional financing.

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

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

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

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

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

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

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

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

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

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

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

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

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

Because we are dependent on 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 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.

Because we are dependent on Medtronic, Inc. for the perfusion platform used in our bioartificial liver products, any failure or delay by Medtronic to make the perfusion platform commercially available will negatively affect our future operations.

We currently expect that a perfusion system known as the PERFORMER will become the platform for both our HepatAssist-2™ and LIVERAID™ systems. The PERFORMER has been equipped with proprietary software and our tubing in order to enable the machine to work with our bioartificial liver products. A limited number of the PERFORMER units have been manufactured to date. The PERFORMER is being manufactured by RanD, S.r.l. (Italy) and marketed by Medtronic, Inc. We currently do not have an agreement to purchase the PERFORMER from Medtronic or any other source. In the event that RanD and Medtronic are either unable or unwilling to manufacture the number of the PERFORMERS needed to ensure that HepatAssist-2™ and LIVERAID™ are commercially viable, we would not have an alternate platform immediately available for use, and the development and sales of such systems would cease until an alternate platform is found. We may have difficulty in finding a replacement platform and may be required to develop a new platform in collaboration with a third party contract manufacturer. While we believe there are several potential contract manufactures who can develop and manufacture perfusion platforms meeting the HepatAssist-2™ and LIVERAID™ functional and operational characteristics, there can be no assurance that we will be able to enter into such an arrangement on commercially favorable terms, or at all. In addition, we may encounter substantial delays and increased costs in completing our clinical trials if we have difficulty in finding a replacement platform or if we are required to develop a new platform for bioartificial liver use.

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

Our ability to compete successfully will depend, in part, on our ability to defend patents that have issued, obtain new patents, protect trade secrets and operate without infringing the proprietary rights of others. We currently own 7 U.S. patents on our liver support products, three foreign patents, have one patent application pending, and are the licensee of seven additional liver support patents. We have relied substantially on the patent legal work that was performed for our assignors and licensors with respect to all of these patents, application and licenses, and have not independently verified the validity or any other aspects of the patents or patent applications covering our products with our own patent counsel.

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

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

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

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

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

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 March 15, 2005, we had outstanding 16,207,909 shares of common stock. 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. In October 2004 and in February 2005, we registered a total of 7,208,000 shares of our common stock issuable upon the exercise of outstanding warrants. The shares underlying the warrants have not yet been issued and will not be issued until the warrants are exercised. Since the shares underlying these warrants have been registered, they can be sold immediately following the exercise. Accordingly, 7,208,000 additional shares could be released onto the trading market at any time. Because of the limited trading volume, the sudden release of 7,208,000 additional freely trading shares 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, 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 7,208,000 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 Annual Report.

ITEM 7. FINANCIAL STATEMENTS.

The consolidated financial statements and the reports and notes, which are attached hereto beginning at page F-1, are incorporated herein by reference.

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

On January 27, 2004, our board of directors, by unanimous written consent, adopted resolutions to dismiss our former independent accountants, Williams & Webster, P.S. (“Williams”). Williams’ report on our financial statements for the past 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 most recent 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 Williams to make reference to the subject matter of the disagreement in connection with its report. Williams did not advise this company of any of the events requiring reporting in a Form 8-K under Item 304(a)(iv)(B).

On January 27, 2004, our board of directors also approved, by unanimous written consent, resolutions to engage Stonefield Josephson, Inc. (“Stonefield”) as our independent accountants to audit our financial statements for the year ending December 31, 2003, and to review our quarterly statements during 2004. Stonefield audited the financial statements of ATI for the past two fiscal years. We did not consult with Stonefield 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.

ITEM 8A. CONTROLS AND PROCEDURES

As of the end of the period covered by this report, our company conducted an evaluation, under the supervision and with the participation of our chief executive officer and chief financial officer, of our disclosure controls and procedures (as defined in Rules 13a-15(e) of the Exchange Act). Based on this evaluation, our chief executive officer and chief financial officer concluded that our company’s disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

There was no change in our internal controls, which are included within disclosure controls and procedures, during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls.

ITEM 8B. OTHER INFORMATION

On March 24, 2005, the Board of Directors approved an unwritten plan for compensating the company's directors. The plan consists of the following:

- Directors will receive annual grants of stock options to purchase 15,000 shares of common stock. The options will be granted on the date of the annual meeting of stockholders to those members of the Board who are elected at that meeting. The options will have a term of seven years and will have an exercise price equal to the market price on the date of grant. The options will vest in equal monthly installments over the 12-month period following the grant.

- New directors who are elected by the Board or by our stockholders for the first time, will be granted stock options to purchase 30,000 shares of common stock at the time that the new directors join the Board. The options will have a term of seven years and will have an exercise price equal to the market price on the date of grant. One half of the options will vest on the date of grant, and the balance will vest on the first anniversary of the grant.

- All non-employee directors will receive a cash payment of $1,500 for each day that they attend a Board of Directors meeting ($1,000 if they attend a meeting by telephone), and $500 for each telephonic Board meeting ($1,000 for each telephonic meeting if the meeting lasts longer than two hours). In addition, the Chairman of the Board and Chairman of the Audit Committee will each be paid $25,000 annually (payable quarterly), and the Chairman of the Nomination Committee and the Chairman of the Compensation Committee will each be paid $10,000 annually (payable quarterly). We will also continue our policy of reimbursing all directors for any expenses incurred by them in attending meetings of the Board of Directors.

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT.

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 third calendar quarter of 2005) at which their successors are duly elected by the stockholders.

Name	Age	Position
Jacek Rozga, M.D., Ph.D.	56	President and Director
Roy Eddleman	65	Director
Marvin S. Hausman M.D. (2)	63	Director
John M. Vierling, M.D. (1) (2)	59	Chairman of the Board
Jack E. Stover (1) (2)	51	Director
Scott L. Hayashi	33	Vice President of Administration, Chief Financial Officer, and Secretary
David J. Zeffren	48	Vice President of Business Development

(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 and the Chief Scientific Officer of this company since October 30, 2003. From October 2003 until March 2005, Dr. Rozga also acted as our Chief Financial Officer. 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 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 Perstorf/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. From January 1997 until March 2005, Dr. Hausman was 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 is currently the Chairman of the Board of Directors of Axonyx, Inc., a position he has held since January 1997. 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.

John M. Vierling, MD, **FACP**. Dr. Vierling has been a Professor of Medicine at the David Geffen School of Medicine at UCLA from 1996 to 2005 and was the Director of Hepatology and Medical Director of Multi-Organ Transplantation Program at Cedars-Sinai Medical Center from 1990-2004. In April 2005, he will assume the position of Professor of Medicine and Surgery, Director of Baylor Liver Health and Chief of Hepatology at the Baylor College of Medicine in Houston, Texas. 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 was elected the President and Chief Operating Officer of Antares Pharma, Inc., (a public specialty pharmaceutical company) in 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 Nasdaq traded injectable pharmaceutical company that was acquired by Teva Pharmaceutical Inc. 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 pharmaceutical company. For over 16 years, Mr. Stover was an employee and then a partner with PricewaterhouseCoopers, working in their bioscience industry division.

Scott L. 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. In March 2005, Mr. Hayashi assumed the role as our Chief Financial Officer. 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. Mr. Zeffren was Vice President of Operations until he was appointed as Vice President of Business Development in March 2005. 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 to1999. 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.

Audit, Compensation and Nominating 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 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.

ITEM 10. 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 other person who was an executive officer 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

		Annual Compensation			Long-Term Compensation Awards
Name and Principal Position	Year	Salary	Bonus	Other Annual Compensation	Securities Underlying Options
Jacek Rozga, M.D., Ph.D Chief Executive Officer	2004	$ 198,909	$ 20,000	—	30,000
	2003(1)	$ 143,125	$ 15,000	—	18,000(2)
	2002	$ 85,000	$ 5,000	—	18,000(2)
Scott L. Hayashi	2004(3)	$ 80,000	$ 12,000	$ 8,000(4)	10,000
David J. Zeffren	2004(5)	$ 120,000			10,000

(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[1]
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.

Equity Compensation Plan Information

The following table summarizes as of March 15, 2005, the number of securities to be issued upon the exercise of outstanding derivative securities (options, warrants, and rights); the weighted-average exercise price of the outstanding derivative securities; and the number of securities remaining available for future issuance under our equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants, and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance
	(a)	(b)	(c)
Equity compensation plans approved by security holders(1)	833,000	$2.04	167,000
Equity compensation plans not approved by security holders	536,904	$2.86	-0-
Total	1,369,904	$2.36	167,000

(1) The compensation plan approved by the security holders is the company's 2001 Stock Option Plan.

Employment Agreements

Dr. Rozga, receives compensation from us in his capacity as the President and Chief Scientific Officer of this company and in his capacity as President and Chief Scientific Officer of ATI, our operating subsidiary. In his capacity as the President and Chief Scientific 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.

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 and accelerated the vesting of his stock options. In March 2005, the Board of Directors terminated the special investor relations committee.

On March 24, 2005, the Board of Directors approved a new compensation plan for the company's directors. See, "Item 8B—Other Information."

Code of Ethics

The Board of Directors adopted a Code of Ethics which covers all of our executive officers and key employees. The Code of Ethics requires that senior management avoid conflicts of interest; maintain the confidentiality of our confidential and proprietary information; engage in transactions in our common stock only in compliance with applicable laws and regulations and the requirements set forth in the Code of Ethics; and comply with other requirements which are intended to ensure that our officers conduct business in an honest and ethical manner and otherwise act with integrity and in the best interest of this company.

All of our executive officers are required to affirm in writing that they have reviewed and understand the Code of Ethics.

The code of ethics is filed as Exhibit 14.1 to this Annual Report on Form 10-KSB. A copy of our Code of Ethics will be furnished to any person upon written request from any such person. Requests should be sent to: Secretary, Arbios Systems, Inc., 8797 Beverly Blvd., Suite 206, Los Angeles, California, 90048.

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 incentive stock 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 incentive stock options are granted to a person who controls more than 10% of our stock, then the exercise price of those incentive stock options 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 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.

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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 of an incentive stock option 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.

ITEM 11. 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 March 15, 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., Suite 206, 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)	15.6%
John M. Vierling, MD	91,000(4)	*
Roy Eddleman	428,669 (5)	2.6%
Marvin S. Hausman MD	629,500(6)	3.9%
Jack E. Stover	15,000(7)	*
Gary Ballen (8) 140 Burlingame, Los Angeles, California 90049	1,139,222(8)	7.0%
Neuberger Berman LLC	2,440,199(9)	15.1%

111 River Street - Suite 1000 Hoboken, NJ 07030-5776(9)		
LibertyView Special Opportunities Fund, LP 111 River Street - Suite 1000 Hoboken, NJ 07030-5776(10)	1,357,466(10)	8. 1%
All executive officers and directors as a group (5 persons)	3,495,169 (11)	21.5%

* 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) Consists of currently exercisable options.

(8) 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.

(9) 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.

(10) Consists of (i) 904,977 shares of common stock, and (ii) currently exercisable warrants to purchase 452,489 shares of common stock.

(11) Includes currently exercisable options and warrants to purchase 508,500 shares of common stock.

ITEM 12. 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:

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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 was paid in full in 2004), 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 40,000 shares of our common stock and 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.

ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K.

(a) Exhibits

The following exhibits are filed as part of this report:

Exhibit Number	Description
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)
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, Inc. (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
16.1	Letter on Change in Certifying Accountant (3)
21.1	List of Subsidiaries
31.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350

(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.

(b) Reports on Form 8-K

The Company filed the following report on Form 8-K during the last quarter of the fiscal year ending December 31, 2004:

On November 5, 2004, the Company filed a Current Report on Form 8-K attaching a press release announcing the appointment of Jack E. Stover to the Board of Directors of Arbios Systems, Inc.

Stockholders of our company may obtain a copy of any exhibit referenced in this 10-KSB Annual Report by writing to: Secretary, Arbios Systems, Inc., 8797 Beverly Blvd., Suite 206, Los Angeles, California, 90048. The written request must specify the stockholder's good faith representation that such stockholder is a stockholder of record of common stock of the company.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Williams & Webster, P.S. audited the financial statements of our company during the fiscal years ended December 31, 2002 and 2001. As stated in Item 8 above, on January 27, 2004, our board of directors replaced Williams & Webster, P.S. as this company's auditors and engaged Stonefield Josephson, Inc. as our independent accountants to audit our financial statements for the year ending December 31, 2003 and 2004. See, "Item 8. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure."

Audit Fees

The aggregate fees we paid Stonefield Josephson, Inc. during the fiscal year ended December 31, 2004 for professional services for the audit of our financial statements and the review of financial statements included in our Forms 10-QSB and SEC filings were $52,769.

The aggregate fees we paid Williams & Webster, P.S. during the fiscal year ended December 31, 2003 for professional services for the audit of our financial statements for and the review of financial statements included in our Forms 10-QSB were $7,951.

Audit-Related Fees

Stonefield Josephson, Inc. and Williams & Webster, P.S. did not provide, and it did not bill and it was not paid any fees for, audit-related services in the fiscal years ended December 31, 2004 and 2003.

Tax Fees

Stonefield Josephson, Inc. and Williams & Webster, P.S. did not provide, and did not bill and was not paid any fees for, tax compliance, tax advice, and tax planning services for the fiscal years ended December 31, 2004 and December 31, 2003.

All Other Fees

Stonefield Josephson, Inc. and Williams & Webster, P.S. did not provide, and did not bill and were not paid any fees for, any other services in the fiscal years ended December 31, 2004 and 2003.

ADDITIONAL INFORMATION

We are subject to the informational requirements of the Exchange Act and, in accordance with the rules and regulations of the Securities and Exchange Commission; we file reports, proxy statements and other information. You may inspect such reports, proxy statements and other information at public reference facilities of the Commission at Judiciary Plaza, 450 Fifth Street N.W., Washington D.C. 20549; Northwest Atrium Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661; and 5670 Wilshire Boulevard, Los Angeles, California 90036. Copies of such material can be obtained from the Public Reference Section of the Commission at Judiciary Plaza, 450 Fifth Street N.W., Washington, D.C. 20549, at prescribed rates. For further information, the SEC maintains a website that contains reports, proxy and information statements, and other information regarding reporting companies at http://www.sec.gov or call (800) SEC-0330.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors
Arbios Systems, Inc. and Subsidiary
Los Angeles, California

We have audited the accompanying consolidated balance sheets of Arbios Systems, Inc. and Subsidiary as of December 31, 2004 and 2003 and the related consolidated statements of operations, stockholders' equity and cash flows for the years ended December 31, 2004 and 2003, and from August 23, 2000 (inception) to December 31, 2004. 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 the 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 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Arbios Systems, Inc. and Subsidiary as of December 31, 2004 and 2003 and the consolidated results of their operations and cash flows for the years ended December 31, 2004 and 2003, and from August 23, 2000 (inception) to December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

Stonefield Josephson, Inc.

Santa Monica, California
March 10, 2005

ARBIOS SYSTEMS, INC. AND SUBSIDIARY
(A development stage company)
CONSOLIDATED BALANCE SHEETS
December 31, 2004 and 2003

ASSETS	December 31, 2004	2003
Current assets		
Cash and cash equivalents	$ 1,501,905	$ 3,507,086
Prepaid expenses	97,653	155,986
Total current assets	$ 1,599,558	$ 3,663,072
Property and equipment, net	107,789	45,633
Patent rights, net of accumulated amortization of $105,457 for 2004 & $75,856 for 2003	294,543	324,145
Other assets	33,164	7,434
Total assets	$ 2,035,054	$ 4,040,284
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 92,304	$ 33,995
Accrued expenses	121,460	114,234
Contract commitment	250,000	
Current portion of capitalized lease obligation	5,341	8,526
Total current liabilities	469,105	156,755
Long-term liabilities		
Capital lease obligation, less current portion		6,826
Other liabilities		5,555
Total long-term liabilities	—	12,381
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; 13,216,097 and 13,150,598 shares issued and outstanding in 2004 and 2003, respectively	13,216	13,151
Additional paid-in capital	6,508,061	

	5,485,498
Deficit accumulated during the development stage	
	(4,955,328)
	(1,627,501)
Total stockholders' equity	
	1,565,949
	3,871,148
Total liabilities and stockholders' equity	
$	
	2,035,054
$	
	4,040,284

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

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

	For the years ended December 31, 2004	2003	Inception, Aug. 23, 2000 to Dec. 31, 2004
Revenues	$ 72,030	$ 137,828	$ 320,966
Operating expenses:			
General and administrative	1,988,763	343,442	2,612,369
Research and development	1,426,379	436,849	2,436,053
Total operating expenses	3,415,142	780,291	5,048,422
Loss before other income (expense)	(3,343,112)	(642,463)	(4,727,456)
Other income (expense):			
Interest income	16,132		16,132
Interest expense	(847)	(243,230)	(244,004)
Total other income (expense)	15,285	(243,230)	(227,872)
Net loss	$ (3,327,827)	$ (885,693)	$ (4,955,328)
Net earnings per share:			
Basic and diluted	$ (0.25)	$ (0.11)	$ (0.64)
Weighted-average shares:			
Basic and diluted	13,199,325	7,887,237	7,726,266

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

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

	For the years ended December 31,		Inception to December 31,
	2004	2003	2004
Cash flows from operating activities:			
Net loss	$ (3,327,827)	$ (885,693)	$ (4,955,328)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of debt discount			244,795
			244,795
Depreciation and amortization			48,191
			40,243
			140,528
Issuance of common stock and warrants for compensation			1,045,552
			1,056,052
Settlement of accrued expenses			54,401
Deferred compensation costs			88,889
			319,553
Changes in operating assets and liabilities:			
Prepaid expenses			58,333
			(135,177

)

(97,655
)
Other assets

(25,730
)

(33,164
)
Accounts payable and accrued expenses

36,727

78,411

184,957

Other liabilities

(5,556
)

—

Contract obligation

250,000

250,000

Net cash used in operating activities

(1,920,310
)

(568,532
)

(2,835,861
)
Cash flows from investing activities:

Additions of property and equipment

(80,745
)

(23,470
)

(117,860
)
Net cash used in investing activities

(80,745
)

(23,470
)

(117,860
)
Cash flows from financing activities:

Proceeds from issuance of convertible debt

400,000

400,000

Proceeds from common stock option exercise

2,700

2,700

Proceeds from issuance of common stock, net of costs

3,678,514

3,830,668

Proceeds from issuance of preferred stock, net of costs

238,732

Payments on capital lease obligation, net

(6,826
)

(7,275
)

(16,474
)
Net cash provided by (used in) financing activities

(4,126
)

		4,071,239
		4,455,626
Net (decrease) increase in cash		
		(2,005,181)
		3,479,237
		1,501,905
Cash:		
At beginning of period		
		3,507,086
		27,849
At end of period		
$		1,501,905
$		3,507,086
$		1,501,905
Supplemental disclosures of non-cash financing activity		
Issuance of securities for obligation related to finder's fees		
$		47,500
$		47,500

The accompanying notes are an integral part of these 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, 2004

	Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Deferred Costs	Deficit Accumulated During the Development Stage	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			5,000,000	50	4,950			5,000
Net loss							(9,454)	

						(9,454)
Balance, December 31, 2000, as restated						—
						—
					5,000,000	
					50	
					4,950	
						—
						(9,454)
						(4,454)
Issuance of junior preferred stock for cash of $250,000 and in exchange for $400,000 in patent rights, research and development costs, and employee loanout costs less issuance expenses of $11,268, June 29, 2001					681,818	
					7	
					958,278	
						(343,553)
					614,732	
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
)

The accompanying notes are 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, 2004

	Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Deferred Costs	Deficit Accumulated During the Development Stage	Total
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

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

The accompanying notes are 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, 2004

	Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Deferred Costs	Deficit Accumulated During the Development Stage	Total
Issuance of common stock for cash less issuance expense of $2,956			417,000	417	246,827			247,244
Issuance of common stock in private placement for cash 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

The accompanying notes are 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, 2004

	Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Deferred Costs	Deficit Accumulated During the Development Stage	Total
Issuance of common stock options and warrants for compensation					972,430			972,430
Exercise of common stock options			18,000	18	2,682			2,700
Issuance of securities for payable			47,499	47	47,451			

	47,498
Net loss	(3,327,827)
	(3,327,827)
Balance, December 31, 2004	—
	—
	13,216,097
	13,216
	6,508,061
	—
	(4,955,328)
	1,565,949

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

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

(1) Summary of Significant Accounting Policies:

General:

Arbios Systems, Inc. and its wholly owned subsidiary (collectively, the "Company") are engaged in the business of developing liver-assist devices to meet the urgent need for therapy that facilitates recovery from liver failure. The Company's three products that are currently under development are SEPET™, which is a blood purification therapy device for patients with liver failure, HepatAssist-2™ and LIVERAID™, which are bioartificial liver systems.

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 named to Arbios Systems, Inc. and is herein referred to as "Systems". The stockholders 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, $.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.

Principles of Consolidation:

The accompanying consolidated financial statements include the accounts of 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

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

(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 has been 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 are deferred and recognized as revenue when the research projects are performed. Reimbursements recorded under these grants are subject to governmental audit. In addition, Management believes that material adjustments of costs reflected in the accompanying consolidated financial statements will not result from subsequent audits, if any, and that the Company has utilized all remaining government grant funds.

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, 2004 and 2003, 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 to seven years.

Patent Rights:

The Company capitalizes 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.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

(1) Summary of Significant Accounting Policies, Continued:

Patent Rights, Continued:

We periodically evaluate whether events or circumstances have occurred that may affect the estimated useful lives or the recoverability of the remaining balance of the patents. Impairment of the assets is triggered when the estimated future undiscounted cash flows do not exceed the carrying amount of the intangible assets. If the events or circumstances indicate that the remaining balance of the assets may be permanently impaired, such potential impairment will be measured based upon the difference between the carrying amount of the assets and the fair value of such assets, determined using the estimated future discounted cash flows generated.

Fair Value of Financial Instruments:

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

Cash and Cash Equivalents:

The Company considers highly liquid debt instruments with original maturities of 90 days or less to be cash equivalents.

Income Taxes:

Deferred income taxes are recognized for the tax consequences in future years of temporary 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.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

(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, 2004	December 31, 2003
Net loss as reported	$ (3,327,827)	$ (885,693)
Compensation recognized under APB 25	—	—
Compensation recognized under SFAS 123	(471,437)	(12,710)
Proforma	$ (3,799,264)	$ (898,403)
Basic and diluted loss per common share:		
As reported	$ (0.25)	$ (0.11)
Proforma	$ (0.29)	$ (0.11)

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 range of .86 and .96 for 2004 and 0.05 for 2003, risk free interest rate range of 3.53% to 3% for 2004 and 3.0% for 2003 and an expected life of 3 to 7 years for 2004 and 7 years for 2003.

Net Loss Per Common Share:

The Company utilizes SFAS No. 128, “Earnings 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. For the years ended December 31, 2004 and 2003, potential common shares aggregating 6,404,000 and 5,764,000 respectively, were excluded in computing the per share amounts.

Presentation:

Certain prior year amounts have been reclassified to conform with current year presentation.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

(1) Summary of Significant Accounting Policies, Continued:

Recent Accounting Pronouncements:

In November 2004, the FASB issued SFAS No. 151, “Inventory Costs, an amendment of ARB No. 43, Chapter 4”. The amendments made by Statement 151 clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage) should be recognized as current period charges and require the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. The guidance is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Earlier application is permitted for inventory costs incurred during fiscal years beginning after November 23, 2004. The Company has evaluated the impact of the adoption of SFAS 151, and does not believe the impact will be significant to the Company's current overall results of operations or financial position.

In December 2004, the FASB issued SFAS No.152, “Accounting for Real Estate Time-Sharing Transactions, an amendment of FASB Statements No. 66 and 67 (SFAS 152)”. The amendments made by Statement 152 amend FASB Statement No. 66, Accounting for Sales of Real Estate, to reference the financial accounting and reporting guidance for real estate time-sharing transactions that is provided in AICPA Statement of Position (SOP) 04-2, Accounting for Real Estate Time-Sharing Transactions. This Statement also amends FASB Statement No. 67, Accounting for Costs and Initial Rental Operations of Real Estate Projects, to state that the guidance for (a) incidental operations and (b) costs incurred to sell real estate projects does not apply to real estate time-sharing transactions. The accounting for those operations and costs is subject to the guidance in SOP 04-2. This Statement is effective for financial statements for fiscal years beginning after June 15, 2005, with earlier application encouraged. The Company has evaluated the impact of the adoption of SFAS 152, and does not believe the impact will be significant to the Company's overall current results of operations or financial position.

In December 2004, the FASB issued SFAS No.153, “Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions.” The amendments made by Statement 153 are based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. Further, the amendments eliminate the narrow exception for nonmonetary exchanges of similar productive assets and replace it with a broader exception for exchanges of nonmonetary assets that do not have commercial substance. Previously, Opinion 29 required that the accounting for an exchange of a productive asset for a similar productive asset or an equivalent interest in the same or similar productive asset should be based on the recorded amount of the asset relinquished. Opinion 29 provided an exception to its basic measurement principle (fair value) for exchanges of similar productive assets. The FASB believes that exception required that some nonmonetary exchanges, although commercially substantive, be recorded on a carryover basis. By focusing the exception on exchanges that lack commercial substance, the FASB believes this Statement produces financial reporting that more faithfully represents the economics of the transactions.

In December 2004 the Financial Accounting Standards Board issued two FASB Staff Positions—FSP FAS 109-1, *Application of FASB Statement 109 "Accounting for Income Taxes" to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004*, and FSP FAS 109-2 *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004.* Neither of these affected the Company as it does not participate in the related activities.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

(1) Summary of Significant Accounting Policies, Continued:

Recent Accounting Pronouncements:

The Statement is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. Earlier application is permitted for nonmonetary asset exchanges occurring in fiscal periods beginning after the date of issuance. The provisions of this Statement shall be applied prospectively. The Company has evaluated the impact of the adoption of SFAS 152, and does not believe the impact will be significant to the Company's overall current results of operations or financial position.

In December 2004, the FASB issued SFAS No.123 (revised 2004), “Share-Based Payment”. Statement 123(R) will provide investors and other users of financial statements with more complete and neutral financial information by requiring that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. Statement 123(R) covers a wide range of share-based compensation arrangements including share options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. Statement 123(R) replaces FASB Statement No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees. Statement 123, as originally issued in 1995, established as preferable a fair-value-based method of accounting for share-based payment transactions with employees. However, that Statement permitted entities the option of continuing to apply the guidance in Opinion 25, as long as the footnotes to financial statements disclosed what net income would have been had the preferable fair-value-based method been used. Public entities (other than those filing as small business issuers) will be required to apply Statement 123(R) as of the first interim or annual reporting period that begins after June 15, 2005. If the Company adopted this accounting pronouncement as of January 1, 2005, the change to our income statement in 2005 would be approximately $267,000 based upon options granted as of December 31, 2004.

(2) Property and Equipment:

Property and equipment consisted of the following:

		2004		2003
Office equipment	$	2,154	$	866
Office furniture		7,217		
Computer equipment		31,545		23,277
Medical equipment		101,943		37,971
		142,859		62,114
Less: accumulated depreciation		(35,070)		(16,481)
	$	107,789	$	45,633

Depreciation expense was $18,589, $10,641, and $35,070 for the year ended December 31, 2004 and 2003, and the period from August 23, 2000 (inception) to December 31, 2004, respectively.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

(3) Patent Rights:

In June 2001, the Company received exclusive rights to five existing patents. At the date of exchange, the aggregate value of these rights was $400,000. At December 31, 2004 and 2003, the accumulated amortization of these rights was $105,457 and $75,856, and the estimated remaining life was 7 years. Amortization expense was $29,602, $29,602, and $105,457 for the years ended December 31, 2004 and 2003 and the period from August 23, 2000 (inception) to December 31, 2004, respectively.

Future estimated amortization expense is as follows:

Year ending December 31,	
2005	$ 29,602
2006	29,602
2007	29,602
2008	29,602
2009	29,602
Thereafter	146,533
	$ 294,543

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.

The Company has made expenditures to date to satisfy the entire research and development costs obligation of the agreement.

The Company is subject to paying royalty fees to the licensor initially 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, 2004 and 2003, the Company had not paid any royalty fees since it did not have any sales of royalty bearing products.

In April 2004, the Company purchased patents and other selected assets from Circe Biomedical, Inc. In connection with the acquisition of these patents, the Company assumed a Royalty Agreement dated as of January 29, 1999, between Circe Biomedical, Inc. and Circe Acquisition Corp. The Company assumed the obligation to pay a royalty of 2% of “net sales” of any product that utilizes or incorporates the bioartificial liver patents, technology, inventions, and technical or scientific data that the Company acquired from Circe Biomedical.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

(4) Deferred Employee Loan-Out Costs:

In June 2001, the Company received a commitment from a shareholder in the Company for the loan-out of certain employees over a two-year period in exchange for junior preferred stock (see note 7). The Company deferred the estimated loan-out costs over the two-year period. The loan-out costs were expensed as the services were performed. At the expiration of the two-year period, the Company received an extension of the employee loan-out agreement for an additional two years. The employee loan out agreement is scheduled to expire June 30, 2005. For the years ended December 31, 2004 and 2003, the employee loan out costs were $343,553 and $281,048, respectively. The employee loan out costs from inception to December 31, 2004 were $624,601.

(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 of 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. For each share issued upon the conversion of the note, each noteholder received additional warrants for the purchase of common stock. 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 relative fair value allocated to the warrants issued of $122,390. The Notes also contained a beneficial conversion feature, which resulted in an 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.

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(6) Commitments and Contingencies:

Description of Property

The Company currently maintains laboratory and office space at Cedars-Sinai Medical Center in Los Angeles, California, which facilities are leased under a three-year lease that expires on June 30, 2007. The Company currently pays rent of $6,441 per month for the 1,008 square foot facility under the lease. Cedars-Sinai Medical Center is a stockholder of the Company.

Since April 1, 2004, the Company has leased an additional 1,700 square feet of executive and administrative office space in a building across the street from its laboratories located at Cedars-Sinai Medical Center. The rent for this space is $5,000 per month and the lease has a term of two years.

The following is a schedule of the future minimum lease payments required under the operating leases for non-cancelable lease terms in excess of one year.

2005	$ 139,107
2006	$ 92,910
2007	$ 38,646
2008	—
2009	—

Rent expense was $105,509, $77,202, and $292,589 for the years ended December 31, 2004 and 2003, and the period from August 23, 2000 (inception) to December 31, 2004, 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 for LIVERAID, one of the Company’s bioartificial liver devices. The agreement stipulates that the Company will contract with Spectrum for the manufacture and supply of Liveraid cartridges.

In April 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

(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, value, 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).
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 founders 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 two patents.

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 $0.15 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 vested 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.

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ARBIOS SYSTEMS, INC. AND SUBSIDIARY
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

(7) Stockholders' Equity, Continued:

Common Stock (Continued)

In July 2003, Arbios Technologies, Inc. issued a warrant to purchase 50,000 shares of common stock to a Board member for services rendered to the Company. The warrant is exercisable at $1.00 per share and has a five year life.

In September 2003, convertible promissory notes totaling $400,000 were converted into 400,000 shares of the Company's common stock. The Company also issued warrants to purchase 300,000 shares of common stock. The warrants are exercisable at $1.00 per share and have a three year life.

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.

In October 2003, Arbios Technologies, Inc. entered into a reorganization transaction wherein the stockholders 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.

In January 2004, Arbios Systems, Inc. issued 40,000 shares of common stock and warrants to purchase 40,000 shares of common stock to a director as compensation for finder's fees. The warrant has a three year life and is exercisable at $2.50 per share.

In February 2004, Arbios Systems, Inc. issued 7,500 shares of common stock and warrants to purchase 7,500 shares of common stock to a son of a director as compensation for finder's fees. The warrant has a three year life and is exercisable at $2.50 per share.

In March 2004, Arbios Systems, Inc. entered into a retainer agreement with an investor relations firm and issued warrants to purchase 150,000 shares of common stock as compensation. The warrant has a five year life and is exercisable at $3.40 per share. Pursuant to the terms of the warrant, the number of shares that can be purchased under the warrant was reduced in December 2004 to 75,000 shares.

In July 2004, Arbios Systems, Inc. entered into an agreement with an investor relations firm based in Switzerland to perform investor relations services for the Company in Europe. The Company issued two warrants 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 has 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 has a five year expiration term.

In October 2004, an option holder exercised his option to purchase 18,000 shares of common stock at an exercise price of $0.15 per share.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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Warrants

At December 31, 2004, outstanding warrants to acquire shares of the Company's common stock are as follows:

Number of Shares	Exercise Price	Expiration date
100,000	$ 0.15	August 18, 2009
600,000	1.00	January 23, 2006
50,000	1.00	July 3, 2008
700,000	1.00	September 30, 2006
4,000,000	2.50	October 29, 2006
47,500	2.50	January 5, 2007
75,000	3.40	April 1, 2009

		50,000
	1.50	
August 4, 2009		
		50,000
	3.50	
August 4, 2009		
		5,672,500

The weighted average exercise price of warrants outstanding at December 31, 2004 was $2.11 and the weighted average remaining contractual life of the warrants was 1.88 years.

For the year ended December 31, 2004, the Company granted 182,500 warrants to consultants and recorded expenses of $490,000 relating to the vested portion of these warrants.

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 Arbios Technologies, Inc. Plan.

For the years ended December 31, 2004 and 2003, the Company granted 140,000 and 75,000 options, respectively, to consultants and recorded expenses of $555,000 in 2004, relating to the vested portion of these options.

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FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

Transactions under the Plan during the year ended December 31, 2004 and 2003 are summarized as follows:

	For the year ended December 31,			
	2004		2003	
	Shares	Weighted Average Price	Shares	Weighted Average Price
Options at beginning of year	314,000	$ 0.78	90,000	$ 0.15
Options issued	510,000	2.29	233,000	1.00
Options exercised	(18,000)	0.15		
Options forfeited	(75,000)	1.30	(9,000)	0.15
Options at end of year	731,000	1.79	314,000	0.78
Options exercisable at end of year	513,500	1.49	194,000	0.61

As of December 31, 2004, 242,000 options are available for future grant under the 2001 Stock Option Plan.

Additional information with respect to option activity is summarized as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Shares	Weighted Average Remaining Contractually (in years)	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
$0.15	54,000	7.56	$ 0.15	54,000	$ 0.15
$1.00	297,000	4.30	1.00	272,000	1.00
$2.00 - $3.40	380,000	6.21	2.63	187,500	2.58
	731,000	5.54	1.77	513,500	1.49

(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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

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 related to $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. Furthermore, the Company agreed that billings of $109,360, through September 29, 2002, were due for research costs already provided, in addition to the $550,000 obligation. This amount was reduced by $54,400 in payment for the 362,669 shares previously received, and the Company paid the balance of $54,960 to Spectrum in cash in monthly payments over an 18-month period starting November 1, 2002. As of May 1, 2004, the Company has fulfilled its obligation to pay the $54,960 cash payment to Spectrum.

(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, 2004 and 2003, and the period from August 23, 2000 (inception) to December 31, 2004:

	Year Ended December 31, 2004	Year Ended December 31, 2003	Period from August 23, 2000 (inception) to December 31, 2004
Expected tax benefit	$ (1,131,461)	$ (301,136)	$ (1,685,023)
State income taxes, net of federal benefit	(196,295)	(49,767)	(272,486)
Other			(20,979)
Changes in valuation allowance	1,327,756	350,903	1,978,488
Net tax benefit	$ —	$ —	$ —

The following table summaries the significant components of the Company's deferred tax asset at December 31, 2004:

	December 31, 2004
Deferred tax asset arising from net operating loss carryforward	$ 1,978,488
Less: valuation allowance	(1,978,488)
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.

ARBIOS SYSTEMS, INC. AND SUBSIDIARY
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

For the year ended December 31, 2004, the Company had an operating loss carryforward of approximately $4,955,328, which begins expiring in 2016.

(10) Related Party Transactions:

In 2001, the Company received the exclusive worldwide rights and a license to use certain proprietary rights from Spectrum Laboratories, Inc. ("Spectrum"), partially in exchange for 362,669 shares of common stock. The Chairman of the Board of Spectrum ("Spectrum Chairman") is one of the majority stockholders of Spectrum Laboratories, Inc. and also currently serves as a Director of the Company. In 2002, the Spectrum Chairman received stock options to purchase 18,000 shares of common stock at an exercise price of $0.15 per share as compensation as a Director of the Company. In 2003, the Spectrum Chairman received stock options to purchase 18,000 shares of common stock at an exercise price of $1.00 per share as compensation as a Director of the Company. In 2004, the Spectrum Chairman received options to purchase 30,000 shares of common stock at an exercise price of $2.25 per share as compensation as a Director of the Company.

In 2003, the son of a Director received 7,500 shares of common stock valued at $1 per share and warrants to purchase 7,500 shares of common stock exercisable at $2.50 per share as a finder's fee.

In 2003, a Director received warrants to purchase 50,000 shares of common stock exercisable at $1 per share as a finder's fee.

In 2004, a Director received common stock valued at $1.00 per share and warrants to purchase 40,000 shares of common stock exercisable at $2.50 per share as a finder's fee.

(11) Subsequent Events:

On January 11, 2005, the Company completed a $6,611,905 private equity financing to a group of institutional investors and accredited investors. In the offering, 2,991,812 shares of the Company's common stock was sold, at a price of $2.21 per share and the investors also received 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 the Company 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 general working capital needs and the further development of the Company products. The placement agent in the offering, was issued warrants to purchase 114,404 shares of common stock.

On January 18, 2005, the Company paid the $250,000 contractual commitment to Circe Biomedical, Inc. related to the relating to assets acquired in April 2004.

On January 15, 2005, the Company entered into a research and development agreement with Warsaw University of Technology in Warsaw, Poland to develop a proprietary membrane for the SEPET™ product. During 2005, the Company is obligated to make scheduled payments totaling up to $166,000 as specified progress is made.

On February 1, 2005 we issued a warrant to purchase 200,000 shares of our common stock to AFO Advisors LLC, an advisor to this company, as additional compensation for services rendered to us during the past 15 months. The warrant has a term of five years and 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.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ARBIOS SYSTEMS, INC.

Date: March 29, 2005

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

Jacek Rozga, M.D., Ph.D,
President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JACEK ROZGA, M.D., PH.D Jacek Rozga, M.D., Ph.D	President (principal executive officer)	March 29, 2005
/s/ SCOTT HAYASHI Scott Hayashi	Chief Financial Officer (principal financial officer and principal accounting officer)	March 29, 2005
/s/ JOHN M.VIERLING, MD John M. Vierling, MD	Chairman of the Board, and Director	March 29, 2005
/s/ JACK E. STOVER Jack E. Stover	Director	March 29, 2005
/s/ ROY EDDLEMAN Roy Eddleman	Director	March 29, 2005
/s/MARVIN S. HAUSMAN MD Marvin S. Hausman MD	Director	March 29, 2005

INDEX TO EXHIBITS

Exhibit Number	Description
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
4.2	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)
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
16.1	Letter on Change in Certifying Accountant (3)
21.1	List of Subsidiaries
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350
32.1	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350

(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.
