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

(State or Other Jurisdiction of Incorporation or Organization) 3841

(Primary Standard Industrial Classification Code Number)

98-0373793

(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⁾	M e A	roposed faximum ggregate ring Price ⁽²⁾	Regi	nount of istration
	9,312,273			_		
Common Stock	shares	\$ 1.2	8 \$ 1	1,919,709.44	\$	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.

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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 CytoSorbTM, the first device we intend to bring to market. If we obtain FDA approval, we anticipate commencing clinical studies for CytoSorbTM 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 CytoSorbTM 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 CytoSorbTM or any other device.

We have developed two products, CytoSorbTM and BetaSorbTM 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 CytoSorbTM product, which we believe will provide a relatively faster regulatory pathway to market. The first indication for CytoSorbTM will be in the treatment of sepsis (bacterial infection of the blood), which causes systematic inflammatory response syndrome. CytoSorbTM 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 CytoSorbTM 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 CytoSorbTM 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 CytoSorbTM 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 CytoSorbTM device.

Following the sepsis indication, we intend to continue our research in other acute conditions where CytoSorbTM 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 CytoSorbTM device may have in removing drugs from blood in situations such as patient overdoses.

Previous studies using our BetaSorbTM device in patients with chronic kidney failure have provided valuable data which we will use in conducting clinical studies using our CytoSorbTM device. However, limited studies have been conducted using our CytoSorbTM device to date and no assurance can be given that our proposed CytoSorbTM product will work as intended or that we will be able to obtain FDA approval to sell CytoSorbTM. 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 BetaSorbTM device is intended to remove betanicroglobulin from the blood of patients suffering from chronic kidney failure who rely on long term dialysis therapy to sustain their life. BetaSorbTM utilizes an absorbent polymer packed into an identically shaped and constructed cylinder as utilized for our CytoSorbTM product, although the polymers used in the two devices are physically different. The BetaSorbTM 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 BetaSorbTM 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 BetaSorbTM, 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'sTM 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 BetaSorbTM product after the commercialization of the CytoSorbTM product. At such time as we determine to proceed with our proposed BetaSorbTM product, if ever, we will need to conduct additional clinical studies using the BetaSorbTM device and obtain FDA approval.

To date, we have conducted clinical studies using our BetaSorbTM 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 BetaSorbTM 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 BetaSorbTM 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'sTM 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 CytoSorbTM 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;

- 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 CytoSorbTM 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 CytoSorbTM 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 BetaSorbTMevice and no clinical studies of our CytoSorbTM 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 FDA and other regulatory requirements. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we or the third-party manufacturers of our products fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products.

Due to our limited marketing, sales and distribution experience, we may be unsuccessful in our efforts to sell our products.

We expect to enter into agreements with third parties for the commercial manufacture and distribution of our products. There can be no assurance that parties we may engage to market and distribute our products will:

- · satisfy their financial or contractual obligations to us;
 - · adequately market our products; or
- · not offer, design, manufacture or promote competing products.

If for any reason any party we engage is unable or chooses not to perform its obligations under our marketing and distribution agreement, we would experience delays in product sales and incur increased costs, which would harm our business and financial results.

If we are unable to convince physicians and other health care providers as to the benefits of our products, we may incur delays or additional expense in our attempt to establish market acceptance.

Broad use of our products may require physicians and other health care providers to be informed about our products and their intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully carry out this education process may adversely affect market acceptance of our products. We may be unable to educate physicians regarding our products in sufficient numbers or in a timely manner to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our products. In addition, we may expend significant funds towards physician education before any acceptance or demand for our products is created, if at all.

The market for our products is rapidly changing and competitive, and new devices and drugs which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The medical device and pharmaceutical industries are subject to rapid and substantial technological change. Developments by others may render our technologies and products noncompetitive or obsolete. We also may be unable to keep pace with technological developments and other market factors. Technological competition from medical device, pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us.

If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of medical devices is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of medical devices and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of these proposals could materially harm our business, financial condition and results of operations.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations ("HMOs"). Third-party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and medical devices, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for our products. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

INVESTMENT RISKS

Directors, executive officers and principal stockholders own a significant percentage of the shares of Common Stock, which will limit your ability to influence corporate matters.

Our directors, executive officers and principal stockholders together beneficially own approximately 75% of our outstanding shares of Common Stock. Accordingly, these stockholders could have a significant influence over the outcome of any corporate transaction or other matter submitted to stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets and also could prevent or cause a change in control. The interests of these stockholders may differ from the interests of our other stockholders. Third parties may be discouraged from making a tender offer or bid to acquire us because of this concentration of ownership.

Our Series A Preferred Stock provides for the payment of penalties, which we are currently obligated to pay.

Immediately following our June 30, 2006 merger, we issued 5,250,000 shares of Series A 10% Cumulative Convertible Preferred Stock with an aggregate stated value of \$5,250,000. We subsequently issued an additional 2,153,585 shares of Series A Preferred Stock through December 31, 2006 to additional investors as well as in respect of dividends issued on the shares of Series A Preferred Stock we initially issued, and we may issue additional shares of this series of preferred stock in the future as dividends. The Certificate of Designation designating the Series A Preferred Stock provides that upon the following events, among others, the dividend rate with respect to the Series A Preferred Stock increases to 20% per annum, which dividends would then be required to be paid in cash:

- the occurrence of "Non-Registration Events" including, the failure to cause a registration statement registering the shares of Common Stock underlying the Series A Preferred Stock and Warrants issued in connection therewith to be effective by February 25, 2007 (240 days following the closing of the private placement);
 - · an uncured breach by us of any material covenant, term or condition in the Certificate of Designation or any of the related transaction documents; and
 - · any money judgment or similar final process being filed against us for more than \$100,000.

Because the registration statement in which this prospectus is included was not effective until April ___, 2007, the dividends on the shares of Series A Preferred Stock issued to the June 30, 2006 purchasers accrued at the rate of 20% per annum from February 26, 2007 through April ___, 2007, and are payable in cash for such period.

In addition, the registration rights provided for in the subscription agreement we entered into with the purchasers in this offering:

- · require that we file a registration statement with the SEC on or before 120 days from the closing to register the shares of Common Stock issuable upon conversion of the Series A Preferred Stock and exercise of the Warrants, and cause such registration statement to be effective by February 25, 2007 (240 days following the closing); and
- entitles each of these investors to liquidated damages in an amount equal to two percent (2%) of the purchase price of the Series A Preferred Stock if we fail to timely file that registration statement with, or have it declared effective by, the SEC.

Because the registration statement in which this prospectus is included was not effective until April ___, 2007, we are obligated to pay the June 30, 2006 purchasers of our Series A Preferred Stock an aggregate of \$105,000 per 30-day period from February 26, 2007 through April ___, 2007.

The Certificate of Designation, Subscription Agreement and related transaction documents also provide for various penalties and fees for breaches or failures to comply with provisions of those documents, such as the timely payment of dividends, delivery of stock certificates, and obtaining and maintaining an effective registration statement with respect to the shares of Common Stock underlying the Series A Preferred Stock and Warrants sold in the offering.

Anti-Dilution Provisions Of The Series A Preferred Stock And Warrants, As Well As The Terms Of The Employment Agreement With Our Chief Executive Officer, Could Result In Dilution Of Stockholders

Both the conversion price of the Series A Preferred Stock and the exercise price of the Warrants are subject to "full-ratchet" anti-dilution provisions, so that upon future issuances of our Common Stock or equivalents thereof, subject to specified customary exceptions, at a price below the conversion price of the Series A Preferred Stock and/or exercise price of the Warrants, such conversion price and/or exercise price will be reduced to such lower price, further diluting holders of our Common Stock.

In addition, under our Employment Agreement with Al Kraus, our Chief Executive Officer, Mr. Kraus is entitled to be issued options to purchase Common Stock at a price of \$6.64 per share so that the combined total of Common Stock owned by Mr. Kraus, including upon exercise of options, equals 5% of our outstanding Common Stock on a fully diluted basis. Mr. Kraus has such right until such time as an aggregate of \$20 million of financing has been received by us following the commencement of his employment. Pursuant to his Employment Agreement, based on the number of currently outstanding shares of Common Stock, Series A Preferred Stock, warrants and options, Mr. Kraus is entitled to purchase approximately 413, 920 shares of Common Stock at a price \$6.64 per share.

Penny Stock Regulations May Affect Your Ability To Sell Our Common Stock.

To the extent the price of our Common Stock remains below \$5.00 per share, our Common Stock will be subject to Rule 15g-9 under the Exchange Act, which imposes additional sales practice requirements on broker dealers which sell these securities to persons other than established customers and accredited investors. Under these rules, broker-dealers who recommend penny stocks to persons other than established customers and "accredited investors" must make a special written suitability determination for the purchaser and receive the purchaser's written agreement to a transaction prior to sale. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our Common Stock and may make it more difficult for holders of our Common Stock to sell shares to third parties or to otherwise dispose of them.

Future Sales of Common Stock Could Result in a Decline in Market Price.

Following the completion of the merger, the holders of 3,750,000 shares of Common Stock are able to sell such shares without registering them under the Securities Act. In addition, this registration statement covers the resale of 9,312,273 shares of Common Stock underlying the Series A Preferred Stock and Warrants sold in the offering or issuable in connection therewith. Sales of a significant number of shares of Common Stock in the public market could result in a decline in the market price of our Common Stock.

Our Board of Directors may, without stockholder approval, issue and fix the terms of shares of preferred stock and issue additional shares of common stock adversely affecting the rights of holders of our common stock.

Our certificate of incorporation authorizes the issuance of up to 100,000,000 shares of "blank check" preferred stock, with such designation rights and preferences as may be determined from time to time by the Board of Directors. We have designated 12,000,000 shares of Series A Preferred Stock as described above. Subject to the rights of the holders of the Series A Preferred Stock, our Board of Directors is empowered, without stockholder approval, to issue up to 88,000,000 additional shares of preferred stock with dividend, liquidation, conversion, voting or other rights which could adversely affect the rights of the holders of our common stock. In addition, our certificate of incorporation authorizes the issuance of up to 100,000,000 shares of common stock, of which approximately 75,000,000 shares remain available for issuance and may be issued by us without stockholder approval. Issuances of additional shares of common stock and/or preferred stock may be utilized as a method of discouraging, delaying or preventing a change in control of our company.

Our Charter Documents and Nevada Law May Inhibit A Takeover That Stockholders May Consider Favorable.

Provisions in our articles of incorporation and bylaws, and Nevada law, could delay or prevent a change of control or change in management that would provide stockholders with a premium to the market price of their Common Stock. The authorization of undesignated preferred stock, for example, gives our board the ability to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change in control of us, or otherwise adversely affect holders of Common Stock in relation to holders of preferred stock.

Compliance with changing corporate governance and public disclosure regulations may result in additional expense.

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations will require an increased amount of management attention and external resources. In addition, prior to the merger, our current management team was not subject to these laws and regulations, as MedaSorb was a private corporation. We intend to continue to invest all reasonably necessary resources to comply with evolving standards, which may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to

compliance activities.

Our Common Stock is thinly traded on the OTC Bulletin Board, and we may be unable to obtain listing of our common stock on a more liquid market.

Our Common Stock is quoted on the OTC Bulletin Board, which provides significantly less liquidity than a securities exchange (such as the American or New York Stock Exchange) or an automated quotation system (such as the Nasdaq Stock Market). There is uncertainty that we will ever be accepted for a listing on an automated quotation system or securities exchange.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This document contains "forward-looking statements". These statements are subject to risks and uncertainties and are based on the beliefs and assumptions of management and information currently available to management. The use of words such as "believes," "expects," "anticipates," "intends," "plans," "estimates," "should," "likely" or similar expressions, in forward-looking statement. Forward-looking statements are not guarantees of performance. They involve risks, uncertainties and assumptions. Future results may differ materially from those expressed in the forward-looking statements. Many of the factors that will determine these results are beyond the ability of MedaSorb to control or predict. Stockholders are cautioned not to put undue reliance on any forward-looking statements, which speak only to the date made. 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 "Risk Factors" beginning on page 4.

The identification in this document of factors that may affect future performance and the accuracy of forward-looking statements is meant to be illustrative and by no means exhaustive. All forward-looking statements should be evaluated with the understanding of their inherent uncertainty. You may rely only on the information contained in this prospectus. We have not authorized anyone to provide information different from that contained in this prospectus. Neither the delivery of this prospectus nor the sale of Common Stock means that information contained in this prospectus is correct after the date of this prospectus. This prospectus is not an offer to sell or solicitation of an offer to buy these securities in any circumstances under which the offer or solicitation is unlawful.

USE OF PROCEEDS

There will be no proceeds to us from the sale of shares of Common Stock in this offering. However, we may receive up to approximately \$4,879,908 upon exercise of the outstanding warrants covered by this prospectus (assuming that no warrant holder acquires shares by a "cashless" exercise). We intend to use any proceeds from the exercise of warrants for working capital purposes.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

Our Common Stock trades in the over-the-counter-market on the OTC Bulletin Board under the symbol "MSBT." Our Common Stock began trading on such market on August 9, 2006. The quotations listed below reflect inter-dealer prices, without retail mark-ups, mark-downs or commissions and may not necessarily represent actual transactions.

	Price	Price		
	High	Low		
2006				
First quarter	n/a	n/a		
Second quarter	n/a	n/a		

Third quarter (from August 9)	\$ 3.95	\$ 1.25
Fourth quarter	\$ 1.73	\$ 0.57
12		

The number of holders of record for our Common Stock as of March 30, 2007 was approximately 385. This number excludes individual stockholders holding stock under nominee security position listings.

Dividends

We have not paid any cash dividends on our Common Stock and do not anticipate declaring or paying any cash dividends in the foreseeable future. In addition, the terms of our Series A Preferred Stock prohibit the payment of dividends on our Common Stock. Nonetheless, the holders of our Common Stock are entitled to dividends when and if declared by our board of directors from legally available funds.

EQUITY COMPENSATION PLAN INFORMATION

The following table summarizes outstanding options as of December 31, 2006, after giving effect to the merger. The Registrant had no options outstanding prior to the merger, and all of the options below were issued in connection with the merger to former option holders of MedaSorb.

	Number of securities to be issued upon exercise of outstanding options	ex	eighted-average xercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column)
Equity compensation plans approved by stockholders	0		n/a	400,000(1)
Equity compensation plans not approved by				2,205,599
stockholders	1,185,001	\$	15.66	(2)
Total	1,185,001(3)		15.66(3)	2,605,599

- (1) Represents options that may be issued under our 2003 Stock Option Plan.
- (2) Represents options that may be issued under our 2006 Long-Term Incentive Plan.
- (3) Represents options to purchase (i) 133,858 shares of Common Stock at a price of \$41.47 per share, (ii) 247,121 shares of Common Stock at a price of \$31.52 per share, (iii) 56,279 shares of Common Stock at a price of \$21.57 per share, (iv) 34,028 shares of Common Stock at a price of \$19.91 per share, (v) 443,507 shares of Common Stock at a price of \$6.64 per share, (vi) 452 shares of Common Stock at a price of \$3.32 per share, (vii) 103,000 shares of Common Stock at a price of \$1.65 per share, and (viii) 166,756 shares of Common Stock at a price of \$1.25 per share.

MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

Reverse Merger

On June 30, 2006, pursuant to an Agreement and Plan of Merger, by and among us (formerly known as Gilder Enterprises, Inc.), MedaSorb Technologies, Inc., a Delaware corporation ("MedaSorb Delaware") and MedaSorb Acquisition Inc., a newly formed wholly-owned Delaware subsidiary of ours, MedaSorb Delaware merged with

MedaSorb Acquisition Inc. (now known as MedaSorb Technologies, Inc.), and the stockholders of MedaSorb Delaware became our stockholders. MedaSorb Technologies, Inc. is now a wholly owned subsidiary of ours, and its business (the business conducted by MedaSorb Delaware prior to the merger) is now our only business.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. We believe the following critical accounting policies have significant effect in the preparation of our consolidated financial statements.

Development Stage Corporation

The Company's financial statements have been prepared in accordance with the provisions of Statement of Financial Accounting Standard (SFAS) No. 7, "Accounting and Reporting by Development Stage Enterprises."

Patents

Legal costs incurred to establish patents are capitalized. When patents are issued, capitalized costs are amortized on the straight-line method over the related patent term. In the event a patent is abandoned, the net book value of the patent is written off.

Convertible Notes Payable

In accordance with Emerging Issues Task Force Issue 98-5, Accounting for Convertible Securities with a Beneficial Conversion Features or Contingently Adjustable Conversion Ratios, the Company evaluates its convertible notes payable to determine if an imbedded beneficial conversion feature (BCF) exists. If a BCF is determined to exist, the Company allocates a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital. The debt discount attributed to the beneficial conversion feature is amortized over the convertible debenture's maturity period as interest expense using the effective yield method.

In accordance with Emerging Issues Task Force Issue 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments, the Company recognizes the value attributable to warrants to additional paid-in capital and a discount against the convertible debentures. The Company values the warrants in accordance with EITF 00-27 using the Black-Scholes pricing model. The debt discount attributed to the value of the warrants issued is amortized over the convertible debenture's maturity period as interest expense using the effective yield method.

Research and Development

All research and development costs, payments to laboratories and research consultants are expensed when incurred.

Stock-Based Compensation

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards 123R, "Share-Based Payment". This statement requires that the cost resulting from all share-based payment transactions be recognized in the financial statements. This statement establishes fair value as the measurement objective in accounting for share-based payment arrangements and requires all entities to apply a fair-value based measurement method in accounting for share-based payment transactions with employees except for equity instruments held by employee share ownership plans.

Prior to the January 1, 2006 adoption of SFAS 123R, the Company accounted for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations. Accordingly, no compensation expense had been recognized for stock options since all options granted had an exercise price equal to the market price on the date of grant. As permitted by SFAS 123, "Accounting for Stock-Based Compensation," stock-based compensation was included as a pro forma disclosure in the notes to the consolidated financial statements.

Plan Of Operations

We are a development stage company and expect to remain so for at least the next twelve months. We have not generated revenues to date and do not expect to do so until we commercialize and receive the necessary approvals to sell our proposed products. We will seek to commercialize a blood purification technology that efficiently removes middle molecular weight toxins from circulating blood.

We intend to initially focus our efforts on the commercialization of our CytoSorbTM product, which we believe will provide a relatively faster regulatory pathway to market. The first indication for CytoSorbTM will be in the treatment of sepsis (bacterial infection of the blood), which causes systematic inflammatory response syndrome. CytoSorbTM 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. To date, we have manufactured the CytoSorbTM 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 CytoSorbTM device.

Following the sepsis indication, we intend to continue our research in other acute conditions where CytoSorbTM 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 CytoSorbTM device may have in removing drugs from blood in situations such as patient overdoses.

In December 2006, we submitted to the FDA a proposed pilot study utilizing the CytoSorbTM device in humans for the treatment of sepsis. If the proposed pilot study is approved by the FDA, we anticipate commencing clinical studies 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 CytoSorbTM by mid-to-late 2009. There can be no assurance that the FDA will allow us to conduct the pivotal study following receipt of data from the pilot study. Previous studies using our BetaSorbTM device in patients with chronic kidney failure have provided valuable data which we will use in conducting clinical studies using our CytoSorbTM device. No assurance can be given that our proposed CytoSorbTM product will work as intended or that we will be able to obtain FDA approval to sell CytoSorbTM. 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 research and development costs were \$1,112,804 and \$1,526,743 for the year ended December 31, 2006 and 2005, respectively. 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 and \$3,665,596 for the years ended December 31, 2006 and December 31, 2005 respectively. Historically, our losses have resulted principally from costs incurred in the research and development of our polymer technology, and general and administrative expenses, which together were \$2,051,932 and \$2,162,703 respectively, for the years ended December 31, 2006 and December 31, 2005 respectively. Legal, financial, and other professional consulting costs were \$912,379 and \$948,209 for the years ended December 31, 2006 and 2005, respectively.

In addition, our loss for the year ended December 31, 2006 includes interest expense of \$4,738,877 primarily consisting of the following, net of interest and dividend income of \$106,392:

- · debt discount charges of \$3,351,961 as a result of the issuance of 3,058,141 shares of common stock to the holders of MedaSorb Delaware convertible notes in the aggregate principal amount of \$6,549,900 to induce those holders to convert those notes into common stock prior to the merger,
 - · \$423,309 of interest expense with respect to those convertible notes,

 \cdot \$1,000,000 of debt discount charges as a result of the issuance to Margie Chassman of 10,000,000 shares of common stock in connection with the funding of a \$1,000,000 bridge loan to MedaSorb Delaware prior to the merger, and

· \$50,000 of interest expense with respect to the \$1,000,000 bridge loan from Ms. Chassman.

Liquidity and Capital Resources

Since inception, the operations of MedaSorb Delaware have been financed through the private placement of its debt and equity securities. At December 31, 2005 (prior to the reverse merger), MedaSorb Delaware had cash of \$707,256, an amount sufficient to fund its operations for approximately four months. Due to its losses and available cash at that time, MedaSorb Delaware's audited consolidated financial statements for its year ended December 31, 2005 (which are now our financial statements) have been prepared assuming MedaSorb Delaware will continue as a going concern, and the auditors' report on those financial statements expresses substantial doubt about the ability of MedaSorb Delaware to continue as a going concern.

As of December 31, 2006 we had cash on hand of \$2,873,138, and current liabilities of \$1,082,044. We believe that we have sufficient cash to fund our operations through the fourth quarter of 2007, following which we will need additional financing before we can complete clinical studies and the commercialization of our proposed products. There can be no assurance that we will be successful in our capital raising efforts.

In October 2005, MedaSorb Delaware entered into an Investment Agreement with Margie Chassman pursuant to which she advanced us \$1,000,000. The advance bore interest at the rate of 6% per annum. Pursuant to the terms of the Investment Agreement, on October 28, 2006, the \$1,000,000 advance was converted into 1,000,000 shares of Series A Preferred Stock and warrants to purchase 400,000 shares of Common Stock at a price of \$2.00 per share.

BUSINESS

Overview

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 CytoSorbTM, the first device we intend to bring to market. If we obtain FDA approval, we anticipate commencing clinical studies for CytoSorbTM 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 CytoSorbTM 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 CytoSorbTM or any other device.

We have developed two products, CytoSorbTM and BetaSorbTM 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.

The CytoSorbTM 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 CytoSorbTM 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 $CytoSorb^{TM}$ 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 devices.

Following the sepsis indication, we intend to continue our research in other acute conditions where CytoSorbTM 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 CytoSorbTM device may have in removing drugs from blood in situations such as patient overdoses.

Previous studies using our BetaSorbTM device in patients with chronic kidney failure have provided valuable data which we will use in conducting clinical studies using our CytoSorbTM device. However, limited studies have been conducted using our CytoSorbTM device to date and no assurance can be given that our proposed CytoSorbTM product will work as intended or that we will be able to obtain FDA approval to sell CytoSorbTM. 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 BetaSorbTM device is intended to remove betanicroglobulin from the blood of patients suffering from chronic kidney failure who rely on long term dialysis therapy to sustain their life. BetaSorbTM utilizes an absorbent polymer packed into an identically shaped and constructed cylinder as utilized for our CytoSorbTM product, although the polymers used in the two devices are physically different. The BetaSorbTM 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 BetaSorbTM 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 BetaSorbTM, 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'sTM 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 BetaSorbTM product after the commercialization of the CytoSorbTM product. At such time as we determine to proceed with our proposed BetaSorbTM product, if ever, we will need to conduct additional clinical studies using the BetaSorbTM device and obtain FDA approval.

To date, we have conducted clinical studies using our BetaSorbTM 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 BetaSorbTM 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 BetaSorbTM 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'sTM 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 CytoSorbTM 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.

Corporate History

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. ("MedaSorb Delaware") in a merger, and its business became our business. In connection with the merger, we also changed our principal executive offices to those of MedaSorb Delaware, which are located at 7 Deer Park Drive, Suite K, Monmouth Junction, New Jersey 08852. Following the merger, in July 2006 we changed our name to MedaSorb Technologies Corporation.

MedaSorb Delaware was originally organized as a Delaware limited liability company in August 1997 as Advanced Renal Technologies, LLC. MedaSorb Delaware changed its name to RenalTech International, LLC in November 1998, and to MedaSorb Technologies, LLC in October 2003. In December 2005, MedaSorb Delaware converted from a limited liability company to a corporation.

MedaSorb Delaware has been engaged in research and development since its inception, and prior to the merger, had raised approximately \$53 million from investors. These proceeds have been used to fund the development of multiple product applications and to conduct clinical studies. These funds have also been used to establish in-house manufacturing capacity to meet clinical testing needs, expand our intellectual property through additional patents and to develop extensive proprietary know-how with regard to our products.

Immediately prior to the merger, MedaSorb Delaware had 292 stockholders that held an aggregate of 20,340,929 shares of common stock of MedaSorb Delaware. In connection with the merger, certain stockholders of ours (i.e., persons who were stockholders of Gilder Enterprises prior to the merger), including Joseph Bowes, a former principal stockholder and our sole director and officer prior to the merger, sold an aggregate of 3,617,500 shares of our Common Stock to several purchasers, and forfeited 4,105,000 shares of Common Stock, which we cancelled. As a result, prior to giving effect to the merger, we had outstanding 3,750,000 shares of Common Stock and, after giving effect to the merger, we had outstanding 24,090,929 shares of Common Stock.

The principal stockholders of MedaSorb Delaware immediately prior to the merger were Margie Chassman, Guillermina Montiel, Al Kraus and Robert Shipley, who respectively beneficially owned 10,000,000 shares (49.2%), 5,052,456 shares (24.6%), 1,393,631 shares (6.9%) and 1,248,372 shares (6%), of the outstanding common stock of MedaSorb Delaware. Immediately following the merger and the closing of the Series A Preferred Stock financing described below, Ms. Chassman beneficially owned an additional 630,000 shares of Common Stock underlying the warrant we issued to her in connection with her pledge of stock to the purchasers of the Series A Preferred Stock, as described below. On July 5, 2006, Ms. Chassman transferred 2,005,000 shares of Common Stock owned by her to her designees as provided for under the Investment Agreement described elsewhere in this prospectus. In addition, following the closing of the Series A Preferred Stock financing, without giving effect to applicable restrictions that prohibit conversion of the Series A Preferred Stock or exercise of warrants if as a result the holder would hold in excess of 4.99% of our Common Stock, Longview Fund, LP beneficially owned 3,600,000 shares (13%) of our Common Stock.

Principal Terms of the Reverse Merger

In connection with the merger, the former stockholders of MedaSorb Delaware were issued an aggregate of 20,340,929 shares of Common Stock in exchange for the shares of MedaSorb common stock previously held by them. In addition, pursuant to the terms of the merger, outstanding warrants and options to purchase a total of 1,697,648 shares of the common stock of MedaSorb Delaware were cancelled in exchange for warrants and options to purchase the same number of shares of our Common Stock at the same exercise prices and otherwise on the same general terms as the MedaSorb Delaware options and warrants that were cancelled. Certain providers of legal services to MedaSorb Delaware who previously had the right to be issued approximately 997,000 shares of MedaSorb Delaware common stock as payment toward accrued legal fees, became entitled to instead be issued the same number of shares of our Common Stock as payment toward such services.

Concurrently with the closing of the merger, Joseph G. Bowes, our sole director and officer prior to the merger, appointed Al Kraus, Joseph Rubin, Esq., and Kurt Katz to the Board of Directors, and then resigned from the Board and from his positions as an officer. In addition, at such time, Al Kraus was appointed our President and Chief Executive Officer, James Winchester, MD was appointed our Chief Medical Officer, Vincent Capponi was appointed our Chief Operating Officer and David Lamadrid was appointed our Chief Financial Officer.

For accounting purposes, the merger is being accounted for as a reverse merger, since we were a shell company prior to the merger, the former stockholders of MedaSorb Delaware own a majority of the issued and outstanding shares of our Common Stock after the merger, and the directors and executive officers of MedaSorb Delaware became our directors and executive officers. Accordingly, MedaSorb Delaware is treated as the acquiror in the merger, which is treated as a recapitalization of MedaSorb Delaware, and the pre-merger financial statements of MedaSorb Delaware are now deemed to be our historical financial statements.

Principal Terms of the Series A Financing Consummated upon the Closing of the Merger

On June 30, 2006, immediately following the merger, we sold to four institutional investors, in a private offering generating gross proceeds of \$5.25 million, an aggregate of 5,250,000 shares of our Series A 10% Cumulative Convertible Preferred Stock initially convertible into 4,200,000 shares of Common Stock, and five-year warrants to purchase an aggregate of 2,100,000 shares of our Common Stock.

The Series A Preferred Stock has a stated value of \$1.00 per share. The Series A Preferred Stock is not redeemable at the holder's option but may be redeemed by us at our option following the third anniversary of the issuance of the Series A Preferred Stock for 120% of the stated value thereof plus any accrued but unpaid dividends upon 30 days' prior written notice (during which time the Series A Preferred Stock may be converted), provided a registration statement is effective under the Securities Act with respect to the shares of our Common Stock into which such Series A Preferred Stock is then convertible, and an event of default, as defined in the Certificate of Designations relating to the Series A Preferred Stock is not then continuing.

The Series A Preferred Stock has a dividend rate of 10% per annum, payable quarterly. The dividend rate increases to 20% per annum upon the occurrence of the events of default specified in the Certificate of Designations. Dividends may be paid in cash or, provided no event of default is then continuing, with additional shares of Series A Preferred Stock valued at the stated value thereof. The Series A Preferred Stock is convertible into Common Stock at the conversion rate of one share of Common Stock for each \$1.25 of stated value or accrued but unpaid dividends converted.

The warrants issued in the private placement have an initial exercise price of \$2.00 per share. The aggregate number of shares of Common Stock covered by the Warrants equaled, at the date of issuance, one-half the number of shares of Common Stock issuable upon the full conversion of the Series A Preferred Stock issued to the investors on that date.

We have agreed to file a registration statement (of which this prospectus is a part) under the Securities Act covering the Common Stock issuable upon conversion of the Series A Preferred Stock and exercise of the warrants within 120 days following closing of the private placement and to cause it to become effective within 240 days of that closing. We also granted the investors demand and piggyback registration rights with respect to such Common Stock.

Because the registration statement in which this prospectus is included was not declared effective within the time required under our agreements with the June 30, 2006 purchasers of the Series A Preferred Stock, dividends on the shares of Series A Preferred Stock issued to those purchasers accrued at the rate of 20% per annum from February 26, 2007 through April ___, 2007 and are payable in cash for such period, and we are obligated to pay those purchasers an aggregate of \$105,000 per 30-day period from February 26, 2007 through April ___, 2007.

Both the conversion price of the Series A Preferred Stock and the exercise price of the warrants are subject to "full-ratchet" anti-dilution provisions, so that upon future issuances of our Common Stock or equivalents thereof, subject to specified customary exceptions, at a price below the conversion price of the Series A Preferred Stock and/or exercise price of the warrants, the conversion price and/or exercise price will be reduced to the lower price.

In connection with the sale of the Series A Preferred Stock and warrants to the four institutional investors, to induce those investors to make the investment, Margie Chassman pledged to those investors securities of other publicly traded companies. The pledged securities consist of a \$400,000 promissory note of Xechem International, Inc. convertible into Xechem common stock at \$.005 per share, and 250,000 shares of the common stock of Novelos Therapeutics, Inc. Based on the market value of the Xechem common stock (\$.07 per share) and the Novelos common stock (\$1.03) per share, on June 30, 2006, the aggregate fair market value of the pledged securities at the date of pledge was approximately \$5,857,500.

In the event those investors have suffered a loss on their investment in our securities as of June 30, 2007 (as determined by actual sales by those investors or the market price of our Common Stock on such date), the investors may sell all or a portion of the pledged securities so that the investors receive proceeds from such sale in an amount equal to their loss on their investment in our securities. No assurance can be given that the sale of the pledged securities will provide these investors with sufficient proceeds to cover the full extent of their loss, if any, on their investment. In consideration of her pledge to these investors, we paid Ms. Chassman (i) \$525,000 in cash (representing 10% of the cash amount raised from the institutional investors), and (ii) five-year warrants to purchase

- · 525,000 shares of Series A Preferred Stock (representing 10% of the Series A Preferred Stock purchased by those investors), and
- · warrants to purchase 210,000 shares of Common Stock at an exercise price of \$2.00 per share (representing 10% of the Series A Preferred Stock purchased by those investors),

for an aggregate exercise price of \$525,000.

Technology, Products and Applications

For approximately the past half-century, the field of blood purification has been focused on hemodialysis, a mature, well accepted medical technique primarily used to sustain the lives of patients with permanent or temporary loss of kidney function. It is widely understood by the medical community that dialysis has inherent limitations in that its ability to remove toxic substances from blood drops precipitously as the size of toxins increases. Our hemocompatible adsorbent technology is expected to address this shortcoming by removing toxins largely untouched by dialysis.

Our products, CytoSorbTM and BetaSorbTM, are known in the medical field 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 believe that our polymer adsorbent technology may remove middle molecular weight toxins, such as cytokines, circulating in the blood. We believe that our technology may have many applications in the treatment of common, chronic and acute healthcare complications including the treatment and/or prevention of sepsis; the treatment of chronic kidney failure; the treatment of liver failure; the prevention of post-operative complications of cardiopulmonary bypass surgery; and the prevention of damage to organs donated by brain-dead donors prior to organ harvest. These applications vary by cause and complexity as well as by severity but share a common characteristic i.e. high concentrations of toxins in the circulating blood.

Both the CytoSorbTM and BetaSorbTM devices consist of a cylinder containing adsorbent polymer beads, although the polymers used in the two devices are physically different. The cylinders in both devices incorporate industry standard connectors at either end of the device which connect directly to the extra-corporeal circuit (bloodlines) in series with a dialyser, in the case of the BetaSorbTM device, or as a stand alone device in the case of the CytoSorbTM device. Both devices will require no additional expensive equipment, and will require minimal training.

The extra-corporeal circuit consists of plastic blood tubing, our CytoSorbTM or BetaSorbTM cartridge, as applicable, 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.

Markets

In the United States alone, there are more than one million new cases of sepsis annually; extrapolated to a global population, the worldwide incidence is several million cases per year. Severe trauma and community acquired pneumonia are often associated with sepsis.

Sepsis patients are critically ill and suffer a very high mortality rate of between 28% and 60%. Because they are so expensive to treat, we believe that efficacy rather than cost will be the determining factor in the adoption of CytoSorbTM in the treatment of sepsis. Based on current pricing of charcoal hemoperfusion devices in the market today, we estimate that our CytoSorbTM device will sell for \$500 per unit. Our current pricing model represents a fraction of what is currently spent on the treatment of a sepsis patient.

Brain-Dead Organ Donors

There are in excess of 6,000 brain dead organ donors each year in the United States; worldwide, the number of these organ donors is estimated to be at least double the U.S. brain dead organ donor population. There is a severe shortage of donor organs. Currently, there are more than 85,000 individuals on transplant waiting lists in the United States. We expect that the use of our CytoSorbTM device in brain dead organ donors will increase the number of viable organs harvested from the donor pool and improve the survival of transplanted organs.

Cardiopulmonary Bypass Procedures

There are approximately 400,000 cardiopulmonary bypass (CPB) and cardiac surgery procedures performed annually in the U.S. and more than 800,000 worldwide. Some patients, nearly one-third, suffer from post-operative complications of cardiopulmonary bypass surgery, including complications from infection, pneumonia, pulmonary, and neurological dysfunction. A common characteristic of these post operative complications is the presence of cytokines in the blood. Extended surgery time leads to longer ICU recovery time and hospital stays, both leading to higher costs - approximately \$32,000 per coronary artery bypass graft procedure. We believe that the use of CytoSorbTM during and after the surgical procedure may prevent or mitigate post-operative complications for many CPB patients.

We anticipate that the CytoSorbTM device, incorporated into the extra-corporeal circuit used with the by-pass equipment during surgery, and/or employed post-operatively for a period of time, may mitigate inflammation and speed recovery.

Chronic Kidney Failure

The National Kidney Foundation estimates that more than 20 million Americans have chronic kidney disease. Left untreated, chronic kidney disease can ultimately lead to chronic kidney failure, which requires a kidney transplant or chronic dialysis (generally three times per week) to sustain life. There are approximately 300,000 patients in the United States currently receiving chronic dialysis and more than 1.4 million worldwide. Approximately 89% of patients with chronic kidney disease are treated with hemodialysis.

Our BetaSorbTM device has been designed for use in conjunction with standard dialysis. Standard dialysis care typically involves three sessions per week, averaging approximately 150 sessions per year. Assuming BetaSorbTM use in each session, every 100,000 patients would require approximately 15 million devices annually.

Products

We believe that the polymer adsorbent technology used in our products has the potential to remove middle molecular weight toxins, such as cytokines, circulating in the blood. All of the potential applications described below (i.e., the treatment and/or prevention of sepsis; the treatment of chronic kidney failure; the treatment of liver failure; the prevention of post-operative complications of cardiopulmonary bypass surgery; and the prevention of damage to organs donated by brain-dead donors prior to organ harvest) share in common high concentrations of toxins in the

circulating blood. However, because of the limited studies we have conducted to date, we are subject to substantial risk that our technology will have little or no effect on the treatment of any of these indications. We only recently submitted a proposed pilot study for approval to the FDA with respect to CytoSorbTM, the first device we intend to bring to market. If we obtain FDA approval, we anticipate commencing clinical studies for CytoSorbTM 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 CytoSorbTM 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 CytoSorbTM or any other device.

The CytoSorbTM Device (Critical Care)

APPLICATION: Treatment and Prevention of Sepsis

Sepsis is defined by high levels of toxic compounds ("cytokines") which are released into the blood stream as part of the body's auto-immune response to severe infection or injury. These toxins cause severe inflammation and damage healthy tissues, which can lead to organ dysfunction and failure. Sepsis is very expensive to treat and has a high mortality rate.

<u>Potential Benefits:</u> To the extent our adsorbent blood purification technology is able to prevent or reduce the accumulation of cytokines in the circulating blood, we believe our products may be able to prevent or mitigate severe inflammation, organ dysfunction and failure in sepsis patients. Therapeutic goals as an adjunctive therapy include reduced ICU and total hospitalization time.

Background and Rationale: We believe that the effective treatment of sepsis is the most valuable potential application for our technology. Sepsis carries mortality rates of between 28% and 60%. Death can occur within hours or days, depending on many variables, including cause, severity, patient age and co-morbidities. Researchers estimate that there are approximately one million new cases of sepsis in the U.S. each year; extrapolated to a global population, this equates to several million new cases annually. In the U.S. alone, treatment of sepsis costs nearly \$18 billion annually. According to the Centers for Disease Control, sepsis is the tenth leading cause of death in the U.S., as reported by (CDC). More than 1,000 people die each day from sepsis.

An effective treatment for sepsis has been elusive. Pharmaceutical companies have been trying to develop drug therapies to treat the condition. With the exception of a single drug, Xigris® from Eli Lilly, which demonstrated a small improvement in survival in a small segment of the patient population, to our knowledge, all other efforts to date have failed to significantly improve patient survival.

We believe that our technology presents a new therapeutic approach in the treatment of sepsis. The potential benefits of blood purification in the treatment of sepsis patients are widely acknowledged by medical professionals and have been studied using dialysis and hemofiltration technology. These studies, while encouraging, demonstrated that dialysis alone produced only limited benefit to sepsis patients. The reason for this appears to be rooted in a primary limitation of dialysis technology itself: the inability of standard dialysis to effectively and efficiently remove larger toxins from circulating blood. Limited studies of our CytoSorbTM device have provided us with data consistent with our belief that CytoSorbTM has the ability to remove these larger toxins. CytoSorb'sTM ability to interact safely with blood (hemocompatibility) has been demonstrated through ISO 10993 testing. Data collected during the "emergency and compassionate use" treatment of a single sepsis patient has been encouraging to us.

CytoSorbTM has been designed to achieve broad-spectrum removal of both pro- and anti-inflammatory cytokines, preventing or reducing the accumulation of high concentrations in the bloodstream. This approach is intended to modulate the immune response without blocking or suppressing the function of any of its mediators. For this reason, researchers have referred to the approach reflected in our technology as 'immunomodulatory' therapy.

Projected Timeline and Budget Requirements: Previous clinical studies using our BetaSorbTM device in patients with chronic kidney failure have provided valuable data which underpin the development of the critical care applications for our technology. The BetaSorbTM 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 BetaSorbTM 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. Our plans for the

development of CytoSorbTM to treat sepsis patients are summarized in the table below.

Task	Status/Estimated Time Required	Estimated Budget Requirements
1. Design pilot study	Completed; Submitted for FDA approval in December 2006	(nominal)
2. Conduct pilot study	six to nine months following design of pilot study and approval from FDA to commence the study	\$1.2 million
3. Design pivotal study	Concurrent with item 2	(nominal)
4. Conduct pivotal study	nine to 12 months following completion of a successful pilot study, submission of final report of pilot study to FDA and FDA approval of pivotal study design	\$1.8 million
5. Approval time following submission	six to nine months	
Total	Mid to late 2009	\$3.0 million

Because our technology pertains to a medical device, the regulatory pathway and approval process are faster and more straightforward than the process related to the approval of a drug. However, 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.

APPLICATION: Prevention and treatment of organ dysfunction in brain-dead organ donors to increase the number and quality of viable organs harvested from donors

<u>Potential Benefits:</u> If CytoSorbTM is able to prevent or reduce high-levels of cytokines from accumulating in the bloodstream of brain-dead organ donors, we believe CytoSorbTM will be able to mitigate organ dysfunction and failure which results from severe inflammation following brain-death. The primary goals for this application are:

- · improving the viability of organs which can be harvested from brain-dead organ donors, and
 - · increasing the likelihood of organ survival following transplant.

<u>Background and Rationale:</u> When brain death occurs, the body responds by generating large quantities of inflammatory cytokines. This process is similar to sepsis. A high percentage of donated organs are never transplanted due to this response, which damages healthy organs and prevents transplant. In addition, inflammation in the donor may damage organs that are harvested and reduce the probability of graft survival following transplant.

There is a shortage of donated organs worldwide, with approximately 85,000 people currently on the waiting list for organ transplants in the United States alone. Because there are an insufficient number of organs donated to satisfy demand, it is vital to maximize the number of viable organs donated, and optimize the probability of organ survival following transplant.

Projected Timeline and Budget Requirements: Studies are currently being conducted under a \$1 million grant from the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services. Researchers at the University of Pittsburgh Medical Center and the University of Texas, Houston Medical Center completed the observational and dosing phases of the project in the third quarter of 2006. The observational and dosing phases of the study involved 30 viable donors and eight non-viable donors, respectively. The next phase of this study, the treatment phase, will involve viable donors treated with the CytoSorbTM device. In this phase of the project, viable donors will be treated and the survival and function of organs in transplant recipients will be tracked and measured. The treatment phase will be contingent upon further discussion with the FDA and HRSA regarding study design, as well as obtaining additional funding.

APPLICATION: Prevention and treatment of post-operative complications of cardiopulmonary bypass surgery

<u>Potential Benefits:</u> If CytoSorbTM is able to prevent or reduce high-levels of cytokines from accumulating in the blood system during and following cardiac surgery, we anticipate that post-operative complications of cardiopulmonary bypass surgery may be able to be prevented or mitigated. The primary goals for this application are to:

- · reduce ventilator and oxygen therapy requirements;
- · reduce length of stay in hospital intensive care units; and
 - · reduce the total cost of patient care.

<u>Background and Rationale:</u> Due to the highly invasive nature of cardiopulmonary bypass surgery, high levels of cytokines are produced by the body, triggering severe inflammation. If our products are able to prevent or reduce the accumulation of cytokines in a patient's blood stream, we expect to prevent or mitigate post-operative complications caused by an excessive or protracted inflammatory response to the surgery. While not all patients undergoing cardiac surgery suffer these complications, it is impossible to predict before surgery which patients will be affected.

Projected Timeline: We commissioned the University of Pittsburgh to conduct a study to characterize the production of cytokines as a function of the surgical timeline for cardiopulmonary bypass surgery. An observational study of 32 patients was completed, and information was obtained with respect to the onset and duration of cytokine release. We expect that this information will aid us in defining the appropriate time to apply the CytoSorbTM device to maximize therapeutic impact. We are not currently focusing our efforts on the commercialization of CytoSorbTM for application to cardiac surgery. Upon successful commercialization of the sepsis application, we will pursue the use of our polymer absorbent technology for other critical care uses, such as cardiopulmonary bypass surgery.

The BetaSorbTM Device (Chronic Care)

APPLICATION: Prevention and treatment of health complications caused by the accumulation of metabolic toxins in patients with chronic renal failure

<u>Potential Benefits:</u> If CytoSorbTM is able to prevent or reduce high levels of metabolic waste products from accumulating in the blood and tissues of long-term dialysis patients, we anticipate that the health complications characteristic to these patients can be prevented or mitigated. The primary goals for this application are to

- · improve and maintain the general health of dialysis patients;
 - · improve the quality of life of these patients
 - · reduce the total cost of patient care; and
 - · increase life expectancy.

Background and Rationale: Our BetaSorbTM device is intended for use on patients suffering from chronic kidney failure who rely on long-term dialysis therapy to sustain life. Due to the widely recognized inability of dialysis to remove larger proteins from blood, metabolic waste products, such as Beta-2 microglobulin, accumulate to toxic levels and are deposited in the joints and tissues of patients. Specific toxins known to accumulate in these patients have been linked to their severe health complications, increased healthcare costs, and reduced quality of life.

Researchers also believe that the accumulation of toxins may play an important role in the significantly reduced life expectancy experienced by dialysis patients. In the U.S., the average life expectancy of a dialysis patient is five years. Industry research has identified links between many of these toxins and poor patient outcomes. If our BetaSorbTM device is able to routinely remove these toxins during dialysis and prevent or reduce their accumulation, we expect our BetaSorbTM device to maintain or improve patient health in the long-term. We believe that by reducing the incidence of health complications, the annual cost of patient care will be reduced and life expectancy increased.

The poor health experienced by chronic dialysis patients is illustrated by the fact that in the U.S. alone, more than \$20 billion is spent annually caring for this patient population. While the cost of providing dialysis therapy alone is approximately \$23,000 per patient per year, the total cost of caring for a patient ranges from \$60,000 to more than \$120,000 annually due to various health complications associated with dialysis.

<u>Projected Timeline:</u> We have collected a significant amount of empirical data for the development of this application. As the developer of this technology, we had to undertake extensive research, as no comparable technology was available for reference purposes. We have completed several pilot studies, and most recently a clinical pilot of six patients in California for up to 24 weeks in which our BetaSorbTM device removed the targeted toxin, beta₂-microglobulin, as expected. In total, we have sponsored clinical studies utilizing our BetaSorbTM device on 20 patients involving approximately 345 total treatments. Each study was conducted by a clinic or hospital personnel with MedaSorb providing technical assistance as requested.

As discussed above, due to practical and economic considerations, we are now focusing our efforts and resources on commercializing our CytoSorbTM device for critical care application. Following commercial introduction of the CytoSorbTM device, we expect to conduct additional clinical studies using the BetaSorbTM device in the treatment of end stage renal disease patients.

Commercial and Research Partners

University of Pittsburgh Medical Center

Pursuant to a "SubAward Agreement" we entered into with the University of Pittsburgh in September 2005, we are working with researchers at the University of Pittsburgh - Critical Care Medicine Department in the development of the sepsis application for our technology. Consisting of more than twenty physicians, as well as numerous full-time scientists, educators and administrative assistants, the Critical Care Medicine Department at the University of Pittsburgh is one of the largest organizations of its type in the world and has established an international reputation for excellence in clinical care, education, and research.

The SubAward Agreement was entered into under a grant from NIH entitled "Systems Engineering of a Pheresis Intervention for Sepsis (SEPsIS)" to study the use of adsorbent polymer technology in the treatment of severe sepsis. The study commenced in September 2005 and is expected to continue for a total of five years. Currently, we believe that the only polymers being used in this study are polymers we have developed specifically for use in the study, which are similar to the polymers used in our devices. Under the SubAward Agreement, during the first year of the study, which concluded in August 2006, we received \$104,921 for our efforts in support of the grant. Although we have not yet formally entered into an additional SubAward Agreement, we continue to supply UPMC with new samples based on our adsorbent polymer technology under the same terms as the initial SubAward Agreement, and expect to do so for the duration of the study. UPMC has indicated to us that the amounts budgeted for our participation under the study are approximately \$142,000, \$110,000, \$133,000 and \$163,000, respectively, for years two, three, four and five of the study, but that our continued participation in the study is subject to our performance and an annual review by UPMC.

Researchers at UPMC have participated in nearly every major clinical study of potential sepsis intervention during the past twenty years. Drs. Derek Angus and John Kellum were investigators for Eli Lilly's sepsis drug, Xigris®. Dr. Kellum, a member of the UPMC faculty since 1994, is our principal investigator for CytoSorbTM. Dr. Kellum, together with several other researchers at UPMC, serve on our Critical Care Advisory Board. Dr. Kellum's research interests span various aspects of Critical Care Medicine, but center on critical care nephrology (including acid-base, and renal replacement therapy), sepsis and multi-organ failure, and clinical epidemiology. He is Chairman of the Fellow Research Committee at the University of Pittsburgh Medical Center and has authored more than 70 publications and has received numerous research grants from foundations and industry.

Fresenius Medical Care AG

In 1999, we entered into an exclusive, long-term agreement with Fresenius Medical Care for the global marketing and distribution of our BetaSorbTM device and any similar product we may develop for the treatment of renal disease. We currently intend to pursue our BetaSorbTM product after the commercialization of the CytoSorbTM product. At such time as we determine to proceed with our proposed BetaSorbTM product, if ever, we will need to conduct additional clinical studies using the BetaSorbTM device and obtain FDA approval.

Fresenius Medical Care is the world's largest, integrated provider of products and services for individuals with chronic kidney failure. Through its network of more than 1,600 dialysis clinics in North America, Europe, Latin America and Asia-Pacific, Fresenius Medical Care provides dialysis treatment to more than 130,000 patients around the globe. Fresenius Medical Care is also the world's largest provider of dialysis products, such as hemodialysis machines, dialyzers and related disposable products.

Advisory Boards

From time to time our management meets with scientific advisors who sit on our Scientific Advisory Board, our Medical Advisory Board - Critical Care Medicine, and our Medical Advisory Board - Chronic Kidney Failure / Dialysis.

Our Scientific Advisory Board consists of four scientists with expertise in the fields of fundamental chemical research, polymer research and development, and dialysis engineering technology.

Our Medical Advisory Board - Critical Care Medicine consists of seven medical doctors, four of whom are affiliated with UPMC, with expertise in critical care medicine, sepsis, multi-organ failure and related clinical study design.

Our Medical Advisory Board - Chronic Kidney Failure / Dialysis consists of four medical doctors with expertise in kidney function, kidney diseases and their treatment, and dialysis technology.

We compensate members of our Advisory Boards at the rate of \$2,000 for each full-day meeting they attend in person; \$1,200 if attendance is by telephone. When we consult with members of our Advisory Board (whether in person or by telephone) for a period of less than one day, we compensate them at the rate of \$150 per hour, except with respect to one of our advisors, who we compensate at the rate of \$200 per hour. We also reimburse members of our Advisory Boards for their travel expenses for attending our meetings.

Royalty Agreements

With Principal Stockholder

In August 2003, in order to induce Guillermina Vega Montiel, a principal stockholder of ours, to make a \$4 million investment in MedaSorb Delaware, we granted Ms. Montiel a perpetual royalty equal to three percent of all gross revenues received by us from sales of CytoSorbTM in the applications of sepsis, cardiopulmonary bypass surgery, organ donor, chemotherapy and inflammation control. In addition, for her investment, Ms. Montiel received 1,230,770 membership units of MedaSorb Delaware, which at the time was a limited liability company. Those membership units ultimately became 185,477 shares of our Common Stock following our June 30, 2006 merger.

With Purolite

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. In particular, the Settlement Agreement relates to twelve of our issued patents and five pending patent applications covering our biocompatible polymeric resins, our methods of producing these polymers, and the methods of using the polymers to remove impurities from physiological fluids, such as blood.

Under the terms of the Settlement Agreement, we have agreed to pay Purolite royalties of 2.5% to 5% on the sale of those of our products, if and when those products are sold commercially, that are used in direct contact with blood. However, if the first product we offer for commercial sale is a biocompatible polymer to be used in direct contact with a physiological fluid other than blood, royalties will be payable with respect to that product as well. The royalty payments provided for under the Settlement Agreement would apply to our currently envisioned CytoSorbTM and BetaSorbTM products.

Following the expiration of the eighteen year term of the Settlement Agreement, the patents and patent applications that are the subject of the Settlement Agreement should have expired under current patent laws, and the technology claimed in them will be available to the public. However, following such time, we continue to exclusively own any confidential and proprietary know how.

Product Payment & Reimbursement

Critical Care Applications

Payment for our CytoSorbTM device in the treatment and prevention of sepsis and other related acute care applications is anticipated to fall under the "diagnosis-related group" (DRG) in-patient reimbursement system, which is currently the predominant basis of hospital medical billing in the United States. Under this system, predetermined payment amounts are assigned to categories of medical patients with respect to their treatments at medical facilities based on the DRG that they fall within (which is a function of such characteristics as medical condition, age, sex, etc.) and the length of time spent by the patient at the facility. Reimbursement is not determined by the actual procedures used in the treatment of these patients, and a separate reimbursement decision would not be required to be made by Medicare, the HMO or other provider of medical benefits in connection with the actual method used to treat the patient.

Critical care applications such as those targeted by our CytoSorbTM device involve a high mortality rate and extended hospitalization, coupled with extremely expensive ICU time. In view of these high costs and high mortality rates, we believe acceptance of our proprietary technology by critical care practitioners and hospital administrators will primarily depend on safety and efficacy factors rather than cost.

Chronic Renal Failure

In the U.S., over 80% of chronic dialysis patients are Medicare-eligible, regardless of age. Therefore, it is expected that Medicare will be the primary payer for the BetaSorbTM device, either through the current "fee for service" mechanism or managed care programs. The large majority of costs not covered by federal programs are covered by the private insurance sector.

While the fee-for-service composite rate system is currently the dominant payment mechanism, many industry participants believe that a managed care system will become the dominant payment mechanism. We believe that movement to a full or shared-risk managed care system would speed market acceptance of BetaSorbTM because, under such a system, providers will have a strong incentive to adopt technologies that lower overall treatment costs. Fresenius is a leading participant in the move to managed care and will play a leading role in the demonstration and introduction of our product to Medicare.

Competition

General

We believe that our products represent a unique approach to disease states and health complications associated with the presence of larger toxins (often referred to as middle molecular weight toxins) in the bloodstream, including

sepsis, post-operative complications of cardiac surgery (cardiopulmonary bypass surgery), damage to organs donated for transplant prior to organ harvest, and renal disease. Researchers have explored the potential of using existing membrane-based dialysis technology to treat patients suffering from sepsis. These techniques are unable to effectively remove the middle molecular weight toxins. We believe that our devices may be able to remove middle molecular weight toxins from circulating blood. This concept has been tested at the University of Pittsburg using a septic rat model based on lipopolysaccharide (a particular kind of toxin, known as a bacterial endotoxin) and the CytoSorbTM polymer.

Both the CytoSorbTM and BetaSorbTM devices consist of a cylinder containing 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 cartridge (CytoSorbTM or BetaSorbTM depending on the condition being treated) containing our 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 are adsorbed from the blood, without filtering any fluids from the blood or the need for replacement fluid or dialysate.

Although standard dialysis also uses extra-corporeal circuits and blood pumps, the technology used in dialysis to remove toxins (osmosis and convection) drains fluids out of the bloodstream in a process called ultrafiltration, and uses semi-permeable membranes as a filter, allowing the passage of certain sized molecules across the membrane, but preventing the passage of other, larger molecules.

MedaSorb's technology uses the same extra-corporeal circuits as dialysis, however, our devices do not rely on membrane technology but instead use an adsorbent of specified pore size, which controls the size of the molecules which can pass into the adsorbent. As blood flows over our polymer adsorbent, middle molecules such as cytokines flow into the polymer adsorbent and are adsorbed. Our devices do not use semipermeable membranes or dialysate. In addition, our devices do not remove fluids from the blood like a dialyser. Accordingly, we believe that our technology has significant advantages as compared to traditional dialysis techniques.

Sepsis

Researchers have explored the potential of using existing membrane-based dialysis technology to treat patients suffering from sepsis. These techniques are unable to effectively remove middle molecular weight toxins, which leading researchers have shown to cause and complicate sepsis. The same experts believe that a blood purification technique that efficiently removes, or significantly reduces, the circulating concentrations of such toxins might represent a successful therapeutic option. We believe that the CytoSorbTM device may have the ability to remove middle molecular weight toxins from circulating blood.

Medical research during the past two decades has focused on drug interventions aimed at chemically blocking or suppressing the function of one or two inflammatory agents. In hindsight, some researchers now believe this approach has little chance of significantly improving patient outcomes because of the complex pathways and multiple chemical factors at play. Clinical studies of these drug therapies have been largely unsuccessful. An Eli Lilly drug, Xigris®, cleared by the FDA in November 2001, is the first and only drug to be approved for the treatment of severe sepsis. Clinical studies demonstrated that use of Xigris® resulted in a 6% reduction in the absolute risk of death, and a 13% risk reduction in the most severe sepsis patients. The drug remains controversial and is considered extremely expensive when compared to the percentage of patients who benefit.

While studies of other potential sepsis drug therapies are in progress, we are not aware of any other broad-spectrum blood detoxification therapy under development for this application that could be considered directly competitive with our approach.

Cardiopulmonary Bypass Surgery

We are not aware of any practical competitive approaches for removing cytokines in CPB patients. Alternative therapies such as "off-pump" surgeries are available but "post-bypass" syndrome has not been shown to be reduced in this less invasive procedure. If successful, CytoSorbTM is expected to be useful in both on-pump and off-pump procedures.

Chronic Dialysis

Although standard dialysis treatment effectively removes urea and creatinine from the blood stream (which are normally filtered by functioning kidneys), standard dialysis has not been effective in removing beta₂-microglobulin toxins from the blood of patients suffering from chronic kidney failure. We know of no other device, medication or therapy considered directly competitive with our technology. Research and development in the field has focused primarily on improving existing dialysis technologies. The introduction of the high-flux dialyzer in the mid-1980s and the approval of Amgen's EpogenTM, a recombinant protein used to treat anemia, are the two most significant developments in the field over the last two decades.

Efforts to improve removal of middle molecular weight toxins with enhanced dialyzer designs have achieved only marginal success. Many experts believe that dialyzer technology has reached its limit in this respect. A variation of high-flux hemodialysis, known as hemodiafiltration, has existed for many years. However, due to the complexity, cost and increased risks, this dialysis technique has not gained significant acceptance worldwide. In addition, many larger toxins are not effectively filtered by hemodiafiltration, despite its more open pore structure. As a result, hemodiafiltration does not approach the quantity of toxins removed by the BetaSorbTM device.

Treatment of Organ Dysfunction in Brain-Dead Organ Donors

We are not aware of any directly competitive products to address the application of our technology for the mitigation of organ dysfunction and failure resulting from severe inflammation following brain-death.

Clinical Studies

Our first clinical studies were conducted in patients with chronic renal failure. The health of these patients is challenged by high levels of toxins circulating in their blood but, unlike sepsis patients, they are not at imminent risk of death. The toxins involved in chronic renal failure are completely different from those involved in sepsis, eroding health gradually over time. The treatment of patients with chronic renal failure is a significant target market for us, although not the current focus of our efforts and resources. Our clinical studies and product development work in this application functioned as a low risk method of evaluating the safety of the technology in a clinical setting, with direct benefit to development of the critical care applications on which we are now focusing our efforts.

We have not conducted any clinical studies of our products with respect to the treatment of any other indications, although data collected during the "emergency and compassionate use" treatment of a single sepsis patient has been encouraging to us. Because of the limited studies we have conducted, we are subject to substantial risk that our technology will have little or no effect on the treatment of any indications that we have targeted.

We only recently submitted a proposed pilot study for approval to the FDA with respect to CytoSorbTM, the first device we intend to bring to market. If we obtain FDA approval, we anticipate commencing clinical studies for CytoSorbTM 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 CytoSorbTM 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 CytoSorbTM or any other device.

Government Research Grants

Two government research grants by the National Institutes of Health (NIH) and Health and Human Services (HHS) have been awarded to investigators at the University of Pittsburgh to explore the use of adsorbent polymers in the treatment of sepsis and organ transplant preservation. Under "SubAward Agreements" with the University of Pittsburgh, we have been developing polymers for use in these studies.

A grant of \$1 million was awarded to the University of Pittsburgh Medical Center in 2003. The project seeks to improve the quantity and viability of organs donated for transplant by using CytoSorbTM to detoxify the donor's blood. The observational and dosing phases of the study, involving 30 viable donors and eight non-viable donors, respectively, have been completed. The next phase of this study, the treatment phase, will involve viable donors. The treatment phase will be contingent upon further discussion with the FDA and HRSA regarding study design, as well as obtaining additional funding.

In addition, in September 2005, the University of Pittsburgh Medical Center was awarded a grant from NIH entitled "Systems Engineering of a Pheresis Intervention for Sepsis (SEPsIS)" to study the use of adsorbent polymer technology in the treatment of severe sepsis. The study, expected to last for a total of five years, commenced in September, 2005 and remains in progress. Under a SubAward Agreement, we are working with researchers at the University of Pittsburgh - Critical Care Medicine Department. Currently, we believe that the only polymers being used in this study are polymers we have developed specifically for use in the study, which are similar to the polymers used in our devices. Under the SubAward Agreement, during the first year of the study, which concluded in August 2006, we received \$104,921 for our efforts in support of the grant. Although we have not yet formally entered into an additional SubAward Agreement, we continue to supply UPMC with new samples based on our adsorbent polymer technology under the same terms as the initial SubAward Agreement, and expect to do so for the duration of the study. UPMC has indicated to us that the amounts budgeted for our participation under the study are approximately \$142,000, \$110,000, \$133,000 and \$163,000, respectively, for years two, three, four and five of the study, but that our continued participation in the study is subject to our performance and an annual review by UPMC.

These grants represent a substantial research cost savings to us and demonstrate the strong interest of the medical and scientific communities in our technology.

Regulation

The medical devices that we manufacture are subject to regulation by numerous regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation program be conducted before a device receives approval for commercial distribution.

In the U.S., permission to distribute a new device generally can be met in one of two ways. The first process requires that a pre-market notification (510(k) Submission) be made to the FDA to demonstrate that the device is as safe and effective as, or substantially equivalent to, a legally marketed device that is not subject to pre-market approval (PMA). A legally marketed device is a device that (i) was legally marketed prior to May 28, 1976, (ii) has been reclassified from Class III to Class II or I, or (iii) has been found to be substantially equivalent to another legally marketed device following a 510(k) Submission. The legally marketed device to which equivalence is drawn is known as the "predicate" device. Applicants must submit descriptive data and, when necessary, performance data to establish that the device is substantially equivalent to a predicate device. In some instances, data from human clinical studies must also be submitted in support of a 510(k) Submission. If so, these data must be collected in a manner that conforms with specific requirements in accordance with federal regulations. The FDA must issue an order finding substantial equivalence before commercial distribution can occur. Changes to existing devices covered by a 510(k) Submission which do not significantly affect safety or effectiveness can generally be made by us without additional 510(k) Submissions.

The second process requires that an application for PMA be made to the FDA to demonstrate that the device is safe and effective for its intended use as manufactured. This approval process applies to certain Class III devices. In this case, two steps of FDA approval are generally required before marketing in the U.S. can begin. First, investigational device exemption (IDE) regulations must be complied with in connection with any human clinical investigation of the device in the U.S. Second, the FDA must review the PMA application which contains, among other things, clinical information acquired under the IDE. The FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose.

In the European Union, distributors of medical devices are required to comply with the Medical Devices Directive and obtain CE Mark certification in order to market medical devices. The CE Mark certification, granted following

approval from an independent Notified Body, is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. Distributors of medical devices may also be required to comply with other foreign regulations such as Ministry of Health Labor and Welfare approval in Japan. The time required to obtain these foreign approvals to market our products may be longer or shorter than that required in the U.S., and requirements for those approvals may differ from those required by the FDA.

In the United States, our CytoSorbTM and BetaSorbTM devices are classified as Class III (CFR 876.5870—Sorbent Hemoperfusion System) and will require 501(k) Submissions to the FDA. However, because the BetaSorbTM device is intended for chronic use, the FDA may require pre-market approval (PMA), which we will submit if required. In the case of CytoSorbTM, because the application is for acute care (short term, less than 30 days), management believes that FDA approval for this product may be obtained based solely on the 510(k) Submission accompanied with clinical data. In Europe, our devices are expected to be classified as class IIb, and will conform to the ISO 13485 Quality Standard in support of our planned applications to obtain CE Mark certification in Europe, and applicable approvals in Canada and Japan.

The process of obtaining clearance to market products is costly and time-consuming in virtually all of the major markets in which we expect to sell products and may delay the marketing and sale of our products. Countries around the world have recently adopted more stringent regulatory requirements which are expected to add to the delays and uncertainties associated with new product releases, as well as the clinical and regulatory costs of supporting those releases. No assurance can be given that any of our medical devices will be approved on a timely basis, if at all. In addition, regulations regarding the development, manufacture and sale of medical devices are subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our busine