ARBIOS SYSTEMS INC
Form 10KSB/A
November 30, 2004

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

FORM 10-KSB/A
(Amendment No. 1)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003

[ ] 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 Blvd., Suite 206 Los Angeles, California	**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 [ ]

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. [__]

Issuer s revenues for its most recent fiscal year: $ 138,000

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 23, 2004 was approximately $17,091,194 based the closing sales price reported by the OTC Bulletin Board on such date.

There were 13,150,598 shares of the Company s common stock outstanding on March 29, 2004.

Transitional Small Business Disclosure Format (check one): YES [ ] NO [X]

DOCUMENTS INCORPORATED BY REFERENCE: None.

Explanatory Note

This Amendment No. 1 on Form 10-KSB/A to the Annual Report on Form 10-KSB amends (i) Item 1 to Part I, (ii) Item 6 to Part II, and (iii) Item 10 to Part III of the annual report. This amendment does not reflect any events occurring after March 30, 2004, the original filing date of the Company s Form 10-KSB for the fiscal year ended December 31, 2003, and does not modify or update any disclosures as originally filed, except as required to reflect the changes made to the foregoing sections.

Introductory Comment

Throughout this Amendment No. 1 on Form 10-KSB/A, the terms we, us, our, and our company refer to Arb 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

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, managemen 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. All subsequent written or oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by 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 currently have two products in development; a novel blood purification therapy called selective plasma exchange therapy (SEPET) and an extracorporeal, bioartificial liver device that incorporates porcine hepatocytes (pig liver cells) (LIVERAID). An extracorporeal bioartificial device is a device that functions outside of the human body that contains biologic components, in this case, pig liver cells. Both of our products consist of a single-use cartridge through which the patient s plasma is circulated to provide various liver support functions.

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

The LIVERAID cartridge, which contains sterile pig liver cells, is dependent upon our proprietary method of procuring, cryopreserving (freezing), storing and handling the porcine hepatocytes (pig liver cells) used in LIVERAID to provide essential liver functions. We commenced the development of LIVERAID in 2000. LIVERAID incorporates several proprietary components and technologies, including a single-use dual hollow-fiber cartridge with fiber-within-fiber geometry. The module is attached to a base instrument which facilitates perfusion of the LIVERAID with a patient s plasma. LIVERAID currently is in pre-clinical development.

Arbios Systems, Inc. was originally incorporated in February 1999 as Historical Autographs U.S.A., Inc. (HAUSA). HAUSA was an e-commerce based company engaged in the business of acquiring and marketing historical documents, such as letters, photographs and signatures of political and military figures, inventors, Nobel Prize winners, entertainers, musicians, composers, authors, artists, and well-known athletes. HAUSA s e-commerce business was not successful. Since its inception through June 30, 2003, it generated less than $200,000 of revenues, while incurring a cumulative loss of approximately $45,000. Accordingly, HAUSA sought other business opportunities, including the acquisition of ATI.

On October 30, 2003, HAUSA completed a reorganization (the Reorganization) in which HAUSA, through its wholly-owned subsidiary, acquired all of the outstanding shares of ATI in exchange for 11,930,598 shares of our common stock. As a result of the Reorganization, ATI became the wholly-owned subsidiary of HAUSA. Shortly thereafter, HAUSA changed its name to Arbios Systems, Inc. In the Reorganization, HAUSA also replaced its officers and directors with those of ATI. Following the Reorganization, we closed HAUSA s offices, ceased HAUSA s e-commerce business, and moved HAUSA s offices to our current offices in Los Angeles, California. We currently do not plan to conduct any business other than operations heretofore conducted by ATI.

Product Overview

The bioartificial liver system that we have been developing is known as LIVERAID . This system was developed by this company s founders, Drs. A. A. Demetriou and J. Rozga. LIVERAID utilizes a single-use cartridge that contains pig liver cells and certain sorbents. When a patient s blood is pumped through the bioartificial liver cartridge, substances normally metabolized by the liver and accumulated in the blood during liver failure move across the porous tubes into two compartments, one of which is filled with pig liver cells and the other that incorporates chemical particles (sorbents). The exposure of the viable pig liver cells to blood or plasma will cause these substances to be metabolized, thereby reducing their level. In addition, the activated charcoal also lowers the level of pathological blood components, such as ammonia. At the same time, substances produced by pig liver cells move across the porous wall into the plasma 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.

LIVERAID is based on a single-use cartridge that contains our proprietary designed porous tubes. We anticipate that the LIVERAID cartridge will be attached to a perfusion platform (a machine, such as a kidney dialysis machine, through which the patient s blood is circulated) that has been customized to operate with this system.

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

Background of Arbios Technologies, Inc.

ATI, our operating subsidiary, was formed in August of 2000 by Drs. A. A. Demetriou and J. Rozga, two leaders in the field of artificial liver therapy, to develop extracorporeal devices for the treatment of liver failure. As employees of Cedars-Sinai Medical Center, Drs. A. A. Demetriou and J. Rozga previously were involved in the development of a first generation bioartificial liver (known as HepatAssist) that was licensed by Cedars-Sinai Medical Center in 1994 to W.R. Grace & Co. and then subsequently transferred to other entities, including Circe Biomedical, Inc. ATI was organized by its founders for the purpose of developing more advanced and effective liver support therapies than the first-generation bioartificial liver that was originally licensed to W.R. Grace & Co.

To date, ATI has been funded the research and development of its two products through funds derived from the sale of approximately $5,485,000 of its equity securities and $304,000 of Small Business Innovation Research (SBIR) grants that have been awarded to ATI by the United States Small Business Administration. We intend to apply for additional SBIR grants to fund a portion of our research expenditures. However, whether or not we receive additional SBIR grants, we will have to raise substantial additional funds to fund our future clinical development expenses and our on-going working capital needs. See Item 6, Management s Discussion and Analysis or Plan of Operation Factors Associated with our Business.

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

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

Strategy

We have established collaborations with Cedars-Sinai Medical Center and Spectrum Labs that are expected to facilitate the development of SEPET and LIVERAID and could potentially accelerate the clinical testing, regulatory approval and commercialization of those products in the United States and other markets. We currently do not intend to engage in the manufacture of our products or of the pig cells that would be used in the bioartificial liver system and intend to rely on third parties for these functions.

We believe that the testing and regulatory requirements for SEPET will be shorter than for LIVERAID . 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 to complete the development of SEPET before the development of LIVERAID is completed. However, we will need to raise significant additional capital to be able to generate the research, clinical and manufacturing data necessary to support applications of our two products to the United States Food and Drug Administration (FDA) and regulatory agencies in other countries. We have engaged a consultant to evaluate whether SEPET could qualify to receive market approval from the FDA through a less complex, less time-consuming and less expensive procedure known as a Section 510(k) notification procedure. We do not know if we will attempt to obtain FDA marketing approval under Section 510(k), of if we do decide to apply under that section, whether the FDA will grant us clearance under that section. We expect to make a determination on whether to submit a Section 510(k) notification later this year.

We have already concluded *in vitro* and *in vivo* testing of the LIVERAID prototype devices and currently plan to commence clinical testing of SEPET during 2004 and clinical testing of LIVERAID in 2005/2006. Based on our current estimates, we anticipate that we will be able to file an application requesting market approval of the SEPET in 2007 and an application requesting marketing approval of the LIVERAID in 2008.

Based on our current assumptions, we estimate that the cost of developing SEPET will be between $1 million and $2 million (if the FDA s Section 510(k) Notification procedure is available for SEPET) or, up to $3 million if that notification procedure is not available. The cost of developing LIVERAID will be between $20 million and $25 million. These amounts, which could vary substantially if our assumptions are not correct, and are well in excess of the amount of cash that we currently have available to us.

Liver Function Background

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

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

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

It is generally believed that liver support at this level of complexity requires utilization of viable isolated liver cells (hepatocytes). The founders of ATI as well as investigators not associated with this company have demonstrated *in vitro* and in animal models of liver failure that cell-based bioartificial livers can provide whole liver functions. However, only a few bioartificial livers were tested in humans and it remains to be seen whether systems utilizing hepatocytes as the only means of liver support are effective. We believe that in order to provide the maximum support for the failing liver, porcine hepatocyte therapy should be combined with blood detoxification. Based on this principle, the founders of ATI have previously developed at Cedars Sinai Medical Center a first-generation bioartificial liver system that was licensed by Cedars-Sinai Medical Center to W.R. Grace & Co. in 1994. A Phase I clinical trial was carried out at Cedars-Sinai Medical Center and the results were encouraging (16 out of 18 liver failure patients were successfully bridged to transplantation; one bioartificial liver-treated patient recovered without transplantation and one patient died because of concomitant severe pancreatitis). This first generation bioartificial liver (known as HepatAssist System, and owned by Circe Biomedical, Inc., Lexington, Massachusetts) was recently tested in FDA-approved Phase II/III clinical trials. To our knowledge, these trials of the HepatAssist System were the first large (171 patients) prospective, randomized, controlled multi-center trial demonstrating a survival advantage for an extracorporeal liver assist system in fulminant and subfulminant hepatic failure in a subgroup.

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Our LIVERAID was designed to become a more advanced, relatively inexpensive, effective application of the basic bioartificial liver concept. In our system, liver cell therapy (porcine hepatocytes) and blood detoxification (selective plasma exchange or sorbent based plasma therapy) are combined in a single device. Depending on the cause of liver disease, severity of illness and deficiency of specific liver functions, these LIVERAID modes of therapy can be provided individually, simultaneously or sequentially. Because of these features, we believe that the system is well suited to treat patients with liver failure of all etiologies and severity, including those requiring maximum liver support. While pre-clinical data has indicated that LIVERAID™ improved hemodynamic status, clearance of ammonia and ICG (a liver function test) and prolonged survival time of pigs with total liver failure, our beliefs have not been clinically proven, and we will have to demonstrate the efficacy of LIVERAID™ in FDA-approved clinical trials before our product can be used by human patients.

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

The Products We Are Developing

We currently are developing two novel treatments for acute and chronic liver failure. We believe that both SEPET and LIVERAID 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 LIVERAID can achieve these effects because it can lower blood levels of substances that are toxic to both the brain and liver. However, proof of feasibility is lacking at this time, and the clinical utility of this product still needs to be demonstrated in patients with acute liver failure. We own certain technologies and rights related to our products, and have licensed certain other technologies.

SEPET™

We are developing SEPET (selective plasma filtration therapy) as a blood purification measure to provide temporary liver support during acute liver failure and acute exacerbation of chronic liver disease. Selective plasma filtration therapy will be provided through our single-use, disposable cartridge that contains a bundle of hollow fibers made of bio- and hemo-compatible material and being capable of sieving substances with molecular weight of up to 100 kDa.

The importance of using fibers with this sieving characteristics is that most hepatic failure toxins have a molecular weight that is less than 100 kDa, while all "good" blood components have molecular weight greater than 100 kDa. At present, Spectrum Labs is the manufacture of these disposable cartridges. 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 with molecular weight of 100 kDa or less will be recovered from the side port of the cartridge, while at the same time, commercially available (e.g., blood bank) fresh frozen plasma and/or its synthetic substitute will be administered to the patient.

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

LIVERAID

LIVERAID is 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 cartridge is 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, LIVERAID is designed to lower the levels of pathological blood components (through charcoal and other purification sorbents).

We have designed and are attempting to demonstrate that our LIVERAID product can provide temporary liver support during acute liver failure and acute exacerbation of chronic liver disease. The LIVERAID utilizes a proprietary multi-compartment hollow fiber module incorporating viable pig liver cells and a blood detoxification circuit. The module is attached to a base instrument that pumps the patient s plasma through the LIVERAID cartridge. The hollow fibers are made of a polyethersulfone membrane or a similar material based on our proprietary fiber-within-a-fiber geometry. This geometry allows for the integration of two different functions within a single module. Depending on the causes of liver disease, severity of illness and deficiency of specific liver functions, LIVERAID is designed to offer liver cell therapy, blood detoxification or a combination thereof. During treatment, individual modes of therapy may be added or removed. The other components of LIVERAID , including blood purification columns (charcoal), oxygenator, filters and tubing kit are available from third party vendors.

At present, most bioartificial liver systems (including the original HepatAssist system) are filled with plasma rather than blood. The LIVERAID system is 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 LIVERAID will utilize a commercially available oxygenator and a disposable tubing kit.

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

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

Hepatocyte harvest. The founders of our ATI subsidiary have developed a semi-automated method for large-scale harvest of pig hepatocytes with excellent yield and cell viability. The method of harvesting and collecting liver cells is covered by two patents, which patents have been licensed to ATI by 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 will be harvested from young purpose-bred, pathogen-free, vaccinated pigs raised in an United States Department of Agriculture (USDA) certified facility specifically for biomedical research purposes. Each batch of cryopreserved pig liver cells will be released for clinical use only after proper verification of biosafety and viability/functionality of the cells. We intend to develop appropriate laboratory and quality assurance protocols in compliance with FDA requirements.

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

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

Product Advantages

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

· Ease of use. The systems bring user friendliness (e.g., pump integration, automation and an intuitive user interface) to traditionally complex liver support procedures.

· Simplicity. Kidney dialysis systems are routinely used and, therefore, there may be no need for extensive personnel training for use of these similar systems in the SEPET .

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- 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.

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

Clinical Utility

The clinical performance of the SEPET and LIVERAID has not been assessed yet. However, *in vivo* large animal studies have provided proofs of feasibility and clinical efficacy for LIVERAID . Additionally, virtually all basic aspects of these new technologies (effect of blood purification, liver cell function, utility of hollow-fiber membranes, performance of a design incorporating both pig liver cells and sorbent) have been validated in the past by Drs. Demetriou and Rozga, the founders of ATI, and other investigators. Furthermore, the animal and clinical data generated and published to date on the first-generation bioartificial liver, indicate that the basic concept of a bioartificial liver utilizing cryopreserved pig liver cells and blood detoxification, is valid and that repeated 6-hour bioartificial liver treatments are safe and yield measurable therapeutic benefits. Accordingly, we believe that our novel, next-generation products will represent improvements and/or enhancements of earlier technologies.

Market Opportunity

There is an urgent need for artificial means of liver replacement and/or assistance to facilitate recovery from liver failure without a transplant. An effective liver assist device could also help maintain liver failure patients alive until an organ becomes available for transplantation. The SEPET and LIVERAID 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, National Center For Health Statistics and data published in medical literature, it is estimated that five million Americans have viral hepatitis and each year as many as 700,000 patients in the United States are diagnosed with liver disease.

According to American Liver Foundation, 25,000,000 Americans - one in every 10 - are or have been suffering from liver and biliary diseases. According to the National Center For Health Statistics published for 2000, there were 360,000 hospital discharges for patients with chronic liver disease or cirrhosis. Of those, 27,035 died (10^{th} leading cause of death in males and 12^{th} in females; 4^{th} 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 April 2002, the liver transplant waiting list contained 17,641 individuals. According to National Institutes of Health and the American Association for the Study of Liver Diseases, 5,000 deaths occur annually as a consequence of hepatitis B virus infection.

Based on these data, we estimate that more than 200,000 extracorporeal liver support treatments may be needed annually in the United States alone to help keep liver failure patients alive until either an organ becomes available for transplantation or the native liver recovers from injury. We believe that SEPET and our bioartificial liver system may address this demand and, based on published data, estimate that there were approximately 250,000 patients hospitalized in the United States in 2001 who had indications for selective plasma filtration and/or bioartificial liver therapy.

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

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

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

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

Sales, Marketing & Distribution

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

Manufacturing

In December 2001 we entered into a manufacturing and supply agreement with Spectrum Laboratories, Inc. for the future manufacture of our LIVERAID cartridges. Under that agreement, we agreed that Spectrum Labs will manufacture the hollow fiber cartridges with fiber-in-fiber geometry that we will need for the LIVERAID bioartificial liver. The agreement provides that the price of the hollow fiber-in-fiber cartridges to be sold by Spectrum Labs to us will be determined by good faith negotiations between the parties. We have agreed that we will not purchase cartridges with fiber-in-fiber geometry from any other manufacturer unless Spectrum Labs is either unable or unwilling to manufacture the cartridges. 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. In the event that Spectrum Labs is either unable or unwilling to manufacture the cartridges for us, 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.

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

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

The platform we currently expect to use for LIVERAID will be an existing instrument manufactured and marketed by an unaffiliated medical device manufacturer. The instrument we expect to use has been certified and approved in

Europe for bioartificial liver use. However, in order to use this existing platform for bioartificial liver therapy, the instrument must be outfitted with customized software and with hook-ups and components (tubing set) that are specifically designed for use with LIVERAID .

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

As regards to cell procurement/cryopreservation for bioartificial liver use, we do not yet own our own specialized and certified bio-secure porcine liver cell manufacturing plant. Currently, we expect to subcontract the manufacture of the bioartificial liver porcine liver cells needed to conduct clinical trials and during early stages of commercialization from one or more third parties who already manufacture such cells. At the conclusion of Phase II/III clinical testing of the LIVERAID , 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

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

1. A hollow fiber module with unique fiber-in-fiber geometry (US Patent #5,015,585 Method and Apparatus for Culturing and Diffusively Oxygenating Cells on Isotropic Membranes issued on May 14, 1991). We have licensed this patent from Spectrum Labs.

2. A bioartificial liver system in which liver cell therapy and blood detoxification are integrated in a single fiber-in-fiber module (US Patent # 6,582,955 B2 for Bioreactor With Application as Blood Therapy Device issued in June 2003). We have licensed this patent from Spectrum Labs.

3. Semi-automated large-scale liver cell procurement technology (US Patent #5,888,409 for Methods for Cell Isolation and Collection issued on March 30, 1999 and 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 these patents from Cedars-Sinai Medical Center.

4. 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.

5. 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.

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

Cedars-Sinai Medical Center Licenses. On June 19, 2001, ATI entered into an agreement with Cedars-Sinai Medical Center pursuant to which Cedars-Sinai granted to ATI exclusive and worldwide rights to the foregoing five patents and to certain other technical information. These rights are and remain exclusive over the legal life of the various patents and include, subject to limitations, the right to sublicense the patent rights to third parties. In order to maintain its rights under the license, ATI is required to expend an aggregate amount of $1,760,000 in research and development expenses toward the development and promotion of products derived from the patents. ATI s research and development commitment remains in full force and effect until June 30, 2008. Under the terms of the license, ATI is obligated to meet expenditure milestones per annum through 2008 in order to reach the required $1,760,000. If ATI expenditures exceed a given year s milestone, however, such excess may be carried over to the following year. To date, we have spent approximately $1,010,000 towards the fulfillment of this obligation. Additionally, Cedars-Sinai Medial Center will have nonexclusive rights to any products derived from the patents. We will have to pay Cedars-Sinai Medical Center royalty fees equal to 1.5% of the gross sales price of royalty bearing products. From the third to tenth years of the license, the royalty fee percent will phase out evenly to 0%. Cedars-Sinai Medical Center is a major stockholder of this company. See Item 12. Certain Relationships and Related Transactions.

Spectrum Labs License Agreement. On December 26, 2001, ATI entered into a license agreement with Spectrum Labs, pursuant to which Spectrum Labs granted to ATI an exclusive, worldwide license to develop, make, use and distribute products based on Spectrum Labs hollow fiber-in-fiber technology, solely for applications in ATI s liver assist devices. The license includes the rights to the two issued patents referred to above. Provided that ATI purchases the hollow fiber cartridges that it expects that it will need for its products from Spectrum Labs, ATI will not have to pay a royalty for the license. In the event that Spectrum Labs is not the manufacturer of the hollow fiber cartridges, ATI will have to pay Spectrum Labs a royalty for the license (see, Item 1. Description of Business--Manufacturing, above). Unless the Spectrum Labs license agreement is terminated sooner due to a breach of the license, the term of the license will continue until the expiration of the two patents. Spectrum Labs also agreed to grant ATI a right of first refusal to obtain a license to make, use, develop or distribute products based on Spectrum Labs technology other than in liver assisted products, provided that such other products are in the fields of artificial blood therapy and bioprocessing and therapeutic devices. See Item 12. Certain Relationships and Related Transactions.

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.

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

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

Research and Development

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

Spectrum Labs on terms that we may in the future agree to.

We have spent a total of $437,000 on research and development during the fiscal year ended December 31, 2003 and $431,000 for the fiscal year ended December 31, 2002. In addition, pursuant to our research agreement with Spectrum Labs, that company provided research and development services valued at approximately $117,379 in 2002 and $17,260 in 2003 for our liver assist systems. See, Item 12. Certain Relationships and Related Transactions.

Competition

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

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

Other technologies offered by competing companies include the following:

Teraklin s MARS system (molecular adsorbents recirculating system) combines the specific removal of the toxins of liver failure (albumin bound toxins) using a hollow-fiber cartridge impregnated with albumin, which is also added to the dialysate solution. Albumin in the dialysate is "regenerated" during continuous recirculation in the closed loop system through adsorbents (charcoal, resin). In addition, standard dialysate circuit could be added. In Europe, initial results in patients with acute liver failure were encouraging. However, controlled clinical trials are needed to establish if the technology has any therapeutic value.

Fresenius s PROMETHEUS system is a variant of Teraklin s MARS system and also combines albumin dialysis with sorbent based plasma detoxification. 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.

Excorp Medical, Inc. s device (BLAD) is a freestanding blood perfusion system including pumps, a heat exchanger, an oxygenator, pressure gauges, safety features and computer-assisted monitoring. To our knowledge, no clinical trials have been carried out with this system. To our knowledge, this product does not include detoxification components.

Algenix, Inc. s device (LIVE-Rx 2000) utilizes pig liver cells and a commercially available dialysis cartridge. In its commercial form, the LIVE-Rx 2000 will consist of an installed base instrument, support equipment and a consumable set of a single-use tubing and disposable bioreactor. The LIVE-Rx 2000 offers cell therapy only. Pig liver cell aggregates will be generated using proprietary technology and maintained in perfusion culture. Cells are suitable for clinical use only after a prolonged processing and have a limited shelf live (up to 2 weeks), making this therapy impractical for many liver failure patients.

VitaGen, Inc. uses technology initially developed and marketed by Hepatix. VitaGen s ELAD utilizes a cell line derived from human liver cancer tissue and a conventional hollow fiber bioreactor. A pilot clinical study was completed in Europe (King s College of Medicine, London, UK). In patients with acute liver failure, treatment with

ELAD had no effect on the clinical course when compared to patients receiving standard therapy. We believe that VitaGen has initiated a clinical trial in the U.S. Their new ELAD has 4 (instead of 1) cell cartridges placed in a plasma recirculation loop.

RanD S.r.I. developed a radial-flow bioreactor for liver cell culture and an integrated pumping apparatus in which the patient s plasma is recirculated through the bioreactor loaded with 200 gm of freshly isolated pig hepatocytes. The RanD system was used in seven patients with fulminant hepatic failure and six of them were successfully bridged to orthotopic liver transplantation. At this time, it is unclear whether this technology will be further developed and tested in prospective randomized controlled clinical trials.

Several other technologies could potentially compete with our LIVERAID product. 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.

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The FDA has separate review procedures for medical devices before such products may be commercially marketed in the United States. There are two basic review procedures for medical devices in the United States. Certain products may qualify for a Section 510(k) procedure, under which the manufacturer gives the FDA a Pre-Market Notification, or 510(k) Notification, of the manufacturer's intention to commence marketing of the product at least 90 days before the product will be introduced into interstate commerce. The manufacturer must obtain written clearance from the FDA before it can commence marketing the product. Among other requirements, the manufacturer must establish in the 510(k) Notification that the product to be marketed is "substantially equivalent" to another legally-marketed, previously existing product. If a device does not qualify for the 510(k) Notification procedure, the manufacturer must file a Pre-Market Approval Application. The Pre-Market Approval Application requires more extensive pre-filing testing than the 510(k) Notification procedure and involves a significantly longer FDA review process. We do not know if we will attempt to obtain FDA marketing approval under Section 510(k) for SEPET , of if we do decide to apply under that section, whether the FDA will grant us clearance for the use of SEPET under that section. We have engaged a consultant to advise us with respect to the availability of a Section 510(k) notification and expect to make a determination on whether to submit a Section 510(k) notification later this year.

We expect SEPET to be classified by the FDA as a Class III medical device. Accordingly, unless Section 510(k) is available, SEPET will be subject to a two-step approval process starting with a submission of an investigational new device exemption application to conduct human studies, followed by Pre-Market Approval Application.

We expect LIVERAID to be classified by the FDA as a biological therapeutic and Class III medical device. Accordingly, it will be subject to a two-step approval process starting with a submission of an investigational new drug application to conduct human studies followed by the submission of a Product Marketing Approval and a new drug application. The latter, if and when accepted, allows the commercialization of the product.

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 LIVERAID product is expected to utilize) due to safety concerns. If we are unable to obtain the approval of the health regulatory authorities in any country, the potential market for our products will be reduced.

Employees

We currently employ five full-time employees, one part-time employee, one full-time consultant, and three independent contractors who provide services to us on a part-time basis. Of the foregoing employees and contractors, six are primarily engaged in administration/management, and remaining four persons are involved in scientific research, product development and/or regulatory compliance matters. In addition, certain members of our Board of Directors provide us with research and development assistance on a part-time, limited basis. For more information about our employees and directors see Item 9. Directors, Executive Officers Promoters and Control Persons. 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.

PART II

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, managemen

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

Until October 30, 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) with ATI, in which ATI became the wholly-owned subsidiary of HAUSA. At the time of the Reorganization, HAUSA had virtually no assets and virtually no liabilities. In addition, between the time of its inception through the Reorganization, HAUSA had generated less than $200,000 of revenues, while incurring a cumulative loss of approximately $45,000. Shortly after the Reorganization, HAUSA changed its name to Arbios Systems, Inc. In the Reorganization, HAUSA also replaced its officers and directors with those of ATI. Following the Reorganization, we closed HAUSA s offices, ceased HAUSA s e-commerce business, and moved HAUSA s offices to our current offices in Los Angeles, California. We currently do not plan to conduct any business other than operations heretofore conducted by ATI. Accordingly, the prior operating results of HAUSA are not indicative of our future operations, and none of the assets or liabilities on our balance sheet as of December 31, 2003 relate to HAUSA prior to the Reorganization.

Although HAUSA was the legal acquirer 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 attached as Item 7 below, and the description of our results of operations and financial condition, reflect (i) the operations of ATI alone prior to the Reorganization, and (ii) the combined results of this company and ATI since the Reorganization. No goodwill was recorded as a result of the Reorganization.

Since the formation of ATI in 2000, our efforts have been principally devoted to research and development activities, raising capital, and recruiting additional scientific and management personnel and advisors. To date, we have not marketed or sold any product and have not generated any revenues from commercial activities, and we do not expect to generate any revenues from commercial activities during the next 12 months. Substantially all of the revenues that we have recognized to date have been Small Business Innovation Research grants (in an aggregate amount of $249,000) that we received from the United States Small Business Administration. We are currently preparing an additional application for a United States governmental grant that we plan to submit during 2004. However, even if the application is prepared and filed and a grant is approved, no funds from such a grant would be received during 2004.

We currently are also considering purchasing certain assets, including additional patents and other intellectual properties, to enhance our proprietary rights and to accelerate the development and regulatory approval of our products. While we are considering such acquisitions, we have not yet entered into a definitive agreement for any such acquisition. Future acquisitions could affect our financial resources and our liquidity in a manner that we cannot currently project.

Our current plan of operation for the next 12 months primarily involves research and development activities, including clinical trials for at least one of our two potential products. and the preparation and submission of applications to the FDA. The actual amounts we may expend on research and development and related activities during the next 12 months may vary significantly depending on numerous factors, including the results of our research and development programs, the results of clinical studies, the timing of regulatory submissions, and the possible acquisition of assets that may reduce the need for certain research and development activities. However, based on our current estimates, we believe that we have sufficient financial resources to conduct our planned operations beyond the next 12 months.

Critical Accounting Policies

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

Results of Operations

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

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

General and administrative expenses consist primarily of salaries, office and equipment lease expenses, and professional fees and expenses. General and administrative doubled from $173,000 in fiscal 2002 to $340,000 in fiscal 2003 due to an increase in the number of employees and consultants employed by us in fiscal 2003, and increased professional fees. In addition, professional fees increased during 2003 due to the legal and accounting fees and expenses related to the Reorganization and the additional legal, consulting and accounting fees and expenses related to our status as an active public company. General and administrative expenses are expected to significantly increase during the current fiscal year ending December 31, 2004 due to the lease of additional office space (which new lease went into effect on April 1, 2004), the addition of more employees and consultants (primarily to assist with our financial controls and to evaluate and prepare submissions to the FDA), and additional professional and other fees related to being a public company.

Research and development expenses consisted primarily of salaries for our scientists and technicians, laboratory costs, and the cost scientific supplies. Research and development expenses remained substantially unchanged from fiscal 2002 to fiscal 2003 because of the limited amount of capital available to us during most of fiscal 2003 and because of our focus on completing the studies sponsored and funded by the SBIR. However, we expect our research and development activities and expenses to increase significantly in the current fiscal year ending December 31, 2004.

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

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

we increase our operations, while revenues are expected to remain insignificant.

Liquidity and Capital Resources

As of December 31, 2003, we had cash of $3,507,000 and only a total of $169,000 of total indebtedness (both long-term and current liabilities). We do not have any bank credit lines. To date, we have funded our operations from the sale of debt and equity securities. During fiscal 2003, these sales of our securities consisted of the following: (i) $250,000 obtained in January 2003 from the sale of our common stock sold at a price of $0.60 per share; (ii) $400,000 raised from the sale of subordinated convertible promissory notes (which notes were converted in October 2003 into common stock and warrants at $1.00 per share immediately prior to the Reorganization); (iii) $2,310,000 raised in a private offering of common stock and warrants sold at a price of $1.00 per share; and (iv) $1,690,000 obtained immediately prior to the Reorganization in an offering of common stock and warrants sold at a price of $1.00 per share.

Our net loss for fiscal 2003 was $886,000. However, net cash used in operations was only $569,000 due primarily to the non-cash expense related to the debt discount recognized in connection with the issuance of the $400,000 of convertible loans.

Based on our current plan of operations, we believe that our current cash balances will be sufficient to fund our foreseeable expenses for at least the next twelve months. However, we are currently considering purchasing some intellectual property and possibly some equipment to supplement our technologies and to possibly accelerate both the development of our products and the approval of our products by the FDA. If we consummate any such sales, our cash balances may be reduced and liquidity will be affected. In addition, unexpected costs could arise that could deplete our existing cash balances sooner than planned.

We do not currently anticipate that we will derive any revenues from either product sales or from governmental research grants during the next twelve months. Although we 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 next twelve months.

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 12-18 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, 2003 is as follows:

Contractual Obligations	Total	2004	2005	2006	2007 and thereafter
Long-Term Office Leases [1]					
$	428,000				
$	137,000				

$	137,000
$	77,000
$	38,000

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

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

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

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

An investment in our common stock is subject to a high degree of risk. The risks described below should be carefully considered, as well as the other information contained in this annual report and in the documents incorporated by reference. If any of the following risks actually occur, our business, financial condition or operating results and the trading price or value of our securities could be materially adversely affected.

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

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

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

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 LIVERAID will require approval from the FDA prior to clinical testing and commercialization. The process for obtaining FDA approval to market therapeutic products is both time-consuming and costly, with no certainty of a successful outcome. This process includes the conduct of extensive pre-clinical and clinical testing, which may take longer or cost more than we currently anticipate due to numerous factors, including without limitation, difficulty in securing centers to conduct trials, difficulty in enrolling patients in conformity with required protocols and/or projected timelines, unexpected adverse reactions by patients in the trials to our products, temporary suspension and/or complete ban on trials of our products due to the risk of transmitting pathogens from the xenogeneic biologic component, and changes in the FDA s requirements for our testing during the course of that testing. We have not yet established with the FDA the nature and number of clinical trials that the FDA will require in connection with its review and approval of either SEPET or LIVERAID 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 LIVERAID product is 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 LIVERAID , 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 LIVERAID . 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 one to three years to obtain approval for SEPET , and approximately five years for LIVERAID . We have not independently confirmed any of the third party claims made with respect to patents, licenses or technologies we have acquired concerning the potential safety or efficacy of these products and technologies. We will need to file an investigational new drug application (IND) for LIVERAID and an investigational drug exemption for SEPET with the FDA and have these applications cleared by the FDA before we can begin clinical testing of these two products, and the FDA may require significant revisions to our clinical testing plans or require us to demonstrate efficacy endpoints that are more time-consuming or difficult to achieve than what we currently anticipate. We have not yet completed preparation of either the IND or the investigational drug exemption application, and there can be no assurance that we will have sufficient experimental data to justify the submission of said applications. Because of the early stage of development of each of our products, we do not know if we will be able to generate clinical data that will support the filing of the FDA applications for these products or the FDA s approval of any product marketing approval application or IND that we do file.

Our LIVERAID™ product utilizes a biological component obtained from pigs that could prevent or restrict the release and use of this product.

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

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

Since we only have sufficient capital to conduct our operations for approximately 12 months to 18 months from the date of this annual report, we will need to obtain significant additional capital, which additional funding may dilute our existing stockholders.

Based on our current proposed plans and assumptions, we anticipate that our existing funds will only be sufficient to fund our operations and capital requirements for approximately 12 months to 18 months from the date of this annual report. Furthermore, the clinical development expenses for each of our products will be very substantial. Based on our current assumptions, we estimate that the cost of developing SEPET will be up to $3 million and the 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 during the next year in order to fund the further development of our products and working capital needs, and/or (ii) enter into a strategic alliance with a larger pharmaceutical or biomedical company to provide its required funding. The amount of funding needed to complete the development of one or both of our products will be very substantial and may be in excess of our ability to raise capital.

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

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

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

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

Our business model calls for the outsourcing of the clinical development, manufacturing and marketing of our products in order to reduce our capital and infrastructure costs as a means of potentially improving the profitability of these products for us. We have not yet entered into any strategic alliances or other licensing or contract manufacturing arrangements (except for the contractual manufacturing of LIVERAID modules by Spectrum Labs) and there can be no assurance that we will be able to enter into satisfactory arrangements for these services or the manufacture or marketing of our products. We will be required to expend substantial amounts to retain and continue to utilize the services of one or more clinical research management organizations without any assurance that the products covered by the clinical trials conducted under their management ultimately will generate any revenues for SEPET and/or LIVERAID . 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. for the fiber-within-fiber LIVERAID cartridges. Although we have no agreement with Spectrum Laboratories, Inc. for the manufacture of the SEPET cartridges, Spectrum Laboratories has also been providing us with cartridges for prototypes of the SEPET . Spectrum Laboratories, Inc. 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 Laboratories, Inc. has informed us that it can, and is willing to acquire or develop an automated manufacturing process for the LIVERAID cartridges that will reduce or eliminate these problems and shorten the manufacturing period. However, since such an automated manufacturing process is expensive, Spectrum Laboratories, Inc. has not yet undertaken to acquire or develop the necessary equipment and technology. No assurance can be given that Spectrum Laboratories, Inc. will, in fact, be able to acquire or develop an automated manufacturing process or that Spectrum Laboratories, Inc. 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 Laboratories, Inc. has agreed to transfer all of the know-how related to these products to any other manufacturer of our products if Spectrum Laboratories is unable to meet its contractual obligations to us, we may have difficulty in finding a replacement manufacturer or may be required to alter the design of the LIVERAID cartridges if we are unable to effectively transfer the Spectrum Labs know-how to another manufacturer.

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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 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 LIVERAID™ 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.

Risk Relating to the Ownership of Our Common Stock

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

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

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

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

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

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

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.

The future issuance of common stock upon exercise of warrants and stock options may depress the price of our common stock.

As of March 29, 2004, we had outstanding options to purchase an aggregate of 629,000 shares of our common stock to our employees, officers, directors, and consultants under our 2001 Stock Option Plan. We may issue options to purchase an additional 371,000 shares of our common stock under the 2001 Stock Option Plan. There are currently outstanding warrants to purchase an aggregate of 5,097,000 shares of common stock.

During the respective terms of the warrants and options granted or to be granted under our stock option plans or otherwise, the holders thereof are given an opportunity to benefit from a rise in the market price of the common stock, with a resultant dilution of the interests of existing stockholders. The existence of these warrants and options could make it more difficult for us to obtain additional financing while such securities are outstanding. The holders may be expected to exercise their rights to acquire common stock and sell at a time when we would, in all likelihood, be able to obtain needed capital through a new offering of securities on terms more favorable than those provided by these warrants and options.

ITEM 10. EXECUTIVE COMPENSATION.

The following table sets forth the compensation for services paid to Jacek Rozga, M.D., Ph.D. (the Named Executive Officer) in all capacities for the fiscal years ended December 31, 2003, December 31, 2002 and December 31, 2001. Dr. Rozga has been the chief executive officer of both this company and ATI since the Reorganization in October 2003, and was the chief executive officer ATI before the Reorganization. The information contained in this Item 10 includes all compensation paid to Dr. Rozga by ATI before the Reorganization by ATI, and all compensation paid to him by both HAUSA and ATI since the Reorganization. No other executive officers of either HAUSA or ATI

received an annual salary and bonus that collectively exceeded $100,000 during any of the fiscal years ended December 31, 2003, December 31, 2002 and December 31, 2001.

Summary Compensation Table

Name and Principal Position	Year	Annual Compensation Salary	Bonus	Other Annual Compensation	Long-Term Compensation Awards Securities Underlying Options
Jacek Rozga, M.D., Ph.D	2003(1)	$ 135,000	$ 15,000		18,000(2)
Chief Executive Officer, Chief Financial Officer, and Chief Scientific Officer	2002	$ 85,000	$ 5,000		18,000(2)
	2001	$ 85,000			

(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.

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. The only compensation that Mr. Kuh received was a commission of 6% of sales that he generated for HAUSA. During the three fiscal years ended December 31, 2003, December 31, 2002 and December 31, 2001, the aggregate total amount of such bonuses paid to Mr. Kuh by HAUSA was only $2,562. Mr. Kuh did not receive any other compensation and was not granted any options. Accordingly, no information is listed in this Item 10 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, 2003 by ATI to the Named Executive Officer (HAUSA did not grant any options). In the Reorganization, all of these options 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, 2003

	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	18,000	8%	$ 1.00	(1)	April 20, 2010

(1)

On the date of grant, the common stock of ATI was not listed for trading on any securities market. Accordingly, there was no market price on the date of grant.

Aggregate Options

The following table sets forth the number and value of unexercised options held by the Named Executive Officer as of December 31, 2003. There were no exercises of options by the Named Executive Officer in fiscal year 2003.

Aggregated Option Exercises in Fiscal Year Ended December 31, 2003 and FY-End Option Values

Name	Shares Acquired in Exercise	Value Realized	Number of Securities Underlying Unexercised Option at FY-End (#) Exercisable/ Unexercisable	Value of Unexercised In-the-Money Options at FY-End (#) Exercisable/ Unexercisable[1]
Jacek Rozga, M.D., Ph.D			36,000/0	$ 69,300/$-0-

(1) Dollar amounts reflect the net values of outstanding stock options computed as the difference between $2.50 (the last reported sale on December 31, 2003) and the exercise price of the options.

Equity Compensation Plan Information

The following table summarizes as of March 29, 2004, 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 (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance (c)
Equity compensation plans approved by security holders	629,000	$ 1.32	371,000
Equity compensation plans not approved by security holders	-0-		
Total	629,000	$ 1.32	371,000

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 Financial Officer of this company and in his capacity as President, Chief Financial Officer and Chief Financial Officer of ATI, our operating subsidiary. In his capacity as the President and Chief Financial Officer of this company, Dr. Rozga earns an annual

salary of $65,000. In addition, Dr. Rozga and three of ATI s other employees provide services to ATI pursuant to that certain Employee Loan-Out Agreement, dated July 1, 2001, as amended, between ATI and Cedars-Sinai Medical Center. Dr. Rozga and the other employees are technically employed and paid by Cedars-Sinai Medical Center. Under the terms of the Loan-Out Agreement, the medical center permits Dr. Rozga to provide services to ATI, and ATI pays Cedars-Sinai Medical Center an amount equal to Dr. Rozga s salary plus an amount equal to the cost of fringe benefits and Cedars-Sinai Medical Center pays to Dr. Rozga. Through this arrangement, Dr. Rozga earns an annual salary of $135,000 (which amount is paid through Cedar-Sinai but funded by ATI). The Loan-Out Agreement expires on June 30, 2004, 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 Cedar-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, 2003, HAUSA did not pay its directors any compensation for serving on the Board of Directors. ATI did, however, grant each of its directors stock options to purchase 18,000 shares of common stock at an exercise price of $1.00 per share. The options have a term of seven years. Providing that the directors still are on the board at that time, one half of the options vest six months after the date of grant, and the remaining options vest on the first anniversary of the grant. We currently also reimburse all directors for any expenses incurred by them in attending meetings of the board of directors.

In February 2004, the Board of Directors voted to increase the number of options that each director would receive annually for services rendered as a director from 18,000 to 30,000. The vesting schedule (one-half vests after six months, the balance after one year) will remain the same as with options granted in 2003. Director options continue to be granted at the market price on the date of grant.

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

Options granted under the stock option plan become exercisable and shall expire on such dates as determined by the Board of Directors, provided, however, that no term may exceed ten years from the date of grant, or five years from the date of grant in the case of any optionee holding more than 10 percent of the combined voting power of all classes

of our capital stock as of the date of grant. After options become exercisable they may be exercised at any time or from time to time as to any part thereof.

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

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No.1 on Form 10-KSB/A to the Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 to be signed on its behalf by the undersigned, thereunto duly authorized.

ARBIOS SYSTEMS, INC.

Date: November 30, 2004

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

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