ARBIOS SYSTEMS INC
Form 10KSB
March 31, 2008

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

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FORM 10-KSB

(Mark One)

x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2007

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**: 781-839-7292**

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 Exchange Act 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 25, 2008 was approximately $6,153,379 based on the closing sales price reported by the OTC Bulletin Board on such date.

There were 25,603,461 shares of the Company's common stock outstanding on March 25, 2008.

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,” “the Company,” “Arbios” and “our Company” r
to Arbios Systems, Inc., a Delaware corporation.

Forward Looking Statements

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

PART I

ITEM 1. DESCRIPTION OF BUSINESS.

Company Overview

Arbios Systems, Inc., or Arbios, is a Delaware corporation with its corporate office in Waltham, Massachusetts, research facility in Medford, Massachusetts, and accounting and administrative office in Pasadena, 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 product candidates for the treatment of liver failure. Our lead product candidates 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 which incorporates porcine pig liver cells. We have postponed further clinical development of our HepatAssist™ program until we secure additional funding or a corporate partner for this program. In addition to the five patents and six patent applications acquired on March 29, 2007 from Immunocept, LLC, we currently own four United States and five foreign patents on our liver support product candidates, have two patent applications pending, and are the licensee of twelve additional liver support patents.

SEPET™ Liver Assist Device. In September 2007, we announced the results of our 15-patient feasibility clinical study of our SEPET™ Liver Assist Device, targeted for the treatment of acute episodes of chronic liver disease, in which 79% of the 14 treated patients met the primary clinical effectiveness endpoint. Based on the results of the feasibility study, in February 2008, the U.S. Food and Drug Administration, or FDA, granted us conditional approval of an Investigational Device Exemption, or IDE, application to begin the pivotal clinical trial for SEPET™ while we respond to the FDA’s conditions and request for additional information. In particular, FDA has requested a survival primary endpoint opposed to the primary endpoint of a two-stage drop in hepatic encephalopathy proposed in our original trial design submitted to the FDA. We are refining our position that a two-stage drop in hepatic encephalopathy is clinically meaningful and an appropriate primary endpoint for the trial as well as assessing their meaning of a survival

primary end point. We have had an additional meeting with the FDA in March 2008 and are discussing our position regarding a suitable primary endpoint for the trial. We plan to submit a revised trial design to the FDA in the beginning of the second quarter of 2008 and hope to commence the pivotal trial once that primary endpoint is finalized.

We further intend to use our clinical data to support the marketing authorization process in the European Union to receive CE Marking for our SEPET™ Liver Assist Device. We intend to engage a notified body to facilitate obtaining a CE Mark for the device, which is a sterile, disposable cartridge with proprietary membrane permeability characteristics for use in treating patients with liver failure. CE Marking indicates that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation and allows sale of the product within the European Union (28 countries) and the European Free Trade Association (3 countries).

We hope to raise additional funds to support the development of the CE Marking and the planned Phase III pivotal trial for SEPET™ during 2008. We hope to commence the first segment of the pivotal trial in Rostock, Germany during the first half of 2008 once we determine a suitable primary endpoint. We anticipate that the current cash and cash equivalents are only sufficient to fund operations through part of the third quarter of 2008, and a significant capital raise is necessary in order to continue operations and planned projects.

HepatAssist™ Cell-Based Liver Support System. Our HepatAssist™ Cell-Based Liver Support System is an enhanced version of a product system which we acquired in 2004 from 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 United States and in Asia to the extent that we obtain additional funding for this program from a potential corporate marketing partner or a significant capital raise.

A glossary of certain terms used in this Annual Report is contained on page 23 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, the holder of the SEPET™ technology, 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, ceased its e-commerce business, and moved its offices to Los Angeles, California. In April 2004, Arbios Systems, Inc. purchased assets of Circe Biomedical, Inc. related to bioartificial liver devices. 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 Systems, Inc. and ATI, on July 26, 2005, ATI merged into Arbios Systems, Inc. As a result, Arbios Systems, Inc. now owns all of the assets of ATI and all of the operations of the two companies have been consolidated into Arbios Systems, Inc.

Our principal operations and executive offices are located at 1050 Winter Street, Suite 1000, Waltham, Massachusetts 02451 and our telephone number at this office is 781-839-7292. We have a research facility located at 200 Boston Road, Medford, Massachusetts and also maintain an administrative office at 200 E. Del Mar Blvd., Suite 208, Pasadena, California 91105 and our telephone number at this office is (626) 356-3105. 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.

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. ATI developed SEPET™, which we acquired upon our purchase of ATI in October 2003. In addition, as previous 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. Circe Biomedical ceased operations in 2003 and 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. In July 2005, we consolidated our corporate structure by merging ATI into our then parent company, Arbios Systems, Inc., creating our current operating structure.

To date, we have funded our operations from the proceeds from the sale of over $18,000,000 of our equity securities and $321,000 of Small Business Innovation Research grants that have been awarded by the U.S. Small Business Administration. We will have to raise substantial additional capital to fund our future clinical development expenses and our on-going working capital needs.

Our current plan of operations for the next 12 months primarily involves research and development activities, including clinical trials for the SEPET™ Liver Assist Device, and the preparation and submission of applications to the FDA. We submitted an IDE application for SEPET™ in March 2005 and commenced clinical trials for SEPET™ in the third quarter of 2005. In the third quarter of 2007, we completed the Phase I feasibility clinical trial for SEPET™ and are in the process of finalizing the design of and preparing for the Phase II/III pivotal clinical trial. We have already submitted a second IDE application for the conduct of this Phase II/III pivotal trial. The actual amounts we may expend on research and development and related clinical activities during the next 12 months may vary significantly depending on numerous factors, including how the results of our clinical trials and proposed trial designs are received by the FDA and the timing and cost of regulatory submissions. We do not expect to make any significant purchases or sales of plant or equipment during the next twelve months. We also intend to continue exploring options to reactivate our development of the HepatAssist™ Cell-Based Liver Support System; however, we will need to obtain significant additional capital to fund this program or find a strategic partner who would be willing to assist in developing this product candidate. Based on our current estimates, we believe that we do not have sufficient financial resources to conduct our planned operations for the next twelve months and that our current cash and cash equivalents are sufficient to fund our operations into the third quarter of 2008. Failure to raise additional capital may result in substantial adverse circumstances, including our inability to continue the development of our product candidates and our liquidation.

Our research offices and laboratories are located in Medford, Massachusetts where we lease 1,783 square feet at $5,044 per month with a term of one year that was entered into on September 15, 2007. We maintain an administrative office in Pasadena, California leased on a month-to-month basis for approximately $1,500 per month and our corporate headquarters is located in Waltham, Massachusetts, which is leased through July 2008 for approximately $3,700 per month.

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 us.

We have also entered into various exclusive manufacturing and supply agreements with Membrana GmbH, or Membrana, and NxStage Medical Inc., or NxStage. Membrana is a Germany company that specializes in the manufacture of membranes used for hemofiltration and will supply us with the membrane material needed for

manufacture of the SEPET™ Liver Assist Device. NxStage is a U.S. based company that will assemble the SEPET™ cartridge utilizing the supplied membrane from Membrana.

On September 19, 2007, Walter C. Ogier, resigned from our Board of Directors and as our President and Chief Executive Officer and our Board of Directors appointed Shawn P. Cain, previously our Vice President of Operations, as our Interim President and Chief Executive Officer.

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 candidate. 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™ can be completed before the development of HepatAssist™ is completed. Therefore, we are focusing our efforts on the development of SEPET™.

We have already performed *in vitro* and *in vivo* testing of the SEPET™ prototype device and commenced clinical testing of SEPET™ in late 2005. We treated 14 patients suffering from acute-on-chronic liver failure with hepatic encephalopathy in the Phase I feasibility clinical trial of SEPET™ and have completed this clinical trial. In February 2008, the FDA granted us conditional approval of an IDE application to begin the pivotal clinical trial for SEPET™ while we respond to the FDA's conditions and request for additional information. In particular, FDA has requested a survival primary endpoint rather than the primary endpoint of a two-stage drop in hepatic encephalopathy proposed in our original trial design submitted to the FDA. We are refining our position that a two-stage drop in hepatic encephalopathy is clinically meaningful and an appropriate primary endpoint for the trial. We have had an additional meeting with the FDA in March 2008 and are discussing our position regarding a suitable primary endpoint for the trial. We plan to submit a revised trial design to the FDA in the beginning of the second quarter of 2008 and hope to commence the pivotal trial once that primary endpoint is finalized. However, there is no assurance that we will be able to negotiate an acceptable primary endpoint that will enable us to attract sufficient capital to continue our planned operations and activities.

Our strategy for realizing sales revenue from SEPET™ is to seek a CE Mark in Europe prior to approval of the product candidate by the FDA. We believe commercialization of SEPET™ under a CE Mark may be possible in the beginning of 2009. 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 United States may only follow successful completion of a pivotal clinical trial of SEPET™ meeting efficacy endpoints approved by the FDA. 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.

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 three 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 liver cells , or hepatocytes, that the cartridge would contain, which 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.

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 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; however, we will need to obtain significant additional funding or establish a corporate partnership in order to further develop this product candidate. Since we are still developing our clinical and regulatory strategies for the HepatAssist™ Cell-Based Liver Support System, and since our continual development of this product candidate depends on our securing additional funding or a corporate collaboration, we cannot estimate when an application requesting marketing approval of HepatAssist™ will be filed.

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 and we need to enroll significantly more patients in our trials, including as a result of the FDA mandating that our pivotal trial of SEPET™ include a survival-based primary endpoint, 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 prior to transplantation. 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 these 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. In addition to demonstrating an extension of survival in large animal model testing of SEPET™, 79% of the patients in our recently completed

feasibility clinical trail of SEPET™ showed full resolution or a reduction in hepatic encephalopathy (H.E., also known as liver coma) by at least two grades of H.E.

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 levels of substances toxic to the brain and liver in the patient's blood and to provide whole liver functions, which are impaired or lost.

Our founders, as well as investigators not associated with us, have demonstrated *in vitro* and in animal models of liver failure that cell-based bioartificial liver systems using viable isolated hepatocytes can provide whole liver functions, to varying degrees depending on the technology approach. Only a few bioartificial livers, however, 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. A new Phase III clinical trial, however, will be needed before our HepatAssist™ system, which is an enhanced version of the original HepatAssist™ system, may be commercialized.

The Product Candidates 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 partial 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 overall 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 levels of substances that are toxic to both the brain and liver and other internal organs. We have obtained final results in the feasibility clinical trial of SEPET™, and we 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 product candidates still needs to be conclusively demonstrated in patients with liver failure through randomized, controlled clinical trials of each therapy.

We own certain technologies and rights related to our product candidates, 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™

The SEPET™ Liver Assist Device

We are developing the SEPET™ Liver Assist Device as a blood purification measure to provide temporary liver support for 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 patient's blood including albumin-bound toxins, inflammatory disease mediators, and soluble toxins. The importance of using fibers with this sieving characteristic, which allows for filtration of molecules larger than 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 generally have relatively high molecular weight. At present, Membrana supplies us with the hemofiltration membranes and NxStage assembles the disposable SEPET™ 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 the use of 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 for use with SEPET™ will be manufactured for us by qualified third-party vendors.

During SEPET™ therapy, a patient's blood is pumped through the hollow fibers contained in the cartridge and substances normally metabolized by the liver and accumulated in the blood during liver failure are transported convectively across the porous fiber wall and an ultrafiltrate containing toxins, inhibitors of hepatic growth and mediators of inflammation is removed from the patient's blood stream by exiting 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 this two-step blood purification, or detoxification, process, 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.

Clinical Development

Our SEPET™ Liver Assist Device has been tested in an IDE clinical feasibility trial in the United States we completed in 2007. This single arm, uncontrolled study enrolled 15 patients at three major liver transplant hospitals (Cedars Sinai Medical Center, Los Angeles; Albert Einstein Medical Center, Philadelphia; and University of California Medical Center, San Diego) under an IDE application approved by the FDA in 2005. The study enrolled patients suffering hepatic encephalopathy (also known as liver coma), ranging from Grade I to Grade III. Of the 15 patients enrolled

into the trial, 14 patients were treated with at least one (typically 5-6 hour) round of SEPET™ treatment, receiving an average of less than two, and a maximum of four, sequential daily treatments until a stable, durable disease response was achieved. Final analysis of the clinical trial results confirmed a high rate of achievement of the primary endpoint for clinical effectiveness with 11/14 (79%) subjects showing full resolution or a reduction in hepatic encephalopathy by at least two grades. The responses were generally rapid and observed within 48 hours after initiation of treatment, with many occurring during the first treatment. Thirteen of 14 (93%) patients' responses were sustained over the 30-day follow-up period, and improved overall liver function was documented as determined by biochemical measures. Just one out of the 14 patients treated proved refractory to repeated SEPET™ treatment, however, achieving a single-grade improvement in their encephalopathy. Two additional patients had treatment halted early, prior to achievement of stable response, due in one case to mild bleeding at a catheterization site and in the other to malfunction of a dialysis machine not associated with our SEPET™ liver assist device. All patients survived until the end of the 30-day follow-up period and 4 patients were subsequently transplanted with a donor liver. SEPET™ treatment was generally well-tolerated and had no negative effects on vital signs (heart rate, blood pressure and respiration) and base blood chemistries. Expected moderate reductions in blood platelets were observed, none with critical consequence. An adverse event of renewed, mild bleeding from a site of prior recent trauma, categorized as severe, was not associated with a low platelet count and was likely caused by the use of heparin for anticoagulation, which is commonly utilized in extracorporeal blood therapy. All treatment-related adverse events were expected and typical of extracorporeal blood therapy procedures, and all were resolved satisfactorily with indicated standard treatment. FDA has allowed a SEPET™ protocol amendment involving discretionary substitution of an alternative anticoagulation method, utilizing sodium citrate instead of heparin, which is anticipated to reduce bleeding risk in subsequent treatments.

Based upon the results of the feasibility study, we submitted an IDE application to the FDA seeking approval to initiate a pivotal trial of SEPET™. The design for this trial submitted to the FDA entailed enrolling approximately 100 patients in the principal randomized, controlled phase of the study, targeted to achieve the primary endpoint of the trial, which is a clinically significant reduction in hepatic encephalopathy. Patients receiving SEPET™ treatment plus standard medical care would be compared to control patients receiving treatment with standard medical care alone, with a 1:1 randomization between the two groups. An adaptive design feature, increasingly common in FDA product approval trials, would permit the size of the trial to be increased after enrollment of the first 100 patients if the primary efficacy endpoint has not yet reached statistical significance but has shown a positive trend. This potential extension of the trial would also be permitted to achieve statistical significance of one or more secondary endpoints of the trial relating to clinical, functional, and reimbursement advantages for SEPET™-treated patients. Following a meeting with the FDA in the summer of 2007, the FDA granted us conditional approval of the IDE application in February 2008 to begin the pivotal clinical trial while we respond to the FDA's conditions and request for additional information. In particular, the FDA has requested a survival primary endpoint rather than the primary endpoint of a two-stage drop in hepatic encephalopathy proposed in our original trial design submitted to the FDA. We have had an additional meeting with the FDA in March 2008 and are discussing our position regarding a suitable primary endpoint for the trial. We plan to submit a revised trial design to the FDA in the beginning of the second quarter of 2008 and hope to commence the pivotal trial once that primary endpoint is finalized. If we are required to include survival as a primary endpoint in this trial, the number of patients that we must enroll in the trial, the time to complete the trial and the cost of this trial may be significantly increased. This could negatively impact our ability to raise additional capital and could delay the potential commercialization of SEPET™ in the United States and abroad.

HepatAssist™

The 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). 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 FDA for use in a new pivotal clinical trial. We have postponed further clinical development of our HepatAssist™ program until we are able to secure additional funding or a potential corporate partner for this program.

Critical to the HepatAssist™ technology is (i) the source and method of procurement of pig liver cells, (ii) the cryopreservation, or freezing, of such liver cells, (iii) the frozen storage of such 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 various 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 candidate. The following addresses our current plans and procedures regarding viable liver cells (hepatocytes).

Hepatocyte donors. Ideally, human hepatocytes would 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, that we 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. Importantly, 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 pigs raised in a facility to be certified specifically by the U.S. Department of Agriculture, or 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.

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 the bioartificial liver components, consisting of the cell cartridge, oxygenator, sorbent detoxification column(s), and tubing kit, into the blood/plasma perfusion platform. Approximately 14 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, 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), it is anticipated that 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 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 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.

Preclinical and Clinical Development

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 supported, 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 ($n=121$; $p<0.0428$) These trials of the original HepatAssist™ system were the first and amongst the largest prospective, randomized, controlled multi-center trials of a liver assist technology, and, to our knowledge, 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, the prospective primary clinical end point in the overall study population was not achieved. As a result, 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 but Circe Biomedical did not initiate this trial before it ceased operations in 2003 and we have postponed further clinical development of our HepatAssist™ program until we are able to secure additional funding or a potential corporate partner for this program.

Advantages of Our Product Candidates

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

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

- Simplicity. Kidney dialysis systems are routinely used 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™. These systems 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, 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 not be demonstrated without head-to-head trials with competitive approaches.

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 can address 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.

We believe 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. According to the American Liver Foundation, liver disease is among the top seven causes of death in adults in the United States between the ages of 25 to 64. In fact, one out of every 10 Americans has some form of liver disease. There is currently no satisfactory therapy available to treat patients in liver failure, other than maintenance and monitoring of vital functions and keeping patients stable through provision of intravenous fluids and blood products, administration of antibiotics and support of vital functions, such as respiration.

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 to 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 14, 2008, the liver transplant waiting list contained 16,390 individuals. Hepatitis B is less prevalent in the United States 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 in the United States 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 or more 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 in the United States the cost to the provider of a single treatment with the SEPET™ therapy could be within a $2,000 to $4,000 range and that the respective cost of HepatAssist™ therapy could be approximately $15,000 to $20,000. 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 product candidates, liver failure patients treated with our product candidates 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 product candidates.

Sales, Marketing & Distribution

We currently do not have any agreements in place to market any of our product candidates 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, if approved, in all regions of the world. We currently expect to outsource at least a portion of the sales, marketing and distribution of our products, if approved, including SEPET™ in Europe if we obtain CE Marking approval, 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 product candidates 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, if approved, 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.

We are also moving forward on the marketing authorization process in the European Union to receive CE Marking for our SEPET™ Liver Assist Device. CE Marking indicates that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation and allows sale of the product within the European Union (28 countries) and the European Free Trade Association (3 countries).

Manufacturing & Supply

With respect to cartridges that we expect will be needed for SEPET™, we expect that such cartridges will be commercially manufactured by NxStage, and the membrane inside the cartridge will be produced by Membrana. Additional disposable components, such as tubing connectors, may also be manufactured by third party subcontractors.

We currently do not have a finalized manufacturing arrangement for the cartridges used in the HepatAssist™ system. 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.

Supply Agreement with Membrana GmbH

On September 14, 2007, we entered into a supply agreement with Membrana, a company organized under the laws of Germany, for the provision of membranes for use in SEPET™. The agreement provides that following the first commercial sale of our product that contains Membrana membranes, Membrana will be our exclusive supplier of certain identified membranes for use in certain of our products. In addition, the agreement provides that following the first commercial sale of our product that contains Membrana membranes, Membrana shall not supply certain identified membranes for use in certain of our products to any other third party that will incorporate such membranes into a product whose composition, method of manufacture or method of use falls within a claim of one of our issued U.S. patents. Such exclusivity may last for up to five years based upon our fulfillment of certain minimum purchase thresholds. The agreement also provides for pre-established per-unit pricing of Membrana membranes, including progressive quantity discounts.

The agreement will terminate following the six-year anniversary of the date of the first commercial sale of our product that contains Membrana membranes. The agreement may be terminated by either party upon 90 days notice in the event of a material breach by the other party that remains uncured for 90 days, or upon 60 days notice if the other party becomes insolvent or becomes the subject of any voluntary or involuntary proceeding in bankruptcy, liquidation, dissolution, receivership, or general assignment for the benefit of creditors that is not dismissed within 60 days. In addition, upon 60 days notice, we may terminate the agreement or terminate the exclusivity of the agreement, upon Membrana's failure to meet certain delivery requirements.

Manufacturing & Supply Agreement with NxStage Medical, Inc.

On October 19, 2007, we entered into a manufacturing & supply agreement with NxStage Medical, Inc. for the manufacture and supply of our SEPET™ Liver Assist Device for use in clinical trials and for commercial sale, if it is approved. The agreement provides that NxStage will be our exclusive manufacturer and supplier of the SEPET™ Liver Assist Device for commercial sale until the fifth anniversary of regulatory approval of the device. Under the agreement, NxStage will not manufacture, supply or sell our device to other parties and if NxStage manufactures, supplies or sells a competing product, as defined in the agreement, subject to certain exceptions, we may terminate the arrangement or convert it into a non-exclusive arrangement. In addition, if we purchase more than a certain number of devices in one calendar year, we will be subject to an annual minimum purchase requirement for the remainder of the agreement, which minimum will be subject to adjustment each year. The agreement provides for pre-established per-unit pricing, including quantity discounts and yearly adjustments.

The agreement will terminate upon the earlier of (i) the seventh anniversary of regulatory approval of the device or (ii) the seventh anniversary of the date of the agreement if regulatory approval of the device is not obtained by such date. The agreement may be terminated by either party (i) upon an extended prior notice period, (ii) upon a material breach by the other party that remains uncured, or (iii) upon notice if the other party becomes insolvent, files for bankruptcy, goes into liquidation or a receiver is appointed over all or a major part of the other parties' assets. In addition, we may

terminate the agreement or terminate the exclusivity of the agreement, upon the occurrence of certain events.

Platforms used for SEPET™ and HepatAssist™ Devices

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 open platform 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 us, and a tubing set for use with our HepatAssist™ system.

Cell Procurement

The pig liver cells will be harvested from young purpose-bred, pathogen-free 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 U.S. 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 from Immunocept, LLC 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, ranging from low- to mid-single digit percentages of net sales. 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 us. Our contingent obligations under the license will total less than $500,000 over approximately the same period (dependent, however, 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.

Our founders, 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 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, we entered into an agreement with Cedars-Sinai Medical Center pursuant to which Cedars-Sinai granted us exclusive and worldwide rights to patents (2) through (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, we were 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 4 “Patent Rights” and 6 “Stockholder’s Equity - Junior Preferred Stock” of the financial statements included elsewhere in the Annual Report.

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 through 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 shall continue until either ten years have elapsed from the first commercial sale date or the last to expire Circe Biomedical patent right has occurred. 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 U.S. trademark protection for our product candidate names, SEPET™ and HepatAssist™, which marks may become registered only upon commercialization of the products.

Research and Development

We spent approximately $2,300,000 on research and development during the fiscal year ended December 31, 2007, $1,823,000 on research and development during the fiscal year ended December 31, 2006 and $8,113,000 on research and development from inception (August 23, 2000) through December 31, 2007.

Competition

Our product candidates will compete with several 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 product candidates 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 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. 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.

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 early positive results.

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/biologics) clinical testing program is then undertaken. In Phase I or feasibility phase, small clinical trials are conducted to determine the safety of the product candidate. In Phase II (typically not required for devices), clinical trials are conducted to assess safety and gain preliminary evidence of the efficacy of the product candidate. In Phase III 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.

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, or 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 versus three-phase clinical trial process described above).

SEPET™ may be regulated in the United States 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 finalizing the design of and preparing for a pivotal 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 amendments to conduct human studies, followed by the submission of a PMA application. 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 candidate; and (iv) the submission to the FDA of a product application. Preclinical tests include laboratory evaluation of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. 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. As discussed above, 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 PMA and Biologic License Approval, or 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 candidate; and (iv) the submission to the FDA of a product application. Preclinical tests include laboratory evaluation of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. 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. As discussed above, 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, when conducted, 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 United States. Label claims for medical devices marketed under the CE Mark are restricted to what has been proven in clinical trials. 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 in the past, 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 31, 2008, we employed four full-time employees and one part-time employee. We have also engaged five independent contractors under consulting agreements who provide services to us on a substantial part-time basis. Of the foregoing employees and contractors, three are primarily engaged in administration or management, and the remaining seven persons are involved in scientific research, product development, clinical development, manufacturing development and/or regulatory compliance matters. On March 29, 2008, we terminated one part-time employee, one full-time employee, and one independent contractor to help preserve our existing cash reserves. Our employees are not represented by a labor organization or covered by a collective bargaining agreement. We have not experienced work stoppages and we believe that our relationship with our employees is good.

Glossary of Terms

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

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

"Extracorporeal" means situated or occurring outside the body.

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

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

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

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

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

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

"IND" means Investigational New Drug application.

"IDE" means Investigational Device Exemption.

"***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 research offices and laboratories in Medford, Massachusetts where we lease 1,783 square feet at $5,044 per month with a term of one year that was entered into on September 15, 2007. We maintain an administrative office in Pasadena, California and our corporate headquarters is located in Waltham, Massachusetts. The Pasadena office is leased on a month-to-month basis for approximately $1,500 per month for 640 square feet of space, and the Waltham office is leased for a term of six months ending on July 31, 2008 for approximately $3,900 per month for 600 square feet of space. We believe our laboratory and office space is adequate for our current operating needs.

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, 2007.

PART II

ITEM 5. MARKET FOR COMMON EQUITY, 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.

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, 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
March 31, 2007	$1.10	$0.43
June 30, 2007	$0.89	$0.60
September 30, 2007	$0.85	$0.29
December 31, 2007	$0.75	$0.55

Holders

As of March 26, 2008, there were 125 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 our 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 2007.

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

Overview

On October 30, 2003, we completed a reorganization, (the "Reorganization") in which we acquired Arbios Technologies, Inc., or ATI, and the SEPET™ program. 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. 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. In July 2005, we consolidated our corporate structure by merging ATI into our then parent company, Arbios Systems, Inc., creating our current operating structure. 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.

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 U.S. Small Business Administration.

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.

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 (i) finalize the design of our planned pivotal trial of SEPET™ with the FDA and commence the trial by the second half of 2008 once a primary endpoint is established, (ii) the preparation and submission of applications to a Notified Body in Europe to secure CE Mark approval to market our SEPET™ Liver Assist Device in Europe, (iii) the completion of an equity or other financing to support operations and the SEPET™ pivotal trial and (iv) identify and recruit a chief executive officer. 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, the timing and cost of regulatory submissions and our ability to reach an agreement with the FDA about the design of our planned pivotal trial of SEPET™. Based on our current estimates, we currently do not have sufficient cash to conduct our plan of operations for the next twelve months from the date of this Annual Report and that our current cash and cash equivalents are only sufficient to fund our operations into the third quarter of 2008. We are, however, seeking additional investment from various investors, but currently have no firm agreements or commitments in this regard to fund future development of our product candidates. Failure to raise additional capital may result in substantial adverse circumstances, including our inability to continue the development of our product candidates and our liquidation.

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, 2007. 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, or FASB, Statement of Financial Accounting Standards, or 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 SFAS No. 2, "Accounting for Research and Development Costs," or SFAS 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 we adopted SFAS No. 123R, "Share Based Payment," or 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, we 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". We have applied the modified prospective method in adopting SFAS 123R. Accordingly, periods prior to adoption have not been restated.

New Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements," or SFAS 157. SFAS 157 establishes a single authoritative definition of fair value, sets out a framework for measuring fair value, and requires additional disclosures about fair-value measurements. SFAS 157 applies only to fair value measurements that are already required or permitted by other accounting standards (except for measurements of share-based payments) and is expected to increase the consistency of those measurements. Accordingly, SFAS 157 does not require any new fair value measurements. However, for some entities, the application of SFAS 157 will change current practice. SFAS 157 is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We do not expect the adoption of SFAS 157 to have a material impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115," or SFAS 159, which is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. SFAS 159 permits entities to measure eligible financial assets, financial liabilities and firm commitments at fair value,

on an instrument-by-instrument basis, that are otherwise not permitted to be accounted for at fair value under other generally accepted accounting principles. The fair value measurement election is irrevocable and subsequent changes in fair value must be recorded in earnings. We are currently evaluating the impact that SFAS 159 will have on our financial statements.

On June 27, 2007, the FASB reached a final consensus on Emerging Issues Task Force, or EITF, Issue 07-3, "Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities," or EITF 07-03. Currently, under SFAS 2 nonrefundable advance payments for future research and development activities for materials, equipment, facilities, and purchased intangible assets that have no alternative future use are expensed as incurred. EITF 07-03 addresses whether such non-refundable advance payments for goods or services that have no alternative future use and that will be used or rendered for research and development activities should be expensed when the advance payments are made or when the research and development activities have been performed. The consensus reached by the FASB requires companies involved in research and development activities to capitalize such non-refundable advance payments for goods and services pursuant to an executory contractual arrangement because the right to receive those services in the future represents a probable future economic benefit. Those advance payments will be capitalized until the goods have been delivered or the related services have been performed. Entities will be required to evaluate whether they expect the goods or services to be rendered. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment will be charged to expense. The consensus on EITF 07-03 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. Entities are required to recognize the effects of applying the guidance in EITF 07-03 prospectively for new contracts entered into after the effective date. We are in the process of evaluating the expected impact of EITF 07-03 on our financial position and results of operations following adoption.

Results of Operations

Comparison of Fiscal Year ended December 31, 2007 to Fiscal Year ended December 31, 2006.

Since we are still developing our product candidates 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 $3,420,048 and $3,315,174 were incurred for the years ended December 31, 2007 and 2006, respectively. For the year ended December 31, 2007, the expenses include $976,000 in fees incurred to outside consultants and professionals, $788,000 in payroll and payroll related costs, $715,000 in non-cash option and warrant charges, $135,000 in investor relation costs, $180,000 in equity offering contingent charges and other administrative expenses. 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. Professional fees increased in 2007 due to increased patent legal costs of $102,000, increased legal costs of $151,000 due to additional administration associated with an acquired patent portfolio and various compliance and contract negotiations, and an increase in executive search recruitment fees of $114,000 related to our search for a CEO. The decrease in non-cash option and warrant charges reflect lower fair value option charge calculations which are impacted by a declining common stock market price in 2007. The 2007 increase in payroll and payroll related expenses primarily reflect the severance costs incurred with the former Chief Executive Officer's separation agreement. An equity offerings contingency for $180,000 was accrued in the first quarter of 2007. Investor relations cost reductions are attributed to lower spending on fixed retainer costs. On March 29, 2008, we reduced our workforce by three people in order to help preserve our cash balance. We anticipate severance costs and vacation payout payments of approximately $17,000 related to this reduction in force.

Research and development expenses of $2,299,632 and $1,822,614 were incurred for the years ended December 31, 2007 and 2006, respectively. Research and development expenses for 2007 consist primarily of $635,000 in payroll and payroll related expenses, $299,000 in SEPET™ development, manufacturing and clinical costs, $701,000 in consultant costs related to manufacturing, regulatory and product management, $425,000 in patent acquisition costs, and $36,000 in HepatAssist™ facility costs. 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 costs increased by $477,018 from 2006 to 2007 and reflect increased expenditures for the SEPET™ program. Payroll cost increases reflect a full year salary in 2007 for clinical research management hired in 2006. The increase in consulting costs reflects outsourced service costs incurred related to the SEPET™ program, $425,000 in patent acquisition costs relate to the patent portfolio acquisition in March 2007. The HepatAssist™ facility lease was terminated in March 2007 and resulted in lower costs for this program.

The change in fair value of warrant liability reflects the elimination of the warrant liability valuation due to our recording a change in accounting principal on 2007. In accordance with SFAS No. 154, "Accounting Changes and Error Corrections," or SFAS 154, we recorded a change in accounting principal related to EITF Issue No. 00-19-2, "Accounting for Registration Payment Arrangements," or EITF 00-19-2. EITF 00-19-2 was issued December 21, 2006 and is effective for fiscal periods beginning after December 15, 2006, and requires the registration rights agreement and any registration rights payments to be considered separately from the financial instruments. In accordance with EITF 00-19-2, we reversed the classification of the warrant liability associated with the warrants issued in our 2005 and 2006 financings from debt to equity during the period ended March 31, 2007. The warrants and registration rights agreement were previously accounted for as a single instrument, and without the consideration of the registration rights payments, the warrants are properly classified as equity in accordance with EITF 00-19. We reviewed the instruments entered into in connection with our 2007 financing and determined that the financing did not have any embedded derivatives requiring derivative accounting treatment.

Interest income of $167,030 and $154,697 was earned for the years ended December 31, 2007 and 2006 respectively. The increase in interest income of $12,333 results from higher average cash balances maintained in 2007.

Our net loss increased to $5,552,650 in 2007 from $4,461,904 in 2006. The increase in net loss is attributed to an increase in operating expenses incurred in the fiscal 2007 periods as compared to the same periods in 2006, without an increase in revenues.

Liquidity and Capital Resources

As of December 31, 2007, we had cash and cash equivalents of $2,735,944. We do not have any bank credit lines. To date, we have funded our operations from the sale of equity securities and government research grants.

On April 23, 2007, we completed a private equity financing of $4,861,000 to a group of current and new accredited investors which was reduced by $377,000 in fund raising costs resulting in net proceeds to us of $4,484,000. In the offering, we sold 3,739,231 Units. Each Unit was sold at a price of $1.30 per Unit. Each Unit consists of: (i) two shares of common stock, (ii) one warrant to purchase one share of common stock exercisable for a period of 2.5 years at an exercise price of $1.00 ("A Warrants") and (iii) one warrant to purchase one share of common stock exercisable for a period of five years at an exercise price of $1.40 ("B Warrants"), comprising a total of 7,478,462 shares of common stock and warrants to purchase 7,478,462 shares of common stock. The warrants have no provision for cashless exercise and, subject to certain requirements, we may call the warrants provided that our common stock trades above $1.50 for the A Warrants and above $2.80 for the B Warrants for a specified time period. The placement agent received: (i) a cash fee of $252,000, (ii) a warrant to purchase 576,615 shares of common stock with an exercise price of $0.65 and a term of five years with a Black Scholes valuation of $275,845 utilizing the following assumptions: risk free interest rate 4.59%, stock price volatility 0.80, expected life 5 years, dividend yield 0%, and (iii) a contingent cash fee of 7% of cash proceeds generated in connection with any additional payments, equity purchases or warrant exercises originating from investors from the April 2007 financing within 12 months of the closing of the financing. As a result of the April 2007 financing and pursuant to certain anti-dilution terms of our prior equity financings, we increased the number of shares issuable under the warrants issued in the 2005 and 2006 financing by approximately 746,000 shares. The exercise price of the warrants from the January 2005 equity financing was reduced from $2.74 to $1.91 per share and the exercise price of the warrants from the March 2006 equity financing was reduced from $1.50 to $1.22 per share.

Based on our current estimates, we currently do not have sufficient cash to conduct our plan of operations for the next twelve months from the date of this Annual Report and our current cash and cash equivalents are only sufficient to fund our operations into only part of the third quarter of 2008. 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 product candidates.

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 product candidates and of obtaining all required regulatory approvals to market our product candidates 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 six months. We currently expect to attempt to obtain additional financing through the sale of additional equity and possibly through strategic alliances with larger pharmaceutical, medical device or biomedical companies or alternative financing vehicles. We cannot be sure that we will be able to obtain additional funding from any of these sources, or that the terms under which we obtain such funding will be beneficial to us. Failure to raise additional capital may result in substantial adverse circumstances, including our inability to continue the development of our product candidates and our liquidation.

A summary of our contractual cash obligations at December 31, 2007 is as follows:

Contractual Obligations	**Total**	**2008**	**2009**	**2010**	**2011**
Long-Term Leases	$ 40,352	$ 40,352		-	
License Agreement	300,000	50,000	$ 100,000	$ 150,000	-
Total	$ 340,352	$ 90,352	$ 100,000	$ 150,000	$ -

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.

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.

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, 2007, 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, our value 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 product candidates. Failure to raise additional capital may result in substantial adverse circumstances, including our inability to continue the development of our product candidates and our liquidation.

We need to obtain significant additional capital to complete the development of our liver assist devices and meet contractual obligations related to our licensed patents, which additional funding may dilute our existing stockholders.

Based on our current proposed plans and assumptions, we estimate that we do not have cash to operate for the next 12 months, and therefore we will need to obtain significant additional funds during the first half of 2008. The clinical development expenses of our product candidates will be very substantial. Based on our current assumptions, we estimate that the clinical cost of developing the SEPET™ liver assist device will be approximately $5 million to $10 million, and the clinical cost of developing the HepatAssist™ cell-based liver support system will be between $10 million and $15 million, in excess of the cost of our basic operations. These amounts, which could vary substantially if our assumptions are not correct and we need to enroll significantly more patients in our trials, including as a result of the FDA mandating that our pivotal trial of SEPET™ include a survival-based primary endpoint, are well in excess of the amount of cash that we currently have available to us. Accordingly, we will be required to (i) obtain additional debt or equity financing in order to fund the further development of our product candidates and working capital needs, and/or (ii) enter into a strategic alliance with a larger pharmaceutical or medical device company to provide its required funding. The amount of funding needed to complete the development of one or both of our product candidates will be very substantial and may be in excess of our ability to raise capital.

As a result of a decrease in our available financial resources, we have significantly curtailed the research, product development, preclinical testing and clinical trials of certain product candidates. The amount and timing of our future capital requirements will depend on numerous factors, including the timing of resuming our research and development

programs, if at all, the number and characteristics of product candidates that we pursue, the conduct of preclinical tests and clinical studies, the status and timelines of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the ability to complete strategic collaborations and the availability of third-party funding, if any.

We have not yet 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 product candidates could be delayed and we could be forced to reduce the scope of our pre-clinical studies 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.

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

The feasibility clinical trial for the SEPET™ Liver Assist Device has been completed and we have obtained conditional approval from the FDA to initiate the pivotal trial of SEPET™; however, we must raise additional funds to support the further development of SEPET™. We have not yet established with the FDA the nature and number of additional clinical trials that the FDA may require in connection with its review and approval of the SEPET™ liver assist device. Based on our internal projections of our operating costs and the costs normally associated with pivotal trials, we do not believe that we currently have sufficient funds to conduct any such pivotal trial(s) but are attempting to identify sources for obtaining the required funds.

We have considered requesting FDA approval of a revised Phase III clinical trial for the HepatAssist™ Cell-Based Liver Support 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. 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 clinical trial in the manner that we currently contemplate is uncertain and could vary significantly, if that Phase III clinical trial is authorized by the FDA, we currently estimate that the cost of conducting the trial would approximately be between $10 million and $15 million, excluding the manufacturing infrastructure. We currently do not have sufficient funds to conduct this trial 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 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™ cell-based liver support system, we will not be able to conduct any clinical trials until we raise substantial amounts of additional financing.

Our capital needs beyond 2008 will depend on many factors, including our research and development activities and the success thereof, the scope of our clinical trial program, the timing of regulatory approval for our product candidates under development and the successful commercialization of our product candidates. Our needs may also depend on the magnitude and scope of the activities, the progress and the level of success in our clinical trials, the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights, competing technological and market developments, changes in or terminations of existing collaboration and licensing arrangements, the establishment of new collaboration and licensing arrangements and the cost of manufacturing scale-up and development of marketing activities, if undertaken by us. We currently do not have committed external sources of funding and may not be able to secure additional funding on any terms or on terms that are favorable to us. If we raise additional funds by issuing additional stock, further dilution to our existing stockholders will result, and new investors may negotiate for rights superior to existing stockholders. If adequate funds are not available, we may be required to:

- delay, reduce the scope of or eliminate one or more of our development programs;

- obtain funds through arrangements with collaboration partners or others that may require us to relinquish rights to some or all of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves;

- license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available;

- seek a buyer for all or a portion of our business; or

- wind down our operations and liquidate our assets on terms that are unfavorable to us.

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 product candidates 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 product candidates. 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 revenues from the sale of any of our product candidates for another year or longer. We have postponed further clinical development of our HepatAssist™ program until we are able to secure additional funding for this project or a corporate partner for this program.

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

The development, production and marketing of our product candidates 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 to allow clinical testing and ultimately 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 product candidates 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™ product candidates and these requirements may be more costly or time-consuming than we currently anticipate. If we are required to include survival as a primary endpoint in the planned pivotal trial of SEPET™, the number of patients that we must enroll in the trial, the time to complete the trial and the cost of this trial may be significantly increased. This could negatively impact our ability to raise additional capital and could delay the potential commercialization of SEPET™ in the United States and abroad.

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 our product candidates 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 product candidates. The failure to receive, or any

significant delay in receiving, FDA approval, or the imposition of significant limitations on the indicated uses of our product candidates, 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 this product, if approved, 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 product candidates will be reduced.

Because our product candidates are at an early stage of development and have never been marketed, we do not know if any of our product candidates 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 product candidates, 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™ product candidates. While the time periods for testing our product candidates 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 product candidates and technologies. Before we can begin clinical testing of these product candidates, we will need to amend the active Phase III IND to resume clinical testing of our HepatAssist™ product candidate and finalize the protocol of our planned pivotal trial of SEPET™ with the FDA to receive unconditional approval of our IDE application. 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. For example, if we are required to include survival as a primary endpoint in the planned pivotal trial of SEPET™, the number of patients that we must enroll in the trial, the time to complete the trial and the cost of this trial may be significantly increased. This could negatively impact our ability to raise additional capital and could delay the potential commercialization of SEPET™ in the United States and abroad. Because of the early stage of development of each of our product candidates, 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 product candidates or the FDA's approval of any product marketing approval applications or biologic license approval application that we do file.

Our cell-based liver support system utilizes a biological component obtained from pigs that could prevent or restrict the release and use of those product candidates.

Use of liver cells harvested from pig livers carries a risk of transmitting viruses harmless to pigs but potentially 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 still unknown. Repeated testing, including a 1999 study of 160 xenotransplantation (transplantation from animals to humans) patients and the Phase II/III testing of the HepatAssist™ system by Circe Biomedical, Inc., has produced no sign of the transmission of PERV to humans. Still, no one can prove that PERV or another virus would not infect bioartificial liver-treated patients and cause potentially serious disease. This may result in the FDA or other health regulatory agencies not approving our HepatAssist™ Cell-Based Liver Support System or subsequently banning any further use of our product candidate 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, 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 product candidates represent new approaches to treatment of liver disease, there are many uncertainties regarding the development, the market acceptance and the commercial potential of our product candidates.

Our product candidates represent new therapeutic approaches for disease conditions. We may, as a result, encounter delays as compared to other product candidates 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 product candidates, if approved. 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 product candidates. Since our product candidates represent new approaches to treating liver diseases, it may be difficult, in any event, to accurately estimate the potential revenues from our product candidates, 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, medical device and biotechnology industries are 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 product candidates. 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, supply and marketing of our product candidates.

Our business model calls for the outsourcing of the clinical development, manufacturing, supply and marketing of our product candidates, if approved, in order to reduce our capital and infrastructure costs as a means of potentially improving the profitability of these product candidates for us. We have not yet entered into any strategic alliances or other licensing arrangements and there can be no assurance that we will be able to enter into satisfactory arrangements for these services or marketing of our product candidates. 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 product candidates 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 product candidates. In addition, we plan to utilize contract manufacturers to manufacture our product candidates or even our commercial supplies, and we may contract with independent sales and marketing firms to use their pharmaceutical or medical device sales force on a contract basis.

To the extent that we rely on other companies or institutions to manage the conduct of our clinical trials and to manufacture or market our product candidates, 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, quality specifications or cost parameters, the timing of our clinical trials and development of our product candidates may be adversely affected. Any manufacturer or supplier that we select, including Membrana and NxStage, 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 any of our manufacturing or marketing companies, including Membrana and NxStage, encounter regulatory problems with the FDA, FDA approval of our product candidates could be delayed or the marketing of our product candidates, if approved, could be suspended or otherwise adversely affected.

Because we are currently dependent on NxStage and Membrana as the manufacturers of our SEPET™ cartridges, any failure or delay by either NxStage or Membrana. to manufacture the cartridges will negatively affect our future operations.

We have exclusive manufacturing and/or supply arrangements both with NxStage and Membrana. If NxStage or Membrana is unable to meet its contractual obligations to us, we may have difficulty in finding a replacement manufacturer/supplier if we are unable to effectively transfer the NxStage or Membrana know-how to another manufacturer. We have no control over NxStage, Membrana or their suppliers, and if NxStage or Membrana are unable to produce the SEPET™ cartridges or it's components 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™ Cell-Based Liver Support System. While we believe there are several potential contract manufacturers who can produce these cartridges, there can be no assurance that we will be able to enter into such an arrangement on commercially favorable terms, or at all.

Because we are dependent on Medtronic, Inc. for the perfusion platform used in our HepatAssist™, 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 preferred 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 product candidate. A limited number of the PERFORMER units have been manufactured to date. The PERFORMER is being manufactured by RanD, S.r.l. (Italy) and marketed by Medtronic, Inc. We currently do not have an agreement to purchase the PERFORMER from Medtronic or any other source. In the event that RanD and Medtronic are either unable or unwilling to manufacture the number of PERFORMERS needed to ensure that HepatAssist™ 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, 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. In addition to the patents acquired on March 29, 2007, we currently own four U.S. and five foreign patents on our liver support product candidates, have two patent applications pending, and are the licensee of twelve additional liver support patents. We have relied substantially on the patent legal work that was performed for our assignors and licensors and investors with respect to all of these patents, application and licenses, and have not independently fully verified the validity or any other aspects of the patents or patent applications covering our product candidates with our own patent counsel. For example, we had received from the European Patent Office an initial rejection of a patent filing citing references to certain issued patents that may represent prior art in the field of large-pore hemofiltration. This and potential other prior art may prevent us from obtaining sufficient legal protection of our proprietary rights to SEPET™. We will need to raise an aggregate of $5.2 million during 2008 in order to maintain the license to the Immunocept patent portfolio that was acquired on March 29, 2007, and there is a possibility that the license may revert to a non-exclusive basis if we are unsuccessful in raising these funds..

Even when we have obtained patent protection for our product candidates, 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 product candidates infringe patents or other proprietary rights held by them.

We 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 product candidates 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. Due to our limited financial resources, we have recently reduced our staffing levels and currently have limited personnel to run our operations. As a result of our limited staff, 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.

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 services of additional senior scientific and management personnel and we are actively searching for a CEO. 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 senior personnel, our overhead expenses for salaries and related items will increase substantially from current levels.

The market success of our product candidates 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 product candidates, if approved, may depend significantly on the availability of reimbursement for our product candidates from third-party payers, such as governmental programs, private insurance and private health plans. We have not yet established with Medicare or any third-party payers what level of reimbursement, if any, will be available for our product candidates, and we cannot predict whether levels of reimbursement for our product candidates, if any, will be high enough to allow us to charge a reasonable profit margin. Even with FDA approval, third-party payers may deny reimbursement if the payer determines that our particular new products are unnecessary, inappropriate or not cost effective. If patients are not entitled to receive reimbursement similar to reimbursement for competing products, they may be unwilling to use our product candidates

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 product candidates could diminish or our ability to sell our product candidates 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 have obtained clinical trial insurance for our SEPET™ trials. 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 continue to secure such insurance for clinical trials for either of our two current product candidates. If our product candidates are approved, we intend to obtain coverage for them when they enter the marketplace (as well as requiring the manufacturers of our product candidates to maintain insurance). We do not know if coverage will be available to us at acceptable costs or at all. We may encounter difficulty in obtaining clinical trial or commercial product liability insurance for any cell-based 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 by 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. Remediation of 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 and the patent acquisition in March 2007, we may 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.

If we are unable to comply with the terms of registration rights agreements to which we are a party, we may be obligated to pay liquidated damages to some of our stockholders and re-characterize outstanding warrants as debt.

We are a party to registration rights agreements with some of our stockholders. The registration rights agreements provide, among other things, that we register shares of our common stock held by those stockholders within a specified period of time and that we keep the registration statement associated with those shares continuously effective. If we are unable to comply with these provisions of the registration rights agreements, we may be obligated to pay those stockholders liquidated damages. Because of the potential operation of the provisions of our registration rights agreements, we may have to re-characterize some of our outstanding warrants from equity to debt. If we have to make this re-characterization, our liabilities would increase and our financial statements would be negatively impacted.

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, or 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) and a two business day "cooling off period" before brokers and dealers can effect transactions in penny stocks. Such rules 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 100,000,000 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, 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.

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 20, 2008, we had outstanding 25,603,461 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. As of March 20, 2008, there were a total of 16,777,159 shares of our common stock issuable upon the exercise of outstanding warrants registered pursuant to effective registration statements under the Securities Act of 1933, as amended. 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 exercise of the warrants. Accordingly, 16,777,159 additional shares could be released onto the trading market at any time. Because of the limited trading volume, the sudden release of 16,777,159 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 4,550,000 shares of unregistered, restricted stock that are currently eligible for public resale under Rule 144 promulgated under the Securities Act of 1933, as amended, some of which shares also may be offered and sold on the market from time to time and an additional 3,465,677 shares that are issuable upon the exercise of outstanding options and other warrants.

No prediction can be made as to the effect, if any, that sales of the 16,777,159 registered warrant shares, or the sale of any of the 4,550,000 shares subject to Rule 144 sales or the 3,465,677 shares that are issuable upon the exercise of outstanding options and other warrants 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 changes in the regulations applicable to us,
- 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, medical device and other industries;
- new accounting standards;
- general economic, political and market conditions and other factors; and
- the occurrence of any of the risks described in this Annual Report.

ITEM 7. FINANCIAL STATEMENTS.

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

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

Not applicable.

ITEM 8A(T). CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. As of the end of the period covered by this report, our company conducted an evaluation, under the supervision and with the participation of our Interim Chief Executive Officer and Chief Financial Officer, of our disclosure controls and procedures (as defined in Rules 13a-15(e) of the Exchange Act). Based on this evaluation, our Interim Chief Executive Officer and Chief Financial Officer concluded that our company's disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosures.

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

(c) Management's Report on Internal Control over Financial Reporting. The management of the company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The company's management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2007. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment, management believes that, as of December 31, 2007, the company's internal control over financial reporting is effective based on those criteria.

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This Annual Report does not include an attestation report of the company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the company to provide only a management's report in this Annual Report.

(d) Limitations on the Effectiveness of Controls. Our management, including our interim chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within an organization have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake.

Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 8B. OTHER INFORMATION

None.

PART III

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

The following table sets forth the name, age and position held by each of our directors and executive officers as of March 29, 2008. Directors are elected at each annual meeting and thereafter serve until the next annual meeting (currently expected to be held during the third calendar quarter of 2008) at which their successors are duly elected by the stockholders.

Name	Age	Position
Shawn P. Cain	41	Interim President and Chief Executive Officer
Jacek Rozga, M.D., Ph.D.	59	Co-founder and Chief Scientific Officer
Scott L. Hayashi	36	Vice President of Administration, Chief Financial Officer and Secretary
Susan Papalia, RN, BSN	50	Vice President of Clinical Affairs
John M. Vierling, M.D., FACP [2]	62	Director, Chairman of the Board
Amy Factor	50	Director, Vice Chairman of the Board
Jack E. Stover [1]	55	Director
Thomas C. Seoh [1][3]	50	Director
Thomas M. Tully [1][2][3]	62	Director
Dennis Kogod [2][3]	48	Director

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[1] Member of Audit Committee.
[2] Member of Compensation Committee
[3] Member of Nominating and Corporate Governance Committee.

Business Experience and Directorships

The following describes the backgrounds of our current executive officers and directors.

Shawn P. Cain. Mr. Cain is currently our Interim President and Chief Executive Officer and has served in this capacity since September 2007. He joined us as our Vice President of Operations in April 2005 and was previously employed by us as a part-time consultant from December 2003 to March 2005. From June 2003 to March 2005, Mr. Cain was employed at Becton Dickinson's Discovery Labware, Biologics Business, where he was responsible for the operation of two manufacturing facilities that produced over 900 biologics products. From January 1997 through May 2003, Mr. Cain was the Vice President of Operations for Circe Biomedical, Inc., where he was instrumental in the early development of the bioartificial liver technology, including development our HepatAssist™ product candidate.

Jacek Rozga, MD, Ph.D. Dr. Rozga is our co-founder and has been our Chief Scientific Officer since our organization in August 2000. Dr. Rozga served as our President from August 2000 until November 2005. From October 2003 until March 2005, Dr. Rozga also acted as our Chief Financial Officer. Dr. Rozga is Chairman and Chief Executive Officer of OncoTx, Inc., a private California corporation since October 2005. Since 1992, Dr. Rozga has been a professor of Surgery at UCLA School of Medicine. Dr. Rozga was previously a research scientist at Cedars-Sinai Medical Center from 1992 to 2005.

Scott L. Hayashi. Mr. Hayashi has been our Chief Financial Officer since March 2005. Mr. Hayashi joined us as our Chief Administrative Officer in February 2004, became our Secretary in July 2004 and was appointed as the Vice President of Administration in November 2004. Prior to joining us, Mr. Hayashi was a Manager of Overseas Development for Cardinal Health, Inc. from July 2000 to April 2002. Mr. Hayashi worked in finance, mergers and acquisitions for Northrop Grumman Corporation from March 1997 to July 2000 and Honeywell, Inc. from July 1994 to December 1996.

Susan Papalia, RN, BSN. Ms. Papalia has been our Vice President of Clinical Affairs since November 2007 and brings more than 20 years of clinical research expertise to Arbios Systems, Inc. From August 2006 to August 2007, Ms. Papalia worked for Mitralign, Inc. (Tewksbury, MA) as Director of Clinical Affairs where she was successful in implementing a strategic clinical plan and obtaining international regulatory approvals for Mitralign's feasibility study of a novel percutaneous mitral valve repair system. From February 1990 to December 2005, Ms. Papalia worked for Boston Scientific, Inc. where she held management positions in United States and International Clinical Research.

John M. Vierling, M.D., **FACP.** Dr. Vierling has served as a director since February 2002. In April 2005, Dr. Vierling assumed the position of Professor of Medicine and Surgery, Director of Baylor Liver Health and Chief of Hepatology at the Baylor College of Medicine and Director, Advanced Liver Therapies at St. Luke's Episcopal Hospital in Houston, Texas. Dr. Vierling had been a Professor of Medicine at the David Geffen School of Medicine at UCLA from 1996 to 2005 and was the Director of Hepatology and Medical Director of Multi-Organ Transplantation Program at Cedars-Sinai Medical Center from 1990 until 2004. Dr. Vierling is also currently the President of the American Association for the Study of Liver Diseases. Dr. Vierling was the Chairman of the Board of the American Liver Foundation from 1994 to 2000, and the President of the Southern California Society for Gastroenterology from 1994 to 1995. Dr. Vierling has also been a member of numerous National Institutes of Health study sections and advisory committees, including the NIDDK Liver Tissue Procurement and Distribution Program. He is currently Chairman of the Data Safety Monitoring Board for the National Institute of Health, NIDDK ViraHep C Multicenter Trial. Dr. Vierling's research has focused on the immunological mechanisms of liver injury caused by hepatitis B and C viruses and autoimmune and alloimmune diseases.

Amy Factor. Ms. Factor was appointed as a director and Vice Chairman in September 2007. Prior to this, Ms. Factor served as a director from March 2005 until July 2006, and she was our interim Chief Executive Officer from April 2005 until November 2005. Ms. Factor has provided us with strategic and financial consulting services from November 2003 until the present. Since 1999, Ms. Factor has been President of AFO Advisors, LLC and the President of AFO Capital Advisors, LLC since 1996. Ms. Factor began her career with the public accounting firm KPMG and has been involved in the biotechnology industry since 1988 serving as the Chief Financial Officer of Immunomedics, Inc.

Jack E. Stover. Mr. Stover has served as a director since November 2004. Mr. Stover is also a director of PDI, Inc. and Antares Pharma, Inc. Mr. Stover was elected the President and Chief Operating Officer of Antares Pharma, Inc., (a public specialty pharmaceutical company) in July 2004. In September 2004, he was named President, CEO and was appointed as a director of that company. Prior thereto, for approximately two years Mr. Stover was Executive Vice President, Chief Financial Officer and Treasurer of SICOR, Inc., a Nasdaq traded injectable pharmaceutical company that was acquired by Teva Pharmaceutical Inc. Prior to that, Mr. Stover was Executive Vice President and Director for Gynetics, Inc., a private women's drug company, and the Senior Vice President, Chief Financial Officer, Chief Information Officer and Director for B. Braun Medical, Inc., a private global medical device and pharmaceutical company. For over 16 years, Mr. Stover was an employee and then a partner with PricewaterhouseCoopers (then Coopers & Lybrand), working in their bioscience industry division. Mr. Stover is also a CPA.

Thomas C. Seoh. Mr. Seoh has served as a director since March 2005. Since February 2006, Mr. Seoh has served as Chief Executive Officer of Faust Pharmaceuticals S.A., a clinical stage product company focused on drugs for neurological diseases and conditions. From 2005 to 2006, Mr. Seoh was Managing Director of Beyond Complexity Ventures, LLC, engaged in life science start-up and business development consulting activities. From 1995 to 2005, Mr. Seoh was Senior Vice President, Corporate and Commercial Development, and previously Vice President, General Counsel and Secretary, with NASDAQ-listed Guilford Pharmaceuticals Inc., engaged in research, development and commercialization of CNS, oncology and cardiovascular products. Previous positions included Vice President and Associate General Counsel of ICN Pharmaceuticals, Inc., General Counsel and Secretary of Consolidated Press U.S., Inc. and corporate attorney in the New York City and London offices of Lord Day & Lord, Barrett Smith.

Thomas M. Tully. Mr. Tully has served as a director since May 2005. Since January 2006, Mr. Tully has served as Chairman and Chief Executive Officer of IDev Technologies, a medical device company focused on the development and marketing of innovative minimally invasive devices for the treatment of peripheral vascular disease. From August 2000 until April 2005, Mr. Tully was the President and Chief Executive Officer of Neothermia Corporation, a medical device company. Prior thereto, from June 1995 to April 2000, Mr. Tully was the President and Chief Executive Officer of Nitinol Medical Technologies, Inc., a medical device company. Mr. Tully was the President of Organogenesis Inc., from 1991 to 1994, and the President of Schneider (USA) Inc. from 1988 to 1991. From 1980 through 1988 he held various positions with Johnson & Johnson, including President, Johnson & Johnson Interventional Systems and Vice President Marketing and Sales at the Johnson & Johnson Cardiovascular division.

Dennis L. Kogod. Mr. Kogod has served as a director since May 2005. Mr. Kogod is Division President, Western Group for Davita, Inc., a leading provider of dialysis services for patients suffering from chronic kidney failure. Mr. Kogod joined Davita when that company acquired Gambro Healthcare in October 2005. Prior to the acquisition, Mr. Kogod was President and Chief Operating Officer of the West Division of Gambro Healthcare USA, which he joined in July 2000. Before that, Mr. Kogod spent 13 years with Teleflex Corporation, a NYSE-traded company. While there, he served as Division President of the Teleflex Medical Group from December 1999 to July 2000.

There are no family relationships between any of the executive officers and directors.

Key Employees and Consultants

Ulrich Baurmeister, Ph.D. Dr. Baurmeister, age 64, has been our Chief Technology Officer since November, 2006. He is an expert in the field of semi-permeable polymer membrane development. From 1982 until 2000, Dr. Baurmeister served in various senior research and development, marketing and business development roles at Membrana GmbH, a leading supplier of semi-permeable membranes for dialysis and water purification, and its parent companies, Akzo Nobel and Acordis AG. He was most recently Managing Director, Business Development, overseeing Membrana's extension into new areas of business and technology. From 2000 to 2004, he continued at Membrana while also serving as Chief Executive Officer of MAT Adsorption Technologies GmbH & Co. KG, a Membrana spin-off venture that developed selective adsorption membrane technology. Dr. Baurmeister serves us on a half-time contractor basis, alongside his role as Advisor and Senior Visiting Scientist at the University Hospital Charite in Berlin, Germany. He also serves on the boards of the Society of Artificial Organs, the International Society of Blood Purification, and the International Society for Apheresis, and he participates in various working groups in the fields of biocompatibility of materials and organ failure.

Jan Stange, MD. Prof. Stange, age 43, has been our Senior Clinical Advisor since early 2006 and he is currently assisting us with our clinical development program. He is an expert in the clinical development of products for the treatment of liver failure, having managed pivotal phase, multi-center clinical trials for various liver failure indications in both the United States and Europe. From 2000 to 2005, he was a founder and the Medical Director of Teraklin GmbH, where he directed clinical trials of that company's MARS Liver Assist system, currently owned by Gambro

AS. Since 1992, Dr. Stange has held academic, clinical and research positions at the University of Rostock, Germany and the University of California, San Diego and has founded other medical products companies in addition to Teraklin. He is currently Professor of Bioartificial Therapies at the University of Rostock. He serves on the board of directors of Forum Liver Dialysis. Dr. Stange serves us on a part-time contractor basis.

Audit, Compensation and Nominating Committees

In February 2004, our Board of Directors established an Audit Committee. According to the Audit Committee Charter, the Audit Committee is to meet periodically with our management and independent accountants to, among other things, review the results of the annual audit and quarterly reviews and discuss the financial statements, recommend to the Board of Directors the independent accountants to be retained, and receive and consider the accountants' comments as to controls, adequacy of staff and management performance and procedures in connection with audit and financial controls. The Audit Committee is also authorized to review related party transactions for potential conflicts of interest. The Audit Committee consists of three persons and is currently composed of Mr. Stover, Mr. Seoh and Mr. Tully. Each of these individuals is a non-employee director and, in the opinion of our Board of Directors, is independent as defined under the Nasdaq Stock Market's listing standards. Mr. Stover is our "audit committee financial expert" as defined under Item 407(d)(5) of Regulation S-B of the Securities Exchange Act of 1934, as amended. The Audit Committee operates under a formal charter that governs its duties and conduct.

In November 2004, we established a Compensation Committee and a Nomination Committee. The Compensation Committee is authorized to review and make recommendations to the full Board of Directors relating to the annual salaries and bonuses of our senior executive officers. The Compensation Committee evaluates management performance goals with the Chief Executive Officer periodically and considers appropriate bonuses and salary adjustments based on achievement of objectives. The Compensation Committee can retain outside consultants to assist in determining compensation if needed. The Compensation Committee is currently composed of Mr. Tully, Dr. Vierling and Mr. Kogod.

The Nomination Committee assists the Board of Directors in identifying qualified candidates, selecting nominees for election as directors at meetings of stockholders and selecting candidates to fill vacancies on our Board of Directors, and developing criteria to be used in making such recommendations. The Nomination Committee evaluates relevant experience and leadership skills for director candidates. The Nomination Committee is currently comprised of Mr. Tully, Mr. Seoh and Mr. Kogod.

Section 16(a) Beneficial Ownership Reporting Compliance

Our records reflect that all reports which were required to be filed pursuant to Section 16(a) of the Exchange Act were filed on a timely basis except for the late filing of a Form 4 to report an equity transaction for Amy Factor and Jacek Rozga which occurred on December 26, 2007.

An Annual Statement of Beneficial Ownership on Form 5 is not required to be filed if there are no previously unreported transactions or holdings to report. Nevertheless, we are required to disclose the names of directors, officers and 10% shareholders who did not file a Form 5 unless we have obtained a written statement that no filing is required. We have received a written statement from each of our other directors, officers and 10% shareholders stating that no filing is required.

Code of Ethics

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

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A copy of our Code of Ethics will be furnished, without charge, to any person upon written request from any such person. Requests should be sent to: Secretary, Arbios Systems, Inc.,1050 Winter Street, Suite 1000, Waltham, MA 02451.

Disclosure regarding any amendments to, or waivers from, provisions of the Code of Ethics that apply to our directors, principal executive and financial officers will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting of such amendments or waivers is then permitted by the rules of the market or exchange on which our common stock is then listed, in which case we intend to post such amendments or waivers on our website, www.arbios.com.

ITEM 10. EXECUTIVE COMPENSATION.

SUMMARY COMPENSATION TABLE

The following table set forth certain information concerning the annual and long-term compensation for services rendered to us in all capacities for the fiscal years ended December 31, 2007 and 2006 of (i) all persons who served as our principal executive officer during the fiscal year ended December 31, 2007, (ii) our other two most highly compensated executive officers serving on December 31, 2007 whose total annual compensation during the fiscal year ended December 31, 2007 exceeded $100,000 and (iii) our former Vice President of Product Development. The principal executive officer and the other named officers are collectively referred to as the “Named Executive Officers.”

Name and Principal Position	Year	Salary	Bonus	Option Awards[1]	All Other Compensation[2]	Total
Shawn P. Cain[3]	2007	$170,624	$10,000	$ 39,104	$ 4,818	$224,546
Interim President and Chief Executive Officer	2006	$160,000	-	$ 22,385	$ 5,505	$187,890
Jacek Rozga, M.D. Ph.D. [4]	2007	$155,000	-	$ 14,126	$23,177	$192,303
Chief Scientist	2006	$183,333	-	$ 7,575	$ 6,220	$197,128
Scott L. Hayashi	2007	$121,250	$10,000	$ 23,662	$ 3,506	$158,418
Vice President of Administration, Chief Financial Officer and Secretary	2006	$109,167	-	$ 8,656	$ 3,759	$121,582
Walter C. Ogier[5]	2007	$221,252	-	$279,850	$64,115	$565,217
Former President and Chief Executive Officer	2006	$300,000	-	$289,114	$ 7,980	$597,094
David J. Zeffren[6]	2007	$76,354	-	$11,192	$41,256	$128,802
Former Vice President of Product Development	2006	$117,000	-	$ 3,939	$ 3,479	$124,418

(1) Represents the compensation expense incurred by us in the applicable fiscal year in connection with option grants to the applicable Named Executive Officer, calculated in accordance with SFAS 123R disregarding the estimate of forfeitures for service-based vesting conditions. See our audited consolidated financial statements included elsewhere in this Annual Report for details as to the assumptions used to determine the fair value of the option awards. Our Named Executive Officers will not realize the value of these awards in cash until these awards are exercised and the underlying shares are subsequently sold.

(2) Includes company matching contributions in the Arbios 401(k) Plan and group life insurance premium gross ups, severance, and consulting fees.

(3) In September 2007, Mr. Cain was appointed as the Company's Interim President and Chief Executive Officer.

(4) Dr. Rozga worked as a consultant to the Company during January to March 2007 and was converted to full-time employment in April 2007. In Other Compensation for 2007, Dr. Rozga earned $10,000 as a consultant and had $3,500 of Company matching contributions in his 401K and had $9,677 of relocation allowance to move him from Los Angeles to Boston

(5) Mr. Ogier resigned from the Company in September 2007. Under the terms of Mr. Ogier's separation agreement, the Company will pay him $25,000 per month for a period of one year from November 2007. Other Compensation for 2007 includes $8,603 for accrued vacation, $50,000 for severance payments for November and December 2007, and $5,512 for Company matching contributions in the 401K Plan.

(6) Mr. Zeffren resigned as an executive officer and was converted from a full-time employee to a consultant in September 2007. Mr. Zeffren received $1,840 of company matching and $39,416 of consulting fees for the period September 2007 to December 2007.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table sets forth the number and value of unexercised options held by the Named Executive Officers as of December 31, 2007. There were no exercises of options by the Named Executive Officers in fiscal year 2007.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date
Shawn P. Cain	30,000	70,000	100,000(1)	$0.49	9/21/2014
	21,875	128,125	150,000(2)	$0.82	5/10/2014
	24,792	45,208	70,000(3)	$0.85	7/31/2013
	30,000	-	30,000(4)	$1.65	3/31/2010
Jacek Rozga, M.D., Ph.D.	10,000	30,000	40,000(5)	$0.49	9/21/2014
	14,583	85,417	100,000(6)	$0.82	5/10/2014
	12,000	-	12,000(7)	$2.22	7/7/2012
	30,000	-	30,000(8)	$2.25	2/9/2011
	18,000	-	18,000(9)	$0.15	7/23/2012
	18,000	-	18,000(10)	$1.00	4/20/2010
Scott L. Hayashi	5,000	65,000	70,000(11)	$0.49	9/21/2014
	21,875	128,125	150,000(12)	$0.82	5/10/2014
	14,167	25,833	40,000(13)	$0.85	7/31/2013
	10,000	-	10,000(14)	$1.85	3/24/2010
	12,000	-	12,000(15)	$2.90	3/1/2010
	10,000	-	10,000(16)	$2.25	2/9/2009
Walter C. Ogier	60,000	-	60,000(17)	$0.80	7/12/2014
	500,000	-	500,000(18)	$1.85	11/8/2010
David J. Zeffren	5,000	25,000	30,000(19)	$0.49	9/21/2014
	15,000	-	15,000(20)	$0.82	5/10/2014
	12,000	-	12,000(21)	$2.90	3/1/2010
	10,000	-	10,000(22)	$2.00	2/9/2009

(1) The option to purchase 100,000 shares of common stock was granted on 09/21/2007 and vests based on achievement of performance based milestones during 2007 and 2008.

(2) The option to purchase 150,000 shares of common stock was granted on 05/10/2007 and vests on a pro-rata monthly basis for a period of 48 months from the date of grant.

(3) The option to purchase 70,000 shares of common stock was granted on 7/31/2006 and vests on a pro-rata monthly basis for a period of 48 months from the date of grant.

(4) The option to purchase 30,000 shares of common stock was fully vested on 4/22/2007.

(5)

The option to purchase 40,000 shares of common stock was granted on 9/21/2007 and vests according to achievement of performance based milestones during 2007 and 2008.

(6) The option to purchase 100,000 shares of common stock was granted on 5/10/2007 and vests on a pro-rata monthly basis for a period of 48 months from the date of grant.

(7) The option to purchase 12,000 shares of common stock was fully vested on 7/7/2006.

(8) The option to purchase 30,000 shares of common stock was fully vested on 2/11/2005.

(9) The option to purchase 18,000 shares of common stock was fully vested on 7/24/2003.

(10) The option to purchase 18,000 shares of common stock was fully vested on 4/21/2004.

(11) The option to purchase 70,000 shares of common stock was granted on 9/21/2007 and vests according to achievement of performance based milestones during 2007 and 2008.

(12) The options to purchase 150,000 shares of common stock were granted on 5/10/2007 and vest on a pro-rata monthly basis for a period of 48 months from the date of grant.

(13) The option to purchase 40,000 shares of common stock was granted on 7/31/2006 and vests on a pro-rata monthly basis for a period of 48 months from the date of grant.

(14) The option to purchase 10,000 shares of common stock was fully vested on 3/24/2006.

(15) The option to purchase 12,000 shares of common stock was fully vested on 2/1/2006.

(16) The option to purchase 10,000 shares of common stock was fully vested on 2/11/2005.

(17) Of the original stock grant to purchase 200,000 shares of common stock, 60,000 option shares are exercisable at 11/13/2007, and the remaining 140,000 option shares were cancelled per the terms of the severance agreement with Mr. Ogier.

(18) The option to purchase 500,000 shares of common stock became fully exercisable as of 11/13/2007.

(19) The option to purchase 30,000 shares of common stock was granted on 9/21/2007 and vests according to achievement of performance based milestones during 2007 and 2008.

(20) The option to purchase 15,000 shares of common stock was fully vested on 9/30/2007.

(21) The option to purchase 12,000 shares of common stock was fully vested on 2/1/2006.

(22) The option to purchase 10,000 shares of common stock was fully vested on 8/11/2004.

Employment Contracts and Termination of Employment, and Change-In-Control Arrangements

In September 2007, we appointed Mr. Cain our Interim President and Chief Executive Officer. Mr. Cain remained an at-will employee under our existing 2005 agreement with him. In connection with this appointment he will receive an annual salary of $185,000 and was granted options to purchase 100,000 shares of our common stock at an exercise price of $0.49 which vest in accordance with predefined milestones along specific timeframes. Pursuant to our 2005 agreement with Mr. Cain, we granted Mr. Cain a five-year incentive stock option to purchase 30,000 shares of our common stock. The options have an exercise price of $1.65 per share and vest in monthly installments of 1,250 shares commencing on May 1, 2005. The agreement also provides that we will match Mr. Cain’s contributions to a 401(k)

plan at a rate of 50% up to 6% of total compensation per year. The agreement also offers to pay Mr. Cain's COBRA costs for an 18-month period commencing on the April 15, 2005. Mr. Cain is also eligible to receive an annual discretionary cash bonus of up to 15% of his base annual salary. The agreement provides that Mr. Cain's employment is "at will" and can be terminated at any time. If we wish to terminate his employment, we must provide him three months' notice.

On April 27, 2007, we appointed Dr. Jacek Rozga, M.D., Ph.D. to serve as our Chief Scientific Officer. Pursuant to Dr. Rozga's offer letter he will receive an annual base salary of $200,000. In addition, he will be eligible to receive an annual cash bonus of up to 15% of his base salary for each calendar year that he is employed by us. The final amount of the annual bonus will be determined at the discretion of the Chief Executive Officer and Compensation Committee based upon conditions and criteria that he considers to be appropriate. The bonus, if paid, generally will be paid within the first quarter of each calendar year, but the timing of any bonus payment will ultimately depend upon an assessment of our financial condition and other circumstances by management. Dr. Rozga's performance will be reviewed annually by the Chief Executive Officer, and at that time adjustments in his compensation may be made. He will be eligible for reimbursement of up to $10,000 of the documented cost of moving his household belongings from California to Massachusetts. Dr. Rozga will be an at-will employee and his employment with us may be terminated at any time by him or us, with or without cause.

We have entered into an agreement with Scott Hayashi, dated March 29, 2005, pursuant to which Mr. Hayashi serves as Chief Financial Officer. The agreement provides for a salary of $105,000 per year that is subject to annual review and adjustment. Mr. Hayashi is eligible to receive an annual discretionary bonus of up to 15% of his salary based on achieving certain goals. The agreement also offered Mr. Hayashi a five-year qualified stock option to purchase 10,000 shares of our common stock. The shares are exercisable at $1.85 per share; 50% of the shares vested immediately and 50% of the shares vested one year from the grant date of the option. The agreement provides that Mr. Hayashi's employment is "at will" and can be terminated at any time.

On November 13, 2007, we entered into a separation agreement with our former President and Chief Executive Officer, Walter C. Ogier. Pursuant to the terms of the separation agreement, Mr. Ogier acknowledged that his employment and all positions held by him were terminated as of September 21, 2007 (the "Separation Date"). As consideration for Mr. Ogier performing consulting services for us for a period of 12 months following the Separation Date, we will pay Mr. Ogier monthly payments of $25,000 and will allow Mr. Ogier to continue to utilize our health insurance plan for the lesser of 12 months following the Separation Date or the time that he becomes eligible to receive health insurance from another employer. In addition, certain of Mr. Ogier's unvested options vested and will remain exercisable for a period of 12 months following the Separation Date. Furthermore, Mr. Ogier agreed to release us from any and all legal claims or causes of action that he may have had arising from any event occurring prior to the Separation Date.

On November 8, 2007, we entered into a consulting agreement with David Zeffren, our former Vice President of Product Development. Pursuant to the terms of the consulting agreement, we will pay Mr. Zeffren $10,400 per month and Mr. Zeffren will advise and support us with our regulatory and clinical affairs. Mr. Zeffren will also be reimbursed for reasonable and customary expenses incurred by him on our behalf. During the term of the consulting agreement and for a period of one year following the termination of the consulting agreement, Mr. Zeffren has agreed not to compete with us in the field the commercialization of medical devices or cell therapies for the treatment of liver disease, viral hepatitis or septic shock. Both we and Mr. Zeffren have the right to terminate the consulting agreement at anytime upon written notice.

DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash	Stock Awards[1]	Option Awards[2]	All Other Compensation	Total
John M.Vierling, M.D., FACP[3]	-	$29,610	$7,660	-	$37,270

Jack E. Stover[4]	-	$29,610	$7,660	-	$37,270
Thomas C. Seoh[5]	-	$16,203	$9,576	-	$25,779
Thomas M. Tully[6]	-	$16,203	$9,576	-	