GILDER ENTERPRISES INC
Form 8-K
July 06, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 30, 2006

GLIDER ENTERPRISES, INC.
(Exact name of registrant as specified in its charter)

Nevada	000-51038	98-0373793
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

7 Deer Park Drive, Suite K, Monmouth Junction, New Jersey 08852
(Address of principal executive office) (Zip Code)

Registrant's telephone number, including area code: (732) 329-8885

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2.below):

[_] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[_] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[_] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[_] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13c-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

Merger

On June 30, 2006, Gilder Enterprises, Inc., a Nevada corporation ("Registrant") completed the acquisition of MedaSorb Corporation, a Delaware corporation ("MedaSorb"), pursuant to an Agreement and Plan of Merger (the "Merger Agreement") by and among the Registrant, MedaSorb Acquisition Inc., a Delaware corporation ("Acquisition Sub") and MedaSorb. A copy of the Merger Agreement is filed as Exhibit 2.1 to this Current Report on Form 8-K.

The principal terms of the merger and a description of the business of MedaSorb is set forth below in Item 2.01.

Private Placement

Immediately following the merger, we sold 5,250,000 shares of our Series A 10% Cumulative Convertible Preferred Stock, par value $.001 per share ("Series A Preferred Stock"), to three institutional investors pursuant to a Subscription Agreement filed as Exhibit 4.3 to this Current Report on Form 8-K and incorporated herein by reference, in a private offering exempt from registration pursuant to Section 4(2) and Regulation D (Rule 506) under the Securities Act of 1933, as amended (the "Securities Act"). The 5,250,000 shares of Series A Preferred Stock are initially convertible into 4,200,000 shares our common stock, par value $.001 per share ("Common Stock").

The Series A Preferred Stock has a stated value of $1.00 per share and was sold for a purchase price equal to the stated value. 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 (the "Certificate of Designations"), is not then continuing. A copy of the Certificate of Designations is filed as Exhibit 4.1 to this Current Report on Form 8-K and incorporated herein by reference.

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. Such 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.

In conjunction with the issuance of the Series A Preferred Stock to the investors, we issued to them, for no additional consideration, five-year warrants (the "Warrants") to purchase an aggregate of 2,100,000 shares of Common Stock at an exercise price of $2.00 per share. The form of the Warrants is filed as Exhibit 4.2 to this Current Report on Form 8-K and incorporated herein by reference. The aggregate number of shares of Common Stock covered by the Warrants equals, at the date of issuance thereof, 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 such date. We have agreed to file a registration statement 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 such closing. We also granted the investors demand and piggyback registration rights with respect to such Common Stock.

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.

In connection with the sale of the Series A Preferred Stock and Warrants to the investors, Margie Chassman, the beneficial holder of approximately 42% of our outstanding shares of Common Stock, agreed to pledge certain securities held by her to the investors, which such investors may sell to ensure they do not suffer a loss on their investment in the first year following the date of their investment. In consideration of her pledge to these investors, we agreed to pay Ms. Chassman (i) $525,000 in cash, and (ii) five-year warrants to purchase 10% of the shares of Series A Preferred Stock and 10% of the Warrants sold to these investors for an exercise price equal to the price paid by the investors in the private placement for the Series A Preferred Stock and Warrants.

We anticipate that our other fees and expenses in connection with the sale of the Series A Preferred Stock and Warrants will amount to approximately $775,000.

Additionally, in connection with the merger, certain stockholders of ours, including our former principal stockholder, 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, so that prior to giving effect to the merger, we had outstanding 3,750,000 shares of Common Stock.

After giving effect to the merger, the surrender of shares described above and the sale of the Series A Preferred Stock and Warrants, we had issued and outstanding 24,090,929 shares of Common Stock and convertible securities, options and warrants that may be converted into or exercised for 9,624,648 additional shares of Common Stock. In addition, the holders of 240,929 shares of Common Stock and warrants to purchase an additional 240,929 shares of Common Stock have the right to exchange such shares of Common Stock and warrants for approximately 800,000 shares of Series A Preferred Stock and Warrants to purchase 400,000 shares of Common Stock at a price of $2.00 per share.

The securities we sold in the private placement have not be registered under the Securities Act, and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements under the Securities Act.

In connection with the closing of the private placement, we agreed to make a short-term advance to Ms. Chassman in the amount of $500,000 bearing interest at the rate of 6% per annum, the repayment of which may be offset against amounts owed by us to Ms. Chassman under the $1,000,000 advance previously made by her to MedaSorb. The short-term advance will be secured by a pledge of publicly-traded securities with a market value equal to $500,000.

Termination of Joint Venture

On June 30, 2006, we also terminated our joint venture agreement with 5G Wireless pursuant to a Termination and Release Agreement, and in connection therewith, we sold our 51% interest in Nex Connectivity Solutions, Inc. to Dennis Tan, a Singapore national for $18,000 (Canadian). Accordingly, we are no longer engaged in the business of providing Internet access to hotels or other properties.

Item 2.01. Completion of Acquisition or Disposition of Assets.

Principal Terms of the Reverse Merger

Pursuant to the Merger Agreement, on June 30, 2006, we completed the acquisition of MedaSorb through a reverse triangular merger in which Acquisition Sub, a wholly owned subsidiary of ours formed solely for the purpose of facilitating the merger, merged with MedaSorb. MedaSorb is now a wholly owned subsidiary of ours, and its business (which is described below) is now our only business.

In connection with the merger (i) the former stockholders of MedaSorb were issued an aggregate of 20,340,929 shares of Common Stock in exchange for the same number of shares of MedaSorb common stock previously held by such stockholders, (ii) outstanding warrants and options to purchase a total of 1,697,648 shares of the common stock of MedaSorb were cancelled in exchange for warrants and stock 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 options and warrants that were cancelled (the options issued to the employees, directors and consultants of MedaSorb being issued under our 2006 Long Term Incentive Plan), and (iii) certain providers of legal services to MedaSorb who previously had the right to be issued approximately 997,000 shares of MedaSorb 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. Immediately prior to the merger, after giving effect to the share cancellation transaction referred to above, we had outstanding 3,750,000 shares of Common Stock and no warrants or options to purchase Common Stock.

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. Additional information with respect to our new directors and officers is provided in Item 2.01 of this Current Report on Form 8-K.

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 now own a majority of the issued and outstanding shares of our Common Stock, and the directors and executive officers of MedaSorb became our directors and executive officers. Accordingly, MedaSorb is treated as the acquiror in the merger, which is treated as a recapitalization of MedaSorb, and the pre-merger financial statements of MedaSorb will now be deemed to be our historical financial statements.

In connection with the merger, we also changed our principal executive offices to those of MedaSorb, which are located at 7 Deer Park Drive, Suite K, Monmouth Junction, New Jersey 08852.

Form 10-SB Disclosure - Description of MedaSorb

Prior to closing of the merger, Registrant was a “shell company” (as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, (the “Exchange Act”). Accordingly, set forth below is the information that would be required if Registrant were filing a general form for registration of securities on Form 10-SB under the Exchange Act.

Unless otherwise indicated or the context otherwise requires, all references below to “we,” “us,” “MedaSorb” and the “Company” are to Registrant together with MedaSorb, its wholly-owned subsidiary.

General

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 are preparing to commercialize a breakthrough blood purification technology that efficiently removes toxic compounds from circulating blood. Current state-of-the-art blood purification technology (such as dialysis) is incapable of effectively clearing these toxins.

Our products, which have not yet been introduced to the market, are known medically as hemoperfusion devices, and incorporate our proprietary adsorbent polymer technology. We believe that there are many potential healthcare applications for our products, including:

- Adjunctive treatment and/or prevention of sepsis (bacterial infection of the blood);
- prevention of damage to organs donated for transplant prior to organ harvest;
- prevention of post-operative complications of cardiac surgery; and
- long-term treatment of chronic kidney failure.

Product Strategy

MedaSorb is developing two product lines, CytoSorb™ and BetaSorb™, for use in acute and chronic treatments, respectively. CytoSorb™ will initially be targeted for use as an adjunctive therapy in the acute treatment of the systemic inflammatory response syndrome (SIRS). BetaSorb™ is intended to be used as a complement to dialysis in the treatment of chronic end stage renal disease (ESRD). We will first focus our efforts on commercializing CytoSorb™, which we believe will provide a relatively faster regulatory pathway to market. BetaSorb™'s potential for usage in chronic conditions such as ESRD is anticipated to have a longer and more complex regulatory pathway and will be pursued after commercialization of the CytoSorb™ product.

The first indication for CytoSorb™ will be in the treatment of sepsis, as an adjunctive therapy to the current standard of care. Following the sepsis indication, we intend to continue our research in other acute conditions where CytoSorb™ has indicated potential, such as for use in cardiopulmonary bypass surgery addressing post operative complications of inflammation, and organ donation from brain dead organ donors, addressing the so-called cytokine storm associated with the decrease of viable organs from donors. We are also exploring the potential benefits the CytoSorb™ device may have in removing drugs from blood in situations such as patient overdoses.

We had initially identified end stage renal disease as the target market for our polymer-based adsorbent technology. End stage renal disease affects more than 1.3 million people worldwide and is the single most common application of blood purification technology today, namely hemodialysis. Hemodialysis is a life saving intervention, but is not nearly as effective as a healthy kidney in removing toxins from the bloodstream.

During the development of our end stage renal product (BetaSorb™), we identified several applications for our adsorbent technology in the treatment of critical care patients and recognized that our absorbent polymer represented a platform of broad application in medicine, well beyond the treatment of patients suffering from renal disease. As a result, we shifted our priorities to pursue critical care applications (such as for the treatment of sepsis) for our technology. We believe that, compared with the chronic renal application for our technology,

- we will able to obtain the necessary regulatory approvals in a shorter period of time, allowing us to bring our CytoSorb™ product to market in a shorter time frame;

- the production of CytoSorb™ will entail a lower capital requirement for manufacturing and generate significantly higher gross margins; and

- the use of CytoSorb™ in critical care applications will result in quicker reimbursement because the use of our products in these situations (generally on an in-patient basis) will generally not be subject to pre-approval, or require a separate decision, by Medicare or the relevant HMO or other providers of medical benefits.

However, we continue to remain confident of the commercial potential of our BetaSorb™ device for chronic applications and will continue its development as a secondary product.

Corporate History

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

MedaSorb has engaged in research and development since its inception, and prior to the merger, we had raised approximately $53 million from investors. These proceeds have been used to fund the development of multiple product applications and to conduct clinical trials. 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.

Gilder Enterprises, Inc., a Nevada corporation, was incorporated on April 25, 2002. Prior to the merger, through a 51% interest in Nex Connectivity Solutions under a joint venture arrangement with 5G Wireless Communications Pte. Ltd, the Registrant was engaged in the business of installing and operating computer networks that enabled business travelers to have high-speed access to the Internet. In connection with the merger, we terminated the joint venture arrangement and disposed of our interest in Nex Connectivity Solutions, which had generated minimal revenues and no profits. At the effective time of the merger, the Registrant fell within the definition of a “shell company” under the Exchange Act.

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 addresses this shortcoming by efficiently removing toxins largely untouched by dialysis.

Our products 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 represents an effective therapeutic approach to severe health complications caused or complicated by large toxins circulating in the blood. Our technology has many potential applications in the treatment of common, chronic and acute healthcare complications including the treatment and/or prevention of sepsis; drug detoxification; the treatment of chronic kidney failure; the treatment of organ dysfunction resulting from trauma and severe burns; 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.

Our products will be easy to use and will be able to be incorporated into existing extracorporeal blood handling equipment, including heart-lung bypass circuits and hemodialysis machines. They will require no additional, expensive equipment and require minimal training.

Markets, Size and Economic Potential

Sepsis

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 CytoSorb™ in the treatment of sepsis. Our current pricing model represents a fraction of what is currently spent on the treatment of a sepsis patient. Critical care specialists project that the average sepsis patient may require 10 CytoSorb™ (single-use, disposable) devices during a treatment regimen, based on the median number of days for which patients typically require ventilator support. Assuming only 2% of the sepsis patient population received CytoSorb™ therapy, based on a pricing model of $500 per device and 10 devices per episode, the annual revenue potential is $100 million in the U.S. alone and $200 million worldwide.

Brain-Dead Organ Donors

There are approximately 6,000 to 12,000 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 CytoSorb™ 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. At $500 per device, the worldwide revenue potential for this application is currently estimated at $12 million annually.

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. Nearly a third of all patients suffer from post-operative complications of cardiopulmonary bypass surgery, including complications from infection, pneumonia, pulmonary, and neurological dysfunction. Extended surgery time leads to longer ICU recovery time and hospital stays, both leading to higher costs - approximately $35,000 per coronary artery bypass graft procedure. We believe that the use of CytoSorb™ during and after the surgical procedure will prevent or mitigate post-operative complications for many CPB patients.

We anticipate that the CytoSorb™ device, incorporated into the extracorporeal circuit used with the by-pass equipment during surgery, and/or employed post-operatively for a period of time, will mitigate inflammation and speed recovery. At $500 per CytoSorb™ device and one device per procedure, and assuming 50% of the patient population receives CytoSorb™ treatment, the annual revenue potential for this application is $100 million in the U.S. and $200 million worldwide.

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 1.3 million worldwide. Approximately 85% of patients with chronic kidney disease are treated with hemodialysis.

Our BetaSorb™ 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 BetaSorb™ use in each session, every 100,000 patients would require approximately 15 million devices annually.

Our pricing model for the BetaSorb™ device is based on a variety of cost/benefit assumptions. The current BetaSorb™ end-user pricing model is $35 per device, or $5,250 per patient per year. Based on high-volume finished product cost assumptions and the terms of our existing marketing and distribution agreement with Fresenius Medical Care (which owns more than 1,600 dialysis clinics with over 130,000 patients), we estimate annual revenue potential for the application of our technology to chronic kidney failure at approximately $780 million in the U.S. and $2.5 billion worldwide.

Other Applications

Additional applications for the critical care market have been identified. These promising areas include:

· Drug detoxification

· Liver failure

· Regional high-dose chemotherapy

· Acute Respiratory Distress Syndrome (ARDS)

· Severe Acute Respiratory Syndrome (SARS)

· Equine sepsis

· Bio-terrorism

Products (Currently in Development)

The CytoSorb™ 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.

Potential Benefits: By preventing or reducing the accumulation of cytokines in the circulating blood, we believe our adsorbent blood purification technology will 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 for Efficacy: We believe that the effective treatment of sepsis is the most valuable potential application for our technology. Sepsis carries mortality rate 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 $20 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.

Our technology presents a new therapeutic approach in the treatment of sepsis, and its potential efficacy is supported by scientific research. 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. Our CytoSorb™ device efficiently removes these larger toxins. CytoSorb's™ toxin clearing ability and the ability to interact safely with blood (hemocompatibility) has been demonstrated clinically. Data collected during the "emergency and compassionate use" treatment of a single sepsis patient has been encouraging to us.

CytoSorb™ 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 in patients with chronic kidney failure have provided valuable data which underpin the development of the critical care applications for our technology. Our current device design has been extensively studied and shown to be efficacious in humans with kidney failure (in multiple treatment sessions lasting up to 4 hours, three times per week for up to 24 weeks in some patients). This same device design was tested on a single patient with bacterial sepsis, producing results that we found very encouraging and confirming to us that our device design is appropriate for a more extensive sepsis study. Our plans for the development of CytoSorb™ to treat sepsis patients are summarized in the table below.

Task	**Estimated Time Required**	**Estimated Budget Requirements**
1. Design pilot study	4 to 6 months	(nominal)
2. Conduct pilot study	6 to 9 months	$1.2 million
3. Design pivotal study	Concurrent with item 2	(nominal)
4. Conduct pivotal study	9 to 12 months	$1.8 million
5. Approval time following submission	6 to 9 months	
Total	Approximately 25 to 36 months	$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.

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

Potential Benefits: By preventing or reducing high-levels of cytokines from accumulating in the bloodstream of a brain-dead organ donor, CytoSorb™ aims 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.

Background and Rationale for Efficacy: 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, and extensive development work has already been completed. Researchers at the University of Pittsburgh Medical Center and the University of Texas, Houston Medical Center have made significant progress on the observational and dosing phases of the project. The observational portion of the study is ongoing, while the dosing study, involving eight non-viable donors, has been completed. These initial phases of the study are expected to be concluded in 2006. The next phase of this study, the treatment phase, will involve viable donors. 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 trial design, as well as obtaining additional funding.

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

Potential Benefits: By preventing or reducing 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 can 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.

Background and Rationale for Efficacy: Due to the highly invasive nature of cardiopulmonary bypass surgery, high levels of cytokines are produced by the body, triggering severe inflammation. By preventing or reducing 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 have completed an observational study of 32 patients to obtain information 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 CytoSorb™ device to maximize therapeutic impact. We are not currently focusing our efforts on the commercialization of our technology 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 BetaSorb™ Device (Chronic Care)

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

Potential Benefits: By preventing or reducing 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 for Efficacy: Our BetaSorb™ 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. By routinely removing these toxins during dialysis and preventing or reducing their accumulation, we expect our BetaSorb™ 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.

Projected Timeline: 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 BetaSorb™ device removed the targeted toxins as expected.

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

Commercial and Research Partners

University of Pittsburgh Medical Center

We are working with researchers at the University of Pittsburgh - Critical Care Medicine Department in the development of critical care applications for 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.

Researchers at UPMC have participated in nearly every major clinical trial of potential sepsis intervention during the past twenty years. Drs. Derek Angus and John Kellum were investigators for Ely Lilly’s sepsis drug, Xigris®. Dr. Kellum, a member of the UPMC faculty since 1994, is our principal investigator for CytoSorb™. 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

We have entered into an exclusive, long-term agreement with Fresenius Medical Care for the global marketing and distribution of our BetaSorb™ device and any similar product we may develop for the treatment of renal disease. The agreement, which we entered into in 1999 is a profit sharing plan under which both we and Fresenius are incentivized to minimize costs and maximize the price to end-users. In particular, under the agreement, to the extent that sales of our products by Fresenius results in gross margins to Fresenius in excess of targeted levels, we would share with Fresenius a portion of the revenues attributable to such excess.

With Fresenius as our exclusive distributor of our renal products, we believe that our agreement with Fresenius will maximize the potential for rapid product introduction and penetration of the chronic kidney failure market.

Today, 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.

Royalty Agreement

In August 2003, in order to induce Guillermina Vega Montiel, a principal stockholder of ours, to make an additional investment in MedaSorb, we granted Ms. Montiel a perpetual royalty equal to three percent of all gross revenues received by us from sales o