

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

ARBIOS SYSTEMS INC
Form 10KSB
March 30, 2004

DRAFT 3/24/04

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

FORM 10-KSB

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
(State or other jurisdiction of
incorporation or organization)

91-19553323
(I.R.S. Employer
Identification No.)

110 NORTH GEORGE BURNS ROAD
SUITE D-4018
LOS ANGELES, CA
(Address of principal executive offices)

90048
(Zip Code)

Issuer's Telephone Number: 310-423-7702

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 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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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.

TABLE OF CONTENTS

PART I

1. Description of Business.....	1
2. Description of Property.....	14
3. Legal Proceedings.....	14
4. Submission of Matters to a Vote of Security Holders.....	14

PART II

5. Market for Common Equity and Related Stockholder Matters.....	15
6. Management's Discussion and Analysis or Plan of Operation.....	15
7. Financial Statements.....	25
8. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.....	25
8A. Controls and Procedures.....	26

PART III

9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act.....	26
10. Executive Compensation.....	28
11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.....	31
12. Certain Relationships and Related Transactions.....	32
13. Exhibits and Reports on Form 8-K.....	33
14. Principal Accountant Fees and Services.....	35

INTRODUCTORY COMMENT

Throughout this Annual Report on Form 10-KSB, the terms "we," "us," "our," and "our company" refer to Arbios Systems, Inc., a Nevada corporation formerly known as Historical Autographs U.S.A., Inc., and, unless the context indicates otherwise, also includes our wholly-owned subsidiary, Arbios Technologies, Inc., a Delaware corporation.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

FORWARD LOOKING STATEMENTS

This annual report contains forward-looking statements within the meaning of the federal securities laws. These include statements about our expectations, beliefs, intentions or strategies for the future, which we indicate by words or phrases such as "anticipate," "expect," "intend," "plan," "will," "we believe," "the company believes," "management believes" and 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(TM)") and a novel bioartificial liver device ("LIVERAID(TM)"). 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 designed to remove toxins in the patient's blood, while the LIVERAID cartridge, which contains sterile pig liver cells, is designed to artificially provide liver functions.

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.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

PRODUCT OVERVIEW

LIVERAID(TM) is a single-use cartridge that contains pig liver cells, certain sorbents, and specially designed porous tubes. When a patient's blood is pumped through the 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) capable of removing toxins that cause liver failure. At the same time, substances produced by pig liver cells move across the porous wall into the blood compartment. As a result of these two processes (provision of whole liver functions by the pig liver cells and removal of toxins by the sorbents), the levels of pathological and normal blood components move toward normal ranges.

SEPET(TM) is a single-use cartridge that contains specially designed porous tubes. When 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, the levels of pathological blood components move toward normal ranges.

In order to provide LIVERAID(TM) or SEPET therapy, each of the cartridges is placed on a blood perfusion apparatus (such as a dialysis machine) that is attached to the patient's blood circulation system. At the end of the treatments with either of our products, the disposable cartridges are discarded, and new cartridges are used for the next therapy.

BACKGROUND OF ARBIOS TECHNOLOGIES, INC.

ATI was formed in August of 2000 by Drs. A. A. Demetriou and J. Rozga, two leaders in the field of artificial liver therapy. As employees of Cedars-Sinai Medical Center, Drs. A. A. Demetriou and J. Rozga previously developed a first generation bioartificial liver that was licensed by Cedars-Sinai Medical Center in 1994 to W.R. Grace & Co. and then subsequently transferred to other entities. However, this first generation device and has not yet been approved for marketing. 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 offices and laboratories (and those of ATI) 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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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 leading supplier of dialysis and ultrafiltration membranes used for biomedical research, molecular biology and clinical diagnostics throughout the world.

2

MARKETS

The total market opportunity for extracorporeal liver support is substantial and unserved. According to the American Liver Foundation and the National Center for Health Statistics (NCHS), liver failure is the 7th leading cause of death in the U.S. In 2000, nearly 700,000 Americans were diagnosed with liver disease and over 250,000 liver patients were hospitalized due to acute liver failure. Of those, nearly 50,000 (20%) died because no donor liver was available or because these patients had contraindications to liver transplantation. The remaining 200,000 patients were discharged from the hospital because they either received a liver transplant or their condition improved after receiving conventional care. Remarkably, half of them were hospitalized again in the same year due to another episode of liver failure requiring full medical support and/or organ replacement. Based on these data, the NCHS estimates that more than 200,000 extracorporeal liver support treatments are needed annually in the U.S. alone as a bridge to recovery with or without transplantation.

Due to the critical nature of liver failure and the resulting adverse effects on other organs, the in-patient cost of liver failure treatment can reach \$200,000 without a transplant. Liver transplants can cost, in some cases, over \$300,000 and that excludes the \$30,000 in anti-rejection drugs required annually for life. Although our products have not yet been developed and, therefore, it is uncertain what the cost would be for treatments using either the LIVERAID(TM) therapy or SEPET(TM) treatment, we currently believe that treatments using our technologies will be significantly less expensive than the cost of the currently available treatments. Thus, the potential market for these two therapies in the U.S. alone is significant, with opportunities throughout the rest of the world. In addition to the potential cost savings on the treatments of liver failure, the use of our potential products could also shorten the time of hospitalization for patients with liver failure, thereby also reducing the overall costs of hospitalization.

STRATEGY

We have established collaborations with Cedars-Sinai Medical Center, Spectrum Labs. These collaborations are expected to facilitate the development of SEPET(TM) and LIVERAID(TM) and could potentially accelerate the clinical testing, regulatory approval and commercialization of those products in the United States and other markets.

We believe that the testing and regulatory requirements for SEPET(TM) will be shorter than for LIVERAID(TM). Accordingly, because of the shorter regulatory period and the ability of SEPET(TM) to operate through the use of a standard, currently available kidney dialysis unit, we expect to complete the development of SEPET(TM) before the development of LIVERAID(TM) 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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

whether SEPET(TM) 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), or 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(TM) prototype devices and currently plan to commence clinical testing of SEPET(TM) during 2004 and clinical testing of LIVERAID(TM) 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(TM) in 2007 and an application requesting marketing approval of the LIVERAID(TM) in 2008.

3

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.

For many years, it was assumed that the toxins that cause coma in hepatic failure are small dialyzable molecules. As a result of this belief, most liver support systems and therapeutic regimens used in the past relied on detoxification, usually by use of sorption therapy. This was performed either directly on whole blood or plasma, or coupled with hemodialysis/hemofiltration to treat either the dialysate or hemofiltrate. None of these modalities have achieved wide clinical use or ability to arrest or reverse liver failure and improve survival. As a consequence, liver failure patients must 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.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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(TM) 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 a subgroup of patients with fulminant and subfulminant hepatic failure.

Our LIVERAID(TM) was designed to become a more advanced, simpler, less costly and more 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(TM) 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(TM) 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(TM) in FDA-approved clinical trials before our product can be used by human patients.

4

In liver failure patients, the clearing of blood of neuro- and hepatotoxins is highly desirable and there is a need for an effective blood purification therapy. SEPET(TM) (selective plasma exchange) is a novel form of such therapy. During SEPET(TM) 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. Recently, preliminary proof of feasibility for selective removal of the toxic plasma fraction was provided by a group of investigators from Hong Kong University School of Medicine. In their studies, pigs with toxic liver injury showed improved survival and regeneration of the diseased liver when subjected to selective plasma filtration.

THE PRODUCTS WE ARE DEVELOPING

SEPETTM

We are developing SEPET(TM) (selective plasma exchange therapy) as a blood purification measure to provide temporary liver support during acute liver failure and acute exacerbation of chronic liver disease. SEPET(TM) therapy will be provided through a single-use, disposable cartridge containing a bundle of hollow fibers made of polysulfone or a similar bio- and hemo-compatible material and being capable of sieving substances with molecular weight of up to 100 kDa. We have entered into an agreement with Spectrum Labs for the manufacture of these disposable cartridges. See, "Item 1. Description of

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

Business--Manufacturing," below. The SEPET(TM) is designed for use with any commercially available kidney dialysis unit and/or plasma apheresis system utilizing hollow-fiber cartridges. Accordingly, no apparatus needs to be developed or manufactured for SEPET(TM). Accessory components for the SEPET(TM) (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, 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.

It is expected 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.

We expect that SEPET(TM) may:

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

We expect to demonstrate that SEPET(TM) 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 vivo with experimentally-induced acute liver failure.

5

LIVERAID(TM)

We have designed and are attempting to demonstrate that our LIVERAID(TM) product can provide temporary liver support during acute liver failure and acute exacerbation of chronic liver disease. The LIVERAID(TM) utilizes a unique multi-compartment hollow fiber module incorporating viable pig liver cells and a blood detoxification circuit. The module is attached to a base instrument which

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

facilitates perfusion of the LIVERAID(TM) with a patient's plasma. The hollow fibers will be made of a polyethersulfone membrane or a similar material based on our proprietary fiber-within-a-fiber geometry. This geometry allows for integration of at least two functions within a single module. Depending on the etiology of liver disease, severity of illness and deficiency of specific liver functions, the LIVERAID(TM) is designed to offer liver cell therapy, blood detoxification or a combination thereof. During treatment, individual modes of therapy may be added or removed. We currently are attempting to demonstrate that pig liver cells can be harvested and cryopreserved through proprietary patent protected technology that has been exclusively licensed to ATI. The other components of LIVERAID(TM), including blood purification columns (charcoal, resin), are available from third party vendors.

The critical aspects of LIVERAID(TM) technology include the source and procurement of liver cells, the storage of the liver cells, the number of cells to be used during therapy, the cell module engineering, and LIVERAID(TM) perfusion technique. 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 even 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.

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 founders of ATI have developed a patented hepatocyte cryopreservation technology, which technology is now owned by Cedars-Sinai Medical Center. The patent for this technology has been licensed to ATI by Cedars-Sinai Medical Center. However, the work on adjusting this technology to clinical needs has as yet not been done.

HEPATOCYTE MODULE. The LIVERAID(TM) is designed to utilize a proprietary three-compartment hollow-fiber module with fiber-in-fiber geometry that allows integration of two different functions.

BIOARTIFICIAL LIVER PERFUSION TECHNIQUE. At present, most bioartificial liver systems are perfused with plasma rather than blood. LIVERAID(TM) is designed to be perfused with a patient's plasma to prevent leakage of porcine cells and cell debris into patient blood circulation. The platform will utilize a commercially available oxygenator and a disposable tubing kit.

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(TM) 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(TM) module 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. Alternatively, LIVERAID(TM) modules with inner fibers that allow selective plasma exchange therapy could be used. At the end of treatment, the disposables will be discarded as biohazardous waste.

We expect to demonstrate that during 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 either by sorbents (hemodiafiltration) or during selective plasma exchange. 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 LIVERAID(TM) module.

We expect that LIVERAID(TM) may:

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

PRODUCT ADVANTAGES

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

We believe that SEPET(TM) as a blood purification therapy will be found more effective than sorbent-based devices (e.g., charcoal, resin, silica, etc.) and whole plasma exchange therapy.

To the best of our knowledge, LIVERAID(TM) is the only liver assist device under development that is capable of providing both liver cell functions and blood purification either simultaneously or sequentially in a versatile and customized manner depending on the cause and severity of liver failure.

We believe that use of currently available hospital kidney dialysis systems to provide SEPET(TM) therapy may offer the following advantages:

7

- o Ease of use. The systems bring user friendliness (e.g., pump integration, automation and an intuitive user interface) to traditionally complex liver support procedures.
- o 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(TM).
- o Low cost. The cost of therapy is expected to be lower than with any other liver assist device that is currently under development.
- o No Intensive Care Unit needed to provide treatment. With further developments, SEPET(TM) may become available for treatment of patients 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(TM) treatment can be commenced with 2-3 hours of patient preparation, thereby making LIVERAID(TM) 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(TM) and LIVERAID(TM) has not been assessed yet. However, in vivo large animal studies have provided proofs of feasibility and clinical efficacy for LIVERAID(TM). 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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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(TM) and LIVERAID(TM) are designed to treat patients with liver failure of all etiologies and severity, including acute exacerbation of chronic liver disease.

The patient and market opportunity is substantial and underserved. According to the American Liver Foundation, NCHS 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 NCHS, approximately 250,000 patients are hospitalized annually in the U.S. due to liver failure. Of those, nearly 50,000 (20%) died (7th leading cause of death) because no donor liver was found or because they had contraindications to transplantation. The remaining 200,000 patients were discharged from the hospital because they either received a liver transplant or their condition improved after receiving standard of care. Remarkably, half of them were hospitalized again in the same year due to another episode of liver failure requiring full medical support. At the same time, 2,000 patients with fulminant hepatic failure were added to the list for urgent transplantation. As of April 2002, the United Network for Organ Sharing national patient waiting list for liver transplants was 17,641 names long; at least a third of those have end-stage hepatitis C, and within the year almost 2,000 will die waiting for a transplant. Because of the hepatitis C epidemic, the transplant waiting list is expected to increase 500% by 2008.

8

Based on these data and NCHS projections, 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(TM) and LIVERAID(TM) may address this demand and, based on published data, estimates that there were approximately 250,000 patients hospitalized in the United States in 2001 who had indications for SEPET(TM) and/or LIVERAID(TM) 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.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

At this time, based on the preliminary information available to us, we estimate that the cost of a single treatment with the SEPET(TM) therapy could be within a \$2,000 - \$4,000 range and that cost of the LIVERAID(TM) therapy could be approximately \$20,000. We anticipate that SEPET(TM) and/or LIVERAID(TM) 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(TM) and LIVERAID(TM) 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. 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. It has been estimated that there are approximately 200 million carriers of the hepatitis virus B or C in China, and primary liver cancer is a common malignancy. In Japan, demand for alternative liver support/replacement therapies is significant because transplantation of cadaver livers is virtually nonexistent.

SALES, MARKETING & DISTRIBUTION

We currently do not have any agreements in place to market either of our SEPET(TM) and LIVERAID(TM) 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.

9

MANUFACTURING

Through our ATI subsidiary, we are a party to agreements with both Spectrum Labs and Cedars-Sinai Medical Center that cover our future manufacturing needs. We currently anticipate that LIVERAID(TM) devices will be commercially manufactured by Spectrum Labs according to an existing manufacturing and supply agreement that ATI entered into with Spectrum in December 2001. Under that agreement, the parties agreed that Spectrum Labs will manufacture for ATI the hollow fiber cartridges with fiber-in-fiber geometry that ATI will need for its bioartificial liver. The agreement provides that the price of the hollow fiber-in-fiber cartridges to be sold by Spectrum Labs to ATI will be determined by good faith negotiations between the parties. ATI has agreed that it will not purchase cartridges with fiber-in-fiber geometry from any other manufacturer unless Spectrum Labs is either unable or unwilling to manufacture the cartridges. See "Item 12. Certain Relationships and Related Transactions."

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

With respect to cartridges that we expect will be needed for SEPET(TM), 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(TM) 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. Blood oxygenator/heat exchangers are available from third party vendors who sell these products.

The platform we currently expect to use for LIVERAID(TM) will be an existing instrument manufactured and marketed by an unaffiliated medical device manufacturer. The instrument we expect to purchase has been certified and approved in Europe for bioartificial liver use. In order to commence clinical testing of LIVERAID(TM), by the end of this current fiscal year we intend to purchase two of the instruments that are outfitted with custom-made software, hook-ups and associated components (tubing set) specifically for use with LIVERAID(TM).

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 cell procurement/cryopreservation, 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 porcine liver cells needed to conduct Phase I/II/III clinical trials and during early stages of commercialization from one or more third parties who already manufacture such cells. At the conclusion of Phase I/II clinical testing of the LIVERAID(TM), 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(TM) 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(TM) technologies include the following licenses patents:

10

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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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 Medical Center will have nonexclusive rights to any products derived from the patents. We will have to pay Cedars-Sinai Medical Center royalty fees equal to 1.5% of the gross sales price of royalty bearing products. From the third to tenth years of the license, the royalty fee percent will phase out evenly to 0%. Cedars-Sinai Medical Center is a 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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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."

11

In addition to the licenses and technologies related to LIVERAID(TM), we also have the rights to a SEPETM patent application and certain related trade secrets. In August 2002, we filed a patent application regarding our selective plasma exchange therapy (SEPET(TM)) technology.

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.

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 (HaemoCleanse, West Lafayette, Indiana) utilizing a mixture of charcoal, silica and exchange resins. Another therapy, known as MARS (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. In Europe and Asia, initial results using MARS in patients with acute exacerbation of chronic liver disease were encouraging. Excorp Medical, Inc., a U.S. company, is developing a freestanding blood perfusion system including pumps, a heat exchanger, an oxygenator, pressure gauges, safety features and computer-assisted monitoring. Algenix, Inc. has a device (LIVE-Rx 2000) that

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

utilizes pig liver cells and a commercially available dialysis cartridge. The technology of VitaGen, Inc. (formerly Hepatix) utilizes a cell line derived from human liver cancer tissue and a conventional hollow fiber bioreactor. Rand S.r.I., an Italian company, has 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 bioartificial liver system has been successfully used in some patients with fulminant hepatic failure. Hep-Art Co., a Dutch company, also is clinically testing a bioartificial liver that uses pig hepatocytes.

12

Several other technologies could potentially compete with a bioartificial liver. These include xenotransplantation (use of pig organs in humans), transplantation of isolated hepatocytes and ex vivo whole liver perfusions.

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 human 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 human 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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

any equipment, facilities, laboratories, or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal, or administrative sanctions and/or remedies against us, including the suspension of the manufacturing operations

The FDA has separate review procedures for medical devices before such products may be commercially marketed in the United States. There are two basic review procedures for medical devices in the United States. Certain products may qualify for a Section 510(k) procedure, under which the manufacturer gives the FDA a Pre-Market Notification, or 510(k) Notification, of the manufacturer's intention to commence marketing of the product at least 90 days before the product will be introduced for clinical use. 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, or 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.

13

We expect SEPET(TM) to be classified by the FDA as a Class II medical device. Accordingly, unless Section 510(k) is available, SEPET(TM) will be subject to a two-step approval process starting with a submission of an investigational new drug exemption application to conduct human studies, and followed by the Product and Establishment Licensing applications (including Product Marketing Approval or "PMA").

We expect LIVERAID(TM) 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.

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.

ITEM 2. DESCRIPTION OF PROPERTY.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

We currently maintain our laboratory and office space at Cedars-Sinai Medical Center in Los Angeles, California, which facilities we lease under a three-year lease that expires on June 30, 2004. We currently pay rent of \$6,441 per month for the 1,008 square foot facility under the lease. Cedars-Sinai Medical Center is a stockholder of our company and was one of the initial stockholders of ATI. See "Item 12. Certain Relationships and Related Transactions."

In March 2004, we signed a second lease for additional office space. The new office lease will commence on April 1, 2004, will require us to pay rent of \$5,000 per month, and will have a term of two years. The new offices consist of 1,700 square feet of office space in a building across the street from our laboratories that are located at Cedars-Sinai Medical Center.

ITEM 3. LEGAL PROCEEDINGS.

We are not a party to any material legal proceedings.

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

On October 7, 2003, stockholders of HAUSA owning 1,000,000 shares of our common stock, or approximately 82% of the then issued and outstanding shares of voting stock, executed a written consent approving the amendment to HAUSA's articles of incorporation to change the name of HAUSA to "Arbios Systems, Inc." The action was taken pursuant to Nevada Revised Statutes 78.320(2), which provides that any action required or permitted to be taken at a meeting of stockholders may be taken without a meeting if, before or after the action, a written consent thereto is signed by the stockholders holding at least a majority of the voting power. On November 10, 2003, we mailed an information statement to the holders of our common stock informing them of the action taken by the majority stockholders on October 7, 2003.

14

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Prior to the Reorganization, our common stock was listed on the Pink Sheets under the symbol "HIAU," but there was virtually no trading in the common stock. After the Reorganization, because we changed the name of our company from Historical Autographs U.S.A., Inc. to Arbios Systems, Inc., we also changed our trading symbol to "ABOS." On March 18, 2004, our common stock was accepted for trading on the OTC Bulletin Board under our existing "ABOS" trading symbol. Between the date of the Reorganization, October 30, 2003, and December 31, 2003, the closing sales prices of our common stock, as reported by Pink Sheets LLC, have ranged from \$2.25 to \$3.25 per share.

As of December 31, 2003, there were approximately 137 record holders of our common stock. On March 26, 2004, the closing price of our common stock was \$3.20.

DIVIDENDS AND DIVIDEND POLICY

We have not paid any cash dividends on our common stock, and we currently intend to retain any future earnings to fund the development and growth of our business.

RECENT SALES OF UNREGISTERED SECURITIES

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

There were no issuances or sales of our securities by us during the fourth quarter of 2003 that were not registered under the Securities Act of 1933 (the "Securities Act") other than the issuance of shares to the former stockholders of ATI in the Reorganization. In the Reorganization, we issued 11,930,598 shares of our common stock to the 72 stockholders of ATI in exchange for all of their shares of ATI. All 72 stockholders were "accredited investors," as that term is defined under Rule 501(a) of the Securities Act, and the shares were issued pursuant to an exemption available under Section 4(2) and Rule 506 of the Securities Act. Prior to the Reorganization, in October 2003, ATI sold \$1,690,000 of its Units. Each Unit consisted of one share of ATI common stock and a warrant to purchase an additional share of ATI common stock at a price of \$2.50 per share. The Units were sold at a price of \$1.00 per Unit. The Units were exchanged in the Reorganization for shares of our common stock and warrants to purchase our common stock. The October 2003 private placement of Units was effected under an exemption from registrations under Rule 506 and Section 18(b)(4)(D) of the Securities Act. The Units were sold to 24 investors, (who are part of the 72 ATI stockholders), all of whom were "accredited investors," as that term is defined under Rule 501(a). We did not retain any underwriters in the October 2003 private placement.

REPURCHASE OF SECURITIES

We did not repurchase any of our common shares during the fourth quarter of 2003.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

This annual report contains forward-looking statements within the meaning of the federal securities laws. These include statements about our expectations, beliefs, intentions or strategies for the future, which we indicate by words or phrases such as "anticipate," "expect," "intend," "plan," "will," "we believe," "the Company believes," "management believes" and 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.

15

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.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

RESULTS OF OPERATIONS

COMPARISON OF FISCAL YEAR ENDED DECEMBER 31, 2003 TO YEAR ENDED DECEMBER 31, 2002.

Since we are still developing our products and do not have any products available for sale, we have not yet generated any revenues from sales. Revenues for fiscal year 2003 (\$138,000) and fiscal year 2002 (\$111,000) represent 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 (including amounts paid under our existing loan-out agreement with Cedars-Sinai Medical Center), 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. On December 31, 2002, we had eight employees and consultants. The number of employees and consultants increased to ten on December 31, 2003. 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 goes 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 in 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 the \$400,000 we borrowed from certain investors during fiscal 2003. The \$400,000 aggregate amount of loans were represented by convertible notes that were issued to the investors. In addition to the convertible loans, the investors also received, in the aggregate, warrants to purchase 300,000 shares of our common stock at an exercise price of \$1.00 per share. All of the loans were converted by the investors in October 2003 into 400,000 shares of common stock. The \$243,000 interest expense in fiscal 2003 represents a non-cash expense recognized under accounting rules based on the value of conversion feature of the convertible notes and the value attributed to the warrants. Since the convertible notes 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.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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.

17

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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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

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

18

FACTORS ASSOCIATED WITH OUR BUSINESS

We are a development stage company subject to all of the risks and uncertainties of a new business.

Prior to the Reorganization in October 2003, HAUSA was unsuccessfully engaged in the e-commerce business of acquiring and marketing historical documents. During the time that we engaged in the e-commerce business, we generated less than \$200,000 of revenues, while incurring a cumulative loss of approximately \$45,000. As a result, we terminated our prior e-commerce business at the time of the Reorganization. The company that we acquired, ATI, however is a start-up company that has not generated any operating revenues to date (its only revenues were two government research grants) Accordingly, while we have been in existence since November 1999, 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 companies. 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 one or both of products. There can be no assurance that our product

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

development efforts will be successfully completed, that we will be able to obtain all required regulatory approvals, that we will be able to manufacture our products at an acceptable cost and with acceptable quality, or that our products can be successfully marketed in the future. We currently do not expect to receive significant revenues from the sale of any of our products for at least the next few years.

We must obtain governmental approval for each of our products, the receipt of which is uncertain.

The development, production and marketing of our products are subject to extensive regulation by government authorities in the United States and other countries. In the U.S., the LIVERAID(TM) and SEPET(TM) will require FDA approval 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(TM) or LIVERAID(TM) 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 LIVERAID(TM), SEPET(TM), and related products from the FDA, and there can be no assurance that we will be able to obtain approval from the FDA or any foreign governmental agencies for marketing of any of our products. Japan's health regulatory authority has, and other countries regulatory authorities could potentially object to the marketing of any therapy that uses pig liver cells (which LIVERAID(TM) is expected to utilize) due to safety concerns. The failure to receive, or any significant delay in receiving, FDA approval, or the imposition of significant limitations on the indicated uses of our products, would have a material adverse effect on our business, operating results and financial condition.

19

Our products are at an early stage of development and have never been completed or marketed.

Before obtaining regulatory approvals for the commercial sale of our SEPET(TM) and LIVERAID(TM) related products, significant and potentially very costly preclinical work will be necessary for SEPET(TM) and the two configurations of LIVERAID(TM). We have completed only preclinical testing of the LIVERAID(TM) utilizing sorbents. There can be no assurance that we will be able to successfully complete preclinical testing of the SEPET(TM) and LIVERAID(TM) combining liver cell therapy with selective plasma exchange (which will take an extended period of time). Therefore, proofs of concept and feasibility for both SEPET(TM) and LIVERAID(TM) utilizing selective plasma exchange are still lacking and there can be no assurance that we will be able to provide such proofs for these two products. We have not independently confirmed

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

any of the claims made by the licensors of any of our products and technologies concerning the potential safety or efficacy of these products and technologies. We will need to file an IND for LIVERAID(TM) and an IDE for SEPET(TM) 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 commenced preparation of either IND or IDE 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 PMAs or new drug applications for these products or the FDA's approval of any PMA or new drug application that we do file.

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

Use of liver cells harvested from pig livers carries a risk of transmitting viruses harmless to pigs but deadly to humans. For instance, all pigs carry porcine endogenous retrovirus ("PERV"), but its potential effects on people are 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(TM)-treated patients and cause potentially serious disease. This may result in the FDA or other health regulatory agencies not approving LIVERAID(TM) 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 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 that were developing bioartificial liver support systems, and it is possible that such groups could object to our LIVERAID(TM) product. Litigation instituted by any of these organizations, and negative publicity regarding our use of pig liver cells in LIVERAID(TM), could have a material adverse effect on our business, operating results and financial condition.

Uncertain development paths and markets for our products.

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

We will need significant additional capital, without which we will have to curtail or cease operations.

Based on our current proposed plans and assumptions, we anticipate that our existing funds will only be sufficient to fund our operations and capital requirements for approximately 12 months to 18 months from the date of this annual report. Furthermore, the clinical development expenses for each of our products will be very substantial, i.e., well in excess of the amount of cash that we currently still have. Accordingly, we will have to either (i) obtain additional debt or equity financing during the next 12 to 18-month period in order to fund the further development of our products and working capital needs, 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 two current products will be very substantial and may be in excess of our ability to raise capital.

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

We are subject to significant competition from numerous large, well funded companies.

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

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

Our business model calls for the outsourcing of the clinical development, manufacturing and marketing of our products in order to reduce our capital and infrastructure costs as a means of potentially improving the profitability of these products for us. We have not yet entered into any strategic alliances or other licensing or contract manufacturing arrangements (except for the contractual manufacturing of LIVERAID(TM) 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(TM) and/or LIVERAID(TM). 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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

sales and marketing firms to use their pharmaceutical sales force on a contract basis.

21

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

We are dependent on Spectrum Laboratories, Inc. as the manufacturer of LIVERAID(TM) and SEPET(TM).

We have an exclusive manufacturing arrangement for LIVERAID(TM) devices with Spectrum Laboratories, Inc., which also has been providing us with cartridges for prototypes of the SEPET(TM). We have encountered certain delays in the delivery of the LIVERAID(TM) and SEPET(TM) cartridges from Spectrum Laboratories, Inc. In addition, the current model of the SEPET(TM) cartridge is made of the semipermeable membrane which needs to be modified to improve sieving of protein-bound toxins. There can be no assurance that we will not encounter delays or other manufacturing problems with Spectrum Labs with respect to our clinical or commercial supplies of LIVERAID(TM) and/or SEPET(TM). There can be no assurance that the SEPET(TM) cartridge allowing unrestricted passage of albumin-bound toxins while retaining blood components with molecular weight higher than 100 kDa will be developed. Although Spectrum Labs has agreed to transfer their know-how to another manufacturer for us if they are unable to meet their contractual obligations to us, we may have difficulty in finding a replacement manufacturer or may be required to alter the design of LIVERAID(TM) if we are unable to effectively transfer the Spectrum Labs know-how to another manufacturer.

We have limited patent protection and may not be able to protect our patents and proprietary rights.

Our ability to compete successfully will depend, in part, on our ability to defend patents that have issued, obtain new patents, protect trade secrets and operate without infringing the proprietary right of others. We have relied substantially on the patent legal work that was performed for our assignors and licensors and have not, in some cases, 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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

against potential infringers. Patent litigation is expensive, and we may not be able to afford the costs. Third parties could also assert that our products infringe patents or other proprietary rights held by them.

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

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

We are highly dependent on Jacek Rozga, MD, PhD, our President and Chief Scientific Officer, and on several key members of our management, including, John Vierling, MD, FACP, Chairman of the Board, Kristin P. Demetriou, Marvin S. Hausman, MD, Richard W. Bank, MD, and Roy Eddleman who are members of our Board of Directors. Each of these individuals, except Dr. Rozga, works for us only on a part-time, very limited basis. We are also dependent upon Achilles A. Demetriou, MD, PhD, FACS, the other co-founder of ATI and the Chairman of our Scientific Advisory Board. We do not have long-term employment contracts with Drs. Jacek Rozga and Achilles A. Demetriou, and the loss of the services of either of them would have a material adverse effect on our business, operations and on the development of our products. We do not carry key man life insurance on either of these individuals.

22

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

The market success of our products will be dependent in part upon third-party reimbursement policies.

Our ability to successfully penetrate the market for our products may depend significantly on the availability of reimbursement for our products from third-party payers, such as governmental programs, private insurance and private health plans. We have not yet established with Medicare or any third-party payers what level of reimbursement, if any, will be available for SEPETTM or LIVERAID(TM), 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.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

We may be subject to product liability claims.

The development, manufacture and sale of medical products expose us to the risk of significant damages from product liability claims. We plan to obtain and maintain product liability insurance for coverage of our clinical trial activities. However, there can be no assurance that we will be able to secure such insurance for clinical trials for either of our two current products. We intend to obtain coverage for our products when they enter the marketplace (as well as requiring the manufacturers of our products to maintain insurance). We do not know if it will be available to us at acceptable costs. We may encounter difficulty in obtaining clinical trial or commercial product liability insurance for LIVERAID(TM) 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

Risks Relating to Low Priced Stocks.

Although our common stock has been approved for trading on the Pink Sheets electronic over-the-counter trading systems for several years, there was virtually no trading in our stock before the Reorganization, and there has been only sporadic trading activity in our stock since the Reorganization. Because all of our operations are being conducted through ATI, our wholly-owned subsidiary, and because ATI is still a development stage company that has no products or revenues, the trading price of our common stock may be below \$5.00. If our common stock trades below \$5.00 per share, trading in the common stock may 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 share 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 our common stock to sell it.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

No Assurance of a Liquid Public Market for Securities.

Although our shares of common stock are eligible for quotation on the OTC Bulletin Board electronic over-the-counter trading system, there currently is only a very limited trading market in our stock. 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. Even if we came to the attention of the investment community, many of the institutional investors or advisors tend to be risk-averse and would be reluctant to follow an unproven development 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.

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:

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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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 7. FINANCIAL STATEMENTS.

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

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

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

During the two most recent fiscal years, we had no disagreements with Williams, whether or not resolved, on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which, if not resolved to Williams' satisfaction, would have caused Williams to make reference to the subject matter of the disagreement in connection with its report. Williams did not advise this company of any of the events requiring reporting in a Form 8-K under Item 304(a)(iv)(B).

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

ITEM 8A. CONTROLS AND PROCEDURES

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

and forms.

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

PART III

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

The following table sets forth our current directors and executive officers. Directors are elected for a period of one year and thereafter serve until the next annual meeting at which their successors are duly elected by the stockholders. Officers and other employees serve at the will of the board of directors.

NAME	AGE	POSITION
Jacek Rozga, M.D., Ph.D.	55	President, Chief Financial Officer, a
Kristin P. Demetriou	55	Director and Secretary
Roy Eddleman	64	Director
Marvin S. Hausman MD	62	Director
John Vierling, MD	58	Chairman of the Board and Director
Richard W. Bank, MD	70	Director

BUSINESS EXPERIENCE OF DIRECTORS AND MANAGEMENT

The following describes the backgrounds of current directors and the key members of the management team. The persons who acted as officers and directors of HAUSA prior to the Reorganization resigned effective upon the Reorganization. All of the our officers and directors also currently hold the same offices with ATI.

JACEK ROZGA, MD, PHD. Dr. Rozga is a co-founder of ATI, a director of this company, and our current President and Chief Financial Officer. He also currently is this company's Chief Scientific Officer and a professor of Surgery at UCLA School of Medicine. Dr. Rozga has 20 years experience in artificial liver support system development, hepatocyte transplantation and liver tissue engineering, and directed all research aspects leading to the development and testing of the first-generation bioartificial liver at Cedars-Sinai Medical Center. Dr. Rozga has six patents and five patent applications pending, most of which have been licensed by ATI.

KRISTIN P. DEMETRIOU. Former President & CEO of Bergen Line, Inc., New York City (1989-94), NY, an international owner/operator of cruise and cargo

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

ships. Prior to that she was Director, Sales & Marketing worldwide (1982-88) for Royal Viking Line, Inc., San Francisco, CA. Mrs. Demetriou holds a B.A. in Psychology from Columbia University, New York, NY, and completed post-graduate work in accounting, finance, media and investor relations.

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

26

MARVIN S. HAUSMAN, MD. Dr. Hausman has, since January 1997, been the President and Chief Executive Officer of Axonyx, Inc., a public company engaged in the business of acquiring and developing novel post-discovery central nervous system drug candidates, primarily in areas of memory and cognition. Dr. Hausman has 30 years of drug development and clinical care experience at various pharmaceutical companies, including working in conjunction with Bristol-Meyers International, Mead-Johnson Pharmaceutical Co., and E.R.Squibb. He was a co-founder of Medco Research Inc., a NYSE-traded biopharmaceutical company which was acquired by King Pharmaceuticals, Inc. Dr. Hausman has been the President of Northwest Medical Research Partners, Inc. since 1995 and previously served as a member of the Board of Directors of Regent Assisted Living, Inc. from 1996 through 2001.

JOHN VIERLING, MD, FACP. Director of Hepatology, Medical Director of Multi-Organ Transplantation Program, Cedars-Sinai Medical Center. Professor of Medicine, UCLA School of Medicine. Councilor of the American Association for the Study of Liver Diseases. Former Chairman of the Board of American Liver Foundation. Expert Reviewer and Witness for FDA. Former President of the Southern California Society for Gastroenterology. Member of numerous NIH advisory committees, including NIH Committee for Liver Tissue Procurement and Distribution Program. Member, Scientific Advisory Committee, NIH Alcohol Center Grant, University of Southern California and West Los Angeles VAMC/UCLA and Chairman of the Data Safety Monitoring Board for the NIH, NIDDK ViraHep C multicenter trial. Dr. Vierling's research has focused on the mechanisms of liver injury caused by hepatitis B and C and autoimmune and alloimmune diseases.

RICHARD W. BANK, MD. Dr. Bank has served as President and Managing Director of First-Tier Biotechnology Partners since February 1995. He has also served as President and Secretary of BioVest Health Sciences, Incorporated since its organization in April 1996. From February 1995 through April 1996, Dr. Bank served as President of Biomedical Sciences, Incorporated. Dr. Bank was the Medical Director of USAT Labs from December 1986 until January 1988, the Senior Research Analyst Director/ Biotechnology SBC Warburg Dillon Read 1998-1999, and the Entrepreneur-In-Residence In Life Sciences for Tucker Anthony Sutro for 2000 through 2001. Currently, Dr. Bank is Clinical Professor Emeritus in the Department of Obstetrics and Gynecology at the University of Southern California School of Medicine where he has been on the active faculty for the last 25 years.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

There are no family relationships between any of the officers and directors. However, Mrs. Demetriou is the wife of Dr. A. A. Demetriou, one of the two founders of ATI and one of the inventors of certain of the technologies used by this company.

AUDIT COMMITTEE

In February 2004, our Board of Directors established an Audit Committee. The Board of Directors has instructed the Audit Committee to meet periodically with the company's management and independent accountants to, among other things, review the results of the annual audit and quarterly reviews and discuss the financial statements, recommend to the Board the independent accountants to be retained, and receive and consider the accountants' comments as to controls, adequacy of staff and management performance and procedures in connection with audit and financial controls. The Audit Committee is also authorized to review related party transactions for potential conflicts of interest. The Audit Committee is composed of Dr. Bank, Mrs. Demetriou and Dr. Vierling. Each of these individuals is a non-employee director and is independent as defined under the Nasdaq Stock Market's listing standards. While each of the members of the Audit Committee has significant knowledge of financial matters, none of the Audit Committee members has been designated as an "audit committee financial expert" as defined under Item 401(h)(2) of Regulation S-K of the Securities Exchange Act of 1934, as amended. The Audit Committee operates under a formal charter that governs its duties and conduct.

27

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE.

The initial report on Form 3 filed on behalf of each of our directors (Jacek Rozga, Kristin P. Demetriou, Roy Eddleman, Marvin S. Hausman, John Vierling, and Richard W. Bank) required to be filed upon their appointment to our Board of Directors was filed late.

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	Salary	Bonus	Other Annual Compensation

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

Jacek Rozga, M.D., Ph.D Chief Executive Officer, Chief Financial Officer, and Chief Scientific Officer	2003(1)	\$135,000	\$15,000	--
	2002	\$85,000	\$5,000	--
	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.

28

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

Name	Number of Shares Underlying Options Granted	Individual Grants		Market Price on Date of Grant
		% of Total Options Granted to Employees In Fiscal Year	Exercise Price	
Jacek Rozga, M.D., Ph.D	18,000	8%	\$1.00	(1)

(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.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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/SAR EXERCISES IN FISCAL YEAR ENDED DECEMBER 31, 2003
AND FY-END OPTION/SAR VALUES

Name	Shares Acquired in Exercise	Value Realized	Number of Securities Underlying Unexercised Option/SARs at FY-End (#) Exercisable/Unexercisable	Value
Jacek Rozga, M.D., Ph.D	-	-	36,000/0	

(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.

29

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants, and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance
	(a)	(b)	
Equity compensation plans approved by security holders	629,000	\$1.32	
Equity compensation plans not approved by security holders	-0-		
Total	629,000	\$1.32	

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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 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.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

The code of ethics is filed as Exhibit 14.1 to this annual report on Form 10-KSB. A copy of our Code of Ethics will be furnished to any person upon written request from any such person. Requests should be sent to: Secretary, Arbios Systems, Inc., 110 North George Burns Road Suite D-4018 Los Angeles, California, 90048.

30

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The following table sets forth certain information regarding beneficial ownership of our common stock as of March 29, 2004 (a) by each person known by us to own beneficially 5% or more of any class of our common stock, (b) by each of our Named Executive Officer and our directors and (c) by all executive officers and directors of this company as a group. As of March 29, 2004 there were 13,150,598 shares of our common stock issued and outstanding. Unless otherwise noted, we believe that all persons named in the table have sole voting and investment power with respect to all the shares beneficially owned by them. Except as otherwise indicated, the address of each stockholder is c/o the company at 110 North George Burns Road Suite D-4018 Los Angeles, California, 90048.

Name and Address of Beneficial Owner	Shares Beneficially Owned	Percentage of Class
Jacek Rozga, M.D., Ph.D	2,536,000 (2)	19.2%
Kristin P. Demetriou	2,536,000 (3)	19.2%
John Vierling, MD	36,000 (4)	*
Roy Eddleman	398,669	3.0%
Marvin S. Hausman MD	562,000 (6)	4.2%
Richard W. Bank, MD	280,000 (7)	2.1%
Achilles A. Demetriou, M.D., Ph.D	2,500,000 (8)	19.0%
Cedars-Sinai Medical Center 8700 Beverly Boulevard, Los Angeles, California 90048	681,818	5.2%
Gary Ballen (9) 140 Burlingame, Los Angeles, California 90049	1,017,000 (9)	7.4%
Suncraft Limited (10) Room 2105, 21/F., West Tower Shun Tak Centre 168-200 Connaught Road Central Sheung Wan, Hong Kong	700,000 (10)	5.2%

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

All executive officers and directors as a group (6 persons) 6,348,669(11) 46.7%

* Less than 1%.

(1) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Shares of common stock subject to options, warrants and convertible securities currently exercisable or convertible, or exercisable or convertible within 60 days, are deemed outstanding, including for purposes of computing the percentage ownership of the person holding such option, warrant or convertible security, but not for purposes of computing the percentage of any other holder.

31

(2) Includes currently exercisable options to purchase 36,000 shares of common stock.

(3) Consists of (i) 2,500,000 shares owned by the A & K Demetriou Family Trust, of which Kristin P. Demetriou is a co-trustee, and (ii) currently exercisable options to purchase 36,000 shares of common stock issued to Kristin P. Demetriou.

(4) Consists of currently exercisable options to purchase 36,000 shares of common stock.

(5) Consists of currently exercisable options to purchase 36,000 shares of common stock, and 362,669 shares of common stock owned by Spectrum Laboratories, Inc. Mr. Eddleman is the Chairman of the Board and Chief Executive Officer of Spectrum Laboratories, Inc.

(6) Consists of (i) currently exercisable options to purchase 68,000 shares of common stock, (ii) currently exercisable warrants to purchase 150,000 shares of common stock, (iii) 100,000 shares owned by the Marvin Hausman Revocable Trust, and (iv) 244,000 shares owned by Northwest Medical Research, Inc. Dr. Hausman is the trustee of the Marvin Hausman Revocable Trust and the Chief Executive Officer and principal stockholder of Northwest Medical Research, Inc.

(7) Includes (i) 40,000 shares of common stock, (ii) currently exercisable warrants to purchase 40,000 shares of common stock, (iii) 100,000 shares of common stock owned by First-Tier Biotechnology Partners LP, and (iv) currently exercisable warrants to purchase 100,000 shares of common stock owned by First-Tier Biotechnology Partners LP. Dr. Bank is the President and Managing Director of First-Tier Biotechnology Partners LP.

(8) Consists of 2,500,000 shares owned by the A & K Demetriou Family Trust, of which Achilles A. Demetriou, M.D., Ph.D. is a co-trustee.

(9) Includes (i) 417,000 shares of common stock, and (ii) currently exercisable options to purchase 600,000 shares of common stock.

(10) Includes (i) 350,000 shares of common stock, and (ii) currently exercisable warrants to purchase 350,000 shares of common stock.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

(11) Includes currently exercisable options to purchase 212,000 shares of common stock.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

We currently maintain our laboratory and office space at Cedars-Sinai Medical Center in Los Angeles, California, which facilities we lease under a three-year lease that expires on June 30, 2004. See "Item 2. Description of Property." We currently pay rent of \$6,441 per month to Cedars-Sinai Medical Center under the lease. Cedars-Sinai Medical Center owns approximately 5.2% of our outstanding common stock.

Cedars-Sinai Medical Center has granted ATI the exclusive and worldwide rights to five patents and other technical information. In consideration for the licenses to the five patents and other technical information, we must expend an aggregate amount of \$1,760,000 in research and development expenses toward the development and promotion of products derived from the patents by June 30, 2008. Additionally, Cedars-Sinai Medical Center will have nonexclusive rights to any products derived from the patents. We will have to pay Cedars-Sinai Medical Center royalty fees equal to 1.5% of the gross sales price of royalty bearing products. From the third to tenth years of the license, the royalty fee percent will phase out evenly to 0%. See "Item 1. Description of Business--Patents and Proprietary Rights" for a description of the licensed patents.

32

On December 26, 2001, ATI entered into various agreements with Spectrum Laboratories, Inc. ("Spectrum Labs"). Concurrently with these agreements, Spectrum Labs also purchased 362,669 shares of ATI' common stock (or 2.8% of our shares of that were outstanding on March 29, 2004). Mr. Eddleman, one of the members of our Board of Directors, is the Chairman and CEO of Spectrum Labs. The three principal agreements entered into by ATI and Spectrum Labs in December 2001 are the following:

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

B. Research Agreement. ATI and Spectrum Labs also entered into a four-year research agreement pursuant to which ATI and Spectrum Labs agreed to combine their expertise and their respective technologies to enable ATI to (i) develop liver assist systems, (ii) conduct pre-clinical and Phase I-III clinical testing, (iii) obtain regulatory approvals and (iv) commercialize such liver assist systems. Under the terms of the agreement, Spectrum Labs agreed to perform certain research 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. In October 2002, ATI and Spectrum Labs agreed that Spectrum Labs has now satisfied its research and development obligations, that ATI owed

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

Spectrum Labs an additional \$54,960 for services provided by Spectrum Labs (which amount is being repaid in 18 monthly installments ending in May 2004), and that the 362,669 shares of ATI common stock previously issued to Spectrum Labs are now fully vested. Spectrum Labs has agreed to perform additional research and development work as may be requested by ATI on such terms as the parties may agree to in good faith negotiations.

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

Our management believes that the foregoing transactions with Cedars-Sinai Medical Center and Spectrum Labs were on terms as favorable to this company as could have been obtained from unrelated third parties.

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

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

(a) Exhibits

The following exhibits are filed as part of this report:

33

Exhibit Number -----	Description -----
2.1	Agreement and Plan of Reorganization, dated October 20, 2003, between the Registrant, Arbios Technologies, Inc., HAUSA Acquisition, Inc., Cindy Swank and Raymond Kuh (1)
3.1	Articles of Incorporation of Historical Autographs U.S.A., Inc. (2)
3.2	Certificate of Amendment of Articles of Incorporation (1)
3.3	Bylaws (2)
4.1	Revised form of Common Stock certificate

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

- 4.2 Form of Warrant for the Purchase of Shares of Common Stock issued by the Registrant upon the assumption of the Arbios Technologies, Inc. outstanding Warrant
- 10.1 Form of 2001 Stock Option Plan (2)
- 10.2 Facilities Lease, entered into as of June 30, 2001, by and between Cedars-Sinai Medical Center and Arbios Technologies
- 10.3 Standard Multi-Tenant Office Lease, dated as of February 13, 2004, by and between Beverly Robertson Design Plaza and Arbios Systems, Inc.
- 10.4 Employee Loan-Out Agreement, entered into effective as of July 1, 2001, by and between Cedars-Sinai Medical Center and Arbios Technologies, Inc.
- 10.5 Second Amendment to Employee Loan-Out Agreement, entered into effective as of May 7, 2003, by and between Cedars-Sinai Medical Center and Arbios Technologies, Inc.
- 10.6 License Agreement, entered into as of June 2001, by and between Cedars-Sinai Medical Center and Arbios Technologies, Inc.
- 10.7 Spectrum Labs License Agreement
- 14.1 Arbios Systems, Inc. Code of Business Conduct and Ethics Adopted by the Board of Directors on January 15, 2004
- 16.1 Letter on Change in Certifying Accountant (3)
- 21.1 List of Subsidiaries
- 31.1 Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350

(1) Previously filed as an exhibit to the Company's Current Report on Form 8-K on October 14, 2003, which exhibit is hereby incorporated herein by reference.

(2) Previously filed as an exhibit to the Company's Registration Statement Form 10-SB filed April 26, 2001, which exhibit is hereby incorporated herein by reference.

(3) Previously filed as an exhibit to the Company's Current Report on Form 8-K on January 30, 2004, which exhibit is hereby incorporated herein by reference.

(b) Reports on Form 8-K

The Company filed the following reports on Form 8-K during the last

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

quarter of the fiscal year ending December 31, 2003:

- o On October 10, 2003, the Company filed a Current Report on Form 8-K attaching a press release concerning Historical Autographs U.S.A., Inc.'s intention to acquire ATI.
- o On November 14, 2003, the Company filed a Current Report on Form 8-K to disclose the Reorganization (Item 5) and the resulting changes in control (Item 1).

Stockholders of our company may obtain a copy of any exhibit referenced in this 10-KSB Annual Report by writing to: Secretary, Arbios Systems, Inc., 110 North George Burns Road Suite D-4018 Los Angeles, California, 90048. The written request must specify the stockholder's good faith representation that such stockholder is a stockholder of record of common stock of the company.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

AUDIT FEES

The aggregate fees we paid Williams & Webster, P.S. during the fiscal years ended December 31, 2003 and December 31, 2002 for professional services for the audit of our financial statements for and the review of financial statements included in our Forms 10-QSB were \$7,951 and \$3,213, respectively.

AUDIT-RELATED FEES

Williams & Webster, P.S. did not provide, and it did not bill and it was not paid any fees for, audit-related services in the fiscal years ended December 31, 2003 and 2002.

TAX FEES

Williams & Webster, P.S. did not provide, and it did not bill and it was not paid any fees for, tax compliance, tax advice, and tax planning services for the fiscal years ended December 31, 2003 and December 31, 2002.

ALL OTHER FEES

Williams & Webster, P.S. did not provide, and it did not bill and it was not paid any fees for, any other services in the fiscal years ended December 31, 2003 and 2002.

ADDITIONAL INFORMATION

We are subject to the informational requirements of the Exchange Act and, in accordance with the rules and regulations of the Securities and Exchange Commission; we file reports, proxy statements and other information. You may inspect such reports, proxy statements and other information at public reference

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

facilities of the Commission at Judiciary Plaza, 450 Fifth Street N.W., Washington D.C. 20549; Northwest Atrium Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661; and 5670 Wilshire Boulevard, Los Angeles, California 90036. Copies of such material can be obtained from the Public Reference Section of the Commission at Judiciary Plaza, 450 Fifth Street N.W., Washington, D.C. 20549, at prescribed rates. For further information, the SEC maintains a website that contains reports, proxy and information statements, and other information regarding reporting companies at <http://www.sec.gov> or call (800) SEC-0330.

36

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

37

CONTENTS

	Page
INDEPENDENT AUDITORS' REPORT	1
FINANCIAL STATEMENTS:	
Consolidated Balance Sheet	2
Consolidated Statements of Operations	3
Consolidated Statement of Stockholders' Equity	4-6
Consolidated Statements of Cash Flows	7
Notes to Consolidated Financial Statements	8-20

INDEPENDENT AUDITORS' REPORT

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

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

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

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

CERTIFIED PUBLIC ACCOUNTANTS

Santa Monica, California
March 9, 2004

F-1

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

CONSOLIDATED BALANCE SHEET - DECEMBER 31, 2003

ASSETS

CURRENT ASSETS:

Cash	\$3,507,
Prepaid expenses	155,

Total current assets

PROPERTY AND EQUIPMENT, net

PATENT RIGHTS, net

DEPOSITS

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES:

Accounts payable and accrued expenses	\$ 148,
Current maturities of capital lease obligation	8,

Total current liabilities

LONG-TERM LIABILITIES:

Capital lease obligation, less current maturities	6,
---	----

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

Other liabilities

5,

Total long-term liabilities

STOCKHOLDERS' EQUITY:

Preferred stock, \$.001 par value, 5,000,000 shares authorized
none issued and outstanding

Common stock, \$.001 par value; 25,000,000 shares
authorized; 13,150,598 shares issued and outstanding

Additional paid-in capital

Deficit accumulated during the development stage

13,
5,485,
(1,627,

Total stockholders' equity

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

F-2

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

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31, 2003	Year ended December 31, 2002	Period from August 23, 2000 (Inception) to Period Ended December 31, 2003
REVENUES	\$ 137,828	\$ 111,108	\$ 248,936
OPERATING EXPENSES:			
General and administrative	340,067	172,737	617,239
Research and development	436,849	431,199	1,009,674
Total operating expenses	776,916	603,936	1,626,913
LOSS BEFORE OTHER EXPENSE	(639,088)	(492,828)	(1,377,977)
INTEREST EXPENSE, NET	(243,230)	(830)	(243,157)
LOSS BEFORE PROVISION FOR INCOME TAXES	(882,318)	(493,658)	(1,621,134)
PROVISION FOR INCOME TAXES	3,375	1,122	6,367

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

NET LOSS	\$ (885,693)	\$ (494,780)	\$ (1,627,501)
	=====	=====	=====
BASIC AND DILUTED LOSS PER SHARE	\$ (0.11)	\$ (0.08)	\$ (0.27)
	=====	=====	=====
BASIC AND DILUTED WEIGHTED AVERAGE COMMON SHARES OUTSTANDING	7,887,237	5,897,225	6,091,089
	=====	=====	=====

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

F-3

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

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

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

	Preferred Stock		Common Stock		Additional Paid-In Capital
	Shares	Amount	Shares	Amount	
Balance, August 23, 2000 (inception) restated for effect of reverse merger with Historical Autographs U.S.A., Inc.			-	\$ -	
Stock issuance in exchange for cash			5,000,000	50	4,
Net loss					
Balance, December 31, 2000, as restated	-	-	5,000,000	50	4,
Issuance of junior preferred stock for cash of \$250,000 and in exchange for patent rights, research and development costs, and employee loan- out costs less issuance expenses of \$11,268, June 29, 2001	681,818	7			958,

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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

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

F-4

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

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

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

	Preferred Stock		Common Stock		Additional Paid-In Capital
	Shares	Amount	Shares	Amount	
	-----	-----	-----	-----	-----
Issuance of common					

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

Amendment of December 31, 2001 agreement for the issuance of common stock agreement in exchange for research and development services	550,000	54,401
Deferred employee loan-out costs receivable earned	171,776	171,776
Issuance of common stock for compensation		10,500
Issuance of common stock for cash		149,866

F-5

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

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

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

	Preferred Stock		Common Stock		Additional Paid-In Capital
	Shares	Amount	Shares	Amount	
Net loss					
Balance, December 31, 2002	681,818	\$ 7	6,431,780	\$ 64	\$ 1,175,
Issuance of common stock for cash less issuance expense of \$2,956			417,000	417	246,
Issuance of common stock in private placement for cash less issuance expense of \$519,230			4,000,000	4,000	3,476,
Issuance of common stock for convertible debenture less issuance expense of \$49,500			400,000	400	350,1
Shares issued in connection with					

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

acquisition of Historical Autographs U.S.A., Inc. on October 30, 2003			1,220,000	8,263	(8,
Value of warrants and beneficial conversion feature of bridge loan					244,
Deferred employee loan-out costs receivable earned					
Preferred Stock converted to Common Stock	(681,818)	(7)	681,818	7	
Net loss					
Balance, December 31, 2003	-	\$ -	13,150,598	\$ 13,151	\$ 5,485,

	Deferred Costs	Deficit Accumulated During the Development Stage	Total
	-----	-----	-----
Net loss		(494,780)	(494,780)
Balance, December 31, 2002	\$ (88,889)	\$ (741,808)	\$ 344,643
Issuance of common stock for cash less issuance expense of \$2,956			247,244
Issuance of common stock in private placement for cash less issuance expense of \$568,730			3,480,770
Issuance of common stock for convertible debenture			350,500
Shares issued in connection with acquisition of Historical Autographs U.S.A., Inc. in October 30, 2003			-
Value of warrants and beneficial conversion feature of bridge loan			244,795
Deferred employee loan-out costs receivable earned	88,889		88,889
Preferred Stock converted to Common Stock			

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

Net loss		(885,693)	(885,693)
		-----	-----
Balance, December 31, 2003	\$ -	\$ (1,627,501)	\$ 3,871,148
	=====	=====	=====

F-6

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31, 2003	Year ended December 31, 2002
	-----	-----
CASH FLOWS USED FOR OPERATING ACTIVITIES:		
Net loss	\$ (885,693)	\$ (494,780)
	-----	-----
ADJUSTMENTS TO RECONCILE NET INCOME (LOSS) TO NET CASH PROVIDED BY (USED FOR) OPERATING ACTIVITIES:		
Amortization of debt discount	244,795	--
Depreciation and amortization	40,243	33,774
Issuance of common stock for compensation	--	10,500
Settlement of accrued expense	--	54,401
Deferred compensation costs	88,889	171,776
CHANGES IN ASSETS AND LIABILITIES:		
(INCREASE) DECREASE IN ASSETS:		
Prepaid expenses	(135,177)	8,798
Deposit	--	--
INCREASE (DECREASE) IN LIABILITIES:		
Accrued liabilities	78,411	53,817
Other	--	5,556
	-----	-----
Total adjustments	317,161	338,622
	-----	-----
Net cash used for operating activities	(568,532)	(156,158)
	-----	-----
CASH FLOWS USED FOR INVESTING ACTIVITIES - purchase of property and equipment	(23,470)	(6,340)
	-----	-----

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

CASH FLOWS PROVIDED BY (USED FOR) FINANCING ACTIVITIES:		
Proceeds from convertible promissory note	400,000	--
Proceeds from issuance of preferred stock	--	--
Proceeds from issuance of common stock	4,250,200	149,866
Payments on capital lease obligations, net	(7,275)	(2,373)
Cost of issuance of preferred stock	--	--
Cost of issuance of common stock	(571,686)	--
Net cash provided by financing activities	4,071,239	147,493
NET INCREASE (DECREASE) IN CASH	3,479,237	(15,005)
CASH, beginning of period	27,849	42,854
CASH, end of year	\$ 3,507,086	\$ 27,849
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	\$ --	\$ --
Income taxes paid	\$ --	\$ 800

SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING INFORMATION:

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

See Note (1) regarding the transaction with historical autographs, U.S.A. Inc.

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

F-7

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

FOR THE YEARS ENDED DECEMBER 31, 2003 AND 2002

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

GENERAL:

Arbios Systems, Inc. and its wholly owned subsidiary (collectively, the "Company") are engaged in developing and marketing liver-assist devices to meet the urgent need for therapy that facilitates recovery from liver failure. The Company's products in development

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

are called SEPET(TM), which is a blood purification therapy device for patients with liver failure, and LIVERAID(TM), which is a bioartificial liver.

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

DEVELOPMENT STAGE ENTERPRISE:

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

PRINCIPLES OF CONSOLIDATION:

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

F-8

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

YEARS ENDED DECEMBER 31, 2003 AND 2002

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, CONTINUED:

USE OF ESTIMATES:

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

FEDERAL GOVERNMENT GRANTS:

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

COMPREHENSIVE INCOME:

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

PROPERTY AND EQUIPMENT:

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

PATENT RIGHTS:

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

DEFERRED EMPLOYEE LOAN-OUT COSTS RECEIVABLE:

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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

YEARS ENDED DECEMBER 31, 2003 AND 2002

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, CONTINUED:

FAIR VALUE OF FINANCIAL INSTRUMENTS:

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

INCOME TAXES:

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

STOCK-BASED COMPENSATION:

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

F-10

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

YEARS ENDED DECEMBER 31, 2003 AND 2002

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, CONTINUED:

STOCK-BASED COMPENSATION, CONTINUED:

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

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

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

LOSS PER SHARE:

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

F-11

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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

YEARS ENDED DECEMBER 31, 2003 AND 2002

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, CONTINUED:

RECENT ACCOUNTING PRONOUNCEMENTS:

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

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

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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

The Company has implemented this pronouncement and has concluded that the adoption has no material impact to the financial statements.

F-12

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

YEARS ENDED DECEMBER 31, 2003 AND 2002

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, CONTINUED:

RECENT ACCOUNTING PRONOUNCEMENTS, CONTINUED:

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities." Interpretation 46 changes the criteria by which one company includes another entity in its consolidated financial statements. Previously, the criteria were based on control through voting interest. Interpretation 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. A company that consolidates a variable interest entity is called the primary beneficiary of that entity.

In December 2003 the FASB concluded to revise certain elements of FIN 46, which will be issued shortly. The FASB also modified the effective date of FIN 46. For all entities that were previously considered special purpose entities, FIN 46 should be applied in periods ending after December 15, 2003. Otherwise, FIN 46 is to be applied for registrants who file under Regulation S-X in periods ending after March 15, 2004, and for registrants who file under Regulation SB, in periods ending after December 15, 2003. The Company does not expect the adoption to have a material impact on the Company's financial position or results of operations.

(2) PROPERTY AND EQUIPMENT:

Property and equipment consisted of the following:

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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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

F-13

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

YEARS ENDED DECEMBER 31, 2003 AND 2002

(3) PATENT RIGHTS:

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

Future estimated amortization expense is as follows:

Year ending December 31,	
2004	\$ 29,602
2005	29,602
2006	29,602
2007	29,602
2008	29,602
Thereafter	176,135

	\$ 324,145
	=====

In conjunction with the patents rights described above, the Company committed to the licensor to spend a total of \$1,760,000 in research and development expenses toward the development and promotion of products, commencing from the acquisition date until June 30, 2008.

Future remaining minimum payments under this agreement were as follows:

Year ending December 31,	
2004	\$ 150,000
2005	200,000
2006	300,000
2007	400,000
2008	500,000

	\$ 1,550,000
	=====

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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

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

F-14

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

YEARS ENDED DECEMBER 31, 2003 AND 2002

(4) DEFERRED EMPLOYEE LOAN-OUT COSTS:

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

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

(5) CONVERTIBLE PROMISSORY NOTES:

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

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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

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

F-15

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

YEARS ENDED DECEMBER 31, 2003 AND 2002

(6) COMMITMENTS AND CONTINGENCIES:

Commitments

The Company leases office facilities and equipment under noncancellable operating leases, which require monthly payments of \$6,441 and expire in June 2004. The Company is required to pay for taxes, insurance, and maintenance. The Company is subleasing lab space for \$2,777 per month.

Rent expense was \$77,202, \$71,736, and \$187,080 for the years ended December 31, 2003 and 2002, and the period from August 23, 2000 (inception) to December 31, 2003, respectively.

Agreements

On December 26, 2001, the Company received the exclusive worldwide rights and license to use certain proprietary rights from Spectrum Laboratories, Inc. ("Spectrum") partially in exchange for 362,669 shares of common stock (see note 8). The license grants the Company the right to use Spectrum's technology and to exploit such rights to develop and distribute products solely for use in the Company's liver-assist devices.

In addition, the Company entered into a manufacturing and supply agreement with Spectrum. The agreement stipulates that the Company must contract with Spectrum for the manufacture and supply of certain products used in the liver-assist devices.

(7) STOCKHOLDERS' EQUITY:

Preferred Stock

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

Junior Preferred Stock

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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

F-16

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

YEARS ENDED DECEMBER 31, 2003 AND 2002

(7) STOCKHOLDERS' EQUITY, CONTINUED:

Junior Preferred Stock (Continued)

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

Common Stock

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

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

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

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

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

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

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

In September and October 2003, Arbios Technologies, Inc, issued 4,000,000

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

shares of common stock and warrants to purchase 4,000,000 shares of common stock at an exercise price of \$2.50 in exchange for \$4,000,000 in cash. The Company recognized \$519,230 in stock issuance expense.

F-17

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

YEARS ENDED DECEMBER 31, 2003 AND 2002

(7) STOCKHOLDERS' EQUITY, CONTINUED:

Common Stock (Continued)

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

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

Stock Option Plan

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

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

	Stock Option Plan	Weighted Average Exercise Price
Balance, December 31, 2001	--	\$ --
Granted	90,000	\$ 0.15
Canceled	--	\$ --

Balance, December 31, 2002	90,000	\$ 0.15
Granted	233,000	\$ 1.00

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

Canceled	9,000	\$ 0.15

Balance, December 31, 2003	314,000	\$ 0.78
	=====	
Options exercisable, December 31, 2003	194,000	\$ 0.61
	=====	

F-18

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

YEARS ENDED DECEMBER 31, 2003 AND 2002

(7) STOCKHOLDERS' EQUITY, CONTINUED:

Warrants:

As of December 31, 2003, warrants to purchase 5,050,000 shares of common stock at prices ranging from \$0.15 to \$2.50 were outstanding.

All warrants are exercisable as of December 31, 2003 and expire at various dates through 2008.

(8) RESEARCH COSTS:

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

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

	\$ 550,000
	=====

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

In July 2002, the original agreement was amended. The Company and Spectrum

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

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

F-19

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

YEARS ENDED DECEMBER 31, 2003 AND 2002

(9) INCOME TAXES:

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

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

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

December 31,
2003

Deferred tax asset arising from

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

net operating loss carryforward	\$	650,732
Less valuation allowance		(650,732)
Net deferred tax asset	\$	-
		=====

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

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

(10) RELATED PARTY TRANSACTION:

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

F-20

SIGNATURES

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

ARBIOS SYSTEMS, INC.

Date: March 29, 2004 By: /s/ JACEK ROZGA, M.D., PH.D

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

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

Signature -----	Title -----	Date -----
/s/ JACEK ROZGA, M.D., PH.D ----- Jacek Rozga, M.D., Ph.D	President (principal executive officer) and Chief Financial Officer (principal financial officer)	March 29, 2004
/s/ JOHN VIERLING, MD ----- John Vierling, MD	Chairman of the Board, and Director	March 29, 2004
/s/ KRISTIN P. DEMETRIOU	Director and Secretary	March 29, 2004

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

 Kristin P. Demetriou

/s/ ROY EDDLEMAN

Director

March 29, 2004

 Roy Eddleman

/s/MARVIN S. HAUSMAN MD Marvin S.

Director

March 29, 2004

 Hausman MD

/s/ RICHARD W. BANK MD

Director

March 29, 2004

 Richard W. Bank MD

INDEX TO EXHIBITS

Exhibit Number -----	Description -----
2.1	Agreement and Plan of Reorganization, dated October 20, 2003, between the Registrant, Arbios Technologies, Inc., HAUSA Acquisition, Inc., Cindy Swank and Raymond Kuh (1)
3.1	Articles of Incorporation of Historical Autographs U.S.A., Inc.(2)
3.2	Certificate of Amendment of Articles of Incorporation (1)
3.3	Bylaws (2)
4.1	Revised form of Common Stock certificate
4.2	Form of Warrant for the Purchase of Shares of Common Stock issued by the Registrant upon the assumption of the Arbios Technologies, Inc. outstanding Warrant
10.1	Form of 2001 Stock Option Plan (2)
10.2	Facilities Lease, entered into as of June 30, 2001, by and between Cedars-Sinai Medical Center and Arbios Technologies
10.3	Standard Multi-Tenant Office Lease, dated as of February 13, 2004, by and between Beverly Robertson Design Plaza and Arbios Systems, Inc.
10.4	Employee Loan-Out Agreement, entered into effective as of July 1, 2001, by and between Cedars-Sinai Medical Center and Arbios Technologies, Inc.
10.5	Second Amendment to Employee Loan-Out Agreement, entered into effective as of May 7, 2003, by and between Cedars-Sinai Medical Center and Arbios Technologies, Inc.

Edgar Filing: ARBIOS SYSTEMS INC - Form 10KSB

- 10.6 License Agreement, entered into as of June 2001, by and between Cedars-Sinai Medical Center and Arbios Technologies, Inc.
- 10.7 Spectrum Labs License Agreement
- 14.1 Arbios Systems, Inc. Code of Business Conduct and Ethics Adopted by the Board of Directors on January 15, 2004
- 16.1 Letter on Change in Certifying Accountant (3)
- 21.1 List of Subsidiaries
- 31.1 Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350

(1) Previously filed as an exhibit to the Company's Current Report on Form 8-K on October 14, 2003, which exhibit is hereby incorporated herein by reference.

(2) Previously filed as an exhibit to the Company's Registration Statement Form 10-SB filed April 26, 2001, which exhibit is hereby incorporated herein by reference.

(3) Previously filed as an exhibit to the Company's Current Report on Form 8-K on January 30, 2004, which exhibit is hereby incorporated herein by reference.