MedaSorb Technologies CORP
Form SB-2/A
April 04, 2007

As filed with the Securities and Exchange Commission on April __, 2007
Registration No. 333-138247

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

Amendment No. 3 to
FORM SB-2/A
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

MEDASORB TECHNOLOGIES CORPORATION
(Exact Name of Registrant as Specified in Its Charter)

Nevada	**3841**	**98-0373793**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

7 Deer Park Drive, Suite K
Monmouth Junction, New Jersey 08852
(732) 329-8885
(Address, Including Zip Code, and Telephone Number,
Including Area Code, of Registrant's Principal Executive Offices)

Al Kraus
President and Chief Executive Officer
MedaSorb Technologies Corporation
7 Deer Park Drive, Suite K
Monmouth Junction, New Jersey 08852
(732) 329-8885
(Name, Address, Including Zip Code, and Telephone Number,
Including Area Code, of Agent for Service)

Copies to:
Alison Newman, Esq.
Cooley Godward Kronish LLP
1114 Avenue of the Americas
New York, New York 10036
(212) 479-6000

Approximate Date of Commencement of Proposed Sale to the Public: From time to time after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, please check the following box. x

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o _____

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨ _____

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨ _____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box ¨.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered[1]	Proposed Maximum Offering Price Per Share[2]	Proposed Maximum Aggregate Offering Price[2]	Amount of Registration Fee[3]
Common Stock	9,312,273 shares	$ 1.28	$ 11,919,709.44	$ 1,275.41

(1) In accordance with Rule 416 under the Securities Act of 1933, this registration statement also covers any additional shares of Common Stock that shall become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration that results in an increase in the number of the outstanding shares of Common Stock.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933. For purposes of this table, we have used the average of the closing bid and asked prices of the registrant's Common Stock on October 25, 2006, two days prior to the initial filing of this registration statement, as reported by the OTC Bulletin Board.

(3) Previously paid upon the initial filing of this registration statement on October 27, 2006.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. THE SELLING STOCKHOLDERS MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND THE SELLING STOCKHOLDERS ARE NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED APRIL __, 2007

MEDASORB TECHNOLOGIES CORPORATION

9,312,273 Shares of Common Stock

This prospectus relates to the sale of up to 9,312,273 shares of our Common Stock by some of our stockholders. The shares offered by this prospectus include:

· 5,109,531 shares issuable to the selling stockholders upon the conversion of currently outstanding shares of our Series A Preferred Stock;

· 1,762,788 shares issuable to the selling stockholders upon the conversion of shares of Series A Preferred Stock that may be issued to the selling stockholders as dividends; and

· 2,439,954 shares issuable to the selling stockholders upon the exercise of warrants.

For a list of the selling stockholders, please see “Selling Stockholders.” We are not selling any shares of Common Stock in this offering and therefore will not receive any proceeds from this offering. We may, however, receive proceeds upon the exercise of the warrants registered for sale hereunder in the event that such warrants are exercised. All costs associated with this registration will be borne by us.

These shares may be sold by the selling stockholders from time to time in the over-the-counter market or other national securities exchange or automated interdealer quotation system on which our Common Stock is then listed or quoted, through negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices.

Our Common Stock currently trades in the over-the-counter market and is quoted on the OTC Bulletin Board under the symbol “MSBT.” On April __, 2007, the last reported sale price of our Common Stock was $1.___ per share.

Investing in our Common Stock involves a high degree of risks. Please refer to the “Risk Factors” beginning on page 5.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April __, 2007.

TABLE OF CONTENTS

PROSPECTUS SUMMARY

This summary highlights selected information from this prospectus and may not contain all of the information that is important to an investor. We encourage you to read this entire prospectus, including our consolidated financial statements and the notes to our consolidated financial statements completely and carefully before deciding whether to invest in our Common Stock. You should also review the other available information referred to in the section entitled "Where You Can Find More Information" on page 51.

Summary of our Business

We are a medical device company that is currently in the development stage, headquartered in Monmouth Junction, New Jersey (near Princeton). We have developed and will seek to commercialize a blood purification technology that we believe will be able to efficiently remove middle molecular weight toxins from circulating blood. We will be required to obtain required approvals from the United States Food and Drug Administration before we can sell our products. In December 2006, we submitted a proposed pilot study for approval to the FDA with respect to CytoSorb™ , the first device we intend to bring to market. If we obtain FDA approval, we anticipate commencing clinical studies for CytoSorb™ by the third quarter of 2007. If these studies are successful and we obtain FDA approval to proceed with our follow-up pivotal study, we anticipate that we will be able to begin sales of CytoSorb™ by mid-to-late 2009, at the earliest, assuming a successful pivotal study. However, there can be no assurance we will ever obtain FDA approval for CytoSorb™ or any other device.

We have developed two products, CytoSorb™ and BetaSorb™ utilizing our adsorbent polymer technology. These products are known medically as hemoperfusion devices. During hemoperfusion, blood is removed from the body via a catheter or other blood access device, perfused through a filter medium where toxic compounds are removed, and returned to the body.

We intend to initially focus our efforts on the commercialization of our CytoSorb™ product, which we believe will provide a relatively faster regulatory pathway to market. The first indication for CytoSorb™ will be in the treatment of sepsis (bacterial infection of the blood), which causes systematic inflammatory response syndrome. CytoSorb™ has been designed to prevent or reduce the accumulation of high concentrates of cytokines in the bloodstream associated with sepsis. It is intended for short term use as an adjunctive device to the standard treatment of sepsis.

The CytoSorb™ device consists of a cylinder containing the adsorbent polymer beads. The cylinder incorporates industry standard connectors at either end of the device which connect directly to an extra-corporeal circuit (bloodlines) on a stand alone basis. The extra-corporeal circuit consists of plastic tubing through which the blood flows, our CytoSorb™ cartridge containing adsorbent polymer beads, pressure monitoring gauges, and a blood pump to maintain blood flow. The patient's blood is accessed through a catheter inserted into his or her veins. The catheter is connected to the extra-corporeal circuit and the blood pump draws blood from the patient, pumps it through the cartridge and returns it back to the patient in a closed loop system. As blood passes over the polymer beads in the cylinder, toxins (cytokines) are adsorbed from the blood.

To date, we have manufactured the CytoSorb™ device on a limited basis for testing purposes, including for use in clinical studies. We believe that current state of the art blood purification technology (such as dialysis) is incapable of effectively clearing the toxins intended to be adsorbed by our CytoSorb™ device.

Following the sepsis indication, we intend to continue our research in other acute conditions where CytoSorb™ has indicated potential in preliminary studies to prevent or reduce the accumulation of cytokines in the bloodstream. These conditions include the prevention of post-operative complications of cardiac surgery (cardiopulmonary bypass surgery) and damage to organs donated for transplant prior to organ harvest. We are also exploring the potential

benefits the CytoSorb™ device may have in removing drugs from blood in situations such as patient overdoses.

Previous studies using our BetaSorb™ device in patients with chronic kidney failure have provided valuable data which we will use in conducting clinical studies using our CytoSorb™ device. However, limited studies have been conducted using our CytoSorb™ device to date and no assurance can be given that our proposed CytoSorb™ product will work as intended or that we will be able to obtain FDA approval to sell CytoSorb™. Even if we ultimately obtain FDA approval, because we can not control the timing of FDA responses to our submissions, there can be no assurance as to when such approval will be obtained.

Our BetaSorb™ device is intended to remove beta-2-microglobulin from the blood of patients suffering from chronic kidney failure who rely on long term dialysis therapy to sustain their life. BetaSorb™ utilizes an absorbent polymer packed into an identically shaped and constructed cylinder as utilized for our CytoSorb™ product, although the polymers used in the two devices are physically different. The BetaSorb™ device also incorporates industry standard connectors at either end of the device which connect directly into the extra-corporeal circuit (bloodlines) in series with a dialyser. To date, we have manufactured the BetaSorb™ device on a limited basis for testing purposes, including for use in clinical studies.

We had initially identified end stage renal disease (ESRD) as the target market for our polymer-based adsorbent technology. However, during the development of BetaSorb™, we identified several applications for our adsorbent technology in the treatment of critical care patients. As a result, we shifted our priorities to pursue critical care applications (such as for the treatment of sepsis) for our technology given that BetaSorb's™ potential for usage in chronic conditions such as end stage renal disease is anticipated to have a longer and more complex regulatory pathway. We currently intend to pursue our BetaSorb™ product after the commercialization of the CytoSorb™ product. At such time as we determine to proceed with our proposed BetaSorb™ product, if ever, we will need to conduct additional clinical studies using the BetaSorb™ device and obtain FDA approval.

To date, we have conducted clinical studies using our BetaSorb™ device in patients with chronic kidney failure, which have provided valuable data which underpin the development of the critical care applications for our technology. The BetaSorb™ device has been used in a total of three human pilot studies, involving 20 patients, in the U.S. and Europe. The studies included approximately 345 treatments, with some patients using the device for up to 24 weeks (in multiple treatment sessions lasting up to four hours, three times per week) in connection with the application of our products to patients suffering from chronic kidney failure. The BetaSorb™ device design was also tested on a single patient with bacterial sepsis, producing results that our management has found encouraging and consistent with our belief that our device design is appropriate for a more extensive sepsis study. In addition, CytoSorb's™ ability to interact safely with blood (hemocompatibility) has been demonstrated through ISO 10993 testing. The studies we have done to date were not done in conjunction with obtaining FDA approval for the use of our CytoSorb™ device, the first device we intend to bring to market.

We have not generated any revenue to date. We have incurred losses in each of our fiscal years and expect these losses to continue for the foreseeable future. We will need to raise significant additional funds to conduct clinical studies and obtain regulatory approvals to commercialize our products. No assurance can be given that we will ever successfully commercialize any products.

The Company

We were incorporated in Nevada on April 25, 2002 as Gilder Enterprises, Inc. and were originally engaged in the business of installing and operating computer networks that provided high-speed access to the Internet. On June 30, 2006, we disposed of our original business, and pursuant to an Agreement and Plan of Merger, acquired all of the stock of MedaSorb Technologies, Inc. in a merger, and its business became our business. Following the merger, in August 2006, we changed our name to MedaSorb Technologies Corporation.

Our executive offices are located at 7 Deer Park Drive, Suite K, Monmouth Junction, New Jersey 08852. Our telephone number is (732) 329-8885.

THE OFFERING

Securities Offered by Selling Stockholders	9,312,273 shares of Common Stock, including 5,109,531 shares issuable upon conversion of currently outstanding shares of Series A Preferred Stock; 1,762,788 shares issuable upon conversion of shares of Series A Preferred Stock that may be issued as dividends; and 2,439,954 shares issuable to the selling stockholders upon the exercise of warrants.
Offering Price	Determined at the time of sale by the selling stockholders.
Use of Proceeds	We will not receive any proceeds from the sale of the shares of Common Stock by the selling stockholders. We intend to use the proceeds from the exercise of outstanding warrants, if any, for general corporate purposes.
Shares of Common Stock outstanding before the offering	24,628,274 shares.
Risk Factors	An investment in MedaSorb involves significant risks and uncertainties. See “Risk Factors,” beginning on page 4.

RISK FACTORS

An investment in our Common Stock involves a high degree of risk. You should carefully consider the risks described below before deciding to purchase shares of our Common Stock. If any of the events, contingencies, circumstances or conditions described in the risks below actually occur, our business, financial condition or results of operations could be seriously harmed. The trading price of our Common Stock could, in turn, decline and you could lose all or part of your investment.

RISKS RELATED TO OUR INDUSTRY AND OUR BUSINESS

We currently have no commercial operations and there can be no assurance that we will be successful in developing commercial operations.

We are a development stage company and have been engaged primarily in research and development activities and have not generated any revenues to date. There can be no assurance that we will be able to successfully manage the transition to a commercial enterprise. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by an enterprise in the early stage of development, which include unanticipated problems relating to development of proposed products, testing, regulatory compliance, manufacturing, competition, marketing problems and additional costs and expenses that may exceed current estimates. Our proposed products will require significant additional research and testing, and we will need to overcome significant regulatory burdens prior to commercialization. We will also need to raise significant additional funds to complete clinical studies and obtain regulatory approvals before we can begin selling our products. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any products, generate any revenues or ever achieve and maintain a substantial level of sales of our products.

We have a history of losses and expect to incur substantial future losses, and the report of our auditor on our consolidated financial statements expresses substantial doubt about our ability to continue as a going concern.

We have experienced substantial operating losses since inception. As of December 31, 2006, we had an accumulated deficit of $67,426,583 which included losses from operations of $7,671,580 for the year ended December 31, 2006 and $3,665,596 for the year ended December 31, 2005. Due to these losses, our audited consolidated financial statements have been prepared assuming we will continue as a going concern, and the auditors' report on those financial statements express substantial doubt about our ability to continue as a going concern. Our losses have resulted principally from costs incurred in the research and development of our polymer technology and general and administrative expenses. Because our predecessor was a limited liability company until December 2005, substantially all of these losses were allocated to that company's members and will not be available for tax purposes to us in future periods. We intend to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for the establishment of manufacturing arrangements and a marketing and distribution presence and other general and administrative expenses, are expected to result in continuing operating losses for the foreseeable future. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our technology and commercial products, obtaining the requisite regulatory approvals, establishing manufacturing and sales and marketing arrangements with third parties, and raising sufficient funds to finance our activities. No assurance can be given that our product development efforts will be successful, that required regulatory approvals will be obtained, that any of our products will be manufactured at a competitive cost and will be of acceptable quality, or that the we will be able to achieve profitability or that profitability, if achieved, can be sustained.

We may have difficulty raising needed capital in the future because of our limited operating history and business risks associated with us.

We generate no revenues from our proposed products or otherwise, and have expended and will continue to expend substantial funds in the research, development and clinical and pre-clinical studies of our polymer products. Following the June 30, 2006 merger, we completed a private placement of securities raising gross proceeds of $5.3 million. We anticipate that the net proceeds of the private placement will only be sufficient to fund our operations through the fourth quarter of 2007, following which we will need additional financing before we can complete the clinical studies and commercialization of our proposed products. However, there can be no assurance that financing will be available on acceptable terms or at all. Our future capital requirements will depend upon many factors, including, but not limited to, continued progress in our research and development activities, costs and timing of conducting clinical studies and seeking regulatory approvals and patent prosecutions, competing technological and market developments, and our ability to establish collaborative relationships with third parties. If adequate funds are unavailable, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs or product launches or marketing efforts or cease operations.

Our long-term capital requirements are expected to depend on many factors, including:

- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical studies;
- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- costs of developing sales, marketing and distribution channels;
- market acceptance of our products; and
- costs for training physicians and other health care personnel.

In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, we may have to relinquish economic and/or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourself.

We depend upon key personnel who may terminate their employment with us at any time.

We currently have only eight employees. Our success will depend to a significant degree upon the continued services of our key management and advisors, including, Al Kraus, our Chief Executive Officer; Dr. James Winchester, our Chief Medical Officer, who is employed by us on a part time basis; David Lamadrid, our Chief Financial Officer; and Vincent Capponi, our Chief Operating Officer. These individuals, other than Mr. Kraus, whose employment agreement terminates in July 2008, do not have long-term employment agreements, and there can be no assurance that they will continue to provide services to us. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Management and other employees may voluntarily terminate their employment with us at any time. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources.

Our Chief Medical Officer's primary employment is with another employer

Dr. James Winchester, our Chief Medical Officer, serves as the Chief of Beth Israel Medical Center's Nephrology division. Although the time Dr. Winchester provides to us varies from time to time, it is generally in the range of one-half day to one full day per week. Because Dr. Winchester's primary employment is with Beth Israel Medical Center, Dr. Winchester may not always be available to provide us with his services when needed by us in a timely manner.

Acceptance of our medical devices in the marketplace is uncertain, and failure to achieve market acceptance will prevent or delay our ability to generate revenues.

Our future financial performance will depend, at least in part, upon the introduction and customer acceptance of our polymer products. Even if approved for marketing by the necessary regulatory authorities, our products may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;

5

- the establishment and demonstration of the advantages, safety and efficacy of the our polymer technology;

- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;

- our ability to attract corporate partners, including medical device companies, to assist in commercializing our products; and

- our ability to market our products.

Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our products. If we are unable to obtain regulatory approval or commercialize and market our products when planned, we may not achieve any market acceptance or generate revenue.

We may face litigation from third parties claiming that our products infringe on their intellectual property rights, or seek to challenge the validity of our patents.

Our future success is also dependent on the strength of our intellectual property, trade secrets and know-how, which have been developed from years of research and development. In addition to the "Purolite" litigation discussed below which we've recently settled, we may be exposed to additional future litigation by third parties seeking to challenge the validity of our rights based on claims that our technologies, products or activities infringe the intellectual property rights of others or are invalid, or that we have misappropriated the trade secrets of others.

Since our inception, we have sought to contract with large, established manufacturers to supply commercial quantities of our adsorbent polymers. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers. We believe that these disclosures, while necessary for our business, have resulted in the attempt by potential suppliers to assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing rights.

We have previously engaged in discussions with the Brotech Corporation and its affiliate, Purolite International, Inc. (collectively "Purolite"), which had demonstrated a strong interest in being our polymer manufacturer. For a period of time beginning in December 1998, Purolite engaged in efforts to develop and optimize the manufacturing process needed to produce our polymer products on a commercial scale. However, the parties eventually decided not to proceed. In 2003, Purolite filed a lawsuit against us asserting, among other things, co-ownership and co-inventorship of certain of our patents. On September 1, 2006, the United States District Court for the Eastern District of Pennsylvania approved a Stipulated Order and Settlement Agreement under which we and Purolite agreed to the settlement of the action. The Settlement Agreement provides us with the exclusive right to use our patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the Settlement Agreement, we have agreed to pay Purolite royalties of 2.5% to 5% on the sale of certain of our products if and when those products are sold commercially.

Several years ago we engaged in discussions with the Dow Chemical Company, which had indicated a strong interest in being our polymer manufacturer. After a Dow representative on our Advisory Board resigned, Dow filed and received several patents naming our former Advisory Board member as an inventor. In management's view the Dow patents improperly incorporate our technology and should not have been granted to Dow. The existence of these Dow patents could result in a potential dispute with Dow in the future and additional expenses for us.

We have not yet commenced the process of seeking FDA approval of our products. The approval process, if permitted to proceed by the FDA, will involve pilot and pivotal clinical studies and is lengthy and costly. The failure to obtain government approvals, including required FDA approvals, for our polymer products, or to comply with

ongoing governmental regulations could prevent, delay or limit introduction or sale of our products and result in the failure to achieve revenues or maintain our operations.

The manufacturing and marketing of our products will be subject to extensive and rigorous government regulation in the United States, in various states and in foreign countries. In the United States and other countries, the process of obtaining and maintaining required regulatory approvals is lengthy, expensive, and uncertain. There can be no assurance that we will ever obtain the necessary approvals to sell our products. Even if we do ultimately receive FDA approval for any of our products, we will be subject to extensive ongoing regulation.

Our products will be subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act. In the United States, the FDA enforces, where applicable, development, clinical studies, labeling, manufacturing, registration, notification, clearance or approval, marketing, distribution, record keeping, and reporting requirements for medical devices. Different regulatory requirements may apply to our products depending on how they are categorized by the FDA under these laws. Current FDA regulations classify our CytoSorb™ device (the first product we intend to seek FDA approval for) as a Class III device (CFR 876.5870—Sorbent Hemoperfusion System). We intend to submit a 510(k) pre-market notification to the FDA for approval to market this product. There can be no assurance, however, that the FDA will grant clearance to market CytoSorb™ in a timely manner, if at all, or that the FDA will not require the submission of additional clinical data or a pre-market approval application ("PMA"), which is a lengthier process. There can be no assurance that the clinical studies we conduct will demonstrate sufficient safety and efficacy to obtain the required regulatory approvals for marketing, or that we will be able to comply with any additional FDA, state or foreign regulatory requirements. In addition, there can be no assurance that government regulations applicable to our products or the interpretation of those regulations will not change. FDA approvals are also required to commence the pilot and pivotal clinical studies we need to conduct to further study our devices. There can be no assurance that the FDA will allow the clinical studies to commence. We also are and will be subject to other Federal, state, and local laws, regulations and recommendations relating to laboratory and manufacturing practices as well as Medicare, Medicaid and anti-kickback laws. Non-compliance with applicable requirements can result in civil penalties, the recall, injunction or seizure of products, an inability to import products into the United States, the refusal by the government to approve or clear product approval applications, the withdrawal of previously approved product applications and criminal prosecution. The extent of potentially adverse government regulation that might arise from future legislation or administrative action cannot be predicted.

We have conducted limited clinical studies of our BetaSorb™ device and no clinical studies of our CytoSorb™ device. Clinical and pre-clinical data is susceptible to varying interpretations, which could delay, limit or prevent regulatory clearances.

To date, we have conducted limited clinical studies on our products. There can be no assurance that we will successfully complete the clinical studies necessary to receive regulatory approvals. While studies conducted by us and others have produced results we believe to be encouraging and indicative of the potential efficacy of our products and technology, data already obtained, or in the future obtained, from pre-clinical studies and clinical studies do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical studies. Moreover, pre-clinical and clinical data are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the medical device and pharmaceutical industries have suffered significant setbacks in advanced clinical studies, even after promising results in earlier studies. The failure to adequately demonstrate the safety and effectiveness of an intended product under development could delay or prevent regulatory clearance of the device, resulting in delays to commercialization, and could materially harm our business.

We rely extensively on research and testing facilities at various universities and institutions, which could be adversely affect us should we lose access to those facilities.

Although we have our own research laboratories and clinical facilities, we collaborate with numerous institutions, universities and commercial entities to conduct research and studies of our products. We currently maintain a good working relationship with these parties. However, should the situation change, the cost and time to establish or locate alternative research and development could be substantial and delay gaining FDA approval and commercializing our products.

We are and will be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon us should we be sued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of medical devices. We cannot be sure that claims will not be asserted against us. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We do not currently have any product liability insurance or other liability insurance relating to clinical studies or any products. We cannot give assurances that we will be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against potential liabilities. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition and results of operations.

Certain university and other relationships are important to our business and may potentially result in conflicts of interests.

Dr. John Kellum and Dr. David Powner, among others, are critical care advisors and consultants of ours and are associated with University of Pittsburgh Medical Center and University of Texas, respectively. Their association with these institutions may currently or in the future involve conflicting interests in the event they or these institutions enter into consulting or other arrangements with competitors of ours.

We have limited manufacturing experience, and once our products are approved, we may not be able to manufacture sufficient quantities at an acceptable cost, or without shut-downs or delays.

We remain in the research and development and clinical and pre-clinical study phase of product commercialization. Accordingly, once our products are approved for commercial sale, we will need to establish the capability to commercially manufacture our products in accordance with