ARBIOS SYSTEMS INC
Form 424B3
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Registration No. 333-150498

PROSPECTUS

ARBIOS SYSTEMS, INC.

17,583,539 Shares of Common Stock

This prospectus relates to (i) the sale or other disposition of up to 7,478,462 shares of our currently outstanding shares of common stock that are owned by some of our stockholders, (ii) 8,055,077 shares of our common stock issuable upon the exercise of currently outstanding common stock purchase warrants held by some of our stockholders, and (iii) 2,050,000 shares of our common stock owned by Jacek Rozga, M.D., Ph.D, our co-founder and Chief Scientific Officer, that we are contractually obligated to include in this prospectus. For a list of the selling stockholders, please refer to the "Selling Stockholders" section of this prospectus. We are not selling any shares of common stock in this offering and therefore will not receive any proceeds from this offering. We will, however, receive the exercise price of the warrants if and when those warrants are exercised by the selling stockholders. None of the warrants have been exercised as of the date of this prospectus. We will pay the expenses of registering these shares.

Our common stock is traded in the over-the-counter market and is quoted on the OTC Bulletin Board under the symbol ABOS. On April 18, 2008 the closing price of our common stock was $0.29, per share.

The shares included in this prospectus may be disposed of on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. We will not control or determine the price at which a selling stockholder decides to sell or otherwise dispose of its shares. Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under applicable state law or that an exemption from registration is available.

You should understand the risks associated with investing in our common stock. Before making an investment, please read the "Risk Factors" section of this prospectus, which begins on page 4.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is May 13, 2008.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus; it does not contain all of the information you should consider before investing in our common stock. Read the entire prospectus before making an investment decision.

Throughout this prospectus, the terms "we," "us," "our," and "our company" refer to Arbios Systems, Inc., a Delaware corporation.

A glossary of certain terms used in this prospectus is contained on page 37 under "Glossary of Terms."

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. After discussions with FDA, we submitted a revised trial design to the FDA and in May 2008 the FDA granted us approval of an IDE to begin the pivotal trial for SEPET™. The revised trial design has co-primary endpoints of (i) a two-stage drop in hepatic encephalopathy, or HE, and (ii) the 30-day transplant free survival in patients who reach a two-stage drop in HE. We expect to enroll an aggregate of 121 patients in the first two stages of this trial and we expect to initiate the first segment of this trial by the end of the second quarter of 2008.

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 have engaged a notified body, British Standards Institute, to assist us in our efforts to obtain 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 project including the pivotal trial.

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.

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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.

Shares Being Offered

On April 23, 2007, we entered into a purchase agreement with several current and new accredited investors. Pursuant to the terms and subject to the conditions contained in the purchase agreement, we issued and sold to the investors in a private placement, 3,739,231 Units for an aggregate purchase price of $4,861,000. Each Unit was sold at a price of $1.30 per Unit. Each Unit consists of: (i) two shares of our common stock, (ii) one warrant to purchase one share of our 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 the Company's common stock exercisable for a period of 5 years at an exercise price of $1.40 ("B Warrants"), comprising a total of 7,478,462 shares of our common stock and warrants to purchase 7,478,462 shares of our common stock. The warrants have no provision for cashless exercise and, subject to certain requirements, may be called by us 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.

In addition to the shares of our common stock sold in the private placement and shares issuable upon exercise of warrants sold in the private placement, we are registering 346,615 shares of our common stock issuable upon exercise of warrants to David B. Musket and 230,000 shares of our common stock issuable upon exercise of warrants to Richard Wehby. Such warrants were issued to Mr. Musket and Mr. Wehby as compensation for the placement agent services provided by Musket Research Associates, Inc. in connection with the private placement.

In addition, we are registering 2,050,000 shares of our common stock owned by Jacek Rozga, M.D., Ph.D., our co-founder and Chief Scientific Officer, that we are contractually obligated to include in this prospectus.

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The Offering

Common stock covered hereby	17,583,539 shares, consisting of (i) 7,478,462 outstanding shares owned by selling stockholders, (ii) 8,055,077 shares issuable to selling stockholders upon exercise of outstanding warrants and (iii) 2,050,000 shares of our common stock owned by Jacek Rozga, M.D., Ph.D, our co-founder and Chief Scientific Officer.
Common stock currently outstanding	25,603,461 shares (1)
Common stock to be outstanding assuming the sale of all shares covered hereby and assuming no exercise of the warrants for the shares covered by this prospectus	25,603,461 shares (1)
Common stock to be outstanding assuming the sale of all shares covered hereby and assuming the exercise of all warrants for the shares covered by this prospectus	33,658,538 shares (1)
OTC Bulletin Board Trading Symbol	ABOS
Risk Factors	An investment in our common stock involves significant risks. See “Risk Factors” beginning on page 4.

(1) In addition to these outstanding shares of common stock, as of April 18, 2008, there were outstanding (i) options to purchase 3,115,677 shares of our common stock (with exercise prices ranging from $0.15 per share to $3.40 per share), and (ii) warrants (other than the warrants owned by the selling stockholders covered by this prospectus) to purchase 9,097,079 shares of our common stock (with exercise prices ranging from $0.65 per share to $3.50 per share).

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RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information contained in this prospectus and in the documents incorporated by reference before deciding to invest in our company. If any of the following risks actually occur, our business, financial condition or operating results and the trading price or value of our securities could be materially adversely affected.

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, 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.

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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 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;

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- 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 increase the number of patients that we must enroll in our trials or conduct additional clinical trials, the cost of developing SEPET™ 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 and have the FDA approve the active Phase III IND to resume clinical testing of our HepatAssist™ product candidate. 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. 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.

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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.

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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.

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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.

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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.

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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 informati