ARBIOS SYSTEMS INC
Form 10KSB
April 17, 2007

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

**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, 2006

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.) |
| **1050 Winter Street, Suite 1000, Waltham, MA** | **02451** |
| (Address of principal executive offices) | (Zip Code) |

Issuer's Telephone Number**: 781-839-7293**

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 29, 2007 was approximately $7,659,000 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 29, 2007.

**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 belie similar language. The forward-looking statements are based on our current expectations and are subject to certain risks, uncertainties and assumptions, including those set forth in the discussion under “Description of Business” and “Management’s Discussion and Analysis or Plan of Operation - Factors that May Affect Future Results and Market Price of Our Stock.” Our actual results may differ materially from results anticipated in these forward-looking statements. We base our forward-looking statements on information currently available to us, and we assume no obligation to update them. For a discussion of some of the factors that may cause actual results to differ materially from those suggested by the forward-looking statements, please read carefully the information under “Management’s Discussion and Analysis or Plan of Operation - Factors that May Affect Future Results and Market Price of Our Stock.”

**Restatement of Financial Statements**

In January 2005 and March 2006 we closed financing transactions that included the issuance of warrants and the grant of registration rights. The Company has been accounting for the warrants in accordance with pronouncement EITF 00-19. Beginning in the quarter ended March 31, 2006 for the warrants issued in the January 2005 financing and in the quarter ended September 30, 2006 for the warrants issued in the March 2006 financing, in accordance with EITF 00-19, the Company recorded the fair value of these warrants as an accrued warrant liability and reduced additional paid-in capital by the amount of the recorded liability. In the quarters ended June 30, and September 30, 2006 changes to the accrued liability were reported in the Company’s statement of operations. However, the Company has determined that it should have included in the calculation of the fair value of the warrant the value of the anti-dilution provisions contained in the warrant agreements. The calculations of the fair value of the warrants did not include the value of the anti-dilutions provision for the filed financial statements included in our Form 10-QSB for the quarters ended March 31, 2006, June 30, 2006, and September 30, 2006. Therefore, we restate our financial statements for these periods as follows: 1) for the three month period ended March 31, 2006, additional paid in capital is decreased by $271,000 with a corresponding increase in the accrued warrant liability, 2) for the three and six month periods ended June 30, 2006, other expense is increased by $63,000 with a corresponding increase in the accrued warrant liability, and 3) for the three month period ended September 30, 2006, additional paid in capital is decreased by $114,000 and other expense is increased by $49,000 with a corresponding increase in the accrued warrant liability of $163,000. For the nine month period ended September 30, 2006 additional paid-in capital is decreased by $385,000, other expense is increased by $112,000, and the accrued warrant liability is increased by $497,000.

| | Three months ended March 31, 2006 | Three months ended June 30, 2006 | Six months ended June 30, 2006 | Three months ended Sept. 30, 2006 | Nine months ended Sept. 30, 2006 |
|---|---|---|---|---|---|
| Net loss | | | | | |
| As originally reported | $ (1,069,468) | $ (837,202) | $ (1,906,670) | $ (1,081,410) | $ (2,988,080) |
| Adjustment | | (63,000) | (63,000) | (49,000) | (112,000) |
| As adjusted | $ (1,069,468) | $ (900,202) | $ (1,969,670) | $ (1,130,410) | $ (3,100,080) |

| | | | |
|---|---|---|---|
| Accrued warrant liability | | | |
| As originally reported | $ 680,841 | $ 407,717 | $ 524,172 |
| Adjustment | 271,000 | 334,000 | 497,000 |
| As adjusted | $ 951,841 | $ 741,717 | $ 1,021,172 |
| | | | |
| Additional paid-in capital | | | |
| As originally reported | $ 14,190,980 | $ 14,296,357 | $ 14,307,052 |
| Adjustment | (271,000) | (271,000) | (385,000) |
| As adjusted | $ 13,919,980 | $ 14,025,357 | $ 13,922,052 |

**PART I**

**ITEM 1. DESCRIPTION OF BUSINESS.**

**Company Overview**

Arbios Systems, Inc., or Arbios, is a Delaware corporation based in Waltham, Massachusetts and 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™ Cell-Based Liver Support System that incorporate porcine pig liver cells. We currently own five issued U.S. patents and six issued foreign patents, and are the licensee of sixteen other issued U.S. patents, as well as the owner or licensee of eight patent applications 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 to 20 patient feasibility clinical study of our SEPET™ Liver Assist Device, targeted for the treatment of acute episodes of chronic liver disease. We have currently enrolled 15 patients and are thus in the final stages of completing the feasibility study. We are currently completing the monitoring and analysis of the data from the 15 enrolled patients. We are encouraged by the preliminary data and intend to submit it to the Food and Drug Administration in preparation for a pivotal trial for SEPET™. We further intend to use the data, once our analysis is complete, in support of gaining the CE Mark for SEPET™ in Europe.

Our HepatAssist™ Cell-Based Liver Support System is an enhanced version of a product system which we acquired in 2003 from another company, Circe Biomedical, Inc., which had tested HepatAssist™ in an unsuccessful Phase II/III pivotal clinical trial. We currently hold a Phase III investigational new drug application, or IND, for conducting an additional pivotal clinical trial of the HepatAssist™ system. Our current plan is to focus on reintroducing this important liver assist technology into clinical development in the U.S. and in Asia to the extent that we obtain additional funding for this program from a potential corporate marketing partner. We are currently seeking such a partnership.

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 1050 Winter Street, Suite 1000, Waltham, Massachusetts 02451 and our telephone number is 781-839-7293. We also maintain corporate offices at 8797 Beverly Blvd., Suite 304, Los Angeles, California 90048 and our telephone number is (310) 657-4898. We also maintain a web site at www.arbios.com. The information on our web site is not, and you should not consider such information to be, a part of this filing.

**Products Overview**

We currently have one product under active development; a novel extracorporeal blood purification therapy called the SEPET™ Liver Assist Device. We also have an additional product which is an extracorporeal, bioartificial liver therapy referred to as the HepatAssist™ Cell-Based Liver Support System that incorporates pig liver cells, or porcine hepatocytes. We have postponed further clinical development of our HepatAssist™ program until we are able to secure additional funding for this project from a potential corporate partner.

SEPET™ is a single-use disposable plastic 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 are transported convectively across the porous fiber 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. Our belief is based on the encouraging preliminary results of the SEPET™ feasibility clinical trial, which is being conducted at prominent liver disease treatment hospitals in the U.S. The data, which remains subject to monitoring and analysis, is preliminary and reflects numerous apparent responses of hepatic encephalopathy associated with acute-on-chronic liver failure to SEPET™ treatment as well as a favorable safety profile to date. These results, if demonstrated by the final data from this study, will need to be statistically proven in a further, randomized, controlled clinical trial and reviewed by the FDA and other regulatory agencies. SEPET™ is designed for use with commercially available kidney hemodialysis systems and/or blood plasma apheresis systems that utilize hollow-fiber cartridges for dialysis and related hemoperfusion procedures.

In April 2004, we acquired from Circe Biomedical, Inc., an unaffiliated biomedical company, the rights to a bioartificial liver, known as the HepatAssist™ Cell-Based Liver Support 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™ Cell-Based Liver Support 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 system, substances normally

metabolized by the liver and accumulated in the blood during liver failure move across the porous fiber walls into two sequential 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 concentration level. At the same time, substances produced by pig liver cells move in reverse across the porous wall back into the blood compartment. In addition, the sorbents lower the level of other pathological blood components, such as ammonia. 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 in the patient's body. Our belief is supported by the results of tests performed during clinical trials using the HepatAssist™ system.

Our HepatAssist™ Cell-Based Liver Support System is similar to the earlier HepatAssist™ system, and we have subsequently enhanced it by employing a larger quantity of pig cells, a change which has been authorized by the U.S. FDA for use in a new pivotal clinical trial. We do not anticipate that HepatAssist™ will use the Circe-designed proprietary perfusion platform, which is a machine through which the patient's blood is circulated, that was originally developed for the HepatAssist™ system. Instead, we have validated 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 specialized tubing set for use with our HepatAssist™ Cell-Based Liver Support System.

Both SEPET™ and HepatAssist™ rely on single-use disposable 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. Achilles A. Demetriou and Jacek 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 most recently tested in a Phase II/III clinical trials authorized by the FDA in patients with fulminant and subfulminant liver failure and primary non-function following liver transplantation, i.e. closely related acute liver failure indications. These trials of the original HepatAssist™ system were the first and amongst the largest (171 patients) prospective, randomized, controlled multi-center trials of a liver assist technology, and the only such trial to have been successful in demonstrating a survival advantage for an extracorporeal liver assist technology, albeit via a retrospective analysis. 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 (overall comparison of 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 $13,100,000 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 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 ("Cedars-Sinai"), Los Angeles, California. Cedars-Sinai Medical Center is also one of the clinical testing sites for our SEPET™ clinical testing program. Under our lease agreement and other arrangements with Cedars-Sinai, we have access to their development resources of that leading medical center, including animal facilities, surgical facilities and clinical laboratories. The Hospital has informed us that they do not intend to renew the lease when it expires on June 30, 2007, and we intend to seek a new laboratory facility for testing our device. We are currently seeking to identify replacement laboratory space in eastern Massachusetts. We also lease administrative office space in Waltham, Massachusetts and Los Angeles, California.

Two members of our management team, Dr. Ulrich Baurmeister, Ph.D., Chief Technology Officer, and Prof. Jan Stange, M.D., Senior Clinical Advisor, are engaged under consulting agreements and are based in Germany (Wuppertal and Rostock, respectively). Their work is divided between their homes, clinical sites and product development sites under contract with the Company.

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™ Cell-Based Liver Support 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™ 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 instrument, we expect that the development of SEPET™ will be completed before the development of HepatAssist™ is completed.

We have already performed *in vitro* and *in vivo* testing of the SEPET™ prototype device and commenced clinical testing of SEPET™ in late 2005. To date, 15 patients suffering from acute-on-chronic liver failure with hepatic encephalopathy have been enrolled in the U.S. clinical feasibility trial of SEPET™. Our strategy for realizing sales revenue for the Company is to seek the first commercialization of SEPET™ under the CE Mark in Europe, which we believe may be possible by 2008. It may also be possible to commercialize SEPET™ in Asia in that same timeframe, although we do not yet have assurance of regulatory pathways in that region. Commercialization of SEPET™ in the US may follow completion of a pivotal clinical trial of SEPET™ intended for U.S. FDA market approval of the product. Our ability to successfully market SEPET™ in these various regions will depend on a number of factors including regulatory approvals, marketing and sales partnerships, and patents protection which is not yet issued outside the United States.

We are currently evaluating the possibility of conducting clinical studies of the HepatAssist™ 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™ Cell-Based Liver Support System, and since our continual development of this product depends on our securing a corporate collaboration and associated funding, 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 opportunities for the development of a bioartificial liver. The Circe Biomedical bioartificial liver device assets that we acquired consist of the following four distinct elements:

(1) *FDA-authorized 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 for use in a pivotal phase clinical trial.

(2) *The cartridge to be used in the Phase III trial of HepatAssist™*. We intend to use the existing, FDA-approved cartridge housing, and we have obtained FDA authorization to increase the number of porcine hepatocyte cells that the cartridge would contain, which increase we believe will improve the functionality of the system with no adverse impact on safety.

(3) *An FDA reviewed, authorized Phase III protocol acquired from Circe Biomedical*. We will likely further modify this protocol, according to the retrospective analysis of the original Phase II-III clinical trial published in the *Annals of Surgery* in 2004 (by A.A. Demetriou et al), and submit the modified protocol to the FDA for approval.

(4) *The HepatAssist™ perfusion instrument platform.* The HepatAssist™ perfusion platform is Circe Biomedical's specially designed machine that pumped the patient's plasma through the 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 believe that the PERFORMER may become the platform for our HepatAssist™ Cell-Based Liver Support 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 to 20 patient clinical feasibility study for SEPET™. We have enrolled 15 patients in our SEPET™ feasibility clinical trial and are currently monitoring and analyzing the trial results for these first 15 patients. Based on our current analysis of the data in preliminary form, we plan to submit the fully monitored and analyzed data to the FDA in the next several months along with a protocol summary for a proposed, randomized, controlled pivotal trial to further test the efficacy of the device for purposes of product approval in the U.S. Based on our current assumptions regarding clinical trial sizes and other factors, we estimate that the future clinical cost of developing SEPET™ will be approximately $5 million to $10 million and the future clinical cost of developing HepatAssist™ 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. We believe that treatments with currently available technologies such as blood detoxification methods are short-term measures, and none of them has achieved wide-spread clinical use or demonstrated ability in randomized, controlled clinical trials 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 liver 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 subjects.

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 liver systems using viable isolated liver cells, or hepatocytes, can provide whole liver functions, to varying degrees depending on the technology approach. 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, primary porcine hepatocyte therapy should be combined with blood purification or detoxification using sorbent technology.

Our bioartificial liver system, the HepatAssist™ Cell-Based Liver Support System, was designed to become an advanced, effective application of the basic bioartificial liver concept. In this bioartificial liver system, liver cell therapy in the form of primary (i.e. living, non-cell line derived) porcine hepatocytes, is combined with blood detoxification, in the form of sorbent based plasma treatment. 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. Pre-clinical data for the HepatAssist™ Cell-Based Liver Support System indicated that this system could improve heart rate and blood pressure and provide clearance of ammonia and indocyanine green (ICG), which is a liver function test. The original HepatAssist™ Phase II/III clinical trial demonstrated a retrospective, statistically significant increase in patient survival in patients with viral and drug-induced fulminant/subfulminant (i.e. acute) hepatic failure. However, a new Phase III clinical trial will be needed before our HepatAssist™ system, which is an enhanced version of the original HepatAssist™ system, can be commercialized.

**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™ Cell-Based Liver Support 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 (act as a "bridge" to liver regeneration);
- support patients during periods of functional recovery and regeneration after liver 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; and
- reduce the cost of care.

We believe that our SEPET™ Liver Assist Device and HepatAssist™ Cell-Based Liver Support System can achieve these effects because they can lower blood levels of substances that are toxic to both the brain and liver. We have obtained preliminary results in the U.S. feasibility clinical trial of SEPET™, and have results from Circe's Phase II-III clinical trial of HepatAssist™. However, final proof of clinical benefit in patients is lacking at this time, and the clinical utility of these products still needs to be conclusively demonstrated in patients with liver failure via randomized, controlled clinical trials of each therapy.

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 filtering a portion of the substances in the patent's blood including albumin-bound toxins, inflammatory disease mediators, and soluble toxins. The importance of using fibers with this sieving characteristic, which allows filtration of moledules larger than for conventional renal dialysis cartridges, is that known hepatic failure toxins as well as mediators of inflammation and inhibitors of hepatic regeneration have low-to-medium sized molecular weights while "good" blood components, for the most part, have relatively high molecular. At present, Spectrum Laboratories is the manufacturer of these disposable cartridges. See "Manufacturing" below. The SEPET™ system is designed for use with commercially available kidney dialysis instruments or other similar machines that utilize disposable hollow-fiber cartridges. Accordingly, no specialized apparatus needs to be developed or manufactured for SEPET™. Accessory components for the SEPET™ system such as disposable tubing sets 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 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. Preliminary results of the SEPET™ U.S. feasibility clinical trial encourage us that these expectations may be realized in human therapy using SEPET™, but these results need to be further monitored, analyzed and finalized, and then will be acquired in a further, randomized, controlled pivotal trial.

**HepatAssist™ Cell-Based Liver Support System**

Our current bioartificial liver system is the HepatAssist™ Cell-Based Liver Support System. We have designed our HepatAssist™ Cell-Based Liver Support System to provide temporary liver support during acute liver failure and acute exacerbation of chronic liver disease. The HepatAssist™ Cell-Based Liver Support 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™ Cell-Based Liver Support 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). We have postponed further clinical development of our HepatAssist™ program until we are able to secure additional funding for this project from a potential corporate partner.

Critical to the HepatAssist™ technology is (i) the source and method of procurement of liver cells, (ii) the cryopreservation, or freezing, of the liver cells, (iii) the frozen storage of the liver cells, (iv) the proprietary high speed 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™ system and should provide competitive protection for the product. 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 thus human hepatocytes of adequate quality. Published data demonstrate 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, which we believe to be the currently optimal source of living, functional hepatocytes.

**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; other methods allow cells to lose viability (i.e. die) as well as physical integrity of their contents (DNA, organelles, etc.). 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. Important, 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 a facility to be certified specifically by the United States Department of Agriculture (USDA) 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 and 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.

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HepatAssist™ is designed to be used in the same manner as any other blood 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 disposable tubing set 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™ 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 cartridge. We have postponed further clinical development of our HepatAssist™ program until we are able to secure additional funding for this project from a potential corporate partner.

**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 have been 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 in hospitals and outpatient clinics and, therefore, there may be a reduced need for extensive personnel training for use of these similar systems with SEPET™. They are commonly available in intensive care units and related settings where SEPET™ may be initially used for treating acute episodes of chronic liver failure

- Reduced cost. The cost of therapy is expected to be lower than with other liver assist devices that are 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. However further (e.g. Phase IV) clinical trials will likely be necessary to fully develop these additional indications for SEPET™.

We believe that HepatAssist™ 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 can remain alive (e.g. >80% viability) after freezing and thawing using carefully developed, patented procedures. 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 within 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).

While these projected advantages appear supported by the clinical trial data evidence to date, some of these product functions may need to be tested in head-to-head trials with competitive approaches.

**Clinical Utility**

Our SEPET™ Liver Assist Device is currently undergoing human testing in an IDE clinical feasibility trial in the US, with patients suffering acute exacerbation of chronic liver failure with hepatic encephalopathy. This 15 to 20 patient clinical trial was authorized by the FDA in 2005, and we have currently enrolled 15 patients in the trial. Based upon our preliminary review of data in the first ten patients enrolled in the trial, a favorable safety profile was established and a majority of patients accomplished a two stage grade improvement in hepatic encephalopathy severity, the clinical effectiveness endpoint of the trial. We have recently announced preliminary results with 15 patients enrolled in the clinical trial, which further bear out these earlier published results. We further plan to request a meeting with the FDA to review the data and to propose a design for a randomized, controlled, pivotal clinical trial of SEPET™ intended to be sufficient for FDA allowance of a future pre-market approval application by the Company and to confirm and prove what we believe to be encouraging results of the current single arm, uncontrolled feasibility clinical trial.

Our HepatAssist™ Cell-Based Liver Support System is an enhanced version of the original HepatAssist™ system. Overall, we believe that the animal and human 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 over earlier technologies.

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™ Cell-Based Liver Support 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™ Cell-Based Liver Support System are designed to treat patients with liver failure across a wide range of causes and severity, including acute exacerbation of chronic liver disease as well as acute liver failure in patients without history of chronic disease.

Arbios believes that the patient and market opportunity is substantial and underserved. According to the American Liver Foundation, 25,000,000 persons in the United States, nearly one in every ten persons, are or have been suffering from liver and biliary diseases. According to the National Center for Health Statistics data published for 2004, there were over 500,000 hospital discharges for patients with chronic liver disease and/or cirrhosis plus additional patients categorized as suffering from other forms of liver failure. Liver failure is reported as the tenth leading cause of death in the U.S., 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 4 million Americans are chronically infected with the hepatitis C virus, and an estimated 25,000 people each year are newly 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. Hepatitis B is less prevalent in the U.S. than hepatitis C - a situation that is dramatically reversed in other parts of the world where chronic hepatitis B infection is endemic or pandemic; however, 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 the 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 most urgent. 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 dependable 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 $10,000 per day. While liver transplants have significantly increased the chances of survival for patients with liver failure, due to a severe shortage of donor livers, far 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 HepatAssist™ therapy could be approximately $15,000 to $20,000 in the United States. Pricing in other world regions will likely vary. We anticipate that SEPET™ and/or HepatAssist™ therapy may have to be repeated up to an average of three to five 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™ 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. Our direct marketing and sales operations may, in these cases, eventually be directed towards supporting sales and distribution activities of any future partner. We currently expect that our products will be marketed in at least North America and Europe, and possibly in Asia. We are currently seeking a commercialization partner for HepatAssist™ and plan to do the same for SEPET™, for some world regions, in the next two years.

**Manufacturing**

We currently do not have a finalized manufacturing arrangement for the cartridges used in the HepatAssist™ system, although our plan is to hopefully establish such relationship(s) in the near future. The HepatAssist™ cartridge is based on a conventional single-bundle hollow-fiber technology and a number of third party manufacturers 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, which are cartridges containing porous membranes used to filter blood. Spectrum Laboratories, Inc. is a provider of hemodialysis products and is based in Los Angeles, California. Additional disposable components, such as tubing kits, may also be manufactured by third party subcontractors.

The kidney dialysis systems 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 instruments will not be affected, only the kidney dialysis cartridge will be replaced by a SEPET™ cartridge, we do not anticipate that 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. Nevertheless, manufacturers of such instruments may in the future have incentives to form partnerships with us for marketing and distribution of disposables, either as stand-alone products or as integrated systems of disposables for use on their instruments.

The platform we currently expect to use for the HepatAssist™ 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™ 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 Phase III clinical testing of HepatAssist™, we will determine whether to build a cell procurement facility to meet the expected requirements for commercial sales, which will likely 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.

**Patents and Proprietary Rights**

Liver Assist Device Rights. Our intellectual property rights relating to the SEPET™ Liver Assist Device consist of a U.S. patent application plus pending foreign counterpart applications, a family of in-licensed U.S. patents plus foreign counterparts and pending patent applications, and certain related trade secrets.

Our U.S. patent application and foreign counterparts regarding our selective plasma filtration therapy (SEPET™) technology was filed in August 2002 with the United States Patent and Trademark Office and European Patent Office and subsequently in other countries and is currently under review for possible issuance. The applications contain claims for the use of various hemofiltration apparatus to treat liver failure and related diseases, as well as claims covering the hemofiltration apparatus itself.

In March 2007, we in-licensed a family of issued U.S. patents and various U.S. and foreign patent applications which include broad claims for methods of treating liver failure, multi-organ failure, multi-organ dysfunction syndrome, sepsis, septic shock, systemic inflammatory response syndrome, and related inflammatory disorders by selective blood filtration. The patents and applications relate to the use of blood filtration devices which remove, from the blood of patients with the above disease conditions, a broad spectrum of inflammatory and other disease mediators ranging from small molecules through intermediate size blood proteins with molecular weights up to the size of beneficial immunoglobulins. Such devices are capable of removing known “bad actor” compounds associated with liver failure,

multi-organ failure and sepsis while preserving critical immunogloblins, clotting factors, lipids, and other beneficial large proteins in the circulating blood of afflicted patients. The patents and/or applications also relate to the combined use of replacement fluids including human serum albumin or combined uses of secondary selective plasma adsorption devices and/or certain classes of anti-inflammatory therapeutic drugs, and to apparatus suitable for the above uses.

Included in this in-licensed family are five issued U.S. patents, four pending U.S. patents, and two pending European patents. We will owe royalties on net sales of products which are covered by the license, including potentially the SEPET™ Liver Assist Device. We will also owe maintenance fees and certain other minimum spending obligations under the license and may owe contingent milestone fees. Our fixed obligations under the license will total less than $500,000 over the next 4 years, a portion of which includes spending on future product development possibly leading to future sales revenues for Arbios. Our contingent obligations under the license will total less than $500,000 over approximately the same period (however dependent on the pace of potential future patent issuances).

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 Medical 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 also a stockholder of this company. See Note 7, “Junior Preferred Stock” of the financial statements.

*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 U.S. patents and patent applications that we acquired from Circe Biomedical and that we expect to maintain and use with our bioartificial liver system:

(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) Cell Innoculation Device. US Patent #5,891,713 (issued on April 6, 1999).

(5) Method of Thawing Cryopreserved Cells. US Patent #5895745 (issued on April 20, 1999).

(6) High Flow Technique for Harvesting Mammalian Cells. US Patent #5912163 (issued on June 15, 1999).

(7) Removal of Agent From Cell Suspension. US Patent #6068775 (issued on May 30, 2000).

(8) Method for Cryopreserving Hepatocytes. US Patent #6136525 (issued on October 24, 2000).

Many of these issued U.S. patents have issued foreign counterparts including in Europe and in Japan.

Pending Patent Applications

| Patent No. | Country | Title of Patent Application |
|---|---|---|
| 515326/97 | JP | Cryopreserved Hepatocytes & High Viability and Metabolic Activity |

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™ system under a modified version of the FDA-approved Phase III IND protocol that we acquired, but must raise additional funds for this project. 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™ system, it is likely that we will have to pay

this royalty with respect of sales of those parts of our HepatAssist™ Cell-Based Liver Support 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 and will expire after the ten year period or last patent right has terminated.

(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™ Cell-Based Liver Support 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. The royalty obligations expire after the ten year period has elapsed.

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.

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

**Research and Development**

We spent a total of $1,823,000 on research and development during the fiscal year ended December 31, 2006, $1,555,000 on research and development during the fiscal year ended December 31, 2005 and $1,426,000 on research and development during the fiscal year ended December 31, 2004. 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.”

**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.

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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 predecessor companies 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 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. This trial has been reported to be initiated with no results yet formally reported, although the company has issued favorable press releases regarding progress and preliminary results of the trial.

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 IDE (in the case of a medical device such as SEPET™) or an IND (in the case of a drug or a combination product such as HepatAssist™) is filed with the FDA to begin human testing. Typically, a two-phase (for devices) or a three-phase (for drugs) clinical testing program is then undertaken. In phase 1 or feasibility phase, small clinical trials are conducted to determine the safety of the product. In phase 2 (typically not required for devices), clinical trials are conducted to assess safety and gain preliminary evidence of the efficacy of the product. In phase 3 or pivotal phase, clinical trials are conducted to provide sufficient data for the statistically valid proof of safety and efficacy. Variations on these paths can also occur, and repetition of particular phases may be required.

The time and expense required to perform this clinical testing can vary and be very substantial. No action can be taken to market any new device, drug or combination 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.

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In addition to regulating and auditing clinical trials, the FDA regulates and usually 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 (PMA) Application requires more extensive pre-filing testing than the 510(k) Notification procedure and involves a significantly longer FDA review process, although the process is typically less than for a new drug or combination product (in part because of the two-phase vs. three-phase clinical trial process described above).

SEPET™ may be regulated in the U.S. as a Class III medical device requiring a PMA review process, similar to medical devices for conducting plasma exchange; however, the FDA may classify it as a Class II device suitable for Section 510(k) approval (described above). We are currently in the process of designing a clinical trial to demonstrate the safety and efficacy of SEPET™ in treating patients with chronic liver failure, which we believe will be required for FDA approval of SEPET™ in case of either a PMA or a 510(k) review process. Accordingly, it is likely to be subject to a two-step approval process starting with a submission of an IDE and subsequent amendements to conduct human studies, followed by the submission of an application for Product Marketing Approval (PMA). The steps required before a product such as SEPET™ is likely to 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 IDE 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 IDE, 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 two sequential phases. Each trial must be reviewed and approved by the FDA before it can begin. The feasibility phase involves the initial introduction of the experimental product into human subjects to evaluate its safety and, if possible, to gain early indications of efficacy. The pivotal phase 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.

HepatAssist™ 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™ 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 HepatAssist™, 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™ Cell-Based Liver Support System. Finally, we will also have to re-establish an approved cell manufacturing capability or engage an approved third party provider of pig cells.

In addition to obtaining FDA approval, we will have to obtain the approval of the various foreign health regulatory agencies of the foreign countries in which we may wish to market our products. In Europe, we plan on seeking approval to market SEPET™ under the CE Mark and related device regulations which often require less clinical testing than comparable approval processes in the U.S. Label claims for medical devices marketed under the CE Mark are restricted to what has been proven in clinical trials, so initial efficacy claims are typically limited vs. those in the U.S. This can have an adverse impact on marketability of 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 system is expected to utilize) due to safety concerns relating to porcine endogenous viruses. 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, 2007, we employed six full-time employees and one part-time employee. We have also engaged seven independent contractors under consulting agreements who provide services to us on a substantial part-time basis. Of the foregoing employees and contractors, four are primarily engaged in administration or management, and the remaining ten persons are involved in scientific research, product development, clinical development, manufacturing 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.

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**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 $4,059 per month for the 628 square foot facility under the lease; however we have been informed by Cedars -Sinai Medical Center that they do not

intend to renew the lease when it expires in June 2007, and we will need to find a new laboratory facility. We currently intend to replace this laboratory space with similar space in eastern Massachusetts and plan to relocate certain personnel to manage that new facility. 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 our corporate headquarters and some of our executive management are located. The office lease, located at 1050 Winter Street, Suite 1000, Waltham, Massachusetts 02154, required us to pay a total of $18,040 for a period of seven months through June 30, 2006. The lease was extended in October 2006 at a rate of $5,102 per month, and is on a month to month basis.

We have also leased an animal breeding facility in Woodstock, Connecticut, originally intended to be used to harvest porcine livers for use in our HepatAssist™ 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. We do not intend to renew the lease for this facility when the term ends on March 31, 2007 and will likely not enter into any lease for replacement of this facility until additional funds are raised for the HepatAssist™ program.

**ITEM 3. LEGAL PROCEEDINGS.**

We are not a party to any material legal proceedings.

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

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

No matters were submitted to a vote of security holders during the quarter ended December 31, 2006.

**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.OB”. 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.OB” 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, 2005 | $ 1.66 | $ 1.60 |
| June 30, 2005 | $ 2.20 | $ 2.10 |
| September 30, 2005 | $ 1.90 | $ 1.80 |
| December 31, 2005 | $ 1.80 | $ 1.74 |
| | | |
| March 31, 2006 | $ 1.85 | $ 0.65 |
| June 30, 2006 | $ 1.25 | $ 0.90 |
| September 30, 2006 | $ 0.92 | $ 0.42 |
| December 31, 2006 | $ 0.79 | $ 0.46 |

**Holders**

As of March 6, 2007, there were 107 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 2006.

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

**Restatement of Financial Statements**

In January 2005 and March 2006 we closed financing transactions that included the issuance of warrants and the grant of registration rights. The Company has been accounting for the warrants in accordance with pronouncement EITF 00-19. Beginning in the quarter ended March 31, 2006 for the warrants issued in the January 2005 financing and in the quarter ended September 30, 2006 for the warrants issued in the March 2006 financing, in accordance with EITF 00-19, the Company recorded the fair value of these warrants as an accrued warrant liability and reduced additional paid-in capital by the amount of the recorded liability. In the quarters ended June 30, and September 30, 2006 changes to the accrued liability were reported in the Company's statement of operations. However, the Company has determined that it should have included in the calculation of the fair value of the warrant the value of the anti-dilution provisions contained in the warrant agreements. The calculations of the fair value of the warrants did not include the value of the anti-dilutions provision for the filed financial statements included in our Form 10-QSB for the quarters

ended March 31, 2006, June 30, 2006, and September 30, 2006. Therefore, we will restate our financial statements for these periods as follows: 1) for the three month period ended March 31, 2006, additional paid in capital is decreased by $271,000 with a corresponding increase in the accrued warrant liability 2) for the three and six month periods ended June 30, 2006, other expense is increased by $63,000 with a corresponding increase in the accrued warrant liability, and 3) for the three month period ended September 30, 2006, additional paid in capital is decreased by $114,000 and other expense is increased by $49,000 with a corresponding increase in the accrued warrant liability of $163,000. For the nine month period ended September 30, 2006 additional paid-in capital is decreased by $385,000, other expense is increased by $112,000, and the accrued warrant liability is increased by $497,000.

| | Three months ended March 31, 2006 | Three months ended June 30, 2006 | Six months ended June 30, 2006 | Three months ended Sept. 30, 2006 | Nine months ended Sept. 30, 2006 |
|---|---|---|---|---|---|
| Net loss | | | | | |
| As originally reported | $ (1,069,468) | $ (837,202) | $ (1,906,670) | $ (1,081,410) | $ (2,988,080) |
| Adjustment | | (63,000) | (63,000) | (49,000) | (112,000) |
| As adjusted | $ (1,069,468) | $ (900,202) | $ (1,969,670) | $ (1,130,410) | $ (3,100,080) |
| | | | | | |
| Accrued warrant liability | | | | | |
| As originally reported | $ 680,841 | | $ 407,717 | | $ 524,172 |
| Adjustment | 271,000 | | 334,000 | | 497,000 |
| As adjusted | $ 951,841 | | $ 741,717 | | $ 1,021,172 |
| | | | | | |
| Additional paid-in capital | | | | | |
| As originally reported | $ 14,190,980 | | $ 14,296,357 | | $ 14,307,052 |
| Adjustment | (271,000) | | (271,000) | | (385,000) |
| As adjusted | $ 13,919,980 | | $ 14,025,357 | | $ 13,922,052 |

**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 additional clinical trials for SEPET™ both domestically and internationally, and the preparation and submission of applications to 1) a Notified Body in Europe to secure CE Mark approval to market our SEPET™ Liver Assist Device in CE countries and 2) the FDA to commence a pivotal trial of SEPET™ targeted for subsequent FDA approval of SEPET™ in the U.S. 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. Based on our current estimates, we currently have sufficient cash to conduct our plan of operations for the next six months from the date of this report; however, we are seeking additional investment from various investors, but currently have no firm agreements or commitments in this regard to fund future development of our products.

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, 2006. 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*

Commencing January 1, 2006 the Company adopted Statement of Financial Accounting Standard ("SFAS") No. 123R, "Share Based Payment ("SFAS 123R"), which requires all share-based payments, including grants of stock options, to be recognized in the income statement as an operating expense, based on fair values. Prior to adopting SFAS 123R, the Company accounted for stock-based employee compensation under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," as allowed by SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). The Company has applied the modified prospective method in adopting SFAS 123R. Accordingly, periods prior to adoption have not been restated.

**New Accounting Pronouncements**

In March 2006, the Financial Accounting Standards Board ("FASB") issued Statement No. 156, *Accounting for Servicing of Financial Assets, an amendment of FASB Statement No. 140* ("SFAS 156"), which clarifies when servicing rights should be separately accounted for, requires companies to account for separately recognized servicing rights initially at fair value, and gives companies the option of subsequently accounting for those servicing rights at either fair value or under the amortization method. SFAS 156 is effective for fiscal years beginning after September 15, 2006. The Company does not expect SFAS 156 to affect the Company's financial condition or results of operations.

In July 2006, the FASB issued FASB Interpretation Number 48, *Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109*, ("FIN48"). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken in a tax return. The Company must determine whether it is "more-likely-than-not" that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. Once it is determined that a position meets the more-likely-than-not recognition threshold, the position is measured to determine the amount of benefit to recognize in the financial statements. FIN 48 applies to all tax positions related to income taxes subject to FASB Statement No. 109, *Accounting for Income Taxes.* The interpretation clearly scopes out income tax positions related to FASB Statement No. 5, *Accounting for Contingencies.* We do not anticipate that the adoption of this statement will have a material effect on our financial position or results of operations.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* ("SAB 108"), to address diversity in practice in quantifying financial statement misstatements. SAB 108 requires that we quantify misstatements based on their impact on each of our financial statements and related disclosures. SAB 108 is effective as of the end of our 2006 fiscal year, allowing a one-time transitional cumulative effect adjustment to retained earnings as of January 1, 2006 for errors that were not previously deemed material, but are material under the guidance in SAB 108. We adopted provisions of SAB 108 in the quarter ended December 31, 2006 without any impact on our financial statements.

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 with earlier application encouraged. We are evaluating the impact of adopting SFAS 157 on our financial statements.

In September 2006, the FASB issued Statement No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans -- An Amendment of FASB Statements No. 87, 88, 106, and 132R* (SFAS 158). SFAS 158 does not apply as the Company does not have a defined benefit pension or another post retirement plan.

In December 2006, the FASB issued FASB Staff Position ("FSP") EITF 00-19-2, *Accounting for Registration Payment Arrangements*. This FSP addresses how to account for registration payment arrangements and clarifies that a financial instrument subject to a registration payment arrangement should be accounted for in accordance with other generally accepted accounting principles without regard to the contingent obligation to transfer consideration pursuant to the registration payment arrangement. This accounting pronouncement further clarifies that a liability for liquidated damages resulting from registration statement obligations should be recorded in accordance with SFAS No. 5, *Accounting for Contingencies*, when the payment of liquidated damages becomes probable and can be reasonably estimated. This FSP shall be effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of this FSP. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this FSP, this guidance shall be effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. The Company is currently assessing the impact that this FSP may have in its financial statements.

**Results of Operations**

**Comparison of Fiscal Year ended December 31, 2006 to Fiscal Year ended December 31, 2005.**

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 from periods prior to 2005 represent revenues recognized from government research grants that we have received.

General and administrative expenses of $3,315,174 and $2,394,546 were incurred for the years ended December 31, 2006 and 2005, respectively. For the year ended December 31, 2006, the expenses include $662,000 in fees incurred to outside consultants, professionals and board member fees, $549,000 in payroll and payroll related costs, $1,076,000 in non-cash option and warrant charges, $239,000 in investor relation costs and other administrative expenses. 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. Professional fees decreased in 2006 due to a one time executive search recruitment fee incurred in 2005. The increase in non-cash option and warrant charges reflects the employee option grant charges recorded in the financial statements

due to the adoption of SFAS 123(R) effective January 1, 2006 and the warrant charges incurred due to the warrant exercise term modifications granted to certain warrants expiring in 2006. The 2006 increase in payroll and payroll related expenses reflects, in part, the employment for the full year in 2006 as compared to nine months in 2005 of a Chief Executive Officer.

Research and development expenses of $1,822,614 and $1,554,507 were incurred for the years ended December 31, 2006 and 2005, respectively. Research and development expenses for 2006 consist primarily of $570,000 in payroll and payroll related expenses, $486,000 in SEPET™ development, manufacturing and clinical costs, $380,000 in consultant costs related to manufacturing, regulatory and product management, and $144,000 in HepatAssist™ facility costs. 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 HepatAssist™ facility costs. Research and development costs increased by $268,107 from 2005 to 2006 and reflect increased expenditures for both the SEPET™ and HepatAssist™ programs. Payroll cost increases reflect 2006 full year salaries for employees that were hired in 2005, increased staff which replaced employee costs from Cedars-Sinai and the addition of new position for clinical research management. The increase in consulting costs reflects outsourced service costs incurred related to the SEPET™ Phase I trial.

The change in fair value of warrant liability reflects the net decline in the warrant liability valuation resulting in a non-cash benefit of $521,187.

Interest income of $154,697 and $125,286 was earned for the years ended December 31, 2006 and 2005 respectively. The increase in interest income of $29,411 results from the increase in short term interest offset, in part, by declining cash balances maintained in 2006.

Our net loss increased to $4,461,904 in 2006 from $3,823,903 in 2005. The increase in net loss is attributed to an increase in operating expenses incurred in the fiscal 2006 periods as compared to the same periods in 2005, without an increase in revenues.

**Liquidity and Capital Resources**

As of December 31, 2006, we had cash of $2,054,280. 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 estimates, we currently have sufficient cash to conduct our plan of operations for the next six months from the date of this report; however, we are seeking additional investment from various investors, but currently have no firm agreements or commitments in this regard to fund future development of our products.

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.

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, 2006 is as follows:

| Contractual Obligations | Total | 2007 | 2008 and thereafter |
|---|---|---|---|
| Short-Term Office Leases | $ 107,000 | $ 107,000 | $ -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. We have postponed further clinical development of our HepatAssist™ program until we are able to secure additional funding for this project from a potential corporate partner.

*Despite our prior private equity financings 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 not be sufficient to fund our operations and capital requirements for at least the 12-month period following the date of this Annual Report. We are seeking additional cash resources from interested investors; however, we can make no assurances that these funds will be raised in a timely manner. Additionally, 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™ 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.

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.

*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™ Cell-Based Liver Support 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™ products and these requirements may be more costly or time-consuming than we currently anticipate.

SEPET™ and HepatAssist™ are both novel in terms of their 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™ Cell-Based Liver Support 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™ 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™. 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™ 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™ and SEPET™ 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™ 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™ 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™, we will not be able

to conduct any clinical trials until we raise substantial amounts of additional financing. Additionally, we will need to raise additional funds to fund the pivotal clinical trial for our SEPET™ product domestically and abroad, since we do not have sufficient funds to cover the costs of these trials.

*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 the potential 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 demonstrated 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™ Cell-Based Liver Support 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™ Cell-Based Liver Support 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.

*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™. 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.*

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™ 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™ system. While we believe there are several potential contract manufactures who can produce these cartridges, and we have taken substantial steps towards qualifying such a manufacturer, 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™, 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™ 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. In the event that RanD and Medtronic are either unable or unwilling to manufacture the number of PERFORMERS needed to ensure that HepatAssist™ 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™ functional and operational characteristics, and there may be further platforms already developed which can meet those 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 five issued U.S. patents on our liver support products, six issued foreign patents, have two patent applications pending, and are the licensee of sixteen additional issued U.S. liver support patents and the licensee of six additional liver support patent applications pending. 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 while we have sought to independently verify aspects of the validity or other aspects of some of the patents or patent applications covering our products with our own patent counsel and with patent counsel for investors in our Company, there can be no assurance that such verifications have been accurate or exhaustive.

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 certain key persons, and the loss of one or more of these key persons would materially and adversely affect our business and prospects.*

We are dependent upon our business and scientific personnel. We also depend upon the medical and scientific advisory services that we receive from the members of our Board of Directors and Scientific Advisory Board, many of whom have extensive backgrounds in the biomedical industry We do not carry key man life insurance on any of these individuals. On November 9, 2006, our Chief Scientific Officer, Jacek Rozga, M.D., Ph.D., announced his resignation from the Company as a full-time employee. The Company has agreed to retain Dr. Rozga as a consultant and will draw upon Dr. Rozga's expertise from time-to-time as needed.

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 un-reimbursed amounts, which may well be substantial. The reimbursement status of newly approved health care products is highly uncertain. If levels of reimbursement are decreased in the future, the demand for our products could diminish or our ability to sell our products on a profitable basis could be adversely affected.

*We may be subject to product liability claims that could have a material negative effect on our operations and on our financial condition.*

The development, manufacture and sale of medical products expose us to the risk of significant damages from product liability claims. We plan to obtain and maintain product liability insurance for coverage of our clinical trial activities. However, there can be no assurance that we will be able to secure such insurance for clinical trials for either of our two current products. We intend to obtain coverage for our products when they enter the marketplace (as well as requiring the manufacturers of our products to maintain insurance). We do not know if it will be available to us at acceptable costs. We may encounter difficulty in obtaining clinical trial or commercial product liability insurance for any bioartificial liver device that we develop since this therapy includes the use of pig liver cells and we are not aware of any therapy using these cells that has sought or obtained such insurance. If the cost of insurance is too high or insurance is unavailable to us, we will have to self-insure. A successful claim in excess of product liability coverage could have a material adverse effect on our business, financial condition and results of operations. The costs for many forms of liability insurance have risen substantially during the past year, and such costs may continue to increase in the future, which could materially impact our costs for clinical or product liability insurance.

*If we are not able to implement the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 in a timely manner or with adequate compliance, we may be unable to provide the required financial information in a timely and reliable manner and may be subject to sanction to regulatory authorities.*

We cannot be certain at this time that we will have the expertise and resources to be able to comply with all of our reporting obligations and successfully complete the procedures, certification and attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 by the time that we are required to do so. If we fail to comply with the requirements of Section 404, or if we or our independent registered public accounting firm identifies any material weaknesses, the accuracy and timeliness of the filing of our annual and quarterly reports may be negatively affected and could cause investors to lose confidence in our financial statements, impair our ability to obtain financing or result in regulatory sanctions. Remediating any material weakness could require additional management attention and increased compliance costs.

*If we make any further acquisitions, we will incur a variety of costs and might never successfully integrate the acquired product or business into ours.*

Following on our acquisition of the HepatAssist™ system from Circe Biomedical, Inc., we might attempt to acquire products or businesses that we believe are a strategic complement to our business model. We might encounter operating difficulties and expenditures relating to integrating HepatAssist™ or any other acquired product or business. These acquisitions might require significant management attention that would otherwise be available for ongoing development of our business. In addition, we might never realize the anticipated benefits of any acquisition. We might also make dilutive issuances of equity securities, incur debt or experience a decrease in cash available for our operations, incur contingent liabilities and/or amortization expenses relating to goodwill and other intangible assets, or incur employee dissatisfaction in connection with future acquisitions.

*Our ability to continue as a going concern is dependent on future financing.*

Our independent registered public accounting firm, has included an explanatory paragraph in its report on our financial statements for the fiscal year ended December 31, 2006, which expresses substantial doubt about our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph in our accountant's report on our financial statements could have a detrimental effect on our stock price and our ability to raise additional capital.

Our financial statements have been prepared on the basis of a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have not made any adjustments to the financial statements as a result of the outcome of the uncertainty described above. Accordingly, the value of the Company in liquidation may be different from the amounts set forth in our financial statements.

Our continued success will depend on our ability to continue to raise capital in order to fund the development and commercialization of our products. Failure to raise additional capital may result in substantial adverse circumstances, including our inability to continue the development of our products and our liquidation.

**RISKS RELATED TO OUR COMMON STOCK**

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

The shares of our common stock are thinly-traded on the OTC Bulletin Board, meaning that the number of persons interested in purchasing our common shares at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment

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

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

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

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

Since our common stock is not listed on the Nasdaq Stock Market, if the trading price of our common stock is below $5.00 per share, trading in our common stock will be subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a penny stock (generally, any non-Nasdaq equity security that has a market price of less than $5.00 per share, subject to certain exceptions). Such rules require the delivery, prior to any penny stock transaction, of a disclosure schedule explaining the penny stock market and the risks associated therewith and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors (generally defined as an investor with a net worth in excess of $1,000,000 or annual income exceeding $200,000 individually or $300,000 together with a spouse). For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to the sale. The broker-dealer also must disclose the commissions payable to the broker-dealer, current bid and offer quotations for the penny stock and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Such information must be provided to the customer orally or in writing before or with the written confirmation of trade sent to the customer. Monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. The additional burdens imposed upon broker-dealers by such requirements could discourage broker-dealers from effecting transactions in our common stock, which could severely limit the market liquidity of the common stock and the ability of holders of the common stock to sell their shares.

*Anti-takeover provisions in our certificate of incorporation could affect the value of our stock*

Our certificate of incorporation contains certain provisions that could be an impediment to a non-negotiated change in control. In particular, without stockholder approval we can issue up to 5,000,000 shares of preferred stock with rights and preferences determined by the board of directors. These provisions could make a hostile takeover or other non-negotiated change in control difficult, so that stockholders would not be able to receive a premium for their common stock.

*Potential issuance of additional common and preferred stock could dilute existing stockholders*

We are authorized to issue up to 60,000,000 shares of common stock. To the extent of such authorization, our board of directors has the ability, without seeking stockholder approval, to issue additional shares of common stock in the future for such consideration as the board of directors may consider sufficient. The issuance of additional common stock in the future will reduce the proportionate ownership and voting power of the common stock offered hereby. We are also authorized to issue up to 5,000,000 shares of preferred stock, the rights and preferences of which may be designated in series by the board of directors. Such designation of new series of preferred stock may be made without stockholder approval, and could create additional securities which would have dividend and liquidation preferences over the common stock offered hereby. Preferred stockholders could adversely affect the rights of holders of common stock by:

- exercising voting, redemption and conversion rights to the detriment of the holders of common stock;
- receiving preferences over the holders of common stock regarding or surplus funds in the event of our dissolution or liquidation;
- delaying, deferring or preventing a change in control of our company; and
- discouraging bids for our common stock.

Additionally, some of our outstanding warrants to purchase common stock have anti-dilution protection. This means that if we issue securities for a price less than the price at which the warrants are exercisable for shares of common stock, the warrants will become eligible to purchase more shares of common stock at a lower price, which will dilute the ownership of our common stockholders. The anti-dilution provision embedded in the warrants may also result in additional non-cash charges to our earnings, the extent of which is dependent on the size of future offerings and the market price of our common stock at the time of offering.

*Substantial number of shares of common stock may be released onto the market at any time, and the sales of such additional shares of common stock could cause stock price to fall*

As of March 6, 2007, we had outstanding 17,460,181 shares of common stock. However, in the past year, the average daily trading volume of our shares has only been a few thousand shares, and there have been many days in which no shares were traded at all. In October 2004, February 2005, and June 2006 we registered a total of 8,015,480 shares of our common stock issuable upon the exercise of outstanding warrants. The shares underlying the warrants have not yet been issued and will not be issued until the warrants are exercised. Since the shares underlying these warrants have been registered, they can be sold immediately following the exercise. Accordingly, 8,015,480 additional shares could be released onto the trading market at any time. Because of the limited trading volume, the sudden release of 8,015,480 additional freely trading shares onto the market, or the perception that such shares will come onto the market, could have an adverse affect on the trading price of the stock. In addition, there are currently 4,660,000 shares of unregistered, restricted stock that are currently eligible for public resale under Rule 144 promulgated under the Securities Act, some of which shares also may be offered and sold on the market from time to time. No prediction can be made as to the effect, if any, that sales of the 8,015,480 registered warrant shares, or the sale of any of the 4,660,000 shares subject to Rule 144 sales will have on the market prices prevailing from time to time. Nevertheless, the possibility that substantial amounts of common stock may be sold in the public market may adversely affect prevailing market prices for our common stock and could impair our ability to raise capital through the sale of our equity securities.

*The market price of our stock may be adversely affected by market volatility.*

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors,

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

**ITEM 7. FINANCIAL STATEMENTS.**

**INDEX TO FINANCIAL STATEMENTS**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying balance sheets of Arbios Systems, Inc. as of December 31, 2006 and 2005 and the related statements of operations, stockholders' equity and cash flows for the years then ended and from August 23, 2000 (inception) to December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Arbios Systems, Inc. as of December 31, 2006 and 2005 and the results of its operations and its cash flows for the years ended December 31, 2006 and 2005, and from August 23, 2000 (inception) to December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 of the financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit, and has been dependent on outside equity to finance operations, all of which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 1 to the consolidated financial statements, in 2006 the Company adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payments.

**/s/Stonefield Josephson, Inc.**
Certified Public Accountants

Los Angeles, California
April 13, 2007

**ARBIOS SYSTEMS, INC.**
(A development stage company)
**BALANCE SHEETS**
**December 31, 2006 and 2005**

| | December 31, 2006 | 2005 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 2,054,280 | $ 2,379,738 |
| Short term investments | - | 1,996,000 |
| Prepaid expenses | 147,163 | 195,841 |
| Total current assets | 2,201,443 | 4,571,579 |
| | | |
| Net property and equipment | 73,110 | 101,629 |
| Patent rights, net of accumulated amortization of $113,894 and $93,418, respectively | 152,773 | 173,249 |
| Other assets | 62,827 | 55,773 |
| | | |
| Total assets | $ 2,490,153 | $ 4,902,230 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 310,162 | $ 160,649 |
| Accrued expenses | 132,073 | 152,362 |
| Total current liabilities | 442,235 | 313,011 |
| | | |
| Accrued warrant liability | 763,654 | - |
| | | |
| Stockholders' equity | | |
| Preferred stock, $.001 par value; 5,000,000 shares authorized: none issued and outstanding | - | - |
| Common stock, $.001 par value; 60,000,000 shares authorized; 17,460,181 and 16,232,909 shares issued and outstanding at December 31, 2006 and 2005 respectively | 17,460 | 16,233 |
| Additional paid-in capital | 14,507,939 | 13,352,217 |
| Deficit accumulated during the development stage | (13,241,135) | (8,779,231) |
| Total stockholders' equity | 1,284,264 | 4,589,219 |
| | | |
| Total liabilities and stockholders' equity | $ 2,490,153 | $ 4,902,230 |

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

**ARBIOS SYSTEMS, INC.**
(A development stage company)
**STATEMENTS OF OPERATIONS**

| | For the years ended December 31, | | Inception to December 31, |
|---|---|---|---|
| | 2006 | 2005 | 2006 |
| Revenues | $ - | $ - | $ 320,966 |
| Operating expenses: | | | |
| General and administrative | 3,315,174 | 2,394,546 | 8,322,089 |
| Research and development | 1,822,614 | 1,554,509 | 5,813,176 |
| Total operating expenses | 5,137,788 | 3,949,055 | 14,135,265 |
| Loss before other income (expense) | (5,137,788) | (3,949,055) | (13,814,299) |
| Other income (expense): | | | |
| Change in fair value of warrant liability | 521,187 | - | 521,187 |
| Interest income | 154,697 | 125,286 | 296,115 |
| Interest expense | - | (134) | (244,138) |
| Total other income (expense) | 675,884 | 125,152 | 573,164 |
| Net loss | $ (4,461,904) | $ (3,823,903) | $ (13,241,135) |
| Net loss per share: | | | |
| Basic and diluted | $ (0.26) | $ (0.24) | |
| Weighted-average shares: | | | |
| Basic and diluted | 17,244,988 | 16,137,676 | |

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

**ARBIOS SYSTEMS, INC.**
(A development stage company)
**STATEMENTS OF CASH FLOWS**

| | For the year ended December 31, | | Inception to December 31, |
|---|---|---|---|
| | 2006 | 2005 | 2006 |
| **Cash flows from operating activities:** | | | |
| Net loss | $ (4,461,904) | $ (3,823,903) | $ (13,241,135) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Amortization of debt discount | - | - | 244,795 |
| Depreciation and amortization | 52,442 | 59,249 | 252,219 |
| Change in fair value of warrant liability | (521,187) | - | (521,187) |
| Patent rights impairment | - | 91,694 | 91,694 |
| Interest earned on discounted short term investments | 8,652 | (8,652) | - |
| Issuance of common stock, options & warrants for compensation | 1,186,803 | 557,079 | 2,799,934 |
| Settlement of accrued expense | - | - | 54,401 |
| Deferred compensation costs | - | - | 319,553 |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses | 48,678 | (98,188) | (147,165) |
| Other assets | (7,054) | (22,609) | (62,827) |
| Accounts payable and accrued expenses | 129,224 | 34,552 | 348,733 |
| Other liabilities | - | 64,695 | 64,695 |
| Contract obligation | - | (250,000) | - |
| Net cash provided by operating activities | (3,564,346) | (3,396,083) | (9,796,290) |
| | | | |
| **Cash flows from investing activities:** | | | |
| Additions of property and equipment | (3,447) | (23,489) | (144,796) |
| Purchase of short term investments | (12,889,073) | (8,977,714) | (21,866,787) |
| Maturities of short term investments | 14,876,421 | 6,990,366 | 21,866,787 |
| Net cash provided by and (used in) investing activities | 1,983,901 | (2,010,837) | (144,796) |
| | | | |
| **Cash flows from financing activities:** | | | |
| Proceeds from issuance of convertible debt | - | - | 400,000 |
| Proceeds from common stock option/warrant exercise | - | 62,500 | 65,200 |
| Net proceeds from issuance of common stock and warrants | 1,254,987 | 6,227,594 | 11,313,249 |
| Net proceeds from issuance of preferred stock | - | - | 238,732 |
| Payments on capital lease obligation, net | - | (5,341) | (21,815) |
| Net cash provided by financing activities | 1,254,987 | 6,284,753 | 11,995,366 |
| Net (decrease) increase in cash | (325,458) | 877,833 | 2,054,280 |
| | | | |
| Cash at beginning of period | 2,379,738 | 1,501,905 | - |

| | | | |
|---|---|---|---|
| Cash at end of period | $ 2,054,280 | $ 2,379,738 | $ 2,054,280 |
| | | | |
| **Supplemental disclosures of non-cash financing activity** | | | |
| Issuance of securities for obligation related to finder's fees | - | - | $ 47,500 |
| Accrued warrant liability | $ 763,654 | - | $ 763,654 |

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

**ARBIOS SYSTEMS, INC.**
**(A Development Stage Company)**
**STATEMENT OF STOCKHOLDERS' EQUITY**
**PERIOD FROM AUGUST 23, 2000 (INCEPTION) TO DECEMBER 31, 2006**

| | Preferred Stock Shares | Preferred Stock Amount | Common Stock Shares | Common Stock Amount | Additional Paid-In Capital | Deferred Costs | Deficit Accumulated During the Development Stage | Total |
|---|---|---|---|---|---|---|---|---|
| Balance, August 23, 2000 (inception) restated for effect of reverse merger with Historical Autographs U.S.A. Inc. | | | - | $ - | $ - | | | $ - |
| Stock issuance in exchange for cash | | | 5,000,000 | 50 | 4,950 | | | 5,000 |
| Net loss | | | | | | | (9,454) | (9,454) |
| Balance, December 31, 2000, as restated | - | - | 5,000,000 | 50 | 4,950 | - | (9,454) | (4,454) |
| Issuance of junior preferred stock for cash of $250,000 and in exchange for $400,000 in patent rights, research and development costs, and employee loanout costs less issuance expenses of $11,268, June 29, 2001 | 681,818 | 7 | | | 958,278 | (343,553) | | 614,732 |
| Issuance of common stock in exchange for patent rights and deferred research and development costs | | | 362,669 | 4 | 547,284 | | | 547,288 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Services receivable | | | | | | (550,000) | | (550,000) |
| Deferred employee loan-out costs receivable earned | | | | | | 82,888 | | 82,888 |
| Net loss | | | | | | | (237,574) | (237,574) |
| Balance, December 31, 2001 | 681,818 | 7 | 5,362,669 | 54 | 1,510,512 | (810,665) | (247,028) | 452,880 |

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

**ARBIOS SYSTEMS, INC.**
**(A Development Stage Company)**
**STATEMENT OF STOCKHOLDERS' EQUITY**
**PERIOD FROM AUGUST 23, 2000 (INCEPTION) TO DECEMBER 31, 2006**

| | Preferred Stock Shares | Preferred Stock Amount | Common Stock Shares | Common Stock Amount | Additional Paid-In Capital | Deferred Costs | Deficit Accumulated During the Development Stage | Total |
|---|---|---|---|---|---|---|---|---|
| Amendment of December 31, 2001 agreement for the issuance of common stock agreement in exchange for research and development services | | | | | (495,599) | 550,000 | | 54,401 |
| Deferred employee loan out costs receivable earned | | | | | | 171,776 | | 171,776 |
| Issuance of common stock for compensation | | | 70,000 | 1 | 10,499 | | | 10,500 |
| Issuance of common stock for cash | | | 999,111 | 9 | 149,857 | | | 149,866 |
| Net loss | | | | | | | (494,780) | (494,780) |
| Balance, December 31, 2002 | 681,818 | 7 | 6,431,780 | 64 | 1,175,269 | (88,889) | (741,808) | 344,643 |
| Issuance of common stock for cash less issuance expense of $2,956 | | | 417,000 | 417 | 246,827 | | | 247,244 |
| Issuance of common stock in private placement for cash less issuance expense of $519,230 | | | 4,000,000 | 4,000 | 3,476,770 | | | 3,480,770 |

| | | | | |
|---|---|---|---|---|
| Issuance of common stock for convertible debenture less issuance expense of $49,500 | 400,000 | 400 | 350,100 | 350,500 |
| Shares issued in connection with acquisition of Historical Autographs U.S.A., Inc. on October 30, 2003 | 1,220,000 | 8,263 | (8,263) | - |

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

**ARBIOS SYSTEMS, INC.**
**(A Development Stage Company)**
**STATEMENT OF STOCKHOLDERS' EQUITY**
**PERIOD FROM AUGUST 23, 2000 (INCEPTION) TO DECEMBER 31, 2006**

| | Preferred Stock | | Common Stock | | Additional | | Deficit Accumulated During the | |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Paid-In Capital | Deferred Costs | Development Stage | Total |
| Value of warrants and beneficial conversion feature of bridge loan | | | | | 244,795 | | | 244,795 |
| Deferred employee loan-out costs receivable earned | | | | | | 88,889 | | 88,889 |
| Preferred Stock converted to Common Stock | (681,818) | (7) | 681,818 | 7 | | | | |
| Net loss | | | | | | | (885,693) | (885,693) |
| Balance, December 31, 2003 | - | - | 13,150,598 | 13,151 | 5,485,498 | - | (1,627,501) | 3,871,148 |
| Issuance of common stock options and warrants for compensation | | | | | 972,430 | | | 972,430 |
| Exercise of common stock options | | | 18,000 | 18 | 2,682 | | | 2,700 |
| Issuance of securities for payable | | | 47,499 | 47 | 47,451 | | | 47,498 |
| Net loss | | | | | | | (3,327,827) | (3,327,827) |
| Balance, December 31, 2004 | - | - | 13,216,097 | 13,216 | 6,508,061 | - | (4,955,328) | 1,565,949 |

| | | | | |
|---|---|---|---|---|
| Issuance of common stock in private placement for cash less issuance expense of $384,312 | 2,991,812 | 2,992 | 6,224,601 | 6,227,593 |
| Issuance of common stock options and warrants for compensation | | | 557,080 | 557,080 |
| Exercise of common stock options | 25,000 | 25 | 62,475 | 62,500 |

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

**(A Development Stage Company)**
**STATEMENT OF STOCKHOLDERS' EQUITY**
**PERIOD FROM AUGUST 23, 2000 (INCEPTION) TO DECEMBER 31, 2006**

| | Preferred Stock Shares | Preferred Stock Amount | Common Stock Shares | Common Stock Amount | Additional Paid-In Capital | Deferred Costs | Deficit Accumulated During the Development Stage | Total |
|---|---|---|---|---|---|---|---|---|
| Net loss | | | | | | | (3,823,903) | (3,823,903) |
| Balance, December 31, 2005 | - | - | 16,232,909 | $ 16,233 | $ 13,352,217 | - | ($8,779,231) | $ 4,589,219 |
| Issuance of common stock in private placement for cash less issuance expense of $95,013 | | | 1,227,272 | 1,227 | 1,253,760 | | | 1,254,987 |
| Issuance of common stock options and warrants for compensation | | | | | 703,839 | | | 703,839 |
| Stock warrant term extension | | | - | | 482,964 | | | 482,964 |
| Warrant liability | | | | | (1,284,841) | | | (1,284,841) |
| Net loss | | | | | | | (4,461,904) | (4,461,904) |
| Balance, December 31, 2006 | - | - | 17,460,181 | $ 17,460 | $ 14,507,939 | - | ($13,241,135) | $ 1,284,264 |

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

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

**NOTES TO FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2006 AND 2005**

## (1) Summary of Significant Accounting Policies:

### General:

Arbios Systems, Inc., a Delaware corporation (the "Company"), seeks to develop, manufacture and market liver assist devices to meet the urgent need for therapy of liver failure.

The Company has a lead product under development, the SEPET™ Liver Assist Device, which is a blood purification therapy device for patients with liver failure. The Company has a second product candidate, the HepatAssist™ Cell-Based Liver Support System, which is a bioartificial liver; whose development is currently on hold pending raising of additional funds via a corporate partnership.

On October 30, 2003, Historical Autographs U.S.A., Inc. and Arbios Technologies, Inc. consummated a reverse merger, in which Arbios Technologies, Inc. became the wholly owned subsidiary of Historical Autographs U.S.A., Inc. Concurrently with the merger, Historical Autographs U.S.A., Inc. changed its named to Arbios Systems, Inc. and is herein referred to as "Arbios Systems". The stockholders of Arbios Technologies, Inc. transferred ownership of one hundred percent of all the issued and outstanding shares of their capital stock of Arbios Technologies, Inc. in exchange for 11,930,598 newly issued shares, or approximately 91%, of the common stock, $.001 par value, of Arbios Systems. At that time, the former management of Arbios Systems resigned and was replaced by the same persons who served as officers and directors of Arbios Technologies, Inc. Inasmuch as the former owners of Arbios Technologies, Inc. controlled the combined entity after the merger, the combination was accounted for as a purchase by Arbios Technologies, Inc. as acquirer, for accounting purposes in accordance with Statement of Financial Accounting Standards No. 141 using reverse merger accounting, and no adjustments to the carrying values of the assets or liabilities of the acquired entity were required. Proforma operating results, as if the acquisition had taken place at the beginning of the period, have not been presented as the operations of the acquiree were negligible. The financial position and results of operations of Arbios Systems is included in the statements of the Company from the date of acquisition.

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. Unless the context indicates otherwise, references herein to the "Company" during periods prior to July 26, 2005 include Arbios Systems, Inc., a Nevada corporation and Arbios Technologies, Inc.

### Development Stage Enterprise and Going Concern:

The Company is a development stage enterprise as defined in Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises." The Company is devoting substantially all of its present efforts to establish a new business. Its planned principal commercial operations have not yet commenced. Research and development, which were initiated in 2000 is being vigorously pursued including conduct of a human clinical trial. All losses accumulated since inception, have been considered as part of the Company's development

stage activities. As of March 2007, the Company currently does not have sufficient resources to fund operations for the next twelve months and its ability to continue as a going concern is in doubt. Our financial statements have been prepared on the basis of a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have not made any adjustments to the financial statements as a result of the outcome of the uncertainty described above. Accordingly, the value of the Company in liquidation may be different from the amounts set forth in our financial statements. The Company is currently in the process of seeking additional capital, but makes no assurances that these funds can or will be raised.

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

**NOTES TO FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2006 AND 2005**

**(1) Summary of Significant Accounting Policies, Continued:**

**Use of Estimates:**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates were used in the calculation of stock option valuation, warrant liability valuation, property and equipment, and amortization of patents.

**Federal Government Grants:**

The Company has been partially funded by certain governmental grants. Payments received under contracts to fund certain research activities are recognized as revenue in the period in which the research activities are performed. Payments received in advance that are related to future performance are deferred and recognized as revenue when the research projects are performed. Reimbursements recorded under these grants are subject to governmental audit. Management believes that subsequent audits will not result in material adjustments to the costs reflected in the accompanying financial statements, and that the Company has utilized all remaining government grant funds in accordance with their intended use.

**Comprehensive Income:**

SFAS No. 130, "Reporting Comprehensive Income", establishes standards for the reporting and display of comprehensive income and its components in the financial statements. As of December 31, 2006 and 2005, the Company has no items that represent comprehensive income and therefore, the Company has not included a schedule of comprehensive income in the financial statements.

**Property and Equipment:**

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

**Patent Rights:**

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 patents 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.

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

**NOTES TO FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2006 AND 2005**

**(1) Summary of Significant Accounting Policies, Continued:**

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

**Fair Value of Financial Instruments:**

The Company's financial instruments include cash, short-term investments, accounts payable, accrued expenses, and warrant liability, some of which have carrying amounts which approximate fair value due to their short maturities.

**Cash and Cash Equivalents:**

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

**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 the Company's short-term investments are classified as available-for-sale and are carried at fair market value which approximates cost plus accrued interest.

**Income Taxes:**

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

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

**NOTES TO FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2006 AND 2005**

**(1) Summary of Significant Accounting Policies, Continued:**

**Stock-Based Compensation, Continued:**

Commencing January 1, 2006 the Company adopted Statement of Financial Accounting Standard ("SFAS") No. 123R, "Share Based Payment ("SFAS 123R"), which requires all share-based payments, including grants of stock options, to be recognized in the income statement as an operating expense, based on fair values.

Prior to adopting SFAS 123R, the Company accounted for stock-based employee compensation under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," as allowed by SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). The Company has applied the modified prospective method in adopting SFAS 123R. Accordingly, periods prior to adoption have not been restated.

The following table illustrates the effect on net income and earnings per share if the fair value method had been applied to the prior period.

| | | Year ended December 31, 2005 |
|---|---|---|
| Net loss as reported | $ | (3,823,903) |
| Compensation recognized under: | | |
| SFAS 123 | | (984,514) |
| Pro forma net loss | $ | (4,808,417) |
| Basic and diluted loss per common share: | | |
| As reported | $ | (0.24) |
| Pro forma | $ | (0.30) |

Under SFAS 123R, forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate. The Company utilized a 5% forfeiture rate based upon historical forfeitures. Under SFAS 123 and APB 25, the Company elected to account for forfeitures when awards were actually forfeited, at which time all previous pro forma expense was reversed to a reduced pro forma expense for the period in which the forfeiture occurred.

For non-employee stock based compensation the Company recognizes an expense in accordance with SFAS 123 and values the equity securities based on the fair value of the security on the date of grant with subsequent adjustments based on the fair value of the equity security as it vests. The fair value of expensed options is estimated using the Black Scholes option-pricing model.

**ARBIOS SYSTEMS, INC.**
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**NOTES TO FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2006 AND 2005**

**Summary of Significant Accounting Policies, Continued:**

**Stock-Based Compensation, Continued:**

As of December 31, 2006, there was $307,000 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under existing stock option plans. This cost is expected to be recognized over a weighted average period of 1.57 years. The total fair value of shares vested and unvested during the twelve months ended December 31, 2006 was $695,000, of which $663,000 is attributed to employee options.

The fair value of options granted to employees was estimated using the Black Scholes option-pricing model. These same assumptions are also used in applying the Black Scholes option-pricing model for any stock based option and warrant compensation paid to non-employees. The fair value of options and warrants at the date of grant and the assumptions utilized are indicated in the following table:

| | For the Year Ended December 31 , | |
|---|---|---|
| | 2006 | 2005 |
| Weighted average of fair value at date of grant for options granted during the period | $ 0.87 | $ 1.31 |
| Risk-free interest rates | 4.35% - 5.04% | 3.77% - 4.45% |
| Expected option life in years | 7 | 5-7 |
| Expected stock price volatility | .72 - .77 | .83 - .72 |
| Expected dividend yield | - | - |

*Expected Volatility.* The Company calculates the expected volatility of its stock options using historical volatility of weekly stock prices.

*Expected Term.* The expected term is based on historical observations of employee exercise patterns during the Company's history.

*Risk-Free Interest Rate*. The interest rate used in valuing awards is based on the yield at the time of grant of the U.S. Treasury security 5 year constant maturity rate.

*Dividend Yield*. The Company has never paid cash dividends, and does not currently intend to pay cash dividends, and thus has assumed a 0% dividend yield.

**Net Loss Per Common Share:**

The Company utilizes SFAS 128, "Earnings per Share." Basic loss per share is computed by dividing loss available to common shareholders by the weighted-average number of common shares outstanding. Diluted loss per share is computed similar to basic loss per share except that the denominator is increased to include the number of additional

common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. The computation of diluted loss per share does not assume conversion, exercise or contingent exercise of securities that would have an anti-dilutive effect on losses. For the years ended December 31, 2006 and 2005, potential common shares aggregating 10,694,000 and 9,345,000, respectively, were excluded in computing the per share amounts because they are anti-dilutive.

**ARBIOS SYSTEMS, INC.**
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**NOTES TO FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2006 AND 2005**

**(1) Summary of Significant Accounting Policies Continued:**

**Recent Accounting Pronouncements:**

In July 2006, the FASB issued FASB Interpretation Number 48, *Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109*, ("FIN48"). FIN 48 prescribes