ARBIOS SYSTEMS INC
Form 10KSB
March 31, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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FORM 10-KSB

(Mark One)

x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2005

o TRANSITION REPORT UNDER 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)

Delaware	**91-1955323**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
8797 Beverly Boulevard, #304 Los Angeles, CA 90048	**90048**
(Address of principal executive offices)	(Zip Code)

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

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

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.001 par value
(Title of class)

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. o

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

Check if there is no disclosure of delinquent filers pursuant to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

Issuer's revenues for its most recent fiscal year: None

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 6, 2006 was approximately $13,648,789 based on the closing sales price reported by the OTC Bulletin Board on such date.

There were 17,460,181 shares of the Company's common stock outstanding on March 6, 2006.

DOCUMENTS INCORPORATED BY REFERENCE: None.

Transitional Small Business Disclosure Format (check one): Yes o No x

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Introductory Comment

Throughout this Annual Report on Form 10-KSB, the terms “we,” “us,” “our,” and “our company” refer to Arbios Systems, Inc., a Delaware corporation.

Forward Looking Statements

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

PART I

ITEM 1. DESCRIPTION OF BUSINESS.

Company Overview

Arbios Systems, Inc., or Arbios, is a Delaware corporation based in Los Angeles, California. We seek to develop, manufacture and market liver assist therapies to meet the urgent need for medical treatment of liver failure.

We are a medical device and cell therapy company that is focusing on the development of products for the treatment of liver failure. Our lead products under development currently consist of a novel extracorporeal blood purification therapy called the SEPET™ Liver Assist Device and an extracorporeal, bioartificial liver therapy referred to as the HepatAssist-2™ Bioartificial Liver System that incorporate porcine pig liver cells. We also have rights and a licensing agreement to the LIVERAID™ Bioartificial Liver System, which is a potential enhancement to HepatAssist-2™, but development of that system is on an indefinite hold. We currently own seven key U.S. patents and are the licensee of seven other U.S. patents, as well as the owner of a patent application and numerous related trade secrets.

In April 2005, we received permission from the United States Food and Drug Administration, or the FDA, to commence a 15 patient feasibility clinical study of our SEPET™ cartridge. The enrollment of patients for the clinical trial has been slower than we anticipated; however, the FDA has granted us permission for additional clinical sites to participate in the clinical trial. We currently have three clinical sites enrolling patients and we have broadened the patient eligibility criteria to expedite patient accrual Our HepatAssist-2™ Bioartificial Liver System is an enhanced version of a system referred to as HepatAssist® which we acquired from another company, Circe Biomedical, Inc. and which has been tested in Phase II/III clinical trials. We have an active Phase III investigational new drug application, or IND, to conduct additional clinical trials using HepatAssist™ and intend to focus on introducing this important liver assist technology into clinical practice. Because of the high cost and technological difficulties in the manufacture of LIVERAID™ devices, we have decided to stop the development of the LIVERAID™ Bioartificial Liver System indefinitely. This decision allows us to allocate our financial and organizational resources to the development of the

SEPET™ and HepatAssist-2™ technologies.

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

Company History. Arbios Systems, Inc. was originally incorporated in February 1999 as Historical Autographs U.S.A., Inc., or HAUSA. Until October 2003, HAUSA was an e-commerce based company engaged in the business of acquiring and marketing historical documents. On October 30, 2003, HAUSA completed a reorganization (the "Reorganization") in which HAUSA, through its wholly-owned subsidiary, acquired all of the outstanding shares of Arbios Technologies, Inc., or ATI, in exchange for 11,930,598 shares of HAUSA common stock. As a result of the Reorganization, ATI became the wholly-owned subsidiary of HAUSA. After the Reorganization, HAUSA changed its name to "Arbios Systems, Inc.," replaced its officers and directors with those of ATI, closed its offices, ceased its e-commerce business, and moved its offices to Los Angeles, California. On July 25, 2005, Arbios Systems, Inc. completed its reincorporation as a Delaware corporation by merging with and into Arbios Systems, Inc., a Delaware corporation. The foregoing merger was approved by the Company's stockholders at the annual meeting of stockholders held on July 7, 2005. In order to consolidate the functions and operations of Arbios and ATI, on July 26, 2005, ATI merged into Arbios. As a result, Arbios now owns all of the assets of ATI and all of the operations of the two companies have been consolidated into Arbios.

Our principal operations and executive offices are located at 8797 Beverly Blvd., Suite 304, Los Angeles, California 90048 and our telephone number is (310) 657-4898. We also maintain corporate offices at 1050 Winter Street, Suite 1000, Waltham, Massachusetts 02451 and a manufacturing facility based in Connecticut. We also maintain a web site at www.arbios.com. The information on our web site is not, and you must not consider such information to be, a part of this filing.

Products Overview

We currently have two products under development; a novel extracorporeal blood purification therapy called the SEPET™ Liver Assist Device and an extracorporeal, bioartificial liver therapy referred to as the HepatAssist-2™ Bioartificial Liver System that incorporates pig liver cells, or porcine hepatocytes.

SEPET™ is a single-use cartridge that contains specially designed microporous tubes called hollow fibers. When a patient's blood is pumped through these hollow fibers, 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, or detoxification, process, we believe that the levels of pathological blood components will move toward normal ranges, leading to amelioration of liver failure and stabilization or improved function of a patient's liver. SEPET™ was designed and qualified for use with the PRISMA hemodialysis system (manufactured by Gambro, Inc.) and for use with other commercially available kidney dialysis units and/or plasma apheresis systems that utilize hollow-fiber cartridges.

In April 2004, we acquired from Circe Biomedical, Inc., an unaffiliated biomedical company, the rights to a bioartificial liver, known as the HepatAssist® system. Certain technologies included in the HepatAssist® bioartificial liver were designed and tested in pre-clinical and early clinical studies by Drs. A. A. Demetriou and J. Rozga, who later founded Arbios Systems, Inc. Our HepatAssist-2 Bioartificial Liver System utilizes a single-use cartridge that contains pig liver cells plus columns that contain certain chemical particles referred to as sorbents. When a patient's blood is pumped through the bioartificial liver cartridge, substances normally metabolized by the liver and accumulated in the blood during liver failure move across the porous tubes into two plasma compartments; one compartment is filled with pig liver cells and the other compartment incorporates columns that contain sorbents. The exposure of the viable pig liver cells to patient plasma causes toxic substances contained in the plasma to be metabolized, thereby reducing their level. In addition, the sorbents lower the level of pathological blood components, such as ammonia. At the same time, substances produced by pig liver cells move across the porous wall back into the blood compartment. As a result of these two processes (provision of whole liver functions by the pig liver cells and removal of toxins by the sorbents) we believe the levels of pathological and normal blood components will move toward normal ranges. Our belief is supported by the results of tests performed during clinical trials using the

HepatAssist® system.

Our HepatAssist-2™ Bioartificial Liver System is similar to the earlier HepatAssist® system, and we have subsequently enhanced it by employing a larger quantity of pig cells. We do not anticipate that HepatAssist-2™ will use the proprietary perfusion platform, which is a machine through which the patient's blood is circulated, that was originally designed and developed for the HepatAssist® system. Instead, we are testing a perfusion platform known as the PERFORMER for use as the platform to provide bioartificial liver therapy. The PERFORMER is a multi-function integrated system capable of supporting extracorporeal blood/plasma/fluid circulation therapies that is manufactured by RanD S.r.l. (Italy) and distributed world-wide by Medtronic, Inc. The PERFORMER has been equipped with proprietary software and a tubing set for use with our HepatAssist-2™ Bioartificial Liver System.

Both SEPET™ and HepatAssist-2™ rely on single-use cartridges that are placed on a blood perfusion apparatus that is attached to the patient's blood circulation system. Following treatments with any of our products, the disposable cartridges are discarded, and new cartridges are used for the next therapy.

Background of our Company

Arbios Technologies, Inc., our former operating subsidiary, was formed in August of 2000 by Drs. A. A. Demetriou and J. Rozga, two leaders in the field of artificial liver therapy, to develop extracorporeal therapies for the treatment of liver failure. As former employees of Cedars-Sinai Medical Center, Drs. Demetriou and Rozga previously were involved in the development of a first generation bioartificial liver known as HepatAssist® that was licensed by Cedars-Sinai Medical Center in 1994 to W.R. Grace & Co. and then subsequently transferred to Circe Biomedical, Inc. The prior owners of this technology spent millions of dollars on the research and development of the original HepatAssist® system, the perfusion platform and on the related technologies and operating procedures necessary to bring the product to market. The original HepatAssist® system was tested in Phase II/III clinical trials approved by the FDA in patients with fulminant and subfulminant liver failure and primary non-function following liver transplantation. These trials of the original HepatAssist® system were the first large (171 patients) prospective, randomized, controlled multi-center trial demonstrating a survival advantage for an extracorporeal liver assist system utilizing pig liver cells. Although treated fulminant/subfulminant hepatic failure patients with viral and drug-induced liver injury retrospectively demonstrated improved survival compared to controls when adjusted for the effect of confounding factors (such as liver transplantation), the prospective primary clinical end point in the overall study population (survival at 30 days post-transplantation) was not achieved. Accordingly, the HepatAssist® system was not approved for marketing, and the FDA requested that a new Phase III clinical study be performed. A new Phase III protocol was prepared and reviewed by the FDA. However in 2003, before these new studies could be undertaken, Circe Biomedical ceased its operations. In April 2004, we purchased the remaining assets of Circe Biomedical that related to its bioartificial liver operations, including rights to the original HepatAssist® system, the new Phase III protocol that had been reviewed by the FDA, and over 400 manufacturing and quality control and quality assurance standard operation protocols previously reviewed by FDA. In July 2005, we merged Arbios Technologies, Inc. into the parent company, Arbios Systems, Inc.

To date, we have funded our operations from the gross proceeds of funds we raised from the sale of over $13,000,000 of our equity securities and $321,000 of Small Business Innovation Research, or SBIR, grants that have been awarded by the United States Small Business Administration. We intend to apply for additional SBIR grants to fund a portion of our research expenditures. However, whether or not we receive additional SBIR grants, we will have to raise substantial additional proceeds to fund our future clinical development expenses and our on-going working capital needs.

Our research offices and laboratories are located at Cedars-Sinai Medical Center, Los Angeles, California. Under our lease agreement and other arrangements with Cedars-Sinai, we have access to all of the key development resources of that leading medical center, including animal facilities, surgical core facilities and clinical laboratories. Cedars-Sinai Medical Center is one of the clinical testing sites for our SEPET™ clinical testing program. We also lease administrative office space in Los Angeles, California and Waltham, Massachusetts, as well as an animal breeding and cell manufacturing facility in Woodstock, Connecticut which will be used to harvest porcine livers for use in our

HepatAssist-2™ product.

We have also entered into various agreements with Spectrum Laboratories, Inc., including research and development agreements and manufacturing agreements. Spectrum Laboratories is a company that specializes in the development and manufacture of innovative molecular separation products for the research community and is a supplier of dialysis and ultrafiltration membranes used for biomedical research, molecular biology and clinical diagnostics throughout the world.

Strategy

We believe that the clinical testing and regulatory approval periods for the SEPET™ Liver Assist Device will be shorter than our HepatAssist-2™ Bioartificial Liver System because SEPET™ may be evaluated as a medical device that does not contain biological components such as the pig cells that are an integral part of our HepatAssist-2™ product. Accordingly, because of the shorter regulatory period and the ability of SEPET™ to operate through the use of a standard, currently available kidney dialysis unit, we expect that the development of SEPET™ will be completed before the development of HepatAssist-2™ is completed.

We have already performed *in vitro* and *in vivo* testing of the SEPET™ prototype device and commenced clinical testing of SEPET™ during 2005. We anticipate that we will be able to file an application requesting market approval of SEPET™ as early as late 2007. We are currently evaluating the possibility of conducting clinical studies of the HepatAssist-2™ system under a modified version of the FDA-reviewed Phase III IND protocol that we acquired in March 2004 from Circe Biomedical. Since we are still currently developing our clinical and regulatory strategies for the HepatAssist-2™ Bioartificial Liver System, we cannot estimate when an application requesting marketing approval of that system will be filed.

The April 2004 acquisition of the assets of Circe Biomedical has provided us with new potential opportunities for the development of a bioartificial liver. The Circe Biomedical bioartificial liver device that we acquired consisted of the following four distinct components that we believe may be useful to the development of our bioartificial liver products:

(1) *FDA-approved standard operating procedures*. These are standard operating procedures for production of porcine cells including harvesting, freezing, storing, shipping and processing by the end user (thawing, washing) of the cells. These procedures and protocols have been reviewed by the FDA.

(2) *The cartridge used in the Phase III trial of HepatAssist™*. We intend to use the existing, FDA-approved cartridge, and intend to seek the FDA's approval to increase the number of pig cells that the cartridge could contain, which increase we believe will improve the functionality of the system.

(3) *An FDA reviewed Phase III protocol acquired from Circe Biomedical*. We may modify this protocol and submit the modified protocol to the FDA for approval.

(4) *The HepatAssist™ perfusion platform.* The HepatAssist perfusion platform is Circe Biomedical's specially designed machine that pumped the patient's plasma through the HepatAssist cartridge. This machine was used in the Phase II/III trial of HepatAssist.

Rather than using Circe Biomedical's specially designed machine, we intend to use the PERFORMER, a commercially available machine that is distributed by Medtronic, Inc. We are currently testing units of The PERFORMER that have been equipped with proprietary software and our tubing to enable the machine to work with our bioartificial liver products. We believe that the PERFORMER may become the platform for our HepatAssist-2™ Bioartificial Liver System.

We are currently in the process of designing further clinical trials to demonstrate the safety and tolerability of SEPET™ in treating patients with acute exacerbation of chronic liver failure. In April 2005 we received permission from the FDA to commence a 15 patient clinical feasibility study for SEPET™. The FDA has since given permission to expand the trial to a total of up to four clinical sites and up to 20 patients. Based on our current assumptions, we estimate that the clinical cost of developing SEPET™ will be approximately $5 million to $10 million and the clinical cost of developing HepatAssist-2™ will be between $15 million and $20 million. These amounts, which could vary substantially if our assumptions are not correct, are well in excess of the amount of cash that we currently have available to us. See “Management’s Discussion and Analysis or Plan of Operation - Factors that May Affect Future Results and Market Price of Our Stock.”

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 of alcohol, chemical toxins, and drugs, and waste removal. Loss of liver function is a devastating and life threatening condition. Liver failure affects all age groups and may be due to many causes, including viral infection, hepatitis, ingestion of common medications, alcohol, and surgical liver removal for trauma and cancer.

Currently, there is no direct treatment for liver failure, except a successful liver transplant. There is, however, a current scarcity of donor livers, and approximately two thousand patients on the waiting list for donor livers die annually before receiving liver transplants. Our management believes that treatments with currently available technologies such as blood detoxification methods are short-term measures, and none of them has achieved wide clinical use or ability to arrest or reverse liver failure and improve survival. As a consequence, liver failure patients must still either undergo liver transplantation or endure the probability of prolonged hospitalization with a low probability of survival. In addition, many patients do not qualify for transplantation or live in regions of the world where transplantation is not readily available. Still others do not recover after transplantation because of irreversible brain damage or other organ damage caused by liver failure. Although the liver has a remarkable capacity for regeneration, the repair process after massive liver damage is markedly impaired by the continued presence of toxins, inflammatory cytokines and other inhibitors of organ regeneration still present in the blood of patients.

In liver failure patients, there is a need for an effective blood purification therapy that will clear the blood of toxins, mediators of inflammation and inhibitors of hepatic growth. SEPET™ is a novel form of such therapy developed by us in which the plasma fraction containing substances that are toxic to the brain, the liver and other internal organs and tissues are removed from patient blood and replaced with normal human plasma. We have demonstrated an extension of survival in large animal model testing of SEPET™, which results have led to the initiation of a clinical feasibility trial in human patients.

There is a further need to develop artificial means of liver replacement 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, effective liver support systems should be able to lower blood levels of substances toxic to the brain and liver and to provide whole liver functions, which are impaired or lost.

The founders of this Company as well as investigators not associated with this Company have demonstrated *in vitro* and in animal models of liver failure that cell-based bioartificial livers using viable isolated liver cells, or hepatocytes, can provide whole liver functions. However, only a few bioartificial livers have been tested in humans and it remains to be seen whether systems utilizing hepatocytes as the only means of liver support are effective. We believe that in order to provide the maximum support for the failing liver, porcine hepatocyte therapy should be combined with blood purification or detoxification.

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Our bioartificial liver system, HepatAssist-2™, was designed to become an advanced effective application of the basic bioartificial liver concept. In the bioartificial liver system, liver cell therapy in the form of porcine hepatocytes, is combined with blood detoxification, in the form of sorbent based plasma therapy. Depending on the cause of liver disease, severity of illness and deficiency of specific liver functions, the bioartificial liver mode of therapy can be provided individually, simultaneously or sequentially. Because of these features, we believe our bioartificial liver technology is well suited to treat patients with liver failure of all causes and severity, including those requiring maximum liver support. While the HepatAssist-2™'s predecessor HepatAssist Phase II/III clinical trial demonstrated an increase in patient survival in patients with viral and drug-induced fulminant/subfulminant hepatic failure, a new Phase III clinical trial will be needed before our HepatAssist-2™ system, which is an enhanced version of the original HepatAssist system, can be used by human patients. Pre-clinical data for our HepatAssist-2™ Bioartificial Liver System indicates that this system can improve heart rate and blood pressure and provide clearance of ammonia and indocyanine green (ICG), which is a liver function test.

The Products We Are Developing

We currently are developing novel treatments for acute and chronic liver failure. We believe that our SEPET™ Liver Assist Device and our HepatAssist-2™ Bioartificial Liver System may:

- help keep liver failure patients alive and neurologically intact before, during and immediately after transplantation;
- allow other patients to recover liver functionality and to survive without a transplant (a "bridge" to liver regeneration);
- support patients during periods of functional recovery and regeneration after extensive removal due to liver trauma and/or cancer;
- accelerate recovery from acute exacerbation of chronic liver disease;
- shorten length of stay in intensive care units;
- shorten hospital stay;
- reduce the cost of care; and
- reduce intractable itching associated with severe jaundice.

We believe that our SEPET™ Liver Assist Device and HepatAssist-2 Bioartificial Liver System can achieve these effects because they can lower blood levels of substances that are toxic to both the brain and liver. However, final proof of clinical benefit in patients is lacking at this time, and the clinical utility of these products still needs to be demonstrated in patients with acute liver failure.

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

SEPET™

We are developing the SEPET™ Liver Assist Device as a blood purification measure to provide temporary liver support during acute liver failure and acute exacerbation of chronic liver disease. SEPET™ therapy will be provided through the sale of our single-use, disposable cartridge that contains a bundle of hollow fibers made of bio- and hemo-compatible material capable of sieving substances with molecular weight of up to 100 kilodaltons, or kDa. The importance of using fibers with this sieving characteristic, which is larger than for conventional renal dialysis cartridges, is that most hepatic failure toxins as well as mediators of inflammation and inhibitors of hepatic regeneration have a molecular weight that is less than 100 kDa, while "good" blood components, for the most part, have molecular weight greater than 100 kDa. At present, Spectrum Laboratories is the manufacturer of these disposable cartridges. See "—Manufacturing" below. The SEPET™ system is designed for use with any commercially available kidney dialysis unit or other similar machines that utilize hollow-fiber cartridges. Accordingly, no specialized apparatus needs to be developed or manufactured for SEPET™. Accessory components for the SEPET™ system such as disposable tubings and

connectors will mostly consist of standard components that are currently used in renal dialysis and provided by manufacturers of those systems. We expect that any new accessory components that may be required will be manufactured for us by third-party vendors.

During SEPET™ therapy, an ultrafiltrate containing toxins, inhibitors of hepatic growth and mediators of inflammation with molecular weight of 100 kDa or less will be removed from the patient's blood stream by exiting from the side port of the cartridge, while at the same time, intravenous electrolyte solutions, albumin solution, fresh frozen plasma, or a combination thereof will be administered to the patient. We believe that as a result of these two processes, the levels of pathological and normal blood components present in the patient's circulation will move toward normal ranges, thereby facilitating recovery from liver failure. Based on published medical literature, rapid and efficient blood detoxification is expected to protect the liver, brain and other organs against further injury, accelerate healing of the native liver and improve its residual functions.

HepatAssist2™ Bioartificial Liver System

Our current bioartificial liver system under development is the HepatAssist-2™ Bioartificial Liver System. We have designed our HepatAssist-2™ Bioartificial Liver System to provide temporary liver support during acute liver failure and acute exacerbation of chronic liver disease. The HepatAssist-2™ Bioartificial Liver System incorporates several proprietary components and technologies into an integrated liver assist system, including a hollow fiber cartridge with porcine hepatocytes and a plasma re-circulation circuit that incorporates a cell cartridge and sorbents. The HepatAssist-2™ Bioartificial Liver System is designed to (i) provide liver cell functions by utilizing viable pig liver cells that are housed in specially designed cartridges and (ii) detoxify blood. Since it has been scientifically established that pig liver cells perform liver functions when maintained in specially designed cartridges outside of the human body, our bioartificial liver cartridge is designed to bring human plasma into contact with viable pig liver cells in a manner similar to that observed in the normal human liver inside the body in order to provide liver functions to the patient. In addition, our bioartificial liver system is designed to lower the levels of pathological blood components (through activated charcoal or other purification sorbents).

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

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

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

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

The pig liver cells are expected to be harvested from young purpose-bred, pathogen-free, vaccinated pigs raised in an United States Department of Agriculture, or the USDA, certified facility specifically for biomedical research purposes. Each batch of cryopreserved pig liver cells will be released for clinical use only after proper verification of biosafety and viability/functionality of the cells. We acquired all of the required laboratory and quality assurance protocols from Circe Biomedical, which protocols were previously reviewed by the FDA and deemed to be in compliance with FDA requirements. We are currently leasing facilities in which we will be able to house and maintains pigs and surgically acquire their livers. The facilities, which are still under development, would be used to monitor the health of these pigs and to assure that the pigs and cells remain free from infection and meet specific FDA requirements and to harvest the pig livers. We believe that once suitable modifications and FDA approved leasehold improvements are implemented and completed, these facilities will be suitable to meet our near-term goals for maintaining and harvesting the number of pig livers that we expect to need until the commercial viability of our products is established.

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

We expect to demonstrate that during HepatAssist-2™ therapy, 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, or detoxification, therapy. In this mode of therapy, small and large protein-bound toxins, which accumulate in the blood during liver failure, are expected to be removed by sorbents. Blood detoxification is believed to protect the liver, brain and other organs against further injury, accelerate healing of the native liver and improve its residual functions. Decreased blood toxicity is also expected to prolong the life and metabolic activity of pig hepatocytes in the bioartificial liver modules.

Product Advantages

We believe that SEPET™ as a blood purification therapy will be more effective than sorbent-based devices such as charcoal, resin and silica, and more effective than whole plasma exchange therapy, because only the plasma fraction containing known toxins of hepatic failure is being removed and discarded during SEPET™ therapy. In contrast, sorbent-based blood purification is not toxin-specific, and in the case of charcoal sorption it is limited because of the protective coating of the charcoal particles. It also fails to remove most mediators of inflammation and protein bound toxins from the blood which are associated with liver failure. Subject to the successful completion of clinical trials and FDA or other regulatory approval, we believe that SEPET™ will be able to be used with currently available hospital kidney dialysis systems, which may offer the following advantages:

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

- Simplicity. Kidney dialysis systems are routinely used and, therefore, there may be no need for extensive personnel training for use of these similar systems in SEPET™. They are also commonly available in intensive care units and other settings where SEPET™ may be used.

- Low cost. The cost of therapy is expected to be lower than with any other liver assist device that is currently under development because the machine to which the SEPET™ cartridge can be attached is a standard machine (such as a kidney dialysis machine) with commercially available tubing. Therefore, unlike other devices, no special equipment is required.

- No Intensive Care Unit needed to provide treatment. SEPET™ may become available for treatment of patients with a lower degree of liver failure outside of the intensive care unit setting. We do not believe that any changes will have to be made to SEPET™ or the dialysis system in order for SEPET™ to become available outside of intensive care unit settings.

To our knowledge, HepatAssist-2™ 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.

Drs. Demetriou and Rozga, the founders of Arbios and the major stockholders of the company, have previously demonstrated that cryopreserved pig hepatocytes remain alive (>80% viability) after thawing. Moreover, the hepatocytes quickly aggregate, forming liver-like 3-dimensional cellular 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, because porcine hepatocytes can be stored frozen at a clinical site, treatment with our bioartificial liver system can be commenced with two to three hours of patient consent and product preparation, thereby making this bioartificial liver therapy available on demand. In instances of liver failure, this rapid availability of therapy should be a critical competitive advantage. In contrast, we believe other liver assist devices under development require longer time for preparation prior to patient treatment (up to several days in some instances, including cumbersome means of shipment to the clinical site).

Clinical Utility

We believe that the animal and clinical data generated and published to date on the original HepatAssist™ system indicate that the basic concept of a bioartificial liver utilizing cryopreserved pig liver cells and blood detoxification is valid and that repeated six-hour bioartificial liver treatments are safe and yield measurable therapeutic benefits. Accordingly, we believe that our novel, next-generation products will represent improvements and/or enhancements of earlier technologies.

Our HepatAssist-2™ Bioartificial Liver System is an enhanced version of the original HepatAssist® system. The safety and efficacy of the original HepatAssist® system were evaluated in a prospective, randomized, controlled, multi-center FDA-approved clinical trial. A total of 171 patients, 86 in the control group, and 85 in the bioartificial liver group, were enrolled. Patients with fulminant and subfulminant hepatic failure and primary non-function following liver transplantation were included. Data were analyzed with and without accounting for the following confounding factors: liver transplantation during the survival endpoint period, time to liver transplant, cause of the disease or condition, disease severity, and treatment site. For the entire patient population, survival at 30 days was 71% for bioartificial liver compared to 62% for the control group. When survival was analyzed accounting for

confounding factors such as liver transplantation and survival prior to transplantation, across the entire patient population, there was thus a trend towards improved survival but not a statistically significant difference between the two groups. However, survival in the 147 fulminant and subfulminant hepatic failure patients (i.e. excluding the primary non-function patients) was significantly higher in the HepatAssist™ Bioartificial Liver System group compared to the control group. Furthermore, HepatAssist™ therapy reduced the risk of pre-transplant death by 67% in patients with drug and chemical toxicity ($p<0.0140$) and by 47% in patients with rapid onset of fulminant hepatic failure ($n=121$; $p<0.0428$) To our knowledge, this was the first prospective, randomized, controlled trial of an extracorporeal liver support system that demonstrated safety and improved survival in patients with fulminant and subfulminant hepatic failure.

Market Opportunity

Based on the number of patients with liver diseases and lack of alternative direct therapy other than liver transplantation, we believe that there is an urgent need for artificial means of liver replacement and/or assistance to facilitate recovery from liver failure without a transplant. Effective liver support therapies could also help maintain liver failure patients' lives until an organ becomes available for transplantation. The SEPET™ Liver Assist Device and HepatAssist-2™ Bioartificial Liver System are designed to treat patients with liver failure across the range of all causes and severity, including acute exacerbation of chronic liver disease.

The patient and market opportunity is substantial and underserved. According to the American Liver Foundation, 25,000,000 Americans - one in every ten persons - are or have been suffering from liver and biliary diseases. According to the National Center for Health Statistics published for 2000, there were 360,000 hospital discharges for patients with chronic liver disease or cirrhosis plus additional patients categorized as suffering from viral hepatitis B or hepatitis C with likely liver failure sequellae. Of the 360,000 documented hospitalizations for chronic liver disease in the United States referenced above, 27,035 died (making liver failure the tenth leading cause of death in males and twelfth in females, and fourth leading cause of death in persons aged 45 - 54 years) because no donor liver was found or because they had contraindications to transplantation.

The mounting crisis of viral hepatitis B and hepatitis C is projected to continue to propel numbers of liver failure episodes as patients age and increasingly suffer hepatic decompensation. Approximately 3.9 million Americans are chronically infected with the hepatitis C virus, and an estimated 25,000 people each year are infected in the United States each year with the hepatitis C virus. At the same time, 10,000 - 12,000 deaths have occurred annually in the United States due to hepatitis C virus infection, and the number is likely rising. Hepatic decompensation, as a result of chronic hepatitis C virus infection, is now the leading cause of liver transplantation in the United States. Despite improved rates of organ donation, increased utilization of deceased donor livers and a resurgence in living donor transplants, the number of liver transplants performed yearly is now approximately 5,500. At the same time, in 2004 alone there were more than 10,000 new waitlist registrations for liver replacement. As of March 6, 2006, the liver transplant waiting list contained 17,650 individuals. According to National Institutes of Health and the American Association for the Study of Liver Diseases, 5,000 deaths occur annually as a consequence of hepatitis B virus infection.

Worldwide, hepatitis B is the leading cause of liver failure. Of the 2 billion people who have been infected with the hepatitis B virus, more than 350 million are estimated to have chronic, or lifelong, infections. These chronically infected persons are at high risk of death from cirrhosis of the liver and liver cancer. The World Health Organization estimates very large numbers of deaths worldwide from hepatitis B virus infection -- an estimated 880,000 per year from liver failure and another 320,000 per year from liver cancer (some of whom may require liver support therapy before and/or after surgical resection of the cancer). Infection is most common in Asia, Africa and Middle East. Hepatitis C is also a major cause of liver failure worldwide. According to the World Health Organization, globally, an estimated 170 million persons are chronically infected with the hepatitis C virus. At the same time, an estimated 3 to 4 million persons are newly infected each year. Liver failure has recently been cast, worldwide, as the third leading cause of death. In China and other Asian countries, liver disease represents a pressing health problem and the need for an effective liver support therapy is more urgent than in some other markets. Although epidemiological data on hepatitis C virus and hepatitis B virus infection in China are not publicly available, we believe there are approximately 200 million carriers of the hepatitis virus B or C in China, and primary liver cancer is a common malignancy.

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

At this time, based on the preliminary information available to us, we estimate that the cost to the provider of a single treatment with the SEPET™ therapy could be within a $2,000 - $4,000 range and that the respective cost of the bioartificial liver therapy could be approximately $20,000 in the United States. Pricing in other world regions will likely vary. We anticipate that SEPET™ and/or bioartificial liver therapy may have to be repeated in some patients up to an average of five to seven times before a satisfactory clinical outcome is obtained, although fewer treatments per patient may be sufficient depending on the severity of disease. Based on these estimates and the above mentioned projections, the potential U.S. market for SEPET™ and HepatAssist-2™ is significant, with similar or possibly larger opportunities in some regions outside North America. 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.

Sales, Marketing & Distribution

We currently do not have any agreements in place to market any of our products if and when those products are commercially released, and we do not currently expect to establish an in-house marketing and sales program to distribute our products in all regions of the world. We currently expect to outsource at least a portion of 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 at least North America, Europe and Asia.

Manufacturing

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

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

The kidney dialysis hardware units that will be used as a platform for SEPET™ therapy are not expected to require any technical adjustments. Since pressure monitors and hemoglobin detectors are standard in kidney dialysis systems, additional safety features are not likely to be required. Since the existing kidney dialysis units will not be affected, only the kidney dialysis cartridge will be replaced by a SEPET™ cartridge, no consents will have to be obtained from the manufacturers of those units, and no additional insurance is expected to be required to use those units.

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The platform we currently expect to use for the HepatAssist-2™ bioartificial liver therapy is a perfusion platform known as the PERFORMER. The PERFORMER is a multi-function integrated system capable of supporting extracorporeal blood/plasma/fluid circulation therapies that is manufactured by RanD S.r.l. (Italy) and distributed by Medtronic, Inc. The PERFORMER may be equipped with proprietary software, which has already been developed by RanD for Arbios, and a tubing set for use with our HepatAssist-2™ system.

The pig liver cells will be harvested from young purpose-bred, pathogen-free, vaccinated pigs raised in a USDA certified facility specifically designed for biomedical research purposes. The liver cells will be harvested and cryopreserved under aseptic conditions using our proprietary technology as well as commercially available equipment.

With regard to cell procurement and cryopreservation for bioartificial liver use, we do not yet own or lease our own specialized and certified bio-secure porcine liver cell manufacturing plant. Prior to of Phase III clinical testing of HepatAssist-2™, we will determine whether to build a cell procurement facility to meet the expected requirements for commercial sales, which will require a substantial lease obligation and/or capital investment. This decision will be based on technical evaluation of the project as well as an economic evaluation of company performance.

In December 2001 we entered into a manufacturing and supply agreement with Spectrum Laboratories, Inc. for the future manufacture a portion of our LIVERAID™ product, a potential variation on the HepatAssist™ product design. The LIVERAID™ cartridge is a bioartificial liver similar to the HepatAssist cartridge with the exception of its fiber within a fiber design. Under that agreement, we agreed that Spectrum Laboratories will manufacture the hollow fiber cartridges with fiber-in-fiber geometry that we will need for the LIVERAID™ bioartificial liver. The agreement provides that the price of the hollow fiber-in-fiber cartridges to be sold by Spectrum Laboratories to us will be determined by good faith negotiations between the parties. We have agreed that we will not purchase cartridges with fiber-in-fiber geometry from any other manufacturer unless Spectrum Laboratories is either unable or unwilling to manufacture the cartridges. The final step in manufacturing the LIVERAID™ cartridges is completed manually, which has resulted in a high incidence of rejected cartridges and a lengthy manufacturing period. These problems, if not remedied, may limit the amount and timeliness of cartridges that can be manufactured. Spectrum Laboratories has informed us that it can, and is willing to, acquire or develop an automated manufacturing process for the LIVERAID™ cartridges. However, since such an automated manufacturing process is expensive, Spectrum Laboratories has not yet undertaken to acquire or develop the necessary equipment and technology. No assurance can be given that Spectrum Laboratories will, in fact, be able to acquire or develop an automated manufacturing process or that Spectrum Laboratories will otherwise be able to satisfy our needs for the LIVERAID™ cartridges. In the event that Spectrum Laboratories is either unable or unwilling to manufacture the amount of LIVERAID™ cartridges that we need, we will have to find one or more alternative manufacturers for the cartridges. While we have identified other possible manufacturers of the LIVERAID™ cartridges, it is uncertain if any of those other companies would want to manufacture the cartridges for us, and if so, on what terms. As such, we have decided to stop further development of the LIVERAID™ technology indefinitely and focus on the HepatAssist-2™ product.

Patents and Proprietary Rights

Bioartificial Liver Rights. We originally obtained exclusive, worldwide rights from Cedars-Sinai Medical Center and Spectrum Laboratories to seven issued U.S. patents protecting our bioartificial liver technology and accompanying cell procurement/cryopreservation technologies. One of the patents we licensed from Spectrum Laboratories, Inc., patent #5,015,585 “Method and Apparatus for Culturing and Diffusively Oxygenating Cells on Isotropic Membranes” has expired.

The founders of Arbios, Drs. Rozga and 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. Currently, the key proprietary bioartificial liver technologies that we intend to use include the following licensed patents:

(1) A bioartificial liver system in which liver cell therapy and blood detoxification are integrated in a single fiber-in-fiber module (US Patent # 6,582,955 B2 for "Bioreactor With Application as Blood Therapy Device" issued in June 2003). We have licensed this patent from Spectrum Laboratories.
(2) Semi-automated large-scale liver cell procurement technology (US Patent #5,888,409 for "Methods for Cell Isolation and Collection" issued on March 30, 1999). We licensed this patent from Cedars-Sinai Medical Center.
(3) Liver cell procurement technology (US Patent #5,968,356 for "System for Hepatocyte Cell Isolation and Collection" issued on October 19, 1999, and related European Patent #0 830 099 for "Apparatus and Method for Cell Isolation and Collection"). We licensed this patent from Cedars-Sinai Medical Center.
(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.

Cedars-Sinai Medical Center Licenses. On June 19, 2001, Arbios entered into an agreement with Cedars-Sinai Medical Center pursuant to which Cedars-Sinai granted to Arbios exclusive and worldwide rights to patents (2)-(4) above and to certain other technical information. These rights are and remain exclusive over the legal life of the various patents and include, subject to limitations, the right to sublicense the patent rights to third parties. In order to maintain its rights under the license, Arbios is required to expend an aggregate amount of $1,760,000 in research and development expenses toward the development and promotion of products derived from the patents. As of the end of the fiscal year ended December 31, 2004, we had expended more than the minimum required $1,760,000 and have, therefore, fully satisfied the research and development expenditure requirement of this license. Cedars-Sinai Medial Center will have nonexclusive rights to any products derived from the patents. We will have to initially pay Cedars-Sinai Medical Center royalty fees equal to 1.5% of the gross sales price of royalty bearing products. From the third to tenth years of the license, the royalty fee percent will phase out evenly to 0%. Cedars-Sinai Medical Center is a stockholder of this company. See "Certain Relationships and Related Transactions."

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

Circe Biomedical Properties. In April 2004, we acquired from Circe Biomedical a portfolio of intellectual properties, including certain U.S. and foreign patents applicable to the HepatAssist bioartificial liver that Circe Biomedical was developing, including various patents related to the harvesting and handling of cells to be used in the bioartificial liver. We also acquired a number of other patents and rights related to Circe Biomedical's bioartificial liver program that we will not be using, as well as patents on other technologies that we do not intend to pursue (such as patents to Circe Biomedical's's artificial pancreas system and three patents for cholesterol removal membranes). The following is a list of the patents and patent applications that we acquired from Circe Biomedical and that we expect to maintain and use with our bioartificial liver systems:

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

Patent Applications

Patent No.	Country	Title of Patent Application
2216203	CA	Method of Thawing Cryopreserved Cells
9-256534	JP	Method of Thawing Cryopreserved Cells
97307459	EU	Method of Thawing Cryopreserved Cells
99106212.6-2113	EU	Removal of Agent From Cell Suspension

In addition to the foregoing Circe Biomedical patents, we acquired other rights to Circe Biomedical's HepatAssist bioartificial liver and related technologies, such as clinical and marketing data and over 400 manufacturing and quality assurance/control standard operation protocols that the FDA had previously reviewed. The Phase I-III clinical data that we acquired is expected to be useful in the preparation of future FDA submissions, since the data is based on pig liver cells from the same source. We also acquired an FDA Phase III IND for an enhanced version of the HepatAssist system. We are currently evaluating the possibility of conducting clinical studies of the HepatAssist-2™ system under a modified version of the FDA-approved Phase III IND protocol that we acquired. In connection with our acquisition of the foregoing patents, we also assumed Circe Biomedical's obligations to make the following royalty payments:

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

(b) We are obligated to make royalty payments equal to 1% of the "net sales" price for that portion of a liver assist system sold by us or any of our sublicensees that comprises or incorporates a cartridge having a combination of porcine hepatocytes with hollow fiber membranes pursuant to that certain Restated License Agreement dated as of August 1, 1999 between Circe Biomedical and Cedars-Sinai Medical Center. Since our HepatAssist-2™ Bioartificial Liver System may utilize this type of cartridge, we will have to pay this royalty with respect of sales of all cartridges used in our bioartificial liver system. Our obligation to pay these royalties will begin with the first commercial sale of a bioartificial liver and continue thereafter for ten years.

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

SEPET™ Rights. Our intellectual property rights relating to the SEPET™ Liver Assist Device consist of a patent application and certain related trade secrets. Our patent application regarding our selective plasma filtration therapy (SEPET™) technology was filed in August 2002 with the United States Patent and Trademark Office and subsequently in other countries and is currently under review for possible issuance.

We have filed for trademark protection for our product names, SEPET™ and HepatAssist-2™, which marks may become registered only upon commercialization of products.

Research and Development

In December 2001, Arbios and Spectrum Laboratories entered into a four-year research agreement pursuant to which Arbios and Spectrum Laboratories agreed to combine their expertise and their respective technologies to enable Arbios to (i) develop liver assist systems, (ii) conduct pre-clinical and Phase I-III clinical testing, (iii) obtain regulatory approvals, and (iv) commercialize such liver assist systems. Under the terms of the agreement, Spectrum Laboratories agreed to perform certain research on liver assist devices for Arbios during product development, pre-clinical and clinical testing at no cost to Arbios. Although all of the obligations of the parties under that research and development agreement were completed during the fiscal year ended December 31, 2004, Spectrum Laboratories has agreed to perform such additional research and development work as we may request, which additional future work will be provided by Spectrum Laboratories on terms upon which we may agree in the future.

We spent a total of $1,555,000 on research and development during the fiscal year ended December 31, 2005, $1,426,000 on research and development during the fiscal year ended December 31, 2004, and $437,000 on research and development during the fiscal year ended December 31, 2003. In addition, pursuant to our research agreement with Spectrum Laboratories, Spectrum Laboratories provided research and development services valued at $17,260 in 2003 for our liver assist systems. See, “Certain Relationships and Related Transactions.”

In January 2005, we entered into a research and development agreement with the Faculty of Chemical and Process Engineering of the Warsaw University of Technology, in Warsaw, Poland. Pursuant to this agreement, Warsaw University agreed to provide research to and develop services for us in connection with the development and manufacture of new membrane-based selective plasma filtration technologies and new selective plasma filtration devices to be used with our liver assist devices. The research agreement had a term of one year and could be extended by the parties. The cost of the research and development agreement to us during FY 2005 was approximately $100,000, and the agreement was terminated In February 2006 for failure to meet the final milestone objectives.

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 United States for treatment of liver failure: (1) the Adsorba column (Gambro, Hechingen, Germany) which contains activated charcoal and (2) the BioLogic-DT system (HemoCleanse, West Lafayette, Indiana) utilizing a mixture of charcoal, silica and exchange resins**.** Published data indicate that in limited, uncontrolled clinical trials utilizing these systems, only a transient improvement in neurological status was observed with no effect on patients' survival.

Other technologies offered by competing companies include the following:

Gambro's MARS system (molecular adsorbents recirculating system) combines the specific removal of the toxins of liver failure (albumin bound toxins) using a hollow-fiber cartridge impregnated with albumin, and sorbent columns placed in a dialysis circuit filled with 20% albumin solution. Albumin in the dialysate is "regenerated" during continuous recirculation in the closed loop system through sorbent columns (charcoal, resin). In addition, standard hemodialysis is performed during MARS treatment. In Europe, initial results in patients with acute liver failure were encouraging. In November 2004, Gambro announced that in a recently completed Phase II controlled study, which was conducted in 79 patients with acute exacerbation of chronic liver disease, MARS treatment improved hepatic encephalopathy and lowered blood levels of certain toxins implicated in the pathophysiology of liver failure.

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

Vital Therapies, Inc. uses technology developed by Hepatix and VitaGen, Inc. Its bioartificial liver ELAD® utilizes a cell line derived from human liver cancer tissue and a conventional hollow fiber bioreactor. A Phase I clinical study of the newest ELAD® version was recently reported at the annual meeting of the American Association for the Study of Liver Disease in November 2004 in Boston. In patients with acute liver failure, treatment with ELAD® had no effect on survival when compared to patients receiving standard therapy. In January 2006, Vital Therapies, Inc. announced that it had received guidance from the FDA to allow it to begin shipment of its ELAD® cartridges to China in anticipation of pivotal clinical trials scheduled to begin in China in early 2006.

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

Government Regulation

In order to clinically test, manufacture, and market products for therapeutic use, we will have to satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. In the United States, the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, labeling, storage, record keeping, approval, advertising, and promotion of our products. Product development and approval within this regulatory framework take a number of years and involve the expenditure of substantial resources. After laboratory analysis and preclinical testing in animals, an IND is filed with the FDA to begin human testing. Typically, a three-phase clinical testing program is then undertaken. In phase 1, small clinical

trials are conducted to determine the safety of the product. In phase 2, clinical trials are conducted to assess safety and gain preliminary evidence of the efficacy of the product. In phase 3, clinical trials are conducted to provide sufficient data for the statistically valid proof of safety and efficacy. The time and expense required to perform this clinical testing can vary and be substantial. No action can be taken to market any new drug or biologic product in the United States until an appropriate marketing application has been approved by the FDA. Even after initial FDA approval has been obtained, further clinical trials may be required to provide additional data on safety and effectiveness and are required to gain clearance for the use of a product as a treatment for indications other than those initially approved. In addition, side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product's use and, potentially, withdrawal of the product from the market. Any adverse event, either before or after marketing approval, can result in product liability claims against us.

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

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

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

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In addition to obtaining FDA approval, we will have to obtain the approval of the various foreign health regulatory agencies of the foreign countries in which we may wish to market our products. Certain health regulatory authority (including those of Japan, France and the United Kingdom) have objected, and other countries regulatory authorities could potentially object, to the marketing of any therapy that uses pig liver cells (which our bioartificial liver systems are expected to utilize) due to safety concerns. If we are unable to obtain the approval of the health regulatory authorities in any country, the potential market for our products will be reduced.

Employees

As of March 6, 2006, we employed six full-time employees. We have also engaged six independent contractors who provide services to us on a part-time basis. Of the foregoing employees and contractors, five are primarily engaged in administration/management, and the remaining seven persons are involved in scientific research, product development and/or regulatory compliance matters. Our employees are not represented by a labor organization or covered by a collective bargaining agreement. We have not experienced work stoppages and we believe that our relationship with our employees is good.

Glossary of Terms

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

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

"Extracorporeal" means situated or occurring outside the body.

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

"Fulminant" means occurring suddenly, rapidly, and with great severity or intensity.

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

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

"Hepatitis" is an inflammation of the liver caused by infectious or toxic agents.

"Hepatocytes" are the organ tissue cells of the liver.

"kDa" is a measure of molecular weight using "Daltons" (abbreviated as "Da"). One "Da" is 1/12 of the weight of an atom carbon ^{12}C. "kDa" is a kilodalton, or a 1,000 Daltons.

"IND" means Investigational New Drug application.

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

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

"**PERV**" means the porcine endogenous retrovirus.

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

"Porcine" means of or pertaining to swine; characteristic of the hog.

"Regeneration" means regrowth of lost or destroyed parts or organs.

"Sorbent" means to take in and adsorb or absorb.

ITEM 2. DESCRIPTION OF PROPERTY.

We currently maintain our laboratory at Cedars-Sinai Medical Center in Los Angeles, California, which facilities we lease under a three-year lease that expires on June 30, 2007. We currently pay rent of $4,531 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 Arbios. See "Certain Relationships and Related Transactions."

Since April 1, 2004, we have been leasing 1,700 square feet of administrative office space in a building across the street from our laboratories that are located at Cedars-Sinai Medical Center. Our office is located at 8797 Beverly Blvd., Suite 304, Los Angeles, California 90048. On September 1, 2005, we re-signed the lease for an additional two years. The office lease requires us to pay rent of $5,777 per month. Since December 5, 2005, we have been leasing approximately 600 square feet of administrative office space in Waltham, Massachusetts where some of our executive management are located. The new office lease, located at 1050 Winter Street, Suite 1000, Waltham, Massachusetts 02154, requires us to pay a total of $18,040 for a period of seven months. We also lease an animal breeding facility in Woodstock, Connecticut which will be used to harvest porcine livers for use in our HepatAssist-2 product. The animal breeding facility lease in Connecticut commenced on April 1, 2005 and has a term of two years which requires us to pay $12,009 per month for approximately 1,680 square feet of space.

ITEM 3. LEGAL PROCEEDINGS.

We are not a party to any material legal proceedings.

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

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

No matters were submitted to a vote of security holders during the quarter ended December 31, 2005.

PART II

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

Market Information

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

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

The following table sets forth the range of high and low bid information for our common stock for each quarter within the last two years, as reported by Yahoo Finance and Bigcharts from CBS Marketwatch.com. The following price information reflects inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions:

Quarter Ending	High	Low
March 31, 2004	$ 3.50	$ 3.40
June 30, 2004	$ 4.25	$ 2.75
September 30, 2004	$ 5.15	$ 4.00
December 31, 2004	$ 2.68	$ 2.65
March 31, 2005	$ 1.66	$ 1.60
June 30, 2005	$ 2.20	$ 2.10
September 30, 2005	$ 1.90	$ 1.80
December 30, 2005	$ 1.80	$ 1.74

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

Holders

As of March 6, 2006, there were 141 listed shareholders of record of our common stock, although we believe there may be substantially more shareholders who hold our common stock in street name.

Dividends

We have not paid any dividends on our common stock to date and do not anticipate that we will be paying dividends in the foreseeable future. Any payment of cash dividends on our common stock in the future will be dependent upon the amount of funds legally available, our earnings, if any, our financial condition, our anticipated capital requirements and other factors that the Board of Directors may think are relevant. However, we currently intend for the foreseeable future to follow a policy of retaining all of our earnings, if any, to finance the development and expansion of our business and, therefore, do not expect to pay any dividends on our common stock in the foreseeable future.

Issuer Purchases of Equity Securities

We did not repurchase any of our common shares during fiscal year 2005.

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

Overview

On October 30, 2003, we completed a reorganization (the "Reorganization") in which Arbios Technologies, Inc., or ATI, our operating company, became our wholly-owned subsidiary. At the time of the Reorganization, we had virtually no assets and virtually no liabilities (prior to the Reorganization we were an e-commerce based company engaged in the business of acquiring and marketing historical documents). Shortly after the Reorganization, we changed our name to "Arbios Systems, Inc." In the Reorganization, we also replaced our officers and directors with those of ATI. Following the Reorganization, we ceased our e-commerce business, closed our former offices, and moved our offices to Los Angeles, California. We currently do not plan to conduct any business other than the business of developing liver assist devices that Arbios Systems, Inc. has conducted since its organization. In July 2005, we merged ATI into the parent company, Arbios Systems, Inc.

Although we acquired ATI in the Reorganization, for accounting purposes, the Reorganization was accounted for as a reverse merger since the stockholders of ATI acquired a majority of the issued and outstanding shares of our common stock, and the directors and executive officers of ATI became our directors and executive officers. Accordingly, the financial statements contained in this Annual Report, and the description of our results of operations and financial condition, reflect (i) the operations of ATI alone prior to the Reorganization, and (ii) the combined results of this company and ATI since the Reorganization. No goodwill was recorded as a result of the Reorganization.

Since the formation of ATI in 2000, our efforts have been principally devoted to research and development activities, raising capital, and recruiting additional scientific and management personnel and advisors. To date, we have not marketed or sold any product and have not generated any revenues from commercial activities, and we do not expect to generate any revenues from commercial activities during the next 12 months. Substantially all of the revenues that we have recognized to date have been Small Business Innovation Research grants (in an aggregate amount of $321,000) that we received from the United States Small Business Administration.

Our current plan of operations for the next 12 months primarily involves research and development activities, including clinical trials for SEPET™, and the preparation and submission of applications to the FDA. We submitted an investigational device exemption, or IDE, application for SEPET™ in March 2005 and commenced clinical studies for SEPET™ in the third quarter of 2005. We also intend to reactivate work on the HepatAssist bioartificial liver system by modifying the FDA-reviewed Phase III IND protocol. Because the anticipated cost of conducting clinical studies for the HepatAssist-2™ system exceeds our current financial resources, we will not, however, be able to commence clinical studies for the HepatAssist-2™ system until we raise additional capital. The actual amounts we may expend on research and development and related activities during the next 12 months may vary significantly depending on numerous factors, including the results of our clinical studies and the timing and cost of regulatory submissions. However, based

on our current estimates, we believe that we have sufficient financial resources to conduct our planned operations for at least the next 12-month period following the date of this Annual Report.

In April 2004 we purchased certain assets of Circe Biomedical including a portfolio of patents, rights to a bioartificial liver (HepatAssist), a Phase III IND, selected equipment, clinical and marketing data, and over 400 standard operating procedures and clinical protocols that have previously been reviewed by the FDA. The purchase price paid for these assets was $450,000, which amount has now been fully paid.

Critical Accounting Policies

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

Our significant accounting policies are summarized in Note 1 to our audited financial statements for the year ended December 31, 2005. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Development Stage Enterprise

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

Short Term Investments

Short-term investments generally mature between three and twelve months. Short term investments consist of U.S. government agency notes purchased at a discount with interest accruing to the notes full value at maturity. All of our short-term investments are classified as available-for-sale and are carried at fair market value which approximates cost plus accrued interest.

Patents

In accordance with FASB No. 2, the costs of intangibles that are purchased from others for use in research and development activities and that have alternative future uses are capitalized and amortized. We capitalize certain patent rights that are believed to have future economic benefit. The licensed capitalized patent costs were recorded based on the estimated value of the equity security issued by us to the licensor. The value ascribed to the equity security took into account, among other factors, our stage of development and the value of other companies developing extracorporeal bioartificial liver assist devices. These patent rights are amortized using the straight-line method over the remaining life of the patent. Certain patent rights received in conjunction with purchased research and development costs have been expensed. Legal costs incurred in obtaining, recording and defending patents are expensed as incurred.

Stock-Based Compensation

SFAS No. 123, "Accounting for Stock-Based Compensation," as in effect prior to December 2004, established and encouraged the use of the fair value based method of accounting for stock-based compensation arrangements under which compensation cost is determined using the fair value of stock-based compensation determined as of the date of grant and is recognized over the periods in which the related services are rendered. The statement also permitted companies to elect to continue using the current intrinsic value accounting method specified in Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," to account for stock-based compensation. To date, we have used the intrinsic value based method and have disclosed the pro forma effect of using the fair value based method to account for our stock-based compensation. For non-employee stock based compensation, we recognized an expense in accordance with SFAS No. 123 and value the equity securities based on the fair value of the security on the date of grant. The fair value of expensed options is estimated using the Black-Scholes option-pricing model. In December 2004, the FASB issued SFAS No. 123 (revised 2004), “Share-Based Payment”. Statement 123(R) requires that the compensation cost relating to a wide range of share-based payment transactions (including stock options) be recognized in financial statements. That cost will be measured based on the fair value of the equity instruments issued. Statement 123(R) replaces FASB Statement No. 123 and supersedes APB Opinion No. 25. As a small business issuer, we will be required to apply Statement 123(R) to reporting periods that begin on January 1, 2006.

New Accounting Pronouncements

In December 2004, the FASB issued SFAS 123(R) (revised 2004), “Share-Based Payment”. SFAS 123(R) will provide investors and other users of financial statements with more complete and neutral financial information by requiring that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. SFAS 123(R) covers a wide range of share-based compensation arrangements including share options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. SFAS 123(R) replaces SFAS No. 123, “Accounting for Stock-Based Compensation”, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS 123, as originally issued in 1995, established as preferable a fair-value-based method of accounting for share-based payment transactions with employees. However, SFAS 123(R) permitted entities the option of continuing to apply the guidance in APB Opinion 25, as long as the footnotes to financial statements disclosed what net income would have been had the preferable fair-value-based method been used. Our Company will be implementing SFAS 123(R) as of January 1, 2006, and the projected additional expense is approximately $400,000 based upon options granted as of December 31, 2005.

In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 107 (SAB 107) regarding the Staff's interpretation of SFAS 123(R). This interpretation expresses the views of the Staff regarding the interaction between SFAS 123(R) and certain rules and regulations and provides the Staff's views regarding the valuation of share-based payment arrangements for public companies. In particular, this SAB provides guidance related to share-based payment transactions with no employees, the transition from nonpublic to public entity status, valuation methods, the accounting for certain redeemable financial instruments issued under share-based payment arrangements, the classification of compensation expense, non-GAAP financial measures, first-time adoption of SFAS 123(R) in an interim period, capitalization of compensation cost related to share-based payment arrangements, the accounting for income tax effects of share-based payment arrangements upon adoption of SFAS 123(R), the modification of employee share options prior to adoption of Statement 123(R) and disclosures in Management's Discussion and Analysis subsequent to adoption of SFAS 123(R). Our company will adopt SAB 107 in connection with its adoption of SFAS 123(R).

In May 2005, the FASB issued SFAS 154, “Accounting Changes and Error Corrections - a replacement of APB Opinion No. 20 and FASB Statement No. 3.” SFAS 154 replaces APB Opinion No. 20, “Accounting Changes,” and FASB Statement No. 3, “Reporting Accounting Changes in Interim Financial Statements” and changes the requirements

for the accounting for and reporting of a change in accounting principles. This statement applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 31, 2005.

In February of 2006 the Financial Accounting Standards Board issued Statement No. 155, "Accounting for Certain Hybrid Financial Instruments: an amendment of FASB Statements Numbers 133 and 140". Management is currently evaluating the effect, if any, that such pronouncement will have on accounting for our company's equity instruments which were issued with detachable warrants.

Results of Operations

Comparison of Fiscal Year ended December 31, 2005 to Fiscal Year ended December 31, 2004.

Since we are still developing our products and do not have any products available for sale, we have not yet generated any revenues from sales. Revenues for fiscal year 2004 of $72,030 represent revenues recognized from government research grants that we have received.

General and administrative expenses of $2,394,546 and $1,988,763 were incurred for the years ended December 31, 2005 and 2004, respectively. For the year ended December 31, 2005, the expenses include $745,000 in fees incurred to outside consultants, professionals and board member fees, $509,000 in payroll and payroll related costs, $477,000 in non-cash option and warrant charges for grants awarded to consultants, $187,000 in investor relation costs and other administrative expenses. For the year ended December 31, 2004, the expenses include $945,000 in non-cash option and warrant charges for grants awarded to consultants, $587,000 in fees incurred to outside consultants and professionals, and $179,000 in salaries and other administrative expenses. Professional fees increased in 2005 due to consulting services for marketing, recruiting fees, and board of directors fees. The reduction in non-cash option and warrant charges reflect the lower stock price in 2005 and fewer option and warrant grants in 2005. The 2005 increase in payroll and payroll related expenses reflects the hiring of an interim and later a permanent Chief Executive Officer in 2005 and employee bonuses.

Research and development expenses of $1,554,509 and $1,426,379 were incurred for the years ended December 31, 2005 and 2004, respectively. Research and development expenses for 2005 consist primarily of $414,000 in payroll and payroll related expenses, $362,000 in SEPET™ development, manufacturing and clinical costs, $226,000 in consultant costs related to manufacturing, regulatory and product management, $141,000 in employee costs from Cedars-Sinai and $108,000 in HepatAssist2™ facility costs. Research and development expenses for the 2004 consist primarily of $450,000 of purchased research and development from Circe Biomedical, Inc., $282,000 incurred for various research and development consultants for manufacturing, regulatory and product management, $281,000 in employee costs from Cedars-Sinai, $151,000 in SEPET™ and HepatAssist2™ development costs and $101,000 non cash option grant charges for options awarded to scientific consultants. Research and development costs increased by $128,130 from 2004 to 2005 and reflect increased expenditures for both the SEPET™ and HepatAssist2™ programs and increased payroll costs as we increased staff which replaced employee costs from Cedars-Sinai and certain consulting costs and the write off of certain patents which have no future commercial use or economic benefit to us.

Interest income of $125,286 and $16,132 was earned for the years ended December 31, 2005 and 2004 respectively. The increase in interest income of $109,154 results from the increase in short term interest rates and higher cash balances maintained in 2005. In January 2005, we raised gross proceeds of $6,611,905 in the private placement of our securities which resulted in the higher cash balances in 2005. Our net loss increased to $3,823,903 in 2005 from $3,327,827 in 2004. The increase in net loss is attributed to an increase in operating expenses incurred in the fiscal 2005 periods as compared to the same periods in 2004, without an increase in revenues.

Liquidity and Capital Resources

As of December 31, 2005, we had cash of $2,379,738 and short term investments of $1,996,000. We do not have any bank credit lines. To date, we have funded our operations from the sale of debt and equity securities and from government research grants.

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

On March 6, 2006, we completed a $1,350,000 private equity financing to a group of institutional investors and accredited investors. In the offering, we sold 1,227,272 shares of our common stock at a price of $1.10 per share to the investors and issued to them warrants to purchase an additional 613,634 shares of our common stock at an exercise price of $1.50 per share. The warrants are exercisable for a period of five years.

Based on our current plan of operations and the private placement we completed on March 6, 2006, we believe that our current cash balances will be sufficient to fund our foreseeable expenses for at least the next twelve months.

We do not currently anticipate that we will derive any revenues from either product sales or from governmental research grants during the current fiscal year. Although we are planning to submit an application for an additional SBIR research grant during 2006, no assurance can be given that the grant application will be approved. Even if the grant is approved, it is unlikely that we would receive any grant funds during the current fiscal year.

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

A summary of our contractual cash obligations at December 31, 2005 is as follows:

Contractual Obligations	Total	2006	2007	2008 and thereafter
Long-Term Office Leases	$395,000	$286,000	$109,000	$-0-

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

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

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

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

RISKS RELATED TO OUR BUSINESS

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

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

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

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

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

The development, production and marketing of our products are subject to extensive regulation by government authorities in the United States and other countries. In the United States, our SEPET™ Liver Assist Device and our HepatAssist-2™ Bioartificial Liver System will require approval from the FDA prior to clinical testing and commercialization. The process for obtaining FDA approval to market therapeutic products is both time-consuming and costly, with no certainty of a successful outcome. This process includes the conduct of extensive pre-clinical and clinical testing, which may take longer or cost more than we currently anticipate due to numerous factors, including, without limitation, difficulty in securing centers to conduct trials, difficulty in enrolling patients in conformity with required protocols and/or projected timelines, unexpected adverse reactions by patients in the trials to our liver assist systems, temporary suspension and/or complete ban on trials of our products due to the risk of transmitting pathogens from the xenogeneic biologic component, and changes in the FDA's requirements for our testing during the course of that testing. We have not yet established with the FDA the nature and number of clinical trials that the FDA will require in connection with its review and approval of either SEPET™ or our HepatAssist-2™ products and these requirements may be more costly or time-consuming than we currently anticipate.

Each of our products in development is novel both in terms of its composition and function. Thus, we may encounter unexpected safety, efficacy or manufacturing issues as we seek to obtain marketing approval for products from the FDA, and there can be no assurance that we will be able to obtain approval from the FDA or any foreign governmental agencies for marketing of any of our products. The failure to receive, or any significant delay in receiving, FDA approval, or the imposition of significant limitations on the indicated uses of our products, would have a material adverse effect on our business, operating results and financial condition. The health regulatory authorities of certain countries, including those of Japan, France and the United Kingdom, have previously objected, and other countries' regulatory authorities could potentially object, to the marketing of any therapy that uses pig liver cells (which our bioartificial liver systems are designed to utilize) due to safety concerns that pig cells may transmit viruses or diseases to humans. If the health regulatory agencies of other countries impose a ban on the use of therapies that incorporate pig cells, such as our HepatAssist-2™ bioartificial liver system, we would be prevented from marketing our products in those countries. If we are unable to obtain the approval of the health regulatory authorities in Japan, France, the United Kingdom or other countries, the potential market for our products will be reduced.

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

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

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

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

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

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

Use of liver cells harvested from pig livers carries a risk of transmitting viruses harmless to pigs but possibly deadly to humans. For instance, all pig cells carry genetic material of the porcine endogenous retrovirus, or PERV, but its ability to infect people is unknown. Repeated testing, including a 1999 study of 160 xenotransplant (transplantation from animals to humans) patients and the Phase II/III testing of the HepatAssist system by Circe Biomedical, Inc., has produced no sign of the transmission of PERV to humans. Still, no one can prove that PERV or another virus would not infect bioartificial liver-treated patients and cause potentially serious disease. This may result in the FDA or other health regulatory agencies not approving our HepatAssist-2™ bioartificial liver system or subsequently banning any further use of our product should health concerns arise after the product has been approved. At this time, it is unclear whether we will be able to obtain clinical and product liability insurance that covers the PERV risk.

In addition to the potential health risks associated with the use of pig liver cells, our use of xenotransplantation technologies may be opposed by individuals or organizations on health, religious or ethical grounds. Certain animal rights groups and other organizations are known to protest animal research and development programs or to boycott products resulting from such programs. Previously, some groups have objected to the use of pig liver cells by other companies, including Circe Biomedical, Inc., that were developing bioartificial liver support systems, and it is possible that such groups could object to our HepatAssist-2™ bioartificial liver system. Litigation instituted by any of these organizations, and negative publicity regarding our use of pig liver cells in a bioartificial liver device, could have a material adverse effect on our business, operating results and financial condition.

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

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

Despite our recent $1.35 million private equity financing and current cash on hand, we still need to obtain significant additional capital to complete the development of our liver assist devices, which additional funding may dilute our existing stockholders.

Based on our current proposed plans and assumptions, we anticipate that our existing funds will be sufficient to fund our operations and capital requirements for at least the 12-month period following the date of this Annual Report. However, the clinical development expenses of our products will be very substantial. Based on our current assumptions, we estimate that the clinical cost of developing SEPET™ will be approximately $5 million to $10 million, and the clinical cost of developing HepatAssist-2™ will be between $15 million and $20 million, in excess of the cost of basic operations of the Company. These amounts, which could vary substantially if our assumptions are not correct, are well in excess of the amount of cash that we currently have available to us. Accordingly, we will have to (i) obtain additional debt or equity financing in order to fund the further development of our products and working capital needs, and/or (ii) enter into a strategic alliance with a larger pharmaceutical or biomedical company to provide its required funding. The amount of funding needed to complete the development of one or both of our products will be very substantial and may be in excess of our ability to raise capital.

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

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

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

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

Our business model calls for the outsourcing of the clinical development, manufacturing and marketing of our products in order to reduce our capital and infrastructure costs as a means of potentially improving the profitability of these products for us. We have not yet entered into any strategic alliances or other licensing or exclusive contract manufacturing arrangements and there can be no assurance that we will be able to enter into satisfactory arrangements for these services or the manufacture or marketing of our products. We will be required to expend substantial amounts to retain and continue to utilize the services of one or more clinical research management organizations without any assurance that the products covered by the clinical trials conducted under their management ultimately will generate any revenues for SEPET™ and/or HepatAssist™2. Consistent with our business model, we will seek to enter into strategic alliances with other larger companies to market and sell our products. In addition, we may need to utilize contract manufacturers to manufacture our products or even our commercial supplies, and we may contract with independent sales and marketing firms to use their pharmaceutical sales force on a contract basis.

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

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

We have an exclusive manufacturing arrangement with Spectrum Laboratories for our fiber-within-fiber LIVERAID™ cartridges, which we no longer intend to pursue. Although we have no agreement with Spectrum Laboratories for the manufacture of the SEPET™ cartridges, Spectrum Laboratories has also been providing us with cartridges for prototypes of SEPET™ and has expressed an interest in manufacturing the HepatAssist-2™ cartridge. Although Spectrum Laboratories has agreed to transfer all of the know-how related to these products to any other manufacturer of our products if Spectrum Laboratories is unable to meet its contractual obligations to us, we may have difficulty in finding a replacement manufacturer if we are unable to effectively transfer the Spectrum Laboratories know-how to another manufacturer. We have no control over Spectrum Laboratories or its suppliers, and if Spectrum Laboratories is unable to produce SEPET™ cartridges on a timely basis, our business may be adversely affected.

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

Because we are dependent on Medtronic, Inc. for the perfusion platform used in our HepatAssist-2™, any failure or delay by Medtronic to make the perfusion platform commercially available will negatively affect our future operations.

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

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

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

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

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

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

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

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

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

Our ability to successfully penetrate the market for our products may depend significantly on the availability of reimbursement for our products from third-party payers, such as governmental programs, private insurance and private health plans. We have not yet established reimbursement guidelines with Medicare, its counterparts in other countries, or any third-party payers .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 or other regulatory approval in foreign countries, 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