MedaSorb Technologies CORP
Form 10-K
April 10, 2009

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

FORM 10-K
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2008
COMMISSION FILE NUMBER 000-51038

MEDASORB TECHNOLOGIES CORPORATION
(Name of Small Business Issuer in Its Charter)

Nevada	98-0373793
(State or Other Jurisdiction of Incorporation or Organization)	(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)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock $0.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. o Yes þ No
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. o Yes þ No

Indicate by checkmark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
þ Yes o No
Indicate by check if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K. þ

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer o Accelerated Filer o

Non-accelerated Filer o (do not check if a smaller reporting company) Smaller reporting company þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.) o Yes þ No

The issuer had no revenues for its fiscal year ended December 31, 2008.

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2008 was approximately $1,035,000. The number of shares outstanding of the registrant's Common Stock as of March 27, 2009 was 30,510,819.

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CAUTIONARY NOTE REGARDING 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”. However, 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.

PART I

Item 1. 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 and physiologic fluids. We will be required to obtain required regulatory approvals from a Notified Body for the European Community (CE Mark) and the United States Food and Drug Administration before we can sell our products in Europe and the United States, respectively. In December 2006, we submitted a proposed pilot study for approval to the FDA with respect to CytoSorb™, the first device we intend to bring to market. In the first quarter of 2007, we received approval from the FDA to conduct a limited study of five patients in the adjunctive treatment of sepsis. Based on management’s belief that proceeding with the approved limited study would add at least one year to the approval process for the United States, we made a determination to focus our efforts on obtaining regulatory approval in Europe before proceeding with the FDA.

We estimate that the market potential in Europe for our products is substantially equivalent to that in the U.S. Given the opportunity to conduct a much larger clinical study in Europe, and management’s belief that the path to a CE Mark should be faster than FDA approval, we have targeted Europe for the initial market introduction of our CytoSorb™ product. To accomplish the European introduction, in July 2007 we prepared and filed a request for a clinical trial with a German Central Ethics Committee.

We received approval from the German Ethics Committee in October of 2007 to conduct a clinical study of up to 80 patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis. At December 31, 2008 we had initiated and opened for enrollment seven (7) hospital units to participate in our clinical study and had identified an additional six (6) sites that may be added to our study to accelerate enrollment. As of March 2009 we have increased the number of hospital units participating in our study to ten (10).

In April 2009, we submitted a protocol revision to expand the options for anti-coagulation that the clinical sites may use, and to increase the total number of patients that may be enrolled from 80 to 100 patients. This revision has been approved by the German Ethics Committee. We believe that the revised protocol will enable more potential sites to participate in the study, and may help accelerate patient enrollment through greater access to potential candidates. Further, while we do not anticipate enrolling more than 80 patients, we now have the flexibility to enroll up to 100

patients if needed.

Additionally, we have updated blood sampling and handling procedures to minimize non-device related artifacts that may potentially arise if the samples are not processed appropriately.

To date we have enrolled twenty two (22) patients in the clinical study, which have been randomized yielding eleven (11) treated and eleven (11) control (non-treated) patients. We hope to enroll approximately sixty (60) additional patients. While we do not anticipate enrolling the entire 100 patients that we are now entitled to enroll, the approved increase allows us some flexibility in the event any of the enrolled patients are not able to complete the study due to withdrawal or inability to complete post treatment follow-up. In conducting the German Clinical study we have utilized our CytoSorb™ device in over 75 treatments to date with no Serious Adverse Events attributable to the device.

We expect to complete the patient enrollment by the end of 2009. Concurrent with the clinical study, we expect to commence the CE Mark submission process. Assuming a successful outcome of the study, management believes it will take an additional 6-9 months following its submission for CE Mark approval to receive the European regulatory approval. Assuming availability of adequate and timely funding, and a successful outcome to the study, management anticipates obtaining CE Mark approval in the first half of 2010, at the earliest.

The clinical protocol for our European clinical study has been designed to allow us to gather information to support future U.S. studies. In the event we receive the CE Mark and are able to successfully commercialize our products in the European market, we will review our plans for the United States to determine whether to conduct clinical trials in support of 510K or PMA registration. No assurance can be given that our proposed CytoSorb™ product will work as intended or that we will be able to obtain CE Mark (or FDA) approval to sell CytoSorb™. Even if we ultimately obtain CE Mark approval, because we cannot control the timing of responses from regulators to our submissions, there can be no assurance as to when such approval will be obtained.

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

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

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

Our CytoSorb™ is intended to remove toxins and other substances from blood and physiologic fluids. We are currently enrolling patients in a European Sepsis trial of our CytoSorb™ device. The study is a randomized, controlled clinical study in twelve sites in Germany of up to 80 patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis. Patients are being treated with our device once per day for up to seven (7) consecutive days. To date we have enrolled twenty two (22) patients in the study. The study protocol was designed to support a request for the European CE Mark (regulatory approval to sell medical devices in Europe).

Following the sepsis indication, we intend to continue our research in other acute conditions where CytoSorb™ has indicated potential in preliminary studies to prevent or reduce the accumulation of cytokines and other toxic compounds in the bloodstream. These conditions include, but are not limited to, the prevention of post-operative complications of cardiac surgery (cardiopulmonary bypass surgery), damage to organs donated for transplant prior to organ harvest, and removing drugs from blood.

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

Our BetaSorb™ device is intended to remove beta2-microglobulin from the blood of patients suffering from chronic kidney failure who rely on long term dialysis therapy to sustain their life. BetaSorb™ utilizes an adsorbent polymer packed into an identically shaped and constructed cartridge as utilized for our CytoSorb™ product, although the polymers used in the two devices are physically different. The BetaSorb™ device also incorporates industry standard connectors at either end of the device which connect directly into the extra-corporeal circuit (bloodlines) in series with a dialyzer. To date, we have manufactured the BetaSorb™ device on a limited basis for testing purposes, including for use in clinical studies.

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

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

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

Corporate History

MedaSorb Technologies Corporation was incorporated in Nevada on April 25, 2002 as Gilder Enterprises, Inc. and was 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., a Delaware corporation in a merger, and its business became our business. Following the merger, in July 2006 we changed our name to MedaSorb Technologies Corporation. In November 2008 we changed the name of our operating subsidiary from MedaSorb Technologies, Inc. to CytoSorbents, Inc. Our parent company name is still MedaSorb Technologies Corporation but we anticipate that we will change our name to better reflect the name of our operating subsidiary. Unless otherwise indicated, all references in this Annual Report to “MedaSorb,”, “CytoSorbents”, “us” or “we” with respect to events prior to June 30, 2006 are references to CytoSorbents, Inc. and its predecessors. Our executive offices are located at 7 Deer Park Drive, Suite K, Monmouth Junction, New Jersey 08852. Our telephone number is (732) 329-8885.

MedaSorb was originally 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.

MedaSorb 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 had 292 stockholders that held an aggregate of 20,340,929 shares of common stock. 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 the sole director and officer of Gilder 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 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. 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. 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 stockholders of MedaSorb prior to the merger 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 prior to the merger 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 options and warrants that were cancelled. 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.

Concurrently with the closing of the merger, Joseph G. Bowes, the sole director and officer of MedaSorb Technologies Corporation (then Gilder Enterprises) 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, Vincent Capponi was appointed our Chief Operating Officer, David Lamadrid was appointed our Chief Financial Officer and James Winchester, MD was appointed our Chief Medical Officer.

For accounting purposes, the merger has been accounted for as a reverse merger, since MedaSorb Technologies Corporation (then Gilder Enterprises) was a shell company prior to the merger, the stockholders of MedaSorb prior to the merger own a majority of the issued and outstanding shares of our Common Stock after the merger, and the directors and executive officers of MedaSorb prior to the merger became our directors and executive officers. Accordingly, pre-merger MedaSorb is treated as the acquiror in the merger, which is treated as a recapitalization of pre-merger MedaSorb, and the pre-merger financial statements of MedaSorb 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 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 that closing. We also granted the investors demand and piggyback registration rights with respect to such Common Stock.

Because the registration statement we agreed to file 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 until May 7, 2007, the date the registration statement was declared effective. During this time period, we were obligated to pay

those purchasers cash dividends and an aggregate of $105,000 per 30-day period from February 26, 2007 through the date such registration statement was declared effective (May 7,2007) in cash. Pursuant to a settlement agreement with the June 30, 2006 purchasers of Series A Preferred Stock, all cash dividends and damages were paid for in full with additional shares of Series A Preferred Stock.

Both the conversion price of the Series A Preferred Stock and the exercise price of the warrants were 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. As of the "Qualified Closing" of our Series B Preferred Stock private placement in August of 2008, these investors' agreed to a modification of their rights and pricing and gave up their anti-dilution protection – see Qualified Closing description in Series B Preferred Stock section)

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 consisted 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.

The terms of the pledge provided that in the event those investors 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 would be entitled to 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. 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.

As of the "Qualified Closing" of our Series B Preferred Stock private placement in August of 2008, Ms. Chassman agreed to a modification of her rights and pricing and gave up her anti-dilution protection – see Qualified Closing description in Series B Preferred Stock section)

Principal Terms of the Series B Financing Consummated in 2008

Each share of Series B Preferred Stock has a stated value of $100.00, and is convertible at the holder's option into that number of shares of Common Stock equal to the Series B stated value at a conversion price of $0.0362, subject to certain adjustments. Additionally, upon the occurrence of a stock split, stock dividend, combination of the Common Stock into a smaller number of shares, issuance of any of shares of Common Stock or other securities by reclassification of the Common Stock, merger or sale of substantially all of our assets, the conversion rate will be adjusted so that the conversion rights of the Series B Preferred Stock stockholders will remain equivalent to those prior to such event.

Dividend

The holders of Series B Preferred Stock are entitled to receive preferential dividends payable in shares of additional Series B Preferred Stock . Any dividends payable to both the Series A and Series B Preferred shareholders shall be paid before any dividend or other distribution will be paid to any Common Stock shareholder. The Series B Preferred

Stock dividend is based payable at a rate of 10% per annum on the Series B Stated Value payable on the last day of each calendar quarter after June 30, 2008. However, upon the occurrence of any "Event of Default" as defined in the Certificate of Designation of Series B Preferred Stock, the dividend rate increases to 20% per annum, and revert back to 10% after the "Event of Default" is cured. An Event of Default includes, but is not limited to,

- the occurrence of "Non-Registration Events";
- 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.

Dividends must be delivered to the holder of the Series B Preferred Stock no later than five (5) business days after the end of each period for which dividends are payable. Dividends on the Series B Preferred Stock will be made in additional shares of Series B Preferred Stock, valued at the Series B Preferred Stock stated value. Notwithstanding the foregoing, during the first three-years following the initial closing, upon the approval of the holders of a majority of the Series B Preferred Stock, including the lead investor, NJTC Venture Fund, if it then owns 25% of the shares of Series B Preferred Stock initially purchased by it, we may pay dividends in cash instead of additional shares of Series B Preferred Stock, and after such three-year period, the holders of a majority of the Series B Preferred Stock, including NJTC if it then owns the 25% of the shares of the Series B Preferred Stock initially purchased by it, may require us to make such payments in cash.

Liquidation

In the event of the Company's dissolution, liquidation or winding up, the holders of the Series B Preferred Stock will receive, in priority over the holders of Series A Preferred Stock and Common Stock, a liquidation preference equal to the stated value of such shares plus accrued dividends on the shares.

Voting Rights; Board Rights

Holders of Series B Preferred Stock have the right to vote on matters submitted to the holders of Common Stock on an as converted basis. However, the consent of the holders of at least a majority of the shares of the Series B Preferred Stock as a separate class, including NJTC if it is then a holders of at least 25% of the shares of Series B Preferred Stock purchased by it on the Initial Closing Date, shall be required on matters related to the rights of the Series B Preferred Stock.

In addition, so long as NJTC holds 25% of the Series B Preferred Stock it purchased before the initial closing, NJTC is entitled to elect (i) two directors to our Board of Directors, which shall consist of six members, and (ii) two members to our compensation committee, which shall consist of no less than three members. Within the first twelve (12) months following the Initial Closing, the Company must reduce the Board of Directors to five (5) members.

Moreover, so long as Cahn Medical Technologies, LLC is the holder of at least 25% of the shares of the Series B Preferred Stock purchased by it on the initial closing date, it has the right to have its designee receive notices of, and attend as an observer, all meetings of our Board of Directors.

Registration Rights

We have filed a registration statement under the Securities Act covering the Common Stock issuable upon conversion of the Series B Preferred Stock. We have received comments from the Securities and Exchange Commission related to this filing and are in the process of addressing each comment raised. Pursuant to the terms of the Registration

Rights Agreement, we are required to cause the Registration Statement 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. The investors in the Series B Financing are entitled to liquidated damages in an amount equal to two percent (2%) of the purchase price of the Series B Preferred Stock if we fail to timely file that registration statement with, or have it declared effective by, the SEC.

The Company has received a waiver from a majority of the Series B holders for the non-registration event and the timing of the Series B registration does not create a cross-default of the Series A Preferred Series.

Redemption Rights

Following the fifth anniversary of the initial closing, the holders of a majority of the Series B Preferred Stock, including NJTC if it then holds 25% of the shares of Series B Preferred Stock initially purchased by it, may elect to require us to redeem all, but not less than all, of their shares of Series B Preferred Stock at the original purchase price for such shares plus all accrued and unpaid dividends whether or not declared, if the market price of our Common Stock is then below the conversion price of the Series B Preferred Stock.

Dilution and Subordination

As one of the conditions to the closing of the Series B financing with an initial closing on June 25, 2008, we entered into an Agreement and Consent as of the same date with the holders of more than 80% of our Series A Preferred Stock, par value 0.001 per share and the holders of more than 80% of the outstanding common stock purchase warrants issued to the purchasers of our Series A Preferred Stock (the “Class A Warrant”). Pursuant to the Agreement and Consent, our holders of the Series A Preferred Stock consented to the permanent waiver of the anti-dilution protection previously provided to the holders of the Series A Preferred Stock and the holders of the Class A Warrant.

In connection with such Agreement and Consent, the conversion price with respect to the June 30, 2006 purchasers of Series A Preferred Stock held by the Holders was reduced effective June 25, 2008, the initial closing of the Series B Financing according to the Schedule A to the Agreement and Consent as set forth below. In the event that within the 60-day period following the Initial Closing, at additional closings, the Company issued additional shares of Series B Preferred Stock so that the aggregate gross proceeds that were raised on the Initial Closing and such additional closings (excluding the principal amount of our outstanding debt converted into the Series B Preferred Stock) from the holders of the Series A Preferred Stock or their affiliates, is $1,500,000 or more, the conversion price with respect to the Series A Preferred Stock held by these holders was agreed to be further reduced in accordance with Schedule A to the Agreement and Consent as set forth below. Based on the total amount raised and in accordance with our investor agreements, MedaSorb’s Series B Preferred Stock private placement was considered a “Qualified” closing.

In addition, June 30, 2006 purchasers of the Series A Preferred Stock also agreed the conversion price with respect to the Class A Warrant shall be reduced effectively on the initial closing. Pursuant to our agreement for a Qualified closing, Conversion pricing and warrant exercise pricing was further reduced as disclosed in the following chart.

06/30/06 Purchasers of Series A Preferred Stock	Initial Closing (06/25/08)		Qualified Closing (08/25/08)	
	Preferred Stock Conversion Price	Warrant Exercise Price	Preferred Stock Conversion Price	Warrant Exercise Price
Alpha Capital Aktiengesellschaft	$ 0.26	$ 0.52	$ 0.20	$ 0.40
Longview Fund, LP	$ 1.25	$ 2.00	$ 0.45	$ 0.90
Platinum Partners Long Term Growth III LLC	$ 1.25	$ 2.00	$ 0.10	$ 0.40
Ellis International Ltd.	$ 0.26	$ 0.52	$ 0.20	$ 0.40

Margie Chassman	$ 1.25	$ 2.00	$ 0.10	$ 0.40

Research and Development

We have been engaged in research and development since inception. Our research and development costs were approximately $1,983,000 and $1,416,000 for the years ended December 31, 2008 and 2007, respectively.

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 and toxic compounds largely untouched by dialysis technology.

Our initial products, CytoSorb™ and BetaSorb™, 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 and toxic compounds, such as cytokines, from blood and physiologic fluids. We believe that our technology may have many applications in the treatment of common, chronic and acute healthcare complications including the adjunctive 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 CytoSorb™ and BetaSorb™ devices consist of a cartridge containing adsorbent polymer beads, although the polymers used in the two devices are physically different. The cartridges 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 dialyzer, in the case of the BetaSorb™ device, or as a stand alone device in the case of the CytoSorb™ device. Both devices will require no additional expensive equipment, and will require minimal training.

The extra-corporeal circuit consists of plastic blood tubing, our CytoSorb™ or BetaSorb™ 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

Sepsis

In the United States alone, there are more than one million new cases of sepsis annually; based on the reported incidence in a number of developed countries, the worldwide incidence is estimated to be 18 million cases per year. Severe trauma and community acquired pneumonia are often associated with sepsis. The Company estimates that the market potential in Europe for its products is substantially equivalent to that in the U.S.

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. Based on current pricing of charcoal hemoperfusion devices in the market today, we estimate that our CytoSorb™ 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 100,000 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.

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 CytoSorb™ during and after the surgical procedure may prevent or mitigate post-operative complications for many CPB patients.

We anticipate that the CytoSorb™ 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, will 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 more than 340,000 patients in the United States currently receiving chronic dialysis and more than 1.5 million worldwide. Approximately 66% 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.

Products

We believe that the polymer adsorbent technology used in our products has the potential to remove middle molecular weight toxins, such as cytokines, from blood and physiologic fluids. All of the potential applications described below (i.e., the adjunctive 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 are currently enrolling patients in a European Sepsis trial of our CytoSorb™ device. The study is a randomized, open label, controlled clinical study in ten (10) sites in Germany of up to eighty (80) patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis. If these studies are successful and we obtain European regulatory approval, we anticipate that we will be able to begin sales of CytoSorb™ during 2010, at the earliest. However, there can be no assurance we will ever obtain regulatory approval for CytoSorb™ or any other device.

The CytoSorb™ Device (Critical Care)

APPLICATION: Adjunctive Therapy in the Treatment of Sepsis

Sepsis is a potentially life threatening disease defined as a systemic inflammatory response in the presence of a known or suspected infection. Sepsis is mediated 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: 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. Severe sepsis (sepsis with organ dysfunction) and septic shock (severe sepsis with persistent hypotension despite fluid resuscitation) carries mortality rates of between 28% and 80%. 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; and based on the reported incidence in a number of developed countries, the worldwide incidence is estimated to be 18 million cases annually. The incidence of sepsis is also rising due to:

1) An aging population
2) Increased incidence of antibiotic resistance
3) Increase in co-morbid conditions like cancer and diabetes
4) Increased use of indwelling medical devices that are susceptible to infections

In the U.S. alone, treatment of sepsis costs nearly $18 billion annually. According to the Centers for Disease Control, sepsis is a top ten cause of death in the U.S. The incidence of sepsis is believed to be under-reported as the primary infection (i.e. pneumonia, pyelonephritis, etc.) is often cited as the cause of death.

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 in the U.S.

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 significant quantities of larger toxins from circulating blood. Limited studies of our CytoSorb™ device have provided us with data consistent with our belief that CytoSorb™ has the ability to remove these larger toxins. CytoSorb's™ 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.

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: Previous clinical studies using our BetaSorb™ device in patients with chronic kidney failure have provided valuable data which underpin the development of the critical care applications for our technology. The BetaSorb™ device has been used in a total of three human pilot studies, involving 20 patients, in the U.S. and Europe. The studies included approximately 345 treatments, with some patients using the device for up to 24 weeks (in multiple treatment sessions lasting up to four hours, three times per week) in connection with the application of our products to patients suffering from chronic kidney failure. The BetaSorb™ device design was also tested on a single patient with bacterial sepsis, producing results that our management has found encouraging and consistent with our belief that our device design is appropriate for more extensive sepsis study.

We received approval from the German Ethics Committee in October of 2007 to conduct a clinical study of up to 80 patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis. At December 31, 2008 we had initiated and opened for enrollment seven (7) hospital units to participate in our clinical study and had identified an additional six (6) sites that may be added to our study to accelerate enrollment. As of March 2009 we have increased the number of hospital units participating in our study to ten (10).

In April 2009, we submitted a protocol revision to expand the options for anti-coagulation that the clinical sites may use, and to increase the total number of patients that may be enrolled from 80 to 100 patients. This revision has been approved by the German Ethics Committee. We believe that the revised protocol will enable more potential sites to participate in the study, and may help accelerate patient enrollment through greater access to potential candidates. Further, while we do not anticipate enrolling more than 80 patients, we now have the flexibility to enroll up to 100 patients if needed.

Additionally, we have updated blood sampling and handling procedures to minimize non-device related artifacts that may potentially arise if the samples are not processed appropriately.

To date we have enrolled twenty two (22) patients in the clinical study, which have been randomized yielding eleven (11) treated and eleven (11) control (non-treated) patients. We hope to enroll approximately sixty (60) additional patients. While we do not anticipate enrolling the entire 100 patients that we are now entitled to enroll, the approved increase allows us some flexibility in the event any of the enrolled patients are not able to complete the study due to withdrawal or inability to complete post treatment follow-up. In conducting the German Clinical study we have utilized our CytoSorb™ device in over 75 treatments to date with no Serious Adverse Events attributable to the device.

We expect to complete the patient enrollment by the end of 2009. Concurrent with the clinical study, we expect to commence the CE Mark submission process. Assuming a successful outcome of the study, management believes it will take an additional 6-9 months following its submission for CE Mark approval to receive the European regulatory

approval. Assuming availability of adequate and timely funding, and a successful outcome to the study, management anticipates obtaining CE Mark approval in the first half of 2010, at the earliest.

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 the CE Mark, because we cannot control the timing of the regulatory approval process, 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

Potential Benefits: If CytoSorb™ is able to prevent or reduce high-levels of cytokines from accumulating in the bloodstream of brain-dead organ donors, we believe CytoSorb™ 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.

Background and Rationale: 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 100,000 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: Studies have been 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 have completed the observational and dosing phases of the project. The results were published in Critical Care Medicine, January 2008. The next phase of this study, the treatment phase, will involve viable donors treated with the CytoSorb™ 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. We are not currently focusing our efforts on the commercialization of CytoSorb™ for application in organ donors. The treatment phase would 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

Potential Benefits: If CytoSorb™ 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.

Background and Rationale: 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 CytoSorb™ device to maximize therapeutic impact. We are not currently focusing our efforts on the commercialization of CytoSorb™ for application to cardiac surgery. Upon successful commercialization of the sepsis application, we will pursue the use of our polymer adsorbent 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: If BetaSorb™ 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 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. If our BetaSorb™ device is able to routinely remove these toxins during dialysis and prevent or reduce 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, including a clinical pilot of six patients in California for up to 24 weeks in which our BetaSorb™ device removed the targeted toxin, beta2-microglobulin, as expected. In total, we have sponsored clinical studies utilizing our BetaSorb™ 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 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

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 CytoSorb™ 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. We are not currently focusing our efforts on the commercialization of CytoSorb™ for application in organ donors. The treatment phase would 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 of approximately $7 million 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, for each of 2006 and 2007, we received approximately $102,000 for our efforts in support of the grant. Additionally for 2008 we received an approximate $59,000 for our supporting efforts. 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 $78,000 and $163,000, respectively for the remaining two grant periods commencing September 2008 and ending September 2010. The amounts are subject to change on an annual basis by the NIH, and 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.

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 the Chairman of our Severe Sepsis and Inflammatory Disease 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 BetaSorb™ device and any similar product we may develop for the treatment of renal disease. We currently intend to pursue our BetaSorb™ product after the commercialization of the CytoSorb™ product. At such time as we determine to proceed with our proposed BetaSorb™ product, if ever, we will need to conduct additional clinical studies using the BetaSorb™ device to obtain European or 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 2,100 dialysis clinics in North America, Europe, Latin America and Asia-Pacific, Fresenius Medical Care provides dialysis treatment to more than 163,000 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 three scientists with expertise in the fields of fundamental chemical research, and polymer research and development.

Our Medical Advisory Board for Severe Sepsis / Inflammatory Disease consists of four medical doctors, one of whom is affiliated with UPMC, with expertise in critical care medicine, sepsis, multi-organ failure and related clinical study design.

Our Medical Advisory Board for 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 $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, 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, 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 several of our issued patents and several of our 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 CytoSorb™ and BetaSorb™ 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 would continue to exclusively own any confidential and proprietary know how.

Product Payment & Reimbursement

Critical Care Applications

Europe

Payment for our CytoSorb™ device for the removal of cytokines in patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis and other related acute care applications will be applied for on a country by country basis in Europe. We intend to initially apply for reimbursement in Germany where we are conducting our clinical trial. If we are able to successfully introduce the CytoSorb™ device into the German market we intend to apply for reimbursement in France, England, Italy and Spain representing the five economic leaders in Europe and introduce our products in those countries accordingly. We will first need to establish the CE Mark for the CytoSorb™ device, then pursue reimbursement on a country by country basis. Each country will determine reimbursement status of the device based on the data obtained from the clinical trial. There can be no assurances that reimbursement will be granted or that additional clinical data may not be required to establish reimbursement.

United States

Payment for our CytoSorb™ 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.

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Critical care applications such as those targeted by our CytoSorb™ 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 Europe chronic dialysis is predominately provided by government supported clinics accounting for approximately 75% of dialysis treatment, with the remainder being provided by private clinics. However, these figures vary widely among countries within Europe. For example dialysis clinics in Denmark and Finland are 100% publicly managed facilities while those in Portugal are 90% privately managed facilities. Generally speaking, dialysis services are always regulated and controlled by the healthcare authorities and not homogeneous between the various European countries.

There are three main types of reimbursement in Europe: budget transfer, fee for service and flat rate. In some cases, the reimbursement method varies within the same country depending on the type of provider (public or private). Europe is similar to the U.S. in that a product such as BetaSorb™ may be part of a composite rate or separate line item reimbursement. In either case, a country by country application for reimbursement must be made.

It is expected that in the U.S., Medicare will be the primary payer for the BetaSorb™ 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 BetaSorb™ 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 may 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 successfully tested at the University of Pittsburgh using septic rat models with our CytoSorb™ polymer, which were based on lipopolysaccharide (a particular kind of toxin, known as a bacterial endotoxin) and cecal ligation puncture.

Both the CytoSorb™ and BetaSorb™ devices consist of a cartridge containing adsorbent polymer beads. The cartridge 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 (CytoSorb™ or BetaSorb™ 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 cartridge, 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 dialyzer. 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 CytoSorb™ 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 expensive when compared to the percentage of patients who benefit.

Pharmaceutical research for the treatment of sepsis continues with a number of clinical stage drug trials being presently conducted including, but not limited to, drug candidates from Takeda Pharmaceutical Company, Eisai, and BTG plc. Using a medical device to treat sepsis remains a relatively novel approach for the treatment of sepsis. There are a number of companies that claim enabling blood purification technology for the treatment of sepsis. Toray Industries currently markets an endotoxin removal cartridge called Toraymyxin for the treatment of sepsis in Europe and Japan. To date, it has been used to treat more than 70,000 patients. However, the ability of Toraymyxin to remove cytokines, the key mediators of sepsis, has not been well documented. Kaneka Corporation currently markets Lixelle, a modified porous cellulosic bead, for the removal of beta2–microglobulin during hemodialysis in Japan. In 2002, Kaneka published a small pilot study in 5 patients with sepsis demonstrating that treatment with Lixelle was correlated with cytokine reduction. To our knowledge, Kaneka has not published a follow-up clinical study with Lixelle. Kaneka has since developed a modified cellulosic resin called CTR that can also remove cytokines from experimental pre-clinical systems. To our knowledge, Kaneka has not conducted or published any study using CTR to treat human sepsis patients. Ube Industries, LTD is currently developing an adsorbent resin called CF-X for the removal of cytokines. To our knowledge, Ube has not published any study using CF-X to treat human sepsis patients. Other potential competitors include the now defunct Arbios Systems, Inc. Hemolife Medical, Inc. and Hemocleanse Technologies, LLC. We believe our CytoSorb™ cartridge has significant competitive, technological, and economic advantages over systems by these other companies.

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, CytoSorb™ 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 Epogen™, 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 modest 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 BetaSorb™ device. In terms of resin technology, Kaneka Corporation is the only company currently marketing a resin cartridge (Lixelle) in Japan designed to address this need.

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.

The Company is focusing its research efforts on critical care applications of it technology. We are currently enrolling patients in a European Sepsis clinical study.

We received approval from the German Ethics Committee in October of 2007 to conduct a clinical study of up to 80 patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis. At December 31, 2008 we had initiated and opened for enrollment seven (7) hospital units to participate in our clinical study and had identified an additional six (6) sites that may be added to our study to accelerate enrollment. As of March 2009 we have increased the number of hospital units participating in our study to ten (10).

In April 2009, we submitted a protocol revision to expand the options for anti-coagulation that the clinical sites may use, and to increase the total number of patients that may be enrolled from 80 to 100 patients. This revision has been approved by the German Ethics Committee. We believe that the revised protocol will enable more potential sites to participate in the study, and may help accelerate patient enrollment through greater access to potential candidates. Further, while we do not anticipate enrolling more than 80 patients, we now have the flexibility to enroll up to 100 patients if needed.

Additionally, we have updated blood sampling and handling procedures to minimize non-device related artifacts that may potentially arise if the samples are not processed appropriately.

To date we have enrolled twenty two (22) patients in the clinical study, which have been randomized yielding eleven (11) treated and eleven (11) control (non-treated) patients. We hope to enroll approximately sixty (60) additional patients. While we do not anticipate enrolling the entire 100 patients that we are now entitled to enroll, the approved increase allows us some flexibility in the event any of the enrolled patients are not able to complete the study due to withdrawal or inability to complete post treatment follow-up. In conducting the German Clinical study we have utilized our CytoSorb™ device in over 75 treatments to date with no Serious Adverse Events attributable to the device.

We expect to complete the patient enrollment by the end of 2009. Concurrent with the clinical study, we expect to commence the CE Mark submission process. Assuming a successful outcome of the study, management believes it will take an additional 6-9 months following its submission for CE Mark approval to receive the European regulatory approval. Assuming availability of adequate and timely funding, and a successful outcome to the study, management anticipates obtaining CE Mark approval in the first half of 2010, at the earliest.

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.

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 CytoSorb™ 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. We are not currently focusing our efforts on the commercialization of CytoSorb™ for application in organ donors. The treatment phase would 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 of approximately $7 million 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, for each of 2006 and 2007, we received approximately $102,000 for our efforts in support of the grant. Additionally for 2008 we received an approximate $59,000 for our supporting efforts. 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 $78,000 and $163,000, respectively for the grant periods commencing September 2008 and ending September 2010. The amounts are subject to change on an annual basis by the NIH, and 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 European Union, 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.

As discussed above, we intend to initially pursue CE Mark certification for the CytoSorb™ device in conjunction with German clinical studies before continuing with the approval process in the United States.

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 United States, our CytoSorb™ and BetaSorb™ devices are classified as Class III (CFR 876.5870—Sorbent Hemoperfusion System) and may require pre-market approval (PMA) by the FDA. 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.

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 business, financial condition and results of operations.

Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. to take advantage of differing regulatory requirements.

Sales and Marketing

We currently estimate, provided that we receive adequate and timely funding to support our planned activities and that our products perform as expected in clinical studies, that we will obtain CE Mark approval of our CytoSorb™ device in the treatment of sepsis in the first half of 2010, at the earliest, assuming a successful pivotal study. We plan to initiate sales in several European countries which are known as early adopters of new medical device technology. These countries primarily include Italy, Germany, France, Spain and the United Kingdom. We plan to initially operate through local distributors in each European country where we launch sales operations. Only after establishment of a limited network of local distributors and actual generation of sales, will we formulate a broader distribution strategy on a global basis.

Intellectual Property and Patent Litigation

The medical device market in which we primarily participate is in large part technology driven. As a result, intellectual property rights, particularly patents and trade secrets, play a significant role in product development and differentiation. However, intellectual property litigation to defend or create market advantage is inherently complex, unpredictable and is expensive to pursue. Litigation often is not ultimately resolved until an appeal process is completed and appellate courts frequently overturn lower court patent decisions.

Moreover, competing parties frequently file multiple suits to leverage patent portfolios across product lines, technologies and geographies and to balance risk and exposure between the parties. In some cases, several competitors are parties in the same proceeding, or in a series of related proceedings, or litigate multiple features of a single class of devices. These forces frequently drive settlement not only of individual cases, but also of a series of pending and potentially related and unrelated cases. In addition, although monetary and injunctive relief is typically sought, remedies are generally not determined until the conclusion of the proceedings, and are frequently modified on appeal. Accordingly, the outcomes of individual cases are difficult to time, predict or quantify and are often dependent upon the outcomes of other cases in other forums, both domestic and international.

We rely on a combination of patents, trademarks, trade secrets and non-disclosure agreements to protect our intellectual property. We hold 25 U.S. patents, some of which have foreign counterparts, and additional patent applications pending worldwide that cover various aspects of our technology. There can be no assurance that pending patent applications will result in issued patents, that patents issued to us will not be challenged or circumvented by competitors, or that such patents will be found to be valid or sufficiently broad to protect our technology or to provide us with a competitive advantage. Our portfolio of patents includes:

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U.S. Pat. No. 5,545,131, which expires on November 30, 2014. This patent concerns an artificial kidney containing a polymeric resin to filter impurities from blood.

- U.S. Pat. Nos. 5,773,384, 5,904,663, 6,127,311, 6,136,424, 6,159,377 and 6,582,811, which expire on or before February 6, 2018. These patents concern the use of macronet polymeric resins that are subsequently treated to make them biocompatible for the removal of impurities from physiological fluids.

- U.S. Pat. Nos. 6,087,300, 6,114,466, 6,133,393, 6,153,707, 6,156,851 and 6,303,702, which expire on or before February 6, 2018. These patents concern the use of mesoporous polydivinylbenzene polymeric resins that are subsequently treated to make them biocompatible for the removal of impurities from physiological fluids.

- U.S. Pat. No. 6,416,487, which expires on July 30, 2017. This patent concerns a method of removing Beta-2 microglobulin using polymers with surface-exposed vinyl groups modified for biocompatibility.

- U.S. Pat. No. 6,878,127, which expires in 2021 and U.S. Pat. No.7,312,023, which expires in 2024. These patents concern devices, systems and methods for reducing levels of pro-inflammatory or anti-inflammatory stimulators or mediators in the blood.

- U.S. Pat. No. 6,884,829, which expires in 2022, U.S. Pat. No. 7,112,620 which expires in 2023 and U.S. Pat. No. 7,201,962 which expires in 2025. These patents concern a hemocompatible polymer and a one-step method of producing it.

We also rely on non-disclosure and non-competition agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

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 five patents naming our former Advisory Board member as an inventor. These patents, two of which subsequently lapsed for failure to pay maintenance fees, concern the area of coating high divinylbenzene-content polymers to render them hemocompatible, and using such coated polymers to treat blood or plasma. In management’s view the Dow patents improperly incorporate our technology, are based on our proprietary technology, and should not have been granted to Dow. While we believe that our own patents would prevent Dow from producing our products as they are currently envisioned, Dow could attempt to assert its patents against us. To date, to our knowledge, Dow has not utilized their patents for the commercial manufacture of products that would be competitive with us, and we currently have no plans to challenge Dow’s patents. However, the existence of these Dow patents could result in a potential dispute with Dow in the future and additional expenses for us.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how and to determine the scope and validity of the proprietary rights of others. Patent litigation can be costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that the outcome of litigation will be favorable to us. Accordingly, we may seek to settle some or all of our pending litigation described below. Settlement may include cross-licensing of the patents which are the subject of the litigation as well as our other intellectual property and may involve monetary payments to or from third parties.

Employees

As of December 31, 2008, we had seven employees. None of our employees are represented by a labor union or are subject to collective-bargaining agreements. We believe that we maintain good relationships with our employees.

Item 1A. 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 require additional capital to continue operations.

As of December 31, 2008 we had cash on hand of $2,749,208, and current liabilities of $977,704. We believe that we have sufficient cash to fund our operation through the third quarter of 2009, 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.

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
- cost 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 ourselves.

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, 2008, we had an accumulated deficit of $75,461,481, which included net losses of $3,017,890 for the year ended December 31, 2008 and $3,350,754 for the year ended December 31, 2007. In part 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 depend upon key personnel who may terminate their employment with us at any time.

We currently have only seven employees. Our success will depend to a significant degree upon the continued services of our key management and advisors, including, Dr. Phillip Chan, our Chief Executive Officer; David Lamadrid, our Chief Financial Officer; Vincent Capponi, our Chief Operating Officer and Dr. Robert Bartlett our Chief Medical Officer, who works with us on a consulting basis. These individuals 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 works with us on a consulting basis.

Our Chief Medical Officer, Dr. Robert Bartlett, works with us on a consulting basis. Because of the part time nature of his consulting agreement, Dr. Bartlett 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;
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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.

Even if we receive the CE Mark, there can be no assurance that the data from our clinical studies will be viewed as sufficient by the medical community to support the purchase of our products in substantial quantities or at all.

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, 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 regulatory approval of our products. The approval process will involve clinical studies and is lengthy and costly. The failure to obtain government approvals, internationally or domestically, 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 European market, the United States, in various states and in other 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 CE Mark and/or FDA approval for any of our products, we will be subject to extensive ongoing regulation.

Our products will be subject to international regulation as medical devices under the Medical Device Directive. In Europe, which we expect to provide the initial market for our products, the Notified Body and Competent Authority govern, 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 Notified Body under these laws. Current international regulations classify our CytoSorb™ device (the first product we intend to seek international approval for) as a Class IIb device. Concurrent with the clinical trial in Germany, we plan to pursue CE Mark certification of the CytoSorb™ device. 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 international 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. The extent of potentially adverse government regulation that might arise from future legislation or administrative action cannot be predicted. There can be no assurances that reimbursement will be granted or that additional clinical data may be required to establish reimbursement.

We have conducted limited clinical studies of our CytoSorb™ and BetaSorb™ 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. Patient enrollment in our current study has been slower than originally anticipated. The Company has initiated additional hospital units, but there can be no assurance that these sites will be able to enroll patients and meet the projected enrollment. 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 CE Mark and/or 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 cannot give assurances that we will be able to continue 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 others, are critical care advisors and consultants of ours and are associated with institutions such as the University of Pittsburgh Medical Center. 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 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 international 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 86% 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.

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 issued an additional 3,543,060 shares of Series A Preferred Stock through December 31, 2008 to additional investors, as dividends and in connection with the settlement of amounts owed to certain investors due to our failure to timely register shares of Common Stock issuable upon conversion of Series A Preferred Stock. We will likely 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";

- 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.

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

- required us to 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 we agreed to file 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 until May 7, 2007, the date the registration statement was declared effective. Additionally during this time period, we were obligated to pay those purchasers cash dividends and an aggregate of $105,000 per 30-day period from February 26, 2007 through the date such registration statement was declared effective. Pursuant to a settlement agreement with the June 30, 2006 purchasers of Series A Preferred Stock, all cash dividends and damages were paid for in full with additional shares of Series A Preferred Stock.

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. We may in the future default in our contractual obligations to the holders of our Series A Preferred Stock, and in such event we may be required to pay liquidated damages in cash or additional shares of Preferred Stock .

Our Series B Preferred Stock provides for the payment of penalties.

Immediately following our June 2008 and August 2008 private placement, we issued a total of 52,931.47 shares of Series B 10% Cumulative Convertible Preferred Stock with an aggregate stated value of $5,293,147. We issued an additional 2,627.17 shares of Series B Preferred Stock through December 31, 2008 to investors, as dividends. We will likely issue additional shares of this series of preferred stock in the future as dividends. The Certificate of Designation designating the Series B 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:

- the occurrence of “Non-Registration Events”;

- 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.

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

- required us to file a registration statement with the SEC on or before 180 days from the Initial Closing to register the shares of Common Stock issuable upon conversion of the Series B Preferred Stock, and cause such registration statement to be effective by February 21, 2009 (240 days following the Initial Closing) or March 23, 2009 if the reasons for delay are solely due to SEC delay; 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.

The Company has submitted an original S-1 registration statement to the SEC on December 12, 2008. The SEC has replied with questions and a request to reduce the number of shares to be registered, which the Company is currently working on addressing. The Company has received a waiver from a majority of the Series B holders for the non-registration event and the timing of the Series B registration does not create a cross-default of the Series A Preferred Series. There can be no assurance that the Company will receive such waiver from investors for any future items and no assurance the Company will still not incur penalties or prevent an Event of Default from occurring.

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 B Preferred Stock sold in the offering. We may in the future default in our contractual obligations to the holders of our Series B Preferred Stock, and in such event we may be required to pay liquidated damages in cash or additional shares of Preferred Stock .

Anti-Dilution Provisions Of The Series B Preferred Stock

The conversion price of the Series B Preferred Stock issued to the June and August 2008 purchasers of our Series B Preferred Stock are subject to anti-dilution provisions, so that upon future non-excepted issuances of our Common Stock or equivalents thereof, subject to specified customary exceptions, at a price below the conversion price of the Series B Preferred Stock, such conversion price will be reduced on a weighted average basis, further diluting holders of our Common Stock.

Holders of the Series B Preferred Stock have priority in the event of our dissolution, liquidation or winding up.

In the event of our dissolution, liquidation or winding up, the holders of the Series B Preferred Stock will receive, in priority over the holders of the Series A Preferred Stock and Common Stock, a liquidation preference. Therefore, it is possible that holders of Series A Preferred Stock and Common Stock will not obtain any upon our dissolution, liquidation or winding up.

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.

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 and 200,000 shares of Series B Preferred Stock as described above. Subject to the rights of the holders of the Series A and Series B Preferred Stock, our Board of Directors is empowered, without stockholder approval, to issue up to 87,800,000 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 500,000,000 shares of common stock, of which approximately 469,500,000 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.

Item 2. Properties.

We currently operate a facility near Princeton, New Jersey with approximately 7,375 sq. ft, housing research laboratories, clinical manufacturing operations and administrative offices, under a lease agreement, which expires in February 2010. In the opinion of management, the leased properties are adequately insured, are in good condition and suitable for the conduct of our business. We also collaborate with numerous institutions, universities and commercial entities who conduct research and testing of our products at their facilities.

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Item 3. Legal Proceedings.

We are not party to any material pending legal proceedings.

Item 4. Submission of Matters to a Vote of Security Holders.

On October 29, 2008, the Company received written consents in lieu of a meeting of Stockholders from holders of 100,161,988 shares, which include holders of Series B Preferred Stock which vote on an as-converted basis, representing approximately 57.2% of the 174,997,053 shares of the total shares of voting stock of the Company to increase the number of authorized shares of our Common Stock from 100,000,000 shares to 500,000,000 shares of Common Stock. For a more detailed disclosure of the shareholder vote to increase the authorized number of shares, please refer to the Definitive 14C Information Statement filed with the Securities and Exchange Commission dated as of November 18, 2008.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

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	
	High	Low
2006		
Third quarter (from August 9)	$ 3.95	$ 1.25
Fourth quarter	$ 1.73	$ 0.57
2007		
First quarter	$ 2.85	$ 1.04
Second quarter	$ 1.45	$ 0.40
Third quarter	$ 0.63	$ 0.16
Fourth quarter	$ 0.44	$ 0.14
2008		
First quarter	$ 0.32	$ 0.15
Second quarter	$ 0.23	$ 0.10
Third quarter	$ 0.20	$ 0.07
Fourth quarter	$ 0.17	$ 0.03

The number of holders of record for our Common Stock as of December 31, 2008 was approximately 340. This number excludes individual stockholders holding stock under nominee security position listings.

Dividend Policy

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, 2008, after giving effect to the merger and subsequent grants. The Registrant had no options outstanding prior to the merger, and all of the options below were issued either in connection with the merger to former option holders of MedaSorb or subsequently as new grants to employees, directors, and consultants.

	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise 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 stockholders	18,158,846	$ 1.05	21,841,154(2)
Total	18,158,846(3)	$ 1.05(3)	22,241,154

(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) 118,667 shares of Common Stock at a price of $41.47 per share, (ii) 232,051 shares of Common Stock at a price of $31.52 per share, (iii) 35,488 shares of Common Stock at a price of $21.57 per share, (iv) 15,944 shares of Common Stock at a price of $19.91 per share, (v) 439,740 shares of Common Stock at a price of $6.64 per share, (vi) 173,000 shares of Common Stock at a price of $1.90 per share, (vii) 306,000 shares of Common Stock at a price of $1.65 per share, (viii) 400,000 shares of Common Stock at a price of $1.26 per share, (ix) 166,756 shares of Common Stock at a price of $1.25 per share, (x) 3,014,000 shares of Common Stock at a price of $0.25, (xi) 137,622 shares of Common Stock at a price of $0.22, (xii) 115,000 shares of Common Stock at a price of $0.08, and (xiii) 13,004,578 shares of Common Stock at a price of $0.035.

Item 6. Selected Financial Data.

Not required by smaller reporting companies.

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

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 and MedaSorb Acquisition Inc., a newly formed wholly-owned Delaware subsidiary of ours, MedaSorb Technologies, Inc. merged with MedaSorb Acquisition Inc. (now known as CytoSorbents, Inc.), and the stockholders of MedaSorb Technologies, Inc. became our stockholders. CytoSorbents, Inc. is now a wholly owned subsidiary of ours, and its business 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.

Research and Development

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

Stock Based-Compensation

The Company accounts for its stock-based compensation under the recognition requirements of Statement of Financial Accounting Standards ("SFAS") No. 123(R). "Accounting for Stock-Based Compensation", for employees and directors whereby each option granted is valued at fair market value on the date of grant. Under SFAS No. 123, the fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model.

The Company also follows the guidance in EITF 96-18 "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" for equity instruments issued to consultants.

Effects of Recent Accounting Pronouncements

Effective January 1, 2008, the Company has adopted the provisions of SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. Any amounts recognized upon adoption as a cumulative effect adjustment will be recorded to the opening balance of retained earnings in the year of adoption. The provisions of SFAS 157 did not have a significant impact on the Company's statements of operations or financial position.

Effective January 1, 2008, the Company has adopted the provisions of SFAS No. 159, "Establishing the Fair Value Option for Financial Assets and Liabilities" to permit all entities to choose to elect to measure eligible financial instruments and certain other items at fair value. The decision whether to elect the fair value option may occur for each eligible items either on a specified election date or according to a preexisting policy for specified types of eligible items. However, that decision must also take place on a date on which criteria under SFAS 159 occurs. Finally, the decision to elect the fair value option shall be made on an instrument-by-instrument basis, except in certain circumstances. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. The provisions of SFAS 159 did not have a significant impact on the Company's statements of operations or financial position.

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 regulatory 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 and physiologic fluids.

We are focusing our efforts on the commercialization of our CytoSorb™ product, which we believe will provide a relatively faster regulatory pathway to market. The first indication for CytoSorb™ will be in the adjunctive treatment of sepsis (bacterial infection of the blood), which causes systematic inflammatory response syndrome. CytoSorb™ has been designed to prevent or reduce the accumulation of high concentrates of cytokines in the bloodstream associated with sepsis. It is intended for short term use as an adjunctive device to the standard treatment of sepsis. To date, we have manufactured the CytoSorb™ device on a limited basis for testing purposes, including for use in clinical studies. We believe that current state of the art blood purification technology (such as dialysis) is incapable of effectively clearing the toxins intended to be adsorbed by our CytoSorb™ device.

Following the sepsis indication, we intend to continue our research in other acute conditions where CytoSorb™ has indicated potential in preliminary studies to prevent or reduce the accumulation of cytokines in the bloodstream. These conditions include the prevention of post-operative complications of cardiac surgery (cardiopulmonary bypass

surgery) and damage to organs donated for transplant prior to organ harvest. We are also exploring the potential benefits the CytoSorb™ device may have in removing drugs from blood.

In December 2006, we submitted a proposed pilot study for approval to the FDA with respect to CytoSorb™, the first device we intend to bring to market. In the first quarter of 2007, we received approval from the FDA to conduct a limited study of five patients in the adjunctive treatment of sepsis. Based on management's belief that proceeding with the approved limited study would add at least one year to the approval process for the United States, we made a determination to focus our efforts on obtaining regulatory approval in Europe before proceeding with the FDA.

We estimate that the market potential in Europe for our products is substantially equivalent to that in the U.S. Given the opportunity to conduct a much larger clinical study in Europe, and management's belief that the path to a CE Mark should be faster than FDA approval, we have targeted Europe for the initial market introduction of our CytoSorb™ product. To accomplish the European introduction, in July 2007 we prepared and filed a request for a clinical trial with a German Central Ethics Committee. We received approval of the final study design in October of 2007.

We received approval from the German Ethics Committee in October of 2007 to conduct a clinical study of up to 80 patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis. At December 31, 2008 we had initiated and opened for enrollment seven (7) hospital units to participate in our clinical study and had identified an additional six (6) sites that may be added to our study to accelerate enrollment. As of March 2009 we have increased the number of hospital units participating in our study to ten (10).

In April 2009, we submitted a protocol revision to expand the options for anti-coagulation that the clinical sites may use, and to increase the total number of patients that may be enrolled from 80 to 100 patients. This revision has been approved by the German Ethics Committee. We believe that the revised protocol will enable more potential sites to participate in the study, and may help accelerate patient enrollment through greater access to potential candidates. Further, while we do not anticipate enrolling more than 80 patients, we now have the flexibility to enroll up to 100 patients if needed.

Additionally, we have updated blood sampling and handling procedures to minimize non-device related artifacts that may potentially arise if the samples are not processed appropriately.

To date we have enrolled twenty two (22) patients in the clinical study, which have been randomized yielding eleven (11) treated and eleven (11) control (non-treated) patients. We hope to enroll approximately sixty (60) additional patients. While we do not anticipate enrolling the entire 100 patients that we are now entitled to enroll, the approved increase allows us some flexibility in the event any of the enrolled patients are not able to complete the study due to withdrawal or inability to complete post treatment follow-up. In conducting the German Clinical study we have utilized our CytoSorb™ device in over 75 treatments to date with no Serious Adverse Events attributable to the device.

We expect to complete the patient enrollment by the end of 2009. Concurrent with the clinical study, we expect to commence the CE Mark submission process. Assuming a successful outcome of the study, management believes it will take an additional 6-9 months following its submission for CE Mark approval to receive the European regulatory approval. Assuming availability of adequate and timely funding, and a successful outcome to the study, management anticipates obtaining CE Mark approval in the first half of 2010, at the earliest.

The clinical protocol for our European clinical study has been designed to allow us to gather information to support future U.S. studies. In the event we receive the CE Mark and are able to successfully commercialize our products in the European market, we will review our plans for the United States to determine whether to conduct clinical trials in support of 510K or PMA registration. No assurance can be given that our proposed CytoSorb™ product will work as intended or that we will be able to obtain CE Mark (or FDA) approval to sell CytoSorb™. Even if we ultimately obtain CE Mark approval, because we cannot control the timing of responses from regulators to our submissions, there can be no assurance as to when such approval will be obtained.

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Our research and development costs were $1,983,483 and $1,415,509 for the years ended December 31, 2008 and 2007, respectively. We have experienced substantial operating losses since inception. As of December 31, 2008, we had an accumulated deficit of $75,461,481which included net losses of $3,017,890 and $3,350,754 for the years ended December 31, 2008 and December 31, 2007 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 $2,892,855 and $2,677,475, for the years ended December 31, 2008 and December 31, 2007 respectively. Legal, financial, and other consulting costs were $391,711 and $389,155 for the years ended December 31, 2008 and 2007, respectively.

In addition, our loss for the year ended December 31, 2008 includes net interest and dividend income of $18,147.

Liquidity and Capital Resources

Since inception, our operations have been financed through the private placement of our debt and equity securities. At December 31, 2008, we had cash on hand of $2,749,208 and current liabilities of $977,704. Our increase in cash from December 31, 2007 is a result of the June and August 2008 $5.29 million private placement of Series B Preferred Stock, which is further described in Note 9 to the consolidated financial statements. We believe that we have sufficient cash to fund our operations through the third quarter of 2009, following which we will need additional funding before we can complete our clinical studies and commercialize our products. We will continue to seek funding for the long term needs of the Company. There can be no assurance that financing will be available on acceptable terms or at all. If adequate funds are unavailable, we may have to suspend, delay or eliminate one or more of our research and development programs or product launches or marketing efforts or cease operations.

This Annual Report have been prepared assuming we will continue as a going concern, and the auditors' report on those financial statements expresses substantial doubt about our ability to continue as a going concern.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not required by smaller reporting companies.

ItemFinancial Statements and Supplementary Data.
8.

The Financial Statements and Notes thereto can be found beginning on page F-1, "Index to Financial Statements," at the end of this Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A(T). Controls and Procedures.

An evaluation was performed, under the supervision of, and with the participation of, our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-(e) to the Securities and Exchange Act of 1934). Based on that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures were adequate and effective, as of December 31, 2008, to ensure that information required to be disclosed by us in the reports that we file or submits under the Securities Exchange Act of 1934, is recorded, processed, summarized, and reported within the time periods specified in the

SEC’s rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

There has not been any changes in our internal controls over financial reporting that occurred during our fiscal year ended December 31, 2008 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

In 2008, management conducted tests of our internal controls over financial reporting in accordance with the standards set forth by the U.S. Securities and Exchange Commission ("SEC"). In accordance with these standards, management assessed and tested, on a sample basis, the Company's internal control over financial reporting according to a comprehensive risk analysis using the Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). It is management's opinion that the testing methodology of the internal control framework is appropriate and provides reasonable assurance as to the integrity and reliability of our internal controls over financial reporting.

In management's opinion, based on the assessment completed as at December 31, 2008, our internal controls over financial reporting are operating effectively.

This annual report does not include an audit report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to audit by the Company's registered public accounting firm pursuant to temporary rules of the SEC that permit the Company to provide only management's report in this annual report.

Item 9B. Other Information.

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Control Persons; Compliance with Section 16(a) of the Exchange Act.

Directors and Executive Officers

The following table sets forth our directors and executive officers, their ages and the positions they hold:

Name	Age	Position
Phillip Chan, MD	38	President and Chief Executive Officer, Director
Al Kraus	64	Chairman of the Board
Joseph Rubin, Esq.	70	Director
Edward R. Jones, MD, MBA	60	Director
James Gunton	42	Director
Vincent Capponi	51	Chief Operating Officer
David Lamadrid	38	Chief Financial Officer

Robert Bartlett, MD	69	Chief Medical Officer

Phillip Chan, MD, PhD. Dr. Chan became a director of MedaSorb in 2008 and since January 2009 is also Chief Executive Officer. Prior to MedaSorb, Dr. Chan led healthcare and life science investments as Partner for the NJTC Venture Fund. Dr. Chan co-founded Andrew Technologies, a medical device company developing novel surgical instruments for plastic surgery and continues as a Board Director. He is a Board-certified Internal Medicine physician with a strong background in clinical medicine and research. Dr. Chan received his MD and PhD from the Yale University School of Medicine and completed his Internal Medicine residency at Beth Israel Deaconess Medical Center at Harvard. He also holds a BS in cell and molecular biology from Cornell University.

Al Kraus. Mr. Kraus has been a director of MedaSorb since 2003 and up until the end of 2008 was the Company's President and CEO. Mr. Kraus currently serves as Chairman of the Board of Directors. Mr. Kraus has more than twenty-five years' experience managing companies in the dialysis, medical device products, personal computer and custom software industries. Prior to joining us, from 2001 to 2003, Mr. Kraus was President and CEO of NovoVascular Inc., an early stage company developing coated stent technology. From 1996 to 1998, Mr. Kraus was President and CEO of Althin Healthcare and from 1998 to 2000, of Althin Medical Inc., a manufacturer of products for the treatment of end stage renal disease. While CEO of Althin, he provided strategic direction and management for operations throughout the Americas. From 1979 to 1985, Mr. Kraus was U.S. Subsidiary Manager and Chief Operating Officer of Gambro Inc., a leading medical technology and healthcare company. Mr. Kraus was the Chief Operating Officer of Gambro when it went public in the United States in an offering led by Morgan Stanley.

Joseph Rubin, Esq. Mr. Rubin became a director of MedaSorb in 1997. Mr. Rubin is a founder and Senior Partner of Rubin, Bailin, and Ortoli, LLP an international and domestic corporate and commercial law firm in New York City, where he has practiced law since 1986. Mr. Rubin also teaches at the Columbia University School of International and Public Affairs, where he is also Executive Director of the International Technical Assistance Program for Public Affairs (ITAP). Mr. Rubin was Adjunct Professor at the Columbia University Graduate School of Business from 1973 to 1994, and taught at Columbia Law School in 1996. Mr. Rubin received his law degree from Harvard Law School, and his B.A., MIA, and M.Phil degrees in political science and international relations from Columbia University.

Edward R. Jones, MD, MBA. Dr. Jones has been a director of ours since April 2007. Dr. Jones is an attending physician at the Albert Einstein Medical Center and Chestnut Hill Hospital as well as Clinical Professor of Medicine at Temple University Hospital. Dr. Jones has published or contributed to the publishing of 30 chapters, articles, and abstracts on the subject of treating kidney-related illnesses. He is a sixteen-year member of the Renal Physicians Association, the Philadelphia County Medical Society and a past board member of the National Kidney Foundation of the Delaware Valley. Dr. Jones has been elected to serve as the next President of the Renal Physicians Association starting in 2009.

James Gunton. Mr. Gunton became a director of MedaSorb in 2008. He is a cofounder of the NJTC Venture Fund. Mr. Gunton has been investing in privately-held growth technology companies for fifteen years. Before co-founding in 2001 the $80 million NJTC Venture Fund, Jim was a manager at Oracle Corporation in the Silicon Valley. He represents NJTC Venture Fund at nine portfolio companies and is a former Governor of the National Association of Small Business Investment Companies. Jim earned a BS from Stanford University and an MBA with distinction from Duke University.

Vincent Capponi. Mr. Capponi joined MedaSorb as Vice President of Operations in 2002 and became its Chief Operating Officer in July 2005. He has more than 20 years of management experience in medical device, pharmaceutical and imaging equipment at companies including Upjohn, Sims Deltec and Sabratek. Prior to joining MedaSorb in 2002, Mr. Capponi held several senior management positions at Sabratek and its diagnostics division GDS, and was interim president of GDS diagnostics in 2001. From 1998 to 2000, Mr. Capponi was Senior Vice President and Chief Operating Officer for Sabratek and Vice President Operations from 1996 to 1998. He received his MS in Chemistry and his BS in Chemistry and Microbiology from Bowling Green State University.

David Lamadrid. Mr. Lamadrid has been with MedaSorb since 2000 and has served as its Chief Financial Officer since October 2002. He has over 15 years of business experience in finance and operations. Prior to joining MedaSorb in 2000, Mr. Lamadrid was a financial analyst at Chase Manhattan Bank working in the Middle Market Banking Group. Mr. Lamadrid received his MBA from New York University, a BS in Finance from St. John's University, and an AAS in Accounting from S.U.N.Y. Rockland.

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Robert Bartlett, MD. Dr. Bartlett became our Chief Medical Officer in January 2009. He is Professor Emeritus of Surgery at the University of Michigan Health System. Prior to becoming Professor Emeritus in 2005, Dr. Bartlett was Director of the Surgical Intensive Care Unit, Chief of the Trauma/Clinical Care Division and Director of the Extracorporeal Life Support Program at the University of Michigan Medical Center. Dr. Bartlett was the pioneer in the development of the extracorporeal membrane oxygenation machine (ECMO), used to oxygenate blood in critically ill patients worldwide. He received his MD from the University of Michigan Medical School, cum laude. He completed his general surgery residency at Peter Bent Brigham Hospital in Boston, and was Chief resident in thoracic surgery. Dr. Bartlett was also a NIH Trainee in Academic Surgery at Harvard Medical School, and was previously faculty at the University of California, Irvine. Dr. Bartlett is the recipient of 26 separate research grants, 14 from the National Institute of Health, including an RO1 grant for the development of a totally artificial lung. He has also received numerous national and international awards for his contributions to critical care medicine.

Section 16(a) Beneficial Ownership Reporting Compliance

The members of our Board of Directors, our executive officers and persons who hold more than 10% of our outstanding Common Stock are subject to the reporting requirements of Section 16(a) of the Exchange Act, which requires them to file reports with respect to their ownership of our Common Stock and their transactions in such Common Stock. Based solely upon a review of Forms 3 and 4 and amendments filed with the SEC by persons subject to the reporting requirements of Section 16(a) of the Exchange Act, we believe that, all reporting requirements under Section 16(a) for the 2008 fiscal year were met in a timely manner by our directors, executive officers and beneficial owners of more than 10% of our Common Stock.

Code of Conduct

We maintain a Code of Business Conduct and Ethics that is applicable to all of our employees, including our Chief Executive Officer and Chief Financial Officer, and our directors. The Code of Conduct, which satisfies the requirements of a “code of ethics” under applicable SEC rules, contains written standards that are designed to deter wrongdoing and to promote honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest; full, fair, accurate, timely and understandable public disclosures and communications, including financial reporting; compliance with applicable laws, rules and regulations; prompt internal reporting of violations of the code; and accountability for adherence to the code.

Audit Committee Financial Expert

The Board of Directors does not have an Audit Committee, and therefore does not have an “audit committee financial expert,” as such term is defined in Item 401(h)(2) of Regulation S-K.

Item 11. Executive Compensation.

Summary Compensation Table

The following table shows for the fiscal year ended December 31, 2008, compensation awarded to or paid to, or earned by, our Chief Executive Officer, our Chief Operating Officer, our Chief Financial Officer, and our Chief Medical Officer (the “Named Executive Officers”).

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards (1) ($)	Total ($)
Al Kraus Chief Executive Officer	2008	216,351	-0-	108,381(2)	324,732
	2007	216,351	-0-	251,446(3)	467,797
	2006	201,257	-0-	69,555(4)	270,812
Vincent Capponi, Chief Operating Officer	2008	195,527	150	155,795(5)	351,472
	2007	195,527	-0-	-0-	195,527
	2006	178,441	200	40,297(6)	218,939
David Lamadrid, Chief Financial Officer	2008	157,630(12)	150	196,555(7)	354,335
	2007	145,801	-0-	137,781(8)	283,582
	2006	135,629	200	-0-	135,829
Dr. James Winchester Chief Medical Officer	2008	120,000	-0-	24,760(9)	144,760
	2007	120,000	-0-	2,431(10)	122,431
	2006	120,000	-0-	40,297(11)	160,297

(1) The value of option awards granted to the Named Executive Officers has been estimated pursuant to SFAS No. 123(R) for the options described in the footnotes below, except that for purposes of this table, we have assumed that none of the options will be forfeited. The Named Executive Officers will not realize the estimated value of these awards in cash until these awards are vested and exercised or sold. For information regarding our valuation of option awards, see “Stock-Based Compensation” in Note 2 of our financial statements for the period ended December 31, 2008.

(2) Reflects options to purchase 7,119,328 shares of Common Stock at an exercise price of $0.035 per share, which were granted on June 25, 2008 and expire June 25, 2018.

(3) Reflects options to purchase 400,000 shares of Common Stock at an exercise price of $1.26 per share, which were granted on February 8, 2007 and expire February 8, 2017 and options to purchase 80,122 shares of Common Stock at an exercise price of $0.22 per share, which were granted on December 31, 2007 and expire December 31, 2017.

(4) Reflects options to purchase 413,920 shares of Common Stock, all of which are currently exercisable at an exercise price of $6.64 per share. Options to purchase 332,094 of these shares were granted on September 30, 2006 and expire on September 30, 2016, and options to purchase 81,826 of these shares were granted on December 31, 2006 and expire on December 31, 2016.

(5) Reflects options to purchase 1,100,000 shares of Common Stock at an exercise price of $0.25 per share, which were granted on January 16, 2008 and expire on January 16, 2018. This option vested and became exercisable as to 366,666 shares on the date of grant, vested and became exercisable as to 366,667 shares on January 16, 2009; and vests and becomes exercisable as to 366,667 shares on January 16, 2010. Reflects options to purchase 2,250,000 shares of Common Stock at an exercise price of $0.035 per share, which were granted on June 25, 2008 and expire on June 25, 2018. This option vested and became exercisable as to 562,500 shares on the date of grant, vests and becomes exercisable as to 562,500 shares on June 25, 2009, vests and becomes exercisable as to 562,500 shares on

June 25, 2010, and vests and becomes exercisable as to 562,500 shares on June 25, 2011.

(6) Reflects options to purchase 50,000 shares of Common Stock at an exercise price of $1.65 per share, which were granted on December 31, 2006 and expire on December 31, 2016. This option vested and became exercisable as to 16,667 shares on the date of grant, vested and became exercisable as to 16,667 shares on December 31, 2007; and vested and became exercisable as to 16,666 shares on December 31, 2008.

(7) Reflects options to purchase 1,400,000 shares of Common Stock at an exercise price of $0.25 per share, which were granted on January 16, 2008 and expire on January 16, 2018. This option vested and became exercisable as to 466,667 shares on the date of grant, vested and became exercisable as to 466,667 shares on January 16, 2009; and vests and becomes exercisable as to 466,666 shares on January 16, 2010. Reflects options to purchase 2,750,000 shares of Common Stock at an exercise price of $0.035 per share, which were granted on June 25, 2008 and expire on June 25, 2018. This option vested and became exercisable as to 687,500 shares on the date of grant, vests and becomes exercisable as to 687,500 shares on June 25, 2009, vests and becomes exercisable as to 687,500 shares on June 25, 2010, and vests and becomes exercisable as to 687,500 shares on June 25, 2011.

(8) Reflects options to purchase 150,000 shares of Common Stock at an exercise price of $1.90 per share which were granted on January 16, 2007 and expire on January 16, 2017. This option vested and became exercisable as to 50,000 shares on the date of grant, vested and became exercisable as to 50,000 shares on January 16, 2008; and vested and became exercisable as to 50,000 shares on January 16, 2009.

(9) Reflects options to purchase 175,000 shares of Common Stock at an exercise price of $0.25 per share, which were granted on January 16, 2008 and expire on January 16, 2018. This option vested and became exercisable as to 58,333 shares on the date of grant, vested and became exercisable as to 58,333 shares on January 16, 2009; and vests and becomes exercisable as to 58,334 shares on January 16, 2010. Reflects options to purchase 356,250 shares of Common Stock at an exercise price of $0.035 per share, which were granted on June 25, 2008 and expire on June 25, 2018. This option vested and became exercisable as to 89,063 shares on the date of grant, vests and becomes exercisable as to 89,063 shares on June 25, 2009, vests and becomes exercisable as to 89,062 shares on June 25, 2010, and vests and becomes exercisable as to 89,062 shares on June 25, 2011.

(10) Reflects options to purchase 25,000 shares of Common Stock at an exercise price of $0.22 per share, which were granted on December 31, 2007 and expire on December 31, 2017. This option vested and became exercisable as to 8,334 shares on the date of grant, vested and became exercisable as to 8,333 shares on December 31, 2008; and vest and become exercisable as to 8,333 shares on December 31, 2009.

(11) Reflects options to purchase 50,000 shares of Common Stock at an exercise price of $1.65 per share, which were granted on December 31, 2006 and expire on December 31, 2016. This option vested and became exercisable as to 16,667 shares on the date of grant, vested and become exercisable as to 16,667 shares on December 31, 2007; and vested and become exercisable as to 16,666 shares on December 31, 2008.

(12) Amount includes payments in the approximate amount of $11,800 for certain other expenses pursuant to an employment agreement.

Outstanding Equity Awards at Fiscal Year End

The following table shows for the fiscal year ended December 31, 2008, certain information regarding outstanding equity awards at fiscal year end for the Named Executive Officers.

Outstanding Equity Awards At December 31, 2008

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Al Kraus	332,094		6.64(1)	9/30/16
	81,826		6.64(1)	12/31/16
	400,000		1.26(1)	02/08/17
	80,122		0.22(1)	12/31/17
	7,119,329		0.035(1)	06/25/18
Vincent Capponi	50,000		1.65(2)	12/31/16
	366,666	733,334	0.25(3)	01/16/18
	562,500	1,687,500	0.035(4)	06/25/18
David Lamadrid	100,000	50,000	1.90(5)	01/16/17
	466,666	933,334	0.25(6)	01/16/18
	687,500	2,062,500	0.035(7)	06/25/18
Dr. James Winchester	50,000		1.65(8)	12/31/16
	16,667	8,333	0.22(9)	12/31/17
	58,333	116,667	0.25(10)	01/16/18
	89,063	267,187	0.035(11)	06/25/18

(1) Fully vested

(2) Vests and becomes exercisable as to (i) 16,667 shares on December 31, 2006; (ii) 16,667 shares on December 31, 2007; and (iii) 16,666 shares on December 31, 2008.

(3) Vests and becomes exercisable as to (i) 366,666 shares on January 16, 2008; (ii) 366,667 shares on January 16, 2009; and (iii) 366,667 shares on January 16, 2010.

(4) Vests and becomes exercisable as to (i) 562,500 shares on June 25, 2008; (ii) 562,500 shares on June 25, 2009; (iii) 562,500 shares on June 25, 2010; and (iv) 562,500 shares on June 25, 2011.

(5) Vests and becomes exercisable as to (i) 50,000 shares on January 16, 2007; (ii) 50,000 shares on January 16, 2008; and (iii) 50,000 shares on January 16, 2009.

(6) Vests and becomes exercisable as to (i) 466,666 shares on January 16, 2008; (ii) 466,667 shares on January 16, 2009; and (iii) 466,667 shares on January 16, 2010.

(7) Vests and becomes exercisable as to (i) 562,500 shares on June 25, 2008; (ii) 562,500 shares on June 25, 2009; (iii) 562,500 shares on June 25, 2010; and (iv) 562,500 shares on June 25, 2011.

(8) Vests and becomes exercisable as to (i) 16,667 shares on December 31, 2006; (ii) 16,667 shares on December 31, 2007; and (iii) 16,666 shares on December 31, 2008.

(9) Vests and becomes exercisable as to (i) 8,333 shares on December 31, 2007; (ii) 8,333 shares on December 31, 2008; and (iii) 8,334 shares on December 31, 2009.

(10) Vests and becomes exercisable as to (i) 58,333 shares on January 16, 2008; (ii) 58,333 shares on January 16, 2009; and (iii) 58,334 shares on January 16, 2010.

(11) Vests and becomes exercisable as to (i) 89,063 shares on June 25, 2008; (ii) 89,063 shares on June 25, 2009; (iii) 89,062 shares on June 25, 2010; and (iv) 89,062 shares on June 25, 2011.

Director Compensation

The following table shows for the fiscal year ended December 31, 2008 certain information with respect to the compensation of all non-employee directors of the Company.

Director Compensation for Fiscal 2008

Name		Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	Total ($)
William R. Miller	(10)	20,000	11,430(2)(3)	31,430
Joseph Rubin		8,000	855(2)(4)	8,855
Kurt Katz	(11)	4,000	770(2)(5)	4,770
Edward R. Jones		8,000	855(2)(6)	8,855
Martin F. Whalen	(12)	3,000	285(2)(7)	3,285
Phillip Chan, MD	(13)	4,000	85(2)(8)	4,085
James Gunton	(14)	4,000	85(2)(9)	4,085
Al Kraus	(15)			

(1) The value of option awards granted to directors has been estimated pursuant to SFAS No. 123(R) for the options described in the footnotes below, except that for purposes of this table, we have assumed that none of the options will be forfeited. The directors will not realize the estimated value of these awards in cash until these awards are vested and exercised or sold. For information regarding our valuation of option awards, see "Stock-Based Compensation" in Note 2 of our financial statements for the period ended December 31, 2008.

(2) Fully vested

(3) At December 31, 2008, in connection with his service as a director we had issued Mr. Miller the following: options to purchase 200,000 shares of our Common Stock at an exercise price of $1.65 per share, which were granted on January 1, 2007 and expire on January 1, 2007; options to purchase 100,000 shares of our Common Stock at an exercise price of $0.25 per share, which were granted on January 16, 2008 and expire on January 16, 2018, and options to purchase 25,000 shares of our Common Stock at an exercise price of $0.035 per share, which were granted on June 25, 2008 and expire on June 25, 2018.

(4) At December 31, 2008, in connection with his service as a director we had issued Mr. Rubin the following: options to purchase 21,098 shares of our Common Stock at an exercise price of $31.52 per share, which were granted on June 30, 2006 and expire on December 13, 2010; options to purchase 5,274 shares of our Common Stock at an exercise price of $21.57 per share, which were granted on June 30, 2006 and expire on January 26, 2012; options to purchase 3,014 shares of our Common Stock at an exercise price of $21.57 per share, which were granted on June 30, 2006 and expire on December 11, 2012; options to purchase 753 shares of our Common Stock at an exercise price of $21.57 per share, which were granted on June 30, 2006 and expire on December 28, 2013; options to purchase 1,507 shares of our Common Stock at an exercise price of $6.64 per share, which were granted on June 30, 2006 and expire on December 29, 2014; options to purchase 10,000 shares of our Common Stock at an exercise price of $1.25 per share, which were granted on June 30, 2006 and expire on January 30, 2016; options to purchase 15,069 shares of our Common Stock at an exercise price of $1.25 per share, which were granted on June 30, 2006 and expire on June 12, 2016; options to purchase 5,000 shares of our Common Stock at an exercise price of $1.25 per share, which were granted on August 1, 2006 and expire on August 1, 2016; options to purchase 10,000 shares of our Common Stock at an exercise price of $0.22 per share, which were granted on December 31, 2007 and expire on December 31, 2017; options to purchase 45,000 shares of our Common Stock at an exercise price of $0.035 per share, which were granted on June 25, 2008 and expire on June 25, 2018; and options to purchase 30,000 shares of our Common Stock at an exercise price of $0.08 per share, which were granted on December 31, 2008 and expire on December 31, 2018.

(5) At December 31, 2008, in connection with his service as a director we had issued on behalf of Mr. Katz the following : options to purchase 16,200 shares of our Common Stock at an exercise price of $31.52 per share, which were granted on June 30, 2006 and expire on December 13, 2010; options to purchase 5,274 shares of our Common Stock at an exercise price of $21.57 per share, which were granted on June 30, 2006 and expire on January 26, 2012; options to purchase 3,014 shares of our Common Stock at an exercise price of $21.57 per share, which were granted on June 30, 2006 and expire on December 11, 2012; options to purchase 753 shares of our Common Stock at an exercise price of $21.57 per share, which were granted on June 30, 2006 and expire on December 28, 2013; options to purchase 1,507 shares of our Common Stock at an exercise price of $6.64 per share, which were granted on June 30, 2006 and expire on December 29, 2014; options to purchase 10,000 shares of our Common Stock at an exercise price of $1.25 per share, which were granted on June 30, 2006 and expire on January 30, 2016; options to purchase 15,069 shares of our Common Stock at an exercise price of $1.25 per share, which were granted on June 30, 2006 and expire on June 12, 2016; options to purchase 5,000 shares of our Common Stock at an exercise price of $1.25 per share, which were granted on August 1, 2006 and expire on August 1, 2016; options to purchase 10,000 shares of our Common Stock at an exercise price of $0.22 per share, which were granted on December 31, 2007 and expire on December 31, 2017; options to purchase 45,000 shares

of our Common Stock at an exercise price of $0.035 per share, which were granted on June 25, 2008 and expire on June 25, 2018; and options to purchase 15,000 shares of our Common Stock at an exercise price of $0.08 per share, which were granted on December 31, 2008 and expire on December 31, 2018. All of these options have been issued to a trust established by Mr. Katz for the benefit of his children.

(6) At December 31, 2008, in connection with his service as a director we had issued Dr. Jones the following: options to purchase 7,500 shares of our Common Stock at an exercise price of $0.22 per share, which were granted on December 31, 2007 and expire on December 31, 2017; options to purchase 45,000 shares of our Common Stock at an exercise price of $0.035 per share, which were granted on June 25, 2008 and expire on June 25, 2018; and options to purchase 30,000 shares of our Common Stock at an exercise price of $0.08 per share, which were granted on December 31, 2008 and expire on December 31, 2018.

(7) At December 31, 2008, in connection with his service as a director we had issued Mr. Whalen the following: options to purchase 5,000 shares of our Common Stock at an exercise price of $0.22 per share, which were granted on December 31, 2007 and expire on December 31, 2017; options to purchase 15,000 shares of our Common Stock at an exercise price of $0.035 per share, which were granted on June 25, 2008 and expire on June 25, 2018; and options to purchase 10,000 shares of our Common Stock at an exercise price of $0.08 per share, which were granted on December 31, 2008 and expire on December 31, 2018.

(8) At December 31, 2008, in connection with his service as a director we had issued Dr. Chan the following: options to purchase 15,000 shares of our Common Stock at an exercise price of $0.08 per share, which were granted on December 31, 2008 and expire on December 31, 2018.

(9) At December 31, 2008, in connection with his service as a director we had issued Mr. Gunton the following: options to purchase 15,000 shares of our Common Stock at an exercise price of $0.08 per share, which were granted on December 31, 2008 and expire on December 31, 2018.

(10) Effective December, 31 2008, Mr. Miller resigned his position as a member of the Board of Directors.

(11) Effective July, 23 2008, Mr. Katz resigned his position as a member of the Board of Directors.

(12) Effective April, 25 2008, Mr. Whalen resigned his position as a member of the Board of Directors.

(13) Effective July 24, 2008, Dr. Chan was appointed to the Company’s Board of Directors and Compensation Committee. Effective January 1, 2009, Dr. Chan entered into an employment agreement becoming interim Chief Executive Officer of the Company. In January 2009, Dr. Chan resigned his position as a member on the Compensation Committee.

(14) Effective July, 24 2008, Mr. Gunton was appointed to the Company’s Board of Directors and Compensation Committee.

(15) During 2008 Mr. Kraus was an employee Director and was not eligible to receive compensation for Director services. Effective December 31, 2008, Mr. Kraus resigned his position as Chief Executive Officer of the Company, remaining as a member of the Board of Directors. In January 2009, Mr. Kraus agreed to serve as Chairman of the Board of Directors.

In 2007, we approved arrangements under which each non-employee director receives a fee of $2,000 for each quarterly Board meeting attended in person and a fee of $1,000 for each quarterly Board meeting participated in by telephone. In addition, our Board approved a policy under which each non-employee director will be eligible to be issued options to purchase up to 10,000 shares of our Common Stock on December 31, 2007 based on attendance at

quarterly Board meetings held during 2007. Such options will be exercisable at the closing price of our Common Stock on the date of grant. Our directors are also reimbursed for actual out-of-pocket expenses incurred by them in connection with their attendance at meetings of the Board of Directors.

In connection with his appointment as Chairman of the Board, we agreed to compensate Mr. Miller at the rate of $20,000 per annum, and on January 1, 2007 we issued Mr. Miller a ten year option to purchase 200,000 shares of our Common Stock at a price of $1.65 per share (the last reported sales price on the OTC Bulletin Board on December 29, 2006). In January 2008 we issued Mr. Miller an additional option to purchase 100,000 shares of Common Stock at an exercise price of $0.25 per share. Effective December 31, 2008, Mr. Miller has resigned from the Board of Directors.

In 2008, the Board approved the issuance to each non-employee director, with the exception of the Chairman, options to purchase up to 30,000 shares of Common Stock on December 31, 2008 based on attendance at quarterly Board meetings held during 2008.

In connection with his appointment as Chairman of the Board in January 2009, we agreed to compensate Mr. Kraus at the rate of $20,000 per annum, and on January 8, 2009 we issued Mr. Kraus a ten year option to purchase 200,000 shares of our Common Stock at a price of $0.084 per share. Additionally for services performed as Chief Executive Office of the company through December 31, 2008, the Board approved a 10 year option to purchase 450,000 shares of our Common Stock at a price of $0.168 per share on January 28, 2009.

In 2009, the Board approved the issuance to each non-employee director, with the exception of the Chairman, options to purchase up to 100,000 shares of Common Stock on December 31, 2009 based on attendance at quarterly Board meetings held during 2009.

Employment Agreements with Named Executive Officers

Phillip Chan

Effective January 1, 2009, we entered into a new employment agreement with Dr. Phillip Chan, pursuant to which his employment will terminate on December 31, 2009. Pursuant to this employment agreement, we agree to pay Phillip Chan an initial annual base compensation of $216,351 payable in equal semimonthly installments in accordance with our usual practice. This base compensation shall be subject to semiannual review by our Compensation Committee, but his compensation may not be reduced from then current level. He is eligible for employee stock options which will be adjusted on the same basis as all other shareholders to account for any stock split, stock dividends, combination or recapitalization.

Al Kraus

We entered into an employment agreement with Al Kraus on June 18, 2008 as our Chief Executive Officer. Pursuant to the employment agreement, we agreed to pay Al Kraus an annual base compensation of $216,351 payable in equal semimonthly installments in accordance with our usual practice.

On October 22, 2008, Al Kraus provided notice that he would resign from his position as President and Chief Executive Officer effective as of December 31, 2008.

Effective January 7, 2009, we entered into a new agreement with Al Kraus, pursuant to which he became Chairman of the Board of Directors for a two year term terminating on January 7, 2011. Pursuant to this agreement, we agree to pay Al Kraus compensation at a rate of $20,000 per year, payable in equal payments at the end of each fiscal quarter. He is eligible for stock options which will be adjusted on the same basis as all other shareholders to account for any stock split, stock dividends, combination or recapitalization.

Vincent Capponi

We entered into an employment agreement with Vincent Capponi on June 18, 2008, pursuant to which his employment terminated on December 31, 2008. Pursuant to this employment agreement, we agree to pay Vincent Capponi an initial annual base compensation of $195,767 payable in equal semimonthly installments in accordance with our usual practice. This base compensation shall be subject to annual review by our Compensation Committee, but his compensation may not be reduced from then current level. He is eligible for employee stock options which will be adjusted on the same basis as all other shareholders to account for any stock split, stock dividends, combination or recapitalization.

Effective January 1, 2009, we entered into a new employment agreement with Vincent Capponi, pursuant to which his employment will terminate on December 31, 2009. Pursuant to this employment agreement, we agree to pay Vincent Capponi an initial annual base compensation of $205,303 payable in equal semimonthly installments in accordance with our usual practice. This base compensation shall be subject to semiannual review by our Compensation Committee, but his compensation may not be reduced from then current level. He is eligible for employee stock options which will be adjusted on the same basis as all other shareholders to account for any stock split, stock dividends, combination or recapitalization.

David Lamadrid

We entered into an employment agreement with David Lamadrid on June 18, 2008, pursuant to which his employment terminated on December 31, 2008. Pursuant to this employment agreement, we agree to pay David Lamadrid an initial annual base compensation of $145,801 payable in equal semimonthly installments in accordance with our usual practice. This base compensation shall be subject to annual review by our Compensation Committee, but his compensation may not be reduced from then current level. He is eligible for employee stock options which will be adjusted on the same basis as all other shareholders to account for any stock split, stock dividends, combination or recapitalization.

Effective January 1, 2009, we entered into a new employment agreement with David Lamadrid, pursuant to which his employment will terminate on December 31, 2009. Pursuant to this employment agreement, we agree to pay David Lamadrid an initial annual base compensation of $175,000 payable in equal semimonthly installments in accordance with our usual practice. This base compensation shall be subject to semiannual review by our Compensation Committee. He is eligible for employee stock options which will be adjusted on the same basis as all other shareholders to account for any stock split, stock dividends, combination or recapitalization.

Robert Bartlett

Effective January 1, 2009, we entered into a new consulting agreement with Dr. Robert Bartlett, pursuant to which his consulting will terminate on December 31, 2009. Pursuant to this consulting agreement, we agree to pay Dr. Robert Bartlett consulting fees at an annualized rate of $50,000 payable in equal monthly installments of $4,166.67 per month. He is eligible for stock options which will be adjusted on the same basis as all other shareholders to account for any stock split, stock dividends, combination or recapitalization.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information known to us with respect to the beneficial ownership of Common Stock held of record as of March 31, 2009, by (1) all persons who are owners of 5% or more of our Common Stock, (2) each of our named executive officers (see "Summary Compensation Table"), (3) each director, and (4) all of our executive officers and directors as a group. Each of the stockholders can be reached at our principal executive offices located at 7 Deer Park Drive, Suite K, Monmouth Junction, New Jersey 08852.

	SHARES BENEFICIALLY OWNED1	
	Number	Percent (%)
Beneficial Owners of more than 5% of Common Stock (other than directors and executive officers)		
Margie Chassman(2)	58,237,575(2)	69.4%
Guillermina Montiel(3)	5,052,456	16.5%
Margery Germain(4)	2,000,000	6.6%
Robert Shipley (5)	16,871,553	36.0%
Directors and Executive Officers		