Cytosorbents Corp
Form 10-K
March 30, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For The Fiscal Year Ended December 31, 2011

o TRANSITION REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

COMMISSION FILE NUMBER 000-51038

CYTOSORBENTS 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. ¨ 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. ¨ 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 ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes þ No ¨

Indicate by check if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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 or any amendment to 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 ¨	Accelerated Filer ¨
Non-accelerated Filer ¨ (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.)

¨ Yes þ No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2011 was approximately $32,794,000. The number of shares outstanding of the registrant’s Common Stock as of March 28, 2012 was 189,107,064.

CYTOSORBENTS CORPORATION

2011 FORM 10-K ANNUAL REPORT

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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, indicates a 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 CytoSorbents 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 critical care focused therapeutic medical device company that is currently in the development stage, headquartered in Monmouth Junction, New Jersey (near Princeton). We have developed and are seeking 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 are required to obtain required regulatory approvals from a Notified Body for the European Community (CE Mark) and the United States Food and Drug Administration ("FDA") before we can sell our products in Europe and the United States, respectively.

In March 2011, we received European Union (E.U.) regulatory approval under the CE Mark and Medical Devices Directive for our flagship product, CytoSorb™, as an extracorporeal cytokine filter to be used in clinical situations where cytokines are elevated. In mid-September we started to exhibit the CytoSorb™ device at conferences in Germany as part of our product marketing under a controlled-market release in select geographic territories in Germany. Because of the limited nature of this initial release, we do not anticipate significant sales until we fully expand our marketing efforts into the broader market.

Our CE Mark enables CytoSorb™ to be sold in the European Union for clinical use. Potential uses include many critical care conditions where cytokines are elevated such as sepsis, trauma, ARDS, severe burn injury and acute pancreatitis. CytoSorbents is currently manufacturing the CytoSorb™ device under ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the European Union. We intend to continue to research and seek the necessary regulatory approvals to sell our other proposed products, as well as potential label extensions of our current CE Mark for CytoSorb™.

In 2011 we completed the Company's largest clinical study to date (the "European Sepsis Trial") with the participation of fourteen trial sites enrolling one hundred (100) patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis. The purpose of the trial was to demonstrate safety and the broad, and statistically significant reduction of key cytokines such as IL-6 in these patients. Although the trial was not powered to demonstrate significant reduction in other clinical endpoints such as mortality, these were included as secondary and exploratory endpoints in the trial. Taking into account all 100 patients, the treatment was well-tolerated with no serious device related adverse events reported in more than 300 human treatments in the trial.

The first 22 patients in the study represented a sepsis pilot study. In the next 31 patients, a compromise of the manual randomization schedule at two trial sites led to an imbalance in the severity of illness between the control and treatment patient groups of the study. After a thorough review, the Scientific Advisory Board (SAB) and the independent Data Safety Monitoring Board (DSMB) both recommended that due to this enrollment bias, these 31 patients should only be used for safety evaluation purposes and that new patients should be enrolled into the trial using electronic web-based randomization to randomly assign patients into either the control or treatment arms. Excluding four patients that withdrew, the remaining forty three (43) patients enrolled under electronic randomization were relatively balanced in terms of the severity of illness in treatment and control patients, confirming the findings of the SAB and DSMB. In these forty three (43) patients the European Sepsis Trial successfully demonstrated, on a statistically significant basis ($p<0.05$), CytoSorb™'s ability to reduce circulating levels of key cytokines from whole blood in treated patients on the average of 30-50% over the 7 day treatment period. Additionally, post-hoc subgroup analyses of the clinical outcome data from patients enrolled under electronic randomization demonstrated statistically significant reduction in mortality in patients at high risk of death in sepsis, specifically in patients with very high cytokine levels (IL-6 $\geq$ 1,000 pg/mL and/or IL-1ra $\geq$ 16,000 pg/mL) where 28-day mortality was 0% treated vs 63% control, $p=0.03$, $n=14$ and patients $\geq$ age 65 (14-day mortality: 0% treated vs 36% control, $p=0.04$, $n=21$).

We are focusing our efforts on the commercialization of our CytoSorb™ product and have begun a controlled-marketing program in select territories in Germany. The initial major market focus for CytoSorb™ is the adjunctive treatment of sepsis, a systemic inflammatory response to a serious infection or traumatic event. CytoSorb™ has been designed to prevent or reduce the accumulation of high concentrations of cytokines in the bloodstream associated with sepsis and is intended for short-term use with standard of care therapy that includes antibiotics. 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.

In addition to the sepsis indication, we intend to continue to foster research in other critical care illnesses where CytoSorb™ could be used, such as ARDS, trauma, severe burn injury and severe acute pancreatitis, or in other acute conditions that have demonstrated potential in preliminary studies to prevent or reduce the accumulation of cytokines in the bloodstream. These other 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 our technology may have in removing drugs and other substances from blood and physiologic fluids.

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In mid-September 2011 the Company initiated a controlled market release of the CytoSorb™ device in select territories in Germany with the goal of raising awareness, attending critical care conferences, and to seek initial clinical usage of the device. The Company is currently manufacturing CytoSorb™ under ISO 13485:2003 Full Quality Systems certification for initial sales in the E.U., evaluation purposes by industry thought leaders, and for additional clinical studies. Concurrent with its commercialization plans, the Company intends to conduct additional clinical studies in sepsis and other critical care diseases. Utilizing the data from our initial study, we are planning a dosing study to determine the optimal treatment for critical care patients that have a high risk of mortality including those with very high levels of cytokines and those aged 65 and older. These additional studies will also generate additional clinical data to expand the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. Assuming availability of adequate and timely funding, and continued positive results from our clinical studies, the Company intends to continue commercializing its product in Europe.

The clinical protocol for our European Sepsis Trial was designed to allow us to gather information to support future U.S. studies. In the event we 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 510(k) or PMA registration. No assurance can be given that our CytoSorb™ product will work as intended in these studies or that we will be able to obtain FDA approval to sell CytoSorb™ in the United States. Even though we have obtained CE Mark approval, there is no guarantee or assurance that we will be successful in obtaining FDA approval in the United States or approval in any other country or jurisdiction.

We have developed two products, CytoSorb™ and BetaSorb™, and a technology platform called HemoDefend, utilizing our adsorbent polymer technology. CytoSorb™ has received CE Mark regulatory approval in the European Union (E.U.) and is commercially available for sale throughout the E.U. The BetaSorb™ has not been approved for CE Mark and is not the current focus of our near term commercialization plans. The HemoDefend technology platform is a development-stage blood purification system that targets blood transfusions, and has not yet received regulatory approval. CytoSorb™ and BetaSorb™ 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 hemocompatible, highly porous, adsorbent polymer beads that are intended to remove toxins and other substances from blood and physiologic fluids. 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, recirculating system. As blood passes over the polymer beads in the cartridge, toxins (cytokines) are adsorbed from the blood.

Previous studies using our BetaSorb™ device in patients with chronic kidney failure have provided valuable data, which we used 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 additional necessary regulatory body approvals to sell CytoSorb™ in markets outside of Europe. Even if we ultimately obtain additional regulatory approvals, because we cannot control the timing of responses to our regulatory submissions, there can be no assurance as to when such approvals will be obtained.

Our BetaSorb™ device is intended to remove beta-2 microglobulin from the blood of patients suffering from chronic kidney failure who rely on long term dialysis therapy to sustain their life. BetaSorb™ utilizes an adsorbent polymer packed into a similarly shaped and constructed cartridge as utilized for our CytoSorb™ product, although the polymers used in the two devices are physically different with one optimized for short-term critical care use and the other specifically designed for the needs of long-term chronic usage. 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.

We have conducted clinical studies using our BetaSorb™ device in patients with chronic kidney failure, which have provided valuable data that underpin the development of the critical care applications for our technology. The BetaSorb™ device has been used in a total of four 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.

HemoDefend is a development-stage blood purification technology platform designed to safeguard and protect the blood supply. The Company seeks to license the HemoDefend platform and has not yet received regulatory approval in any markets. HemoDefend consists of a mixture of proprietary porous polymer beads that target the removal of contaminants that can cause transfusion reactions or cause disease in patients receiving the tens of millions of transfused blood products administered worldwide each year. These contaminants include, for example, foreign antibodies, antigens, prions, cytokines, free hemoglobin, bioactive lipids, toxins, drugs, and other inflammatory mediators that either were from the donor or accumulated during blood storage. The goal of the HemoDefend technology is to reduce transfusion reactions, to keep new blood fresh, and to prevent or reduce the transmission of certain infectious agents.

The HemoDefend beads are intended to be used in multiple configurations, including the common in-line filter between the blood bag and the patient as well as a patent-pending "Beads in a Bag" treatment configuration, where the beads are placed directly into a blood storage bag. Once blood is put into this bag, the beads begin to automatically remove contaminants from the blood, and are designed to continue purifying blood throughout the entire blood storage period. The use of neutrally buoyant beads eliminates the need for mixing and is compatible with current blood storage conditions. Integrated filters in the bag prevent beads from leaving the bag during the transfusion process. The base polymer meets ISO 10993 standards for biocompatibility, hemocompatibility, genotoxicity, cytotoxicity, acute sensitivity and complement activation and can therefore directly contact blood for extended periods of time. In addition, the beads are inert and stable at a wide range of temperatures, and do not contain any antibodies, biologics, ligands, or drugs. Because of this, the beads have a very long shelf life that is consistent with blood storage bag manufacturing standards. No special equipment or handling is required, making it well-suited for mainstream and military applications, as well as for use in less developed countries that are not well-equipped to test and process blood products.

CytoSorbents is currently conducting a controlled market release of its approved CytoSorb™ device in limited territories in Germany and has had early product sales of approximately $36,000 in the fourth quarter of the fiscal year ended December 31, 2011. We do not anticipate significant revenues until we formally initiate a full sales launch of the CytoSorb™ device, which is intended to begin in the second quarter of 2012. 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 additional clinical studies, obtain additional regulatory approvals, and to support the commercialization plans for our products. No assurance can be given that we will ever successfully commercialize any products.

Corporate History

CytoSorbents 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 (the "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. In May 2010 we changed the name of our parent company to CytoSorbents Corporation. 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.

CytoSorbents was originally organized as a Delaware limited liability company in August 1997 as Advanced Renal Technologies, LLC. The Company 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.

CytoSorbents 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.

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 for the June 30, 2006 purchasers 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

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. We filed a registration statement under the Securities Act covering the Common Stock issuable upon conversion of the Series B Preferred Stock on December 12, 2008. We received initial comments from the Securities and Exchange Commission related to this filing on January 7, 2009 and received additional comments from the SEC on July 15, 2009. In May 2010 the Company filed to withdraw this registration statement. The company intends to amend and refile the registration statement.

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. The Company is currently not required to redeem any 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, the Company'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 $2,900,000 and $1,757,000 for the years ended December 31, 2011 and 2010, respectively. From our inception date January 22, 1997, through to December 31, 2011 the Company's research and development costs totaled approximately $50,900,000.

Technology, Products and Applications

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

Our polymer adsorbent technology can remove drugs, bioactive lipids, inflammatory mediators such as cytokines, free hemoglobin, toxins, and immunoglobulins from blood and physiologic fluids depending on the polymer construct. We believe that our technology may have many applications in the treatment of common, chronic and acute healthcare conditions including the adjunctive treatment and/or prevention of sepsis; the treatment of other critical care illnesses such as severe burn injury, trauma, acute respiratory distress syndrome and pancreatitis, the treatment of chronic kidney 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 inflammatory mediators and 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 are compatible with standard blood pumps or hemodialysis machines used commonly in hospitals and will therefore not require 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.

The polymer beads designed for the HemoDefend platform are intended to be used in multiple configurations, including the common in-line filter between the blood bag and the patient, as well as a patent-pending "Beads in a Bag" configuration, where the beads are placed directly into a blood storage bag.

Markets

CytoSorbents is a critical care focused medical device company. Critical care medicine includes the treatment of patients with serious or life-threatening conditions who require comprehensive care in the intensive care unit (ICU), with highly-skilled physicians and nurses and advanced technologies to support critical organ function to keep patients alive. Examples of such conditions include severe sepsis and septic shock, severe burn injury, trauma, acute respiratory distress syndrome and severe acute pancreatitis. In the U.S., an estimated $82 billion or 0.7% of the U.S. gross domestic product (GDP) is spent annually on critical care medicine. In most larger hospitals, critical care treatment accounts for up to 20% of a hospital's overall budget and often results in financial losses for the hospital.

In many critical care illnesses, the mortality is often higher than 30%. A major cause of death is multiple organ failure, where vital organs such as the lungs, kidneys, heart and liver are damaged and no longer function properly. Such patients are kept alive with supportive care therapy, such as mechanical ventilation, dialysis and vasopressor treatment, that is designed to keep the patient from dying while using careful patient management to tip the balance towards gradual recovery over time. Unfortunately, many supportive care therapies are only useful in supporting organ function and not designed to address the root cause of why multiple organ failure initially developed, which is typically multi-factorial. Because of this, the treatment course is often poorly defined and highly variable, leading to a higher risk of adverse outcomes from hospital acquired infections, medical errors, and other factors, as well as exorbitant costs. There is an urgent need for more effective "active" therapies that can help to reverse or prevent organ failure. CytoSorbents' main product, CytoSorb™ is a unique cytokine filter designed to try to address this void, by attempting to address the substantial role that an aberrant immune response and "cytokine storm" plays in the

development of organ dysfunction.

Sepsis

Sepsis is characterized by a systemic inflammatory response in response to severe infection. It is commonly seen in the intensive care unit, accounting for approximately 10-20% of all ICU admissions. However, there are currently no approved products that are available to treat sepsis in the U.S. or E.U. Each year, there are more than one million and 1.5 million new cases of severe sepsis or septic shock in the United States and Europe, respectively. Based on the reported incidence of sepsis in a number of developed countries, the worldwide incidence is estimated to be 18 million cases per year. According to the U.S. Centers of Disease Control and Prevention (CDC), the incidence of serious infection and sepsis has doubled in the U.S. in the past 10 years. The main driver of sepsis incidence is the aging demographic, specifically patients who are older than age 65 who are more prone to infection and now account for two-thirds of patients hospitalized for sepsis and the majority of sepsis deaths. Other factors contributing to the increase in sepsis incidence include the spread of antibiotic resistant bacteria like methicillin-resistant Staphylococcus aureus (MRSA), an increase in co-morbid conditions like HIV, cancer and diabetes that increases the risk of infection, an increasing use of implantable devices like artificial hips and knees that are prone to colonization by bacteria, and the appearance of new highly virulent or contagious strains of common pathogens such as H1N1 influenza.

There are generally three categories of sepsis, including mild to moderate sepsis, severe sepsis and septic shock. Mild to moderate sepsis typically occurs with an infection that is responsive to antibiotics or antiviral medication. An example is a patient with self-limiting influenza or a treatable community acquired pneumonia. Mortality is generally very low. Severe sepsis is sepsis with evidence of organ dysfunction. An example is a patient who develops respiratory failure due to a severe pneumonia and requires mechanical ventilation in the intensive care unit. Severe sepsis has a mortality rate of approximately 30-35%. Septic shock, or severe sepsis with low blood pressure that is not responsive to fluid resuscitation, is the most serious form of sepsis with an expected mortality in excess of 50%.

In sepsis, there are two major problems: the infection and the body's immune response to the infection. Antibiotics are main therapy used to treat the triggering infection, and although antibiotic resistance is growing, the infection is often eventually controlled. However, it is the body's immune response to this infection that frequently leads to the most devastating damage. The body's immune system normally produces large amounts of inflammatory mediators called cytokines to help stimulate and regulate the immune response during an infection. In severe infection, however, many people suffer from a massive, unregulated overproduction of cytokines, often termed "cytokine storm" that can kill cells and damage organs, leading to multi-organ failure and in many cases death. Until recently, there have been no available therapies in the U.S. or E.U. that can control the aberrant immune response and cytokine storm. Our CytoSorb™ device is a clinically-proven broad-spectrum cytokine filter and is currently approved for sale in the E.U. It is intended to play a critical role in treating patients with elevated levels of cytokines such as in severe sepsis or septic shock by reducing cytokine storm, while antibiotics work to control the actual infection. CytoSorb™ has demonstrated the ability to safely control cytokine storm in its recently completed randomized, controlled European Sepsis Trial in patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis.

The Company estimates that the market potential in Europe for its products is substantially equivalent to that in the U.S. In Germany alone, according to the German Sepsis Society (GSS), there are approximately 154,000 cases of sepsis each year. Patients are treated in the intensive care unit for 12-18 days on average and for a total of 20-25 days in the hospital. Germany is the largest medical device market in Europe and the third largest in the world.

Severe sepsis and septic shock patients are amongst the most expensive patients to treat in a hospital. Because of this, we believe that cost savings to hospitals and/or clinical efficacy, rather than the cost of treatment itself, will be the determining factor in the adoption of CytoSorb™ in the treatment of sepsis. Based on the limited number of available treatments for this disease, and based on current pricing of charcoal hemoperfusion devices in the market today, we estimate that our CytoSorb™ device will sell for at least $500 per unit. Our current pricing model represents a fraction of what is currently spent on the treatment of a sepsis patient.

In January 2012, CytoSorbents was notified by the DARPA (Defense Advanced Research Projects Agency) that its cytokine and toxin removal technology has been selected for funding for its "Dialysis-like Therapeutics" program for the extracorporeal treatment of sepsis, pending successful contract negotiations.

Acute Respiratory Distress Syndrome

Acute lung injury (ALI) and acute respiratory distress syndrome (ARDS) are two of the most serious conditions on the continuum of respiratory failure when both lungs are compromised by inflammation and fluid infiltration, severely compromising the lung's ability to both oxygenate the blood and rid the blood of carbon dioxide produced by the body. There are an estimated 165,000 cases of acute respiratory distress syndrome in the U.S. each year, with more cases in the E.U. Patients with ALI and ARDS typically require mechanical ventilation, and sometimes extracorporeal membrane oxygenation therapy, to help achieve adequate oxygenation of the blood. Patients on

mechanical ventilation are at high risk of ongoing ventilator-induced lung injury and ventilator-acquired pneumonias and other hospital acquired infections, and outcome is significantly dependent on the presence of other organ dysfunction as well as co-morbid conditions such as pre-existing lung disease (eg. emphysema or chronic obstructive pulmonary disease) and age. Because of this, mortality is typically greater than 30%, even with modern medicine and ventilation techniques. ALI and ARDS can be precipitated by a number of conditions including pneumonia and other infections, burn and smoke inhalation injury, aspiration, reperfusion injury and shock. Cytokine injury plays a major role in the vascular compromise and cell-mediated damage to the lung. Reduction of cytokine levels may either prevent or mitigate lung injury, enabling patients to wean from mechanical ventilation faster, potentially reducing numerous sequelae such as infection, pneumothoraces, and respiratory muscle deconditioning, and allow faster intensive care unit discharge, thereby potentially saving costs. CytoSorb™ treatment of patients with either ALI or ARDS in the setting of sepsis was the subject of our European Sepsis Trial.

Severe Burn Injury

In the U.S., there are approximately 2.4 million burn injuries per year, with 650,000 treated by medical professionals and approximately 75,000 requiring hospitalization. Aggressive modern management of burn injury, including debridement, skin grafts, anti-microbial dressings and mechanical ventilation for smoke and chemical inhalation injury, has led to significant improvements in survival of burn injury to approximately 95% on average in leading burns centers. However, there remains a need for better therapies to reduce the mortality in those patients with large burns and inhalation injury as well as to reduce complications of burn injury and hospital length of stay for all patients. According to National Burn Repository Data, the average hospital stay for burn patients is directly correlated with the percent total body surface area (TBSA) burned. Every 1% increase of TBSA burned equates to approximately 1 additional day in the hospital. A single patient with more than 30% TBSA burned who survives, is hospitalized for an average of 30 days and costs approximately $200,000 to treat. Major causes of death following severe burn and smoke inhalation injury are multi-organ failure (hemodynamic shock, respiratory failure, acute renal failure) and sepsis, particularly in patients with greater than 30% TBSA burns. Specifically, burns and inhalation injury lead to severe systemic and localized lung inflammation, loss of fluid, and cytokine overproduction. This “cytokine storm” causes numerous problems, including: hypovolemic shock and inadequate oxygen and blood flow to critical organs, acute respiratory distress syndrome preventing adequate oxygenation of blood, capillary leakage resulting in tissue edema and intravascular depletion, hypermetabolism leading to massive protein degradation and catabolism and yielding increased risk of infection, impaired healing, severe weakness and delayed recovery, immune dysfunction causing a higher risk of secondary infections (wound infections, pneumonia) and sepsis, and direct apoptosis and cell-mediated killing of cells, leading to organ damage. Up to a third of severe hospitalized burn patients develop multi-organ failure and sepsis that can often lead to complicated, extended hospital courses, or death. Broad reduction of cytokine storm has not been previously feasible and represents a novel approach to limiting or reversing organ failure, potentially enabling more rapid mechanical ventilation weaning, prevention of shock, reversal of the hypermetabolic state encouraging faster healing and patient recovery, reducing hospital costs, and potentially improving survival.

Trauma

According to the National Center for Health Statistics, in the U.S., there are more than 31 million visits to hospital emergency rooms, with 1.9 million hospitalizations, and 167,000 deaths every year due to injury. The leading causes of injury are trauma from motor vehicle accidents, being struck by an object or other person, and falls. Trauma is a well-known trigger of the immune response and a surge of cytokine production or cytokine storm. In trauma, cytokine storm contributes to a systemic inflammatory response syndrome (SIRS) and a cascade of events that cause cell death, organ damage, organ failure and often death. Cytokine storm exacerbates physical trauma in many ways. For instance, trauma can cause hypovolemic shock due to blood loss, while cytokine storm causes capillary leak and intravascular volume loss, and triggers nitric oxide production that causes cardiac depression and peripheral dilation. Shock can lead to a lack of oxygenated blood flow to vital organs, causing organ injury. Severe systemic inflammation and cytokine storm can lead to acute lung injury and acute respiratory distress syndrome as is often seen in ischemia and reperfusion injury following severe bleeding injuries. Penetrating wound injury from bullets, shrapnel and knives, can lead to infection and sepsis, another significant cause of organ failure in trauma. Complicating matters is the breakdown of damaged skeletal muscle, or rhabdomyolysis, from blunt trauma that can lead to a

massive release of myoglobin into the blood that can crystallize in the kidneys, leading to acute kidney injury and renal failure. Renal failure in trauma is associated with a significant increase in expected mortality. Cytokine reduction by CytoSorb™ and related technologies may have benefit in trauma, potentially improving clinical outcome. In December 2011, CytoSorbents was awarded a Phase I SBIR (Small Business Innovation Research) grant from the U.S. Army Medical Research and Materiel Command to develop its technology for the treatment of trauma and rhabdomyolysis.

Severe Acute Pancreatitis

Acute pancreatitis is the inflammation of the pancreas that results in the local release of digestive enzymes and chemicals that cause severe inflammation, necrosis and hemorrhage of the pancreas and local tissues. Approximately 210,000 people in the U.S. are hospitalized each year with acute pancreatitis with roughly 20% requiring ICU care. Overall ICU mortality approaches 10%. It is caused most frequently by a blockage of the pancreatic duct or biliary duct with gallstones, cancer, or from excessive alcohol use. Severe acute pancreatitis is characterized by severe pain, inflammation, and edema in the abdominal cavity, as well as progressive systemic inflammation that can lead to multiple organ failure. High levels of cytokines and digestive enzymes can be found in the blood and are correlated to organ dysfunction. CytoSorb™ may potentially benefit overall outcomes in episodes of acute pancreatitis by removing a diverse set of toxins from blood.

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 high amounts 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.

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. Cytokine storm is common in these organ donors, resulting in reduced viability of potential donor organs. The potential use of CytoSorb™ hemoperfusion to control cytokine storm in brain dead organ donors could increase the number of viable organs harvested from the donor pool and improve the survival of transplanted organs. A proof-of-concept pilot study using the Company's technology in human brain dead donors has been published.

Blood Transfusions

The HemoDefend platform is designed to be a practical, low cost, and effective way to safeguard the quality and safety of the blood supply. In the United States alone, 15 million packed red blood cell (pRBC) transfusions and another 15 million transfusions of other blood products (e.g. platelet, plasma, and cryoprecipitate) are administered each year with an average of 10% of all US hospital admissions requiring a blood transfusion. The sheer volume of transfusions, not just in the US, but worldwide, complicates an already difficult task of maintaining a safe and reliable blood supply. Trauma, invasive operative procedures, critical care illnesses, supportive care in cancer, military usage, and inherited blood disorders are just some of the drivers of the use of transfused blood. In war, hemorrhage from trauma is a leading cause of preventable death, accounting for an estimated 30-40% of all fatalities. For example, in Operation Iraqi Freedom, due to a high rate of penetrating wound injuries, up to 8% of admissions required massive transfusions, defined as 10 units of blood or more in the first 24 hours. There is a clear need for a stable and safe source of blood products. However, blood shortages are common and exacerbated by the finite lifespan of blood. According to the Red Cross, packed red blood cell (pRBC) units have a refrigerated life span of 42 days. However, many medical experts believe there is an increased risk of infection and transfusion reactions once stored blood ages beyond two weeks. Transfusion-related acute lung injury (TRALI) is the leading cause of non-hemolytic transfusion-related morbidity and mortality, with an incidence of 1 in 2,000-5,000 transfusions and a mortality rate of up to 10%. Fatal cases of TRALI have been most closely related to anti-HLA or anti-granulocyte antibodies found in a donor's transfused blood. Other early transfusion reactions such as transfusion-associated dyspnea, fever and allergic reactions occur in 3-5% of all transfusions and can vary in severity depending on the patient's condition. These are caused by cytokines, bioactive lipids, free hemoglobin, toxins, foreign antigens, certain drugs, and a number of other inflammatory mediators that accumulate in transfused blood products during storage. Leukoreduction can remove the majority of white cells that can produce new cytokines but cannot eliminate those cytokines already in blood, and cannot otherwise remove other causative agents. Automated washing of pRBC is effective but is impractical due to the time, cost, and logistics of washing each unit of blood. The HemoDefend platform is a potentially superior alternative to these methods.

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.

One of the problems with standard high-flux dialysis is the limited ability to remove certain mid-molecular weight toxins such as b_2-microglobulin. Over time, b_2-microglobulin can accumulate and cause amyloidosis in joints and elsewhere in the musculoskeletal system, leading to pain and disability.

Our BetaSorb™ device has been designed to remove these mid-molecular weight toxins when used in conjunction with standard dialysis. Standard dialysis care typically involves three sessions per week, averaging approximately 150 sessions per year.

Products

The polymer adsorbent technology used in our products can 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 adjunctive treatment and/or prevention of other critical care conditions such as acute respiratory distress syndrome, burn injury, trauma and pancreatitis; and the prevention of damage to organs donated by brain-dead donors prior to organ harvest; the prevention of post-operative complications of cardiopulmonary bypass surgery; and the treatment of chronic kidney failure) 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. In 2011 we completed our European Sepsis Trial of our CytoSorb™ device. The study was a randomized, open label, controlled clinical study in fourteen (14) sites in Germany of one hundred (100) patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis. The Sepsis Trial has successfully demonstrated CytoSorb™'s ability to reduce circulating levels of cytokines from whole blood in treated patients, and that treatment was safe in these patients. The Company completed the CytoSorb™ technical file review with our Notified Body and CytoSorb™ subsequently received European Union regulatory approval under the CE Mark as an extracorporeal cytokine filter indicated for use in any clinical situation where cytokines are elevated. Given sufficient and timely financial resources, we intend to commercialize in Europe and conduct additional clinical studies of our products. However, there can be no assurance that we will ever obtain regulatory approval for any other device, or that the CytoSorb™ device will be able to generate significant, or any, sales.

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 improved clinical outcome, and 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 infection

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 biologic, Xigris® from Eli Lilly, to our knowledge, no other products have been approved in either the U.S. or Europe for the treatment of sepsis. In 2011 after completing a follow up study required by the FDA, it was subsequently determined that Xigris® does not have a statistically significant mortality benefit, and Eli Lilly has withdrawn Xigris® from all markets worldwide.

Many medical professionals believe that blood purification for the treatment of sepsis holds tremendous promise. Studies using dialysis and hemofiltration technology have been encouraging, but have only had 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 such as cytokines 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 , which includes testing for hemocompatibility, biocompatibility, cytotoxicity, genotoxicity, acute sensitivity and complement activation. Data collected during the "emergency and compassionate use" treatment of a single sepsis patient, as well as a human sepsis pilot study, have 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 causing damage to the immune system. 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 four human pilot studies, involving 20 patients, in the U.S. and Europe. The studies included approximately 350 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 have completed our European Sepsis clinical trial of our CytoSorb™ device, which enrolled one hundred (100) patients with the participation of fourteen hospital units. The Sepsis Trial has successfully demonstrated CytoSorb™'s ability to reduce circulating levels of cytokines from whole blood in treated patients. The treatment was well-tolerated with no serious device related adverse events reported to date in more than 300 treatments.

In March 2011 the Company successfully completed its technical file review with its Notified Body, and CytoSorb™ subsequently received European Union regulatory approval under the CE Mark as an extracorporeal cytokine filter. CytoSorbents has also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the European Union.

The Company is currently manufacturing its CytoSorb™ device for a controlled-market release in the European Union. Concurrent with its commercialization plans, the Company is exploring the potential to treat additional patients in Europe to gather additional clinical data to expand the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. As we analyze clinical data from the current trial and prepare to market CytoSorb™ for clinical use, we plan to conduct additional clinical studies in sepsis and other critical care diseases. Assuming availability of adequate and timely funding, and continued positive results from our clinical studies the Company intends to continue its commercialization plans of its product in Europe.

APPLICATION: Adjunctive Therapy in Other Critical Care Applications

Potential Benefits: Cytokine-mediated organ damage and immune suppression can increase the risk of death and infection in patients with commonly seen critical care illnesses such as acute respiratory distress syndrome, severe burn injury, trauma and pancreatitis. If CytoSorb™ is useful as a cytokine filter and as an immunomodulator, cytokine reduction, both pro-inflammatory and anti-inflammatory, has the potential to:

- prevent or mitigate Multiple Organ Dysfunction Syndrome (MODS) and/or Multiple Organ Failure (MOF)
- prevent or reduce secondary infections
- reduce the need for expensive life-sparing supportive care therapies such as mechanical ventilation
- reduce the need for ICU care, freeing expensive critical care resources, and reducing hospital costs and costs to the healthcare system

Background and Rationale: A shared feature of many life-threatening conditions seen in the ICU is severe inflammation (either sepsis or systemic inflammatory response syndrome) due to an over-reactive immune system and high levels of cytokines that can cause or contribute to organ dysfunction, organ failure and patient death. Examples of such conditions include severe burn injury, trauma, acute respiratory distress syndrome and severe acute pancreatitis. MODS and MOF are common causes of death in these illnesses and mortality is directly correlated with the number of organs involved. There are currently few active therapies to prevent or treat MODS or MOF. If CytoSorb™ can reduce direct or indirect cytokine injury of organs, it may mitigate MODS or MOF, improve overall patient outcome and reduce costs of treatment. In addition, secondary infection, such as ventilator-acquired pneumonia, urinary tract infections, or catheter-related line infections, are another major cause of morbidity and mortality in all patients treated in the ICU. Prolonged illness, malnutrition, age, multiple interventional procedures, and exposure to antibiotic resistant pathogens are just some of the many risk factors for functional immune suppression and infection. In sepsis and SIRS, the overexpression of pro-inflammatory cytokines can also cause a depletion of immune effector cells through apoptosis and other means, and anti-inflammatory cytokines can cause profound immune suppression, both major risk factors for infection.

Projected Timeline: With our CE Mark approval in the E.U. for CytoSorb™ as a cytokine filter, we anticipate additional usage in Europe of the device in critical care applications such as acute respiratory distress syndrome, severe burn injury, trauma and pancreatitis, where cytokine storm, sepsis and/or systemic inflammatory response syndrome (SIRS) plays a prominent role in disease pathology. Our goal is to stimulate investigator-initiated clinical studies with our device for these applications. We have been moving forward in parallel with a program to further understand the potential benefit of CytoSorb™ hemoperfusion in these conditions through additional investigational animal studies and potential human pilot studies in the U.S. funded either directly by the company, through grants, or through third-parties. Commencement of these formal studies is contingent upon adequate funding and, in the case of U.S. human studies, FDA investigational device exemption (IDE) approval of the respective human trial protocols. We have not yet commenced such activity with the FDA.

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™ may 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 systemic inflammatory response syndrome and 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, would 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. Although the company is focused primarily on sepsis and other critical care applications of CytoSorb™, with sufficient additional resources, we plan to pursue this application either directly or through a potential strategic partner.

The HemoDefend Blood Purification Technology Platform (Acute and Critical Care)

APPLICATION: Reduction of contaminants in the blood supply that can cause transfusion reactions or disease when administering blood and blood products to patients.

Potential Benefits: The HemoDefend blood purification technology platform is designed to reduce contaminants in the blood supply that can cause transfusion reactions or disease. It is a development stage technology that is not yet approved in any markets, but is comprised of CytoSorbents' highly advanced, biocompatible, polymer bead technology. If this technology is successfully developed and then incorporated into a regulatory approved product, it could have a number of important benefits.

- reduce the risk of transfusion reactions and improve patient outcome
- improve the quality, or extend the shelf life of stored blood products
- improve the availability of blood and reduce blood shortages by reducing the limitations of donors to donate blood
- allow easier processing of blood

Background and Rationale: The HemoDefend technology platform was built upon our successes in designing and manufacturing porous polymer beads that can remove cytokines. We have expanded the technology to be able to remove substances as small as drugs and bioactive lipids, to proteins as large as antibodies from blood that can cause transfusion reactions and disease. Although the frequency of these reactions are relatively low (~3-5%), the sheer number of blood transfusions is so large, that the number of transfusion reactions, ranging from mild to life-threatening, is substantial, ranging from several hundreds of thousands to more than a million reactions each year in the U.S. alone. In critically-ill patients the risk of transfusion reactions is significantly higher than in the general population and can increase the risk of death because their underlying illnesses have depleted protective mechanisms and have primed their bodies to respond more vigorously to transfusion-associated insults.

A number of retrospective studies have also suggested that administration of older blood leads to increased adverse events and even increased mortality, compared with blood recently harvested. Biological studies have demonstrated the accumulation of erythrocyte storage lesions that compromise the function and structural integrity of packed red blood cells and have also demonstrated the accumulation of substances during blood storage that can lead to transfusion reactions. There are currently two ongoing adult, prospective, randomized, controlled studies, RECESS and ABLE, looking at morbidity and mortality in cardiovascular surgery patients and critically ill patients, respectively, treated with either "new" or "older" blood. The outcome of these studies should not alter the current pressing need for better solutions to reduce transfusion-related adverse events and to improve clinical outcome. However, should they demonstrate that older blood has increased risk, it could result in an increased need for new technologies such as the HemoDefend platform.

Projected Timeline: The HemoDefend platform is based on our advanced polymer technology. The base polymer is ISO 10993 biocompatible, meeting standards for biocompatibility, hemocompatibility, cytotoxicity, genotoxicity, acute sensitivity and complement activation. HemoDefend has demonstrated the *in vitro* removal of many different substances from blood such as antibodies, free hemoglobin, cytokines and bioactive lipids. We have also prototyped a number of different implementations of the HemoDefend technology, including the "Beads in a Bag" blood treatment blood storage bag, and standard in-line blood filters. The Company seeks to out-license this technology to a strategic partner in the transfusion medicine space, but may elect to continue its development in parallel with out-licensing efforts.

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;
- reduce disability and 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 four human 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, beta-2 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 CytoSorbents 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 applications. Following commercial introduction of the CytoSorb™ device, and with sufficient additional resources, we plan to continue development of the BetaSorb™ resin and may 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 “Sub Award 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, which lasted for a total of five years, commenced in September 2005. Under a SubAward Agreement, we worked with researchers at the University of Pittsburgh - Critical Care Medicine Department. We believe that the only polymers used in this study were 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 our efforts in support of the grant during 2006 through 2010, we received approximately

$402,000. The Company has recorded these proceeds as a reduction of research and development expenses during each of the years that we participated in the grant.

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**,** has authored more than 300 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 2,700 dialysis clinics in North America, Europe, Latin America, Asia-Pacific, and Africa, Fresenius Medical Care provides dialysis treatment to more than 215,000 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 five 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 at the time, to make a $4 million investment in the Company, we granted Ms. Montiel a perpetual royalty equal to three percent of all gross revenues received by us from sales of CytoSorb™ 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 the Company, 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. For the year ended December 31, 2011 the Company has accrued royalty costs of $1,082.

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. For the year ended December 31, 2011 per the terms of the license agreement the Company has recorded royalty costs of $731.

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 life-threatening illnesses is country dependent in Europe. We are initially marketing the device in Germany where a path for separate CytoSorb™ reimbursement has been established. Reimbursement can also be covered by the standard "diagnosis related group" (DRG) acute care reimbursement. Under this system, hospitals would purchase CytoSorb™ and subtract the cost from a

pre-determined lump-sum payment made by the payor to the hospital based on the patient's diagnosis. 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 other four economic leaders in Europe and introduce our products in those countries accordingly. Reimbursement is specific to each country. There can be no assurances that reimbursement will be granted or that additional clinical data may not be required to establish reimbursement.

United States

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

Critical care applications such as those targeted by our 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 treatments, 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, through a bundled payment for dialysis. The large majority of costs not covered by federal programs are covered by the private insurance sector.

Dialysis reimbursement for end-stage renal disease patients in the U.S. in 2011 was covered by a dialysis “bundle payment” where the costs of dialysis treatments, medications, labs and supplies were paid to the dialysis clinics by Medicare. In 2014, other medications such as phosphate binders and calcium supplements will also be covered in this bundle. Coverage by this bundle will be required to obtain reimbursement for all new dialysis therapies and represents a potential challenge for BetaSorb™, if or when the treatment becomes approved and available. If BetaSorb™ can demonstrate the reduction of overall costs of treatment, it will have a higher chance of inclusion into the bundle.

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, acute respiratory distress syndrome, trauma, severe burn injury, pancreatitis, 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 have demonstrated the statistically significant reduction of a number of key cytokines by CytoSorb™ on the order of 30-50% in human patients with predominantly septic shock and acute respiratory distress syndrome. In a post-hoc subgroup analysis of our European Sepsis Trial, we have also demonstrated statistically significant improvements in mortality in patients at high risk of death, including patients with either very high cytokine levels or patients older than age 65, both of which have a high predicted mortality.

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 removing any fluids from the blood or the need for replacement fluid or dialysate.

There are three common forms of blood purification, including hemodialysis, hemofiltration, and hemoperfusion. All modes are generally supported by standard hemodialysis machines. All take blood out of the body to remove toxins and unwanted substances from blood, and utilize extracorporeal circuits and blood pumps. Dialysis and hemofiltration remove substances from blood by diffusion and ultrafiltration, respectively, through a semi-permeable membrane, allowing the passage of certain sized molecules across the membrane, but preventing the passage of other, larger molecules. Hemoperfusion utilizes solid or porous sorbents to remove things based on surface adsorption, not filtration.

CytoSorb™ is a hemoperfusion cartridge, using an adsorbent of specified pore size, which controls the size of the molecules which can pass into the adsorbent and vastly increases the area available for surface adsorption.. 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 hemodialysis or hemofiltration. Accordingly, we believe that our technology has significant advantages as compared to traditional dialysis techniques.

CytoSorbents' HemoDefend platform is a development-stage technology utilizing a mixture of proprietary porous polymer beads that target the removal of contaminants that can cause transfusion reactions or cause disease in patients receiving transfused blood products. The HemoDefend beads can be used in multiple configurations, including the common in-line filter between the blood bag and the patient as well as a unique, patent-pending "Beads in a Bag" treatment configuration, where the beads are placed directly into a blood storage bag.

Sepsis

Researchers have explored the potential of using existing membrane-based dialysis technologies 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. CytoSorb™ has demonstrated the ability to remove middle molecular weight toxins, such as cytokines, from circulating blood in a statistically significant manner.

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 an average absolute 6% reduction in 28-day mortality, and an absolute 13% reduction in 28-day mortality in the most severe sepsis patients. The drug remains controversial and is considered expensive when compared to the percentage of patients who benefit. In 2011 after completing a

follow up study required by the FDA, it was subsequently determined that Xigris® does not have a statistically significant mortality benefit, and in October 2011, Eli Lilly withdrew Xigris® from all markets worldwide.

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 and biologic candidates from Eisai Co., Ltd, AM-Pharma B.V., Agennix AG and BTG plc. In February 2012, Agennix announced a halt to its Phase 2/3 OASIS sepsis trial due to increased mortality in treatment arm. The study is being un-blinded to further analyze the cause of this increased mortality. In January 2011, Eisai announced that its 2,000 patient pivotal Phase III ACCESS trial using Eritoran to treat patients with severe sepsis did not meet its primary endpoint of 28-day all-cause mortality, but will continue analyzing its clinical data and determine next steps. Eritoran is a toll-like receptor 4 (TLR-4) antagonist designed to prevent or reduce activation of the immune system by endotoxin.

Using a medical device to treat sepsis remains a relatively novel treatment approach. Toray Industries currently markets an endotoxin removal cartridge called Toraymyxin™ for the treatment of sepsis in Europe, Japan, and 16 other countries, but is not yet approved in the United States. To date, it has been used to treat more than 80,000 patients since 1994. Toraymyxin does not directly reduce cytokines. Spectral Diagnostics, Inc has obtained exclusive development and commercial rights in the U.S. for Toraymyxin, with plans to combine the use of its endotoxin activity assay to create a theranostic product. In June 2010, Spectral began enrollment of its targeted 360 patient, 30-site randomized, controlled U.S.Phase III trial (EUPHRATES) to diagnose endotoxemia and then treat sepsis with Toraymyxin. The endpoint of the trial is 28-day all-cause mortality and interim data is expected at the end of 2012. To date, all anti-endotoxin strategies have failed in large scale randomized controlled sepsis trials. Toray also markets its Hemofeel CH1.0 polymethylmethacrylate membrane (PMMA) in Japan and it has been used in several non-controlled, or historically controlled, clinical or case studies treating patients with sepsis, acute respiratory distress syndrome and pancreatitis. We are not aware of any prospective, randomized controlled studies using this PMMA hemofilter in patients with sepsis. Without such studies, it is difficult to assess the true impact of this technology in these conditions. Gambro AB launched its Prismaflex eXeed system in August 2009 and introduced the SepteX high molecular weight cutoff hemodialyzer in Europe, intended to treat patients with acute renal failure and the removal of inflammatory mediators from blood. It is not specifically approved for the treatment of sepsis. Fresenius has launched a similar high molecular weight cut off filter called the Ultraflux EMiC2. To our knowledge, there has been a lack of published data on the treatment of sepsis with these devices. Bellco S.R.L. also sells the CPFA (coupled plasma filtration and adsorption) system in Europe. This uses a sorbent cartridge to remove cytokines from plasma. However, because the sorbent cannot treat blood directly, it requires the cost and complexity of an additional plasma separator to treat blood. Kaneka Corporation currently markets Lixelle™, a modified porous cellulosic bead, for the removal of $beta_2$–microglobulin during hemodialysis in Japan. Lixelle has been used in several small human pilot studies including a 5 patient pilot study in 2002 and a 4 patient pilot study in 2009. Though these studies correlate Lixelle use with cytokine reduction, they are not randomized, controlled studies and so do not control for natural cytokine clearance. To our knowledge, no large, randomized, controlled trials have been conducted with Lixelle as a treatment for sepsis. Kaneka has since developed a modified cellulosic resin called CTR that can also remove cytokines from experimental pre-clinical systems. In 2009, CTR was used in an 18-patient randomized, controlled trial in patients with septic shock with undisclosed improvements in APACHE II scores and IL-6 and IL-8. To our knowledge, Kaneka has not conducted or published any other study using CTR to treat human sepsis patients since then. 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. CytoPherx Inc., has developed an extracorporeal system based on selective cytopheresis, or the inactivation or removal of activated leukocytes. It is currently enrolling a 344 patient Phase 2 trial that began in August 2011 and is expected to be completed by December 2012. in patients with acute kidney injury with or without severe sepsis, on continuous renal replacement therapy with the goal of reducing mortality. This system does not remove cytokines directly, but attempts to reduce the numbers of activated white blood cells that can produce cytokines or cause cell-mediated injury. 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.

Acute Respiratory Distress Syndrome (ARDS)

Treatment of ARDS is predominantly supportive care using supplemental oxygen, careful fluid management and multiple modes of ventilation incorporating the concepts of low tidal volume, high frequency oscillation, and prone

ventilation. Corticosteroids, nitric oxide, and surfactant therapy have been tried, but are not indicated for the treatment of ARDS. We are not aware of any specific products approved to treat ARDS.

Severe Burn Injury

Modern management of severe burn injury patients involves a combination of therapies. From a burn standpoint, patients undergo active escharotomy and debridement of burns, the use of skin grafts and substitutes, anti-microbial dressings and negative pressure dressings. Tight fluid control, nutrition, prevention of hypothermia and infection are also priorities. Smoke and chemical inhalation injury in burn victims is also common and increasing as a cause of death in severe burn injury. Carbon monoxide and cyanide poisoning is also an issue. Supplemental oxygen and mechanical ventilation are often required and are the mainstay of supportive care treatment. Recently continuous renal replacement therapy has been used to treat patients with acute kidney injury with an improvement in survival compared to a historical control cohort. We believe CytoSorb™ therapy may yield improved results. We are not aware of any specific products approved to directly address inhalational lung injury or multiple organ failure in severe burn injury.

Trauma

Trauma management initially involves respiratory, hemodynamic and physical stabilization of the patient. However, in the days to weeks that ensue, the focus shifts to preventing or treating organ failure and preventing or treating infection. We are not aware of any specific therapies to prevent or treat multiple organ dysfunction or multiple organ failure in trauma. Rhabdomyolysis, or the breakdown of muscle fibers due to crush injury or other means, occurs in trauma and can lead to acute kidney injury or renal failure. Aggressive hydration, urine alkalinzation, and forced diuresis are the main therapies to prevent renal injury. Continuous hemodiafiltration with super-high-flux membranes has demonstrated modest myoglobin clearance but was associated with albumin loss. In general, however, most extracorporeal therapies are not well-suited to remove myoglobin. We have developed a polymer resin that removes myoglobin efficiently without major losses of albumin. The US Army Medical Research and Materiel Command has funded the development of our polymer resins to treat trauma and rhabdomyolysis under a Phase I SBIR grant awarded to CytoSorbents in December 2011.

Severe Acute Pancreatitis

Treatment of severe acute pancreatitis is predominantly supportive care focused on aggressive hydration, intravenous nutrition and pain control. Mechanical ventilation, hemodialysis and vasopressor use is common in cases of multiple organ failure. In cases where cholelithiasis or other obstruction is the underlying cause of the pancreatitis, endoscopic retrograde cholangiopancreatography and/or stent placement can be used to relieve the obstruction. Antibiotics are often instituted to prevent or treat infection. Surgery is sometimes indicated to remove or drain necrotic or infected portions of the pancreas. To our knowledge, there are no other specific treatments approved to treat severe acute pancreatitis or multiple organ failure that is caused by systemic inflammation in this disease.

Cardiopulmonary Bypass Surgery

There is currently a pre-existing market for the use of leukocyte reduction filters sold by Pall Corporation, Terumo Medical Corporation and others in the cardiopulmonary bypass circuit. The purpose of these devices is to reduce cytokine-producing white blood cells from blood. They do not remove cytokines directly and are not considered by many to be an effective solution for cytokine reduction. 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 and cytokine production still remain a problem in this less invasive, but more technically challenging 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 $beta_2$-microglobulin toxins from the blood of patients suffering from chronic kidney failure. High flux dialyzers by Gambro, Fresenius, Nephros and others are capable of removing some $beta_2$-microglobulin. However, we believe our technology would significantly improve clearance of this and other toxins. Kaneka markets Lixelle™ outside the US to remove $beta_2$-microglobulin in dialysis patients. 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 is less widely used. In addition, many larger toxins are not effectively filtered by hemodiafiltration, despite its more open pore structure. As a result, hemodiafiltration is expected to be less efficient in large toxin removal compared with 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.

HemoDefend Purification Technology Platform for Transfused Blood Products

There are only a few directly competitive approved products to address the removal of substances from blood and blood products that can cause transfusion reactions, Leukoreduction (Pall Corporation, Terumo-BCT, Hemerus Corporation, others) is widely used in transfusion medicine and can remove the majority of white cells that can produce new cytokines but cannot eliminate those cytokines already in blood, and cannot otherwise remove other causative agents. Automated washing of pRBC is very effective at cleansing contaminants from blood, but is impractical due to the time, cost, and logistics of washing each unit of blood and is not widely used. Blood filters that utilize affinity technologies are in development to remove antibodies from blood, The HemoDefend platform represents a potentially superior alternative to these methods, as it can provide comprehensive removal of a wide variety of contaminants that can trigger transfusion reactions without washing blood, requires no additional equipment, energy source, or manipulation, and can be incorporated directly into the blood storage bag or used as an in-line blood filter.

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 generally 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 the 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 received approval from the German Ethics Committee in July of 2007 to conduct a clinical study with enrollment of up to 80 patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis, with the goal of obtaining data from a total of 60 patients. After enrolling 22 patients in a sepsis pilot study, in April 2009, we requested the study be expanded to 100 patients to again enroll approximately 80 patients with a target of data from 60 patients. Additionally, we updated blood sampling and handling procedures to minimize non-device related artifacts that may potentially arise if the samples are not processed appropriately.

We have since completed our European Sepsis clinical trial of our CytoSorb™ device, which enrolled one hundred (100) patients with the participation of fourteen hospital units. The Sepsis Trial has successfully demonstrated CytoSorb™'s ability to reduce circulating levels of cytokines from whole blood in treated patients. The treatment was well-tolerated with no serious device related adverse events reported to date in more than 300 treatments.

In March 2011 the Company successfully completed its technical file review with its Notified Body, and has received approval to apply the CE Mark to the CytoSorb™ device as an extracorporeal cytokine filter indicated to be used broadly in any clinical situation where cytokines are elevated. CytoSorbents has also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the European Union.

The Company is currently manufacturing its CytoSorb™ device for a controlled-market release in the European Union. Concurrent with its commercialization plans, the Company is exploring the potential to treat additional patients in Europe to gather additional clinical data to expand the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. As we analyze clinical data from the current trial and prepare to market CytoSorb™ for clinical use, we plan to conduct additional clinical studies in sepsis and other critical care diseases. Assuming availability of adequate and timely funding, and continued positive results from our clinical studies the Company intends to continue its commercialization plans of its product in Europe.

The clinical protocol for our European Sepsis Trial was designed to allow us to gather information to support future U.S. studies. In the event we 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 510(k) or PMA registration. No assurance can be given that our CytoSorb™ product will work as intended in these studies or that we will be able to obtain FDA approval to sell CytoSorb™ in the United States. Even though we have obtained CE Mark approval, there is no guarantee or assurance that we will be successful in obtaining FDA approval in the United States or approval in any other country or jurisdiction.

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, which lasted for a total of five years, commenced in September 2005. Under a SubAward Agreement, we worked with researchers at the University of Pittsburgh - Critical Care Medicine Department. We believe that the only polymers used in this study were 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 our efforts in support of the grant during 2006 through 2010, we received approximately $402,000.

In October 2010 CytoSorbents was awarded a grant of approximately $489,000 from the federal Qualifying Therapeutic Discovery Project (QTDP) program for two products in its pipeline including the development of CytoSorb™ for the treatment of sepsis and other critical care illnesses. The Company received half of the grant in November 2010 and the second half in February 2011.

In December 2011 CytoSorbents was awarded a $100,000 Phase I SBIR (Small Business Innovation Research) grant by the US Army Medical Research and Materiel Command to evaluate our technology for Cytokine and Myoglobin removal in the treatment of trauma.

In addition our technology proposal submitted to the Defense Advanced Research Projects Agency (DARPA) has been selected for funding and we are in contract negotiations with DARPA on the scope of work and budget. This process may take several months and no assurance can be given that we will successfully conclude these negotiations.

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.

In March 2011 the Company successfully completed its technical file review with its Notified Body, and has received approval to apply the CE Mark to the CytoSorb™ device as an extracorporeal cytokine filter. CytoSorbents has also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the E.U.

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 most 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 that 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) 510(k) devices, but may require pre-market approval (PMA) by the FDA. In Europe, our devices are classified as Class IIb, and will need to conform to the Medical Devices Directive.

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 other medical devices will be approved on a timely basis, if at all, or that our CytoSorb™ device will be approved for CE Mark labeling in other potential medical applications or that it will be approved for cytokine filtration in markets not covered by the CE Mark on a timely basis, or 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 continue to perform as expected in clinical studies, that we will continue our commercialization plans in Europe. We have initiated a controlled market release of our product in certain key areas in Germany with the goal of raising awareness, attending critical care conferences, and to seek initial clinical usage of the device. A broader launch to eventually include all of Germany, England, Italy, France and Spain and other countries in the E.U. is planned to begin in the second quarter of 2012. We plan to sell our products in the E.U. with a mixed direct and independent distributor strategy, that can be augmented through strategic partnerships.

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 29 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.

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, 2011, we had eight full-time employees and utilize consultants and temporary hires who are not employees of the company as necessary. 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, 2011 we had cash on hand of $1,186,653 and current liabilities of $1,527,949. We will need additional financing in the future in order to complete additional clinical studies and to support 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 in other countries and/or for other indications;
- 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.

We may direct Lincoln Park Capital ("LPC") to purchase up to $8,500,000 worth of shares of our common stock under our agreement over a 32 month period generally in amounts of up to $50,000 every two business days, which amounts may be increased under certain circumstances. Assuming a purchase price of $0.135 per share (the closing sale price of the common stock on December 9, 2011) and the purchase by LPC of the full 38,000,000 purchase shares and along with issuance of 1,634,615 additional pro rata commitment shares registered under this offering, proceeds to us would be $5,130,000.

To the extent we rely on LPC as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from LPC were to prove unavailable or prohibitively dilutive and if we are unable to sell enough of our products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all $8,500,000 under the Purchase Agreement to LPC, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

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 are in the process of commercializing our products, but 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 generated limited 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, market adoption, 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 and for ongoing compliance for our CE Mark. We will also need to raise significant additional funds to complete additional clinical studies and obtain regulatory approvals in other countries before we can begin selling our products in markets not covered by the CE Mark. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any products, generate any significant 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, 2011, we had an accumulated deficit of $92,557,542, which included net losses of $5,481,648 for the year ended December 31, 2011 and $2,908,865 for the year ended December 31, 2010. 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 additional requisite regulatory approvals in markets not covered by the CE Mark and for potential label extensions of our current CE Mark, 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 our current CE Mark will enable us to achieve profitability, that additional regulatory approvals in other countries 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.

As of March 28, 2012 we currently have thirteen full-time employees and several full-time interim 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 with our approval to apply the CE Mark to our CytoSorb™ device as a cytokine filter, our products may not achieve market acceptance in the European countries that recognize and accept the CE Mark. Additional approvals from other regulatory authorities (such as the FDA) will be required before we can market our device in countries not covered by the CE Mark. There is no guarantee that the Company will be able to achieve additional regulatory approvals, and even if we do, our products may not achieve market acceptance in the countries covered by such approvals. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration of the advantages, safety and efficacy of the our polymer technology;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- our ability to attract corporate partners, including medical device companies, to assist in commercializing our products; and
- our ability to market our products.

Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our products. Approval of our CytoSorb™ device as a cytokine filter as well as the data we have gathered in our clinical studies to support device usage in this indication may not be sufficient for market acceptance in the medical community. We may also need to conduct additional clinical studies to gather additional data for marketing purposes. 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 with our approval to apply the CE Mark to our CytoSorb™ device as a cytokine filter, there can be no assurance that the data from our limited clinical studies will be viewed as sufficient by the medical community to support the purchase of our products in substantial quantities or at all.

The Company anticipates that CytoSorb™ will be eligible for payment in Germany from standard DRG reimbursement rates. However, we plan to seek additional reimbursement specifically for our product, both in Germany and in other European countries, to help further adoption. There can be no assurance when, or if, this additional reimbursement might be approved.

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 commenced the process of seeking regulatory approvals of our products, but the approval process involves lengthy and costly clinical studies and is, in large part, not in the control of the Company. 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 additional approvals to sell our products in the United States or other countries. Even if we do ultimately receive FDA approval for any of our products, we will be subject to extensive ongoing regulation. While the Company has received approval from its Notified Body to apply the CE Mark to our CytoSorb™ device, we will be subject to extensive ongoing regulation and auditing requirements to maintain the CE Mark.

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. Even though we have received CE Mark certification of the CytoSorb™ device, there can be no assurance that we will be able to continue to comply with the required annual auditing requirements or other international regulatory requirements that may be applicable. 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 additional regulatory clearances.

To date, we have conducted limited clinical studies on our products. There can be no assurance that we will successfully complete additional clinical studies necessary to receive additional regulatory approvals in markets not covered by the CE Mark. 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 additional regulatory approvals. 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. Even though we have received approval to apply the CE Mark to our CytoSorb™ device as a cytokine filter, there can be no assurance that we will be able to receive approval for other potential applications of CytoSorb™, or that we will receive regulatory clearances from other targeted regions or countries.

We rely extensively on research and testing facilities at various universities and institutions, which could 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 for other potential applications 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 are in the research and development and clinical study phase of product commercialization. We have received approval from our Notified Body to apply the CE Mark to our CytoSorb™ device for commercial sale as a cytokine filter, but we will need to establish the capability to commercially manufacture our products in accordance with international regulatory requirements and maintain compliance on an ongoing basis. 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.

While we currently believe we have established sufficient production capacity to supply potential near term demand for the CytoSorb™ device, we will need to scale up and increase our manufacturing capabilities in the future. No assurance can be given that we will be able to successfully scale up our manufacturing capabilities or that we will have sufficient financial or technical resources to do so on a timely basis or at all.

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.

The Company anticipates that CytoSorb™ will be eligible for payment in Germany from standard DRG reimbursement rates. However, we plan to seek additional reimbursement specifically for our product, both in Germany and in other European countries, to help further drive adoption. There can be no assurance when, or if, this additional reimbursement might be approved.

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 12.8% of our outstanding shares of Common Stock. Additionally one of our Directors represents an institutional investor which

holds approximately 48% of our Series B Preferred 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 5,752,268 shares of Series A Preferred Stock through December 31, 2011 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. Net of cumulative conversions into Common Stock through March 30, 2012, the Company has a total of 1,447,159 shares of Series A Preferred Stock issued and outstanding. 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 34,937.18 shares of Series B Preferred Stock through December 31, 2011 to additional investors, and as dividends. Net of cumulative conversions into Common Stock through March 30, 2012, the Company has a total of 65,301.78 shares of Series B Preferred Stock issued and outstanding. 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 submitted an original S-1 registration statement to the SEC on December 12, 2008. The SEC replied with questions and a request to reduce the number of shares to be registered. In May 2010 the Company filed to withdraw this registration statement. The company intends to amend and refile the registration statement. 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.

The sale of our common stock to LPC may cause dilution and the sale of the shares of common stock acquired by LPC could cause the price of our common stock to decline.

In connection with entering into a funding agreement with Lincoln Park Capital Fund, LLC (“LPC”), we authorized the issuance to LPC of up to $8,500,000 worth of shares of our common stock plus 1,634,615 shares of common stock as additional commitment shares. The purchase price for the common stock to be sold to LPC pursuant to the Purchase Agreement will fluctuate based on the price of our common stock. 39,634,615 shares of common stock have been registered pursuant to an S-1 registration statement declared effective by the Securities and Exchange Commission (“SEC”). It is anticipated that these registered shares will be sold over a period of up to 32 months from the date of Purchase Agreement. Depending upon market liquidity at the time, a sale of shares pursuant to the Purchase Agreement at any given time could cause the trading price of our common stock to decline.

We can elect to direct purchases in our sole discretion. After LPC has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to LPC by us under the agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock under the Purchase Agreement, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However,

we have the right to control the timing and amount of any sales of our shares to LPC and the agreement may be terminated by us at any time at our discretion without any cost to us.

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 322,373,000 shares remain available for issuance and may be issued by us or issued through conversions of preferred stock or convertible notes 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 the Company 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 1B. Unresolved Staff Comments.

There is no reporting requirement under this item for a smaller reporting company.

Item 2. Properties.

We currently operate a facility near Princeton, New Jersey with approximately 7,657 sq. ft, housing research laboratories, clinical manufacturing operations and administrative offices, under a lease agreement, which expires in March 2013. 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.

Item 3. Legal Proceedings.

The Company is currently not involved, but may at times be involved in various claims and legal actions. Management is currently of the opinion that these claims and legal actions would have no merit, and any ultimate outcome will not have a material adverse impact on the consolidated financial position of the Company and/or the results of its operations.

Item 4. Mine Safety Disclosures

Not applicable

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 "CTSO." Prior to May 2010 our Common Stock traded under the symbol "MSBT", but was changed to "CTSO" as part of our name change to CytoSorbents Corporation. 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
2010		
First quarter	$0.26	$0.15
Second quarter	$0.17	$0.07
Third quarter	$0.09	$0.07
Fourth quarter	$0.15	$0.09
2011		

First quarter	$0.41	$0.12
Second quarter	$0.48	$0.18
Third quarter	$0.30	$0.13
Fourth quarter	$0.18	$0.11

The number of holders of record for our Common Stock as of March 30, 2012 was approximately 3,350. 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, 2011, 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 CytoSorbents 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	39,833,438		$ 0.39		166,562	(2)
Total	39,833,438	(3)	$ 0.39	(3)	166,562	

(1) Represents options that may be issued under our 2003 Stock Option Plan.

(2) Represents the unadjusted number of options that may be issued under our 2006 Long-Term Incentive Plan. The options available under the pool may be increased to maintain 15% of the fully diluted share count as needed.

(3) Represents options to purchase (i) 118,667 shares of Common Stock at a price of $41.47 per share, (ii) 24,112 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) 15,492 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) 2,530,000 shares of Common Stock at a price of $0.173, (xiii) 2,365,000 shares of Common Stock at a price of $0.168, (xiv) 408,000 shares of Common Stock at a price of $0.166, (xv) 5,000 shares of Common Stock at a price of $0.159, (xvi) 2,000 shares of Common Stock at a price of $0.154, (xvii) 35,000 shares of Common Stock at a price of $0.143, (xviii) 13,500,000 shares of Common Stock at a price of $0.138, (xix) 90,000 shares of Common Stock at a price of $0.136 per share, (xx) 302,000 shares of Common Stock at a price of $0.134, (xxi) 30,000 shares of

Common Stock at a price of $0.097, (xxii) 2,000 shares of Common Stock at a price of $0.09, (xxiii) 7,000 shares of Common Stock at a price of $0.089, (xxiv) 2,753,858 shares of Common Stock at a price of $0.084, (xxv) 115,000 shares of Common Stock at a price of $0.08, and (xxvi) 12,857,703 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.

The following plan of operation provides information which management believes is relevant to an assessment and understanding of our results of operations and financial condition. The discussion should be read along with our financial statements and notes thereto. This section includes a number of forward-looking statements that reflect our current views with respect to future events and financial performance. Forward-looking statements are often identified by words like believe, expect, estimate, anticipate, intend, project and similar expressions, or words which, by their nature, refer to future events. You should not place undue certainty on these forward-looking statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our predictions.

PLAN OF OPERATIONS

Overview

We are a development stage company and expect to remain so for at least the next several quarters. CytoSorbents is a critical care focused company using blood purification to treat disease. In March 2011, we received European Union (E.U.) regulatory approval under the CE Mark and Medical Devices Directive for our flagship product, CytoSorb™, as an extracorporeal cytokine filter to be used in clinical situations where cytokines are elevated. CytoSorbents has started the process of commercializing its operations with the launch of sales of its CytoSorb™ device in the E.U. In mid-September we started to exhibit the CytoSorb™ device at conferences in Germany as part of our product marketing under a controlled-market release in select geographic territories in Germany. Because of the limited nature of this initial release, we anticipate only modest sales until we expand our marketing efforts into the broader market.

Our CE Mark enables CytoSorb™ to be sold in the European Union for clinical use. Potential uses include many critical care conditions where cytokines are elevated such as sepsis, trauma, ARDS, severe burn injury and acute pancreatitis. CytoSorbents has also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the European Union. We intend to continue to research and seek the necessary regulatory approvals to sell our other proposed products, as well as potential label extensions of our current CE Mark.

We have completed the targeted enrollment in our European Sepsis clinical trial of one hundred (100) patients with sepsis and respiratory failure with the participation of fourteen trial sites. The purpose of the trial was to demonstrate safety and the broad, and statistically significant reduction of key cytokines such as IL-6 in these patients. Although the trial was not powered to demonstrate significant reduction in clinical endpoints such as mortality, these were included as secondary and exploratory endpoints in the trial. Taking into account all 100 patients, the treatment was well-tolerated with no serious device related adverse events reported in more than 300 human treatments in the trial. The first 22 patients in the study represented a sepsis pilot study. In the next 31 patients, a compromise of the manual randomization schedule at two trial sites led to an imbalance in the severity of illness between the control and treatment patient groups of the study. After a thorough review, the Scientific Advisory Board (SAB) and the independent Data Safety Monitoring Board (DSMB) both recommended that due to this enrollment bias, these 31 patients should only be used for safety evaluation purposes and that new patients should be enrolled into the trial using electronic web-based randomization to randomly assign patients into either the control or treatment arms. Excluding four patients that withdrew, the remaining forty three (43) patients enrolled under electronic randomization were relatively balanced in terms of the severity of illness in treatment and control patients, confirming the findings of the SAB and DSMB. In these forty three (43) patients the European Sepsis Trial successfully demonstrated, on a statistically significant basis ($p<0.05$), CytoSorb™'s ability to reduce circulating levels of key cytokines from whole blood in treated patients on the average of 30-50% over the 7 day treatment period. Additionally, post-hoc subgroup analyses of the clinical outcome data from patients enrolled under electronic randomization demonstrated statistically significant reduction in mortality in patients at high risk of death in sepsis, specifically in patients with very high

cytokine levels (IL-6 ≥ 1,000 pg/mL and/or IL-1ra ≥ 16,000 pg/mL) where 28-day mortality was 0% treated vs 63% control, p=0.03, n=14 and patients ≥ age 65 (14-day mortality: 0% treated vs 36% control, p=0.04, n=21).

We are focusing our efforts on the commercialization of our CytoSorb™ product and have begun a controlled-marketing program in select territories in Germany. The initial major market focus for CytoSorb™ is the adjunctive treatment of sepsis, a systemic inflammatory response to a serious infection or traumatic event. CytoSorb™ has been designed to prevent or reduce the accumulation of high concentrations of cytokines in the bloodstream associated with sepsis and is intended for short-term use with standard of care therapy that includes antibiotics. We believe that current state of the art blood purification technology (such as dialysis) is incapable of effectively clearing the toxins intended to be absorbed by our CytoSorb™ device.

In addition to the sepsis indication, we intend to continue to foster research in other critical care illnesses where CytoSorb™ could be used, such as ARDS, trauma, severe burn injury and acute pancreatitis, or in other acute conditions that have demonstrated potential in preliminary studies to prevent or reduce the accumulation of cytokines in the bloodstream. These other 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 our technology may have in removing drugs and other substances from blood and physiologic fluids.

The Company is currently manufacturing CytoSorb™ under ISO 13485 Full Quality Systems certification for sale in the E.U. and for additional clinical studies. Concurrent with its commercialization plans, the Company intends to conduct additional clinical studies in sepsis and other critical care diseases to generate additional clinical data to expand the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. Assuming availability of adequate and timely funding, and continued positive results from our clinical studies, the Company intends to continue commercializing its product in Europe.

The clinical protocol for our European Sepsis Trial was designed to allow us to gather information to support future U.S. studies. In the event we 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 510(k) or PMA registration. No assurance can be given that our CytoSorb™ product will work as intended or that we will be able to obtain FDA approval to sell CytoSorb™ in the United States. Even though we have obtained CE Mark approval, there is no guarantee or assurance that we will be successful in obtaining FDA approval in the United States or approval in any other country or jurisdiction.

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.

Results of Operations

Our financial statements have been presented on the basis that it is a going concern, which contemplates the realization of revenues from our subscriber base and the satisfaction of liabilities in the normal course of business. We have incurred losses from inception. These factors raise substantial doubt about our ability to continue as a going concern.

Our research and development costs were $2,900,005 and $1,757,370 for the years ended December 31, 2011 and 2010, respectively. We have experienced substantial operating losses since inception. As of December 31, 2011, we had an accumulated deficit of $92,557,542, which included net losses of $5,481,648 and $2,908,865 for the years ended December 31, 2011 and December 31, 2010 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 $4,130,194 and $2,516,757 for the years ended December 31, 2011 and December 31, 2010 respectively. Legal, financial, and other consulting costs were $342,651and $307,262 for the years ended December 31, 2011 and 2010, respectively.

Interest (income) expense, net, in the amounts of $1,044,881 and $84,846 include interest and dividend income in the amounts of $1,464 and $915 for the years ended December 31, 2011 and 2010, respectively.

Liquidity and Capital Resources

Since inception, our operations have been financed through the private placement of our debt and equity securities. At December 31, 2011, we had cash on hand of $1,186,653 and current liabilities of $1,527,949. In February and March 2012 we received approximately $850,000 as proceeds from the sale of 6,007,366 shares of Common Stock per the Purchase Agreement with LPC (See Note 11 of the consolidated financial statements) at an average price of approximately $0.142 per share of Common. In February 2012 the Company issued 12-month Promissory Notes in the principal amount of $700,000, which accrue interest at the rate of 8% per annum, which are further described in Note 11 to the consolidated financial statements.

We believe that we have sufficient cash to fund our operations into the third quarter of 2012, following which we will need additional funding before we can complete additional clinical studies and commercialize our products. The Company has received SEC approval for a registration statement filed for the funding agreement with Lincoln Park Capital Fund LLC. Subject to minimum pricing restrictions per the terms of the funding agreement, Management believes that the Company will be able to receive ongoing funding per the terms of this purchase agreement (See Note 9 of Financial Statements) The agreement with Lincoln Park has the potential to significantly extend the time that we may be able to fund our operations. 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 has been prepared assuming we will continue as a going concern, and the auditors' report on the financial statements expresses substantial doubt about our ability to continue as a going concern.

Effects of Recent Accounting Pronouncements

There have been no recently issued accounting standards which would have an impact on the Company's financial statements.

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 consolidated financial statements have been prepared in accordance with the provisions of 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.

Revenue Recognition

The Company recognizes revenue when it is earned. Delivery of the goods generally completes the criteria for revenue recognition.

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 accounting standards for 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 these accounting standards, 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 of accounting standards for 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.

Determination of Fair Value for Stock Dividend and Stock Based Compensation

Effective January 1, 2010 the Company has changed its basis for estimating the fair value of the preferred stock dividends from the underlying conversion prices of the Series A and Series B Preferred Stock, to a five day volume weighted average price of actual closing market prices for the Company’s common stock. The Company believes that there has been relative improvement in stock trading volumes of its Common Stock over the past two years, and that this new market based methodology is a better proxy for fair valuation of its preferred stock dividends.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, financings, or other relationships with unconsolidated entities or other persons, also known as “special purpose entities” (SPEs).

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

We are subject to certain market risks, including changes in interest rates and currency exchange rates. We have not undertaken any specific actions to limit those exposures.

Item 8. Financial Statements and Supplementary Data.

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. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Pursuant to Rule 13a-15(b) under the Securities Exchange Act of 1934 (“Exchange Act”), the Company carried out an evaluation, with the participation of the Company’s management, including the Company’s Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”) (the Company’s principal financial and accounting officer), of the effectiveness of the Company’s disclosure controls and procedures (as defined under Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, the Company’s CEO and

CFO concluded that the Company’s disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act, 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 the Company’s management, including the Company’s CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting.

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Our internal control system was designed to, in general, provide reasonable assurance to the Company’s management and board regarding the preparation and fair presentation of published financial statements, but because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of the Company’s internal control over financial reporting as of December 31, 2011. The framework used by management in making that assessment was the criteria set forth in the document entitled “ Internal Control – Integrated Framework” issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that assessment, our CEO and CFO have determined and concluded that, as of December 31, 2011, the Company’s internal control over financial reporting was effective.

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

Changes in Internal Control over Financial Reporting

No change in our system of internal control over financial reporting occurred during the period covered by this report, fourth quarter of the fiscal year ended December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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	42	President and Chief Executive Officer, Director
Al Kraus	67	Chairman of the Board
Joseph Rubin, Esq.	73	Director
Edward R. Jones, MD, MBA	62	Director
James Gunton	45	Director
Vincent Capponi	54	Chief Operating Officer
David Lamadrid	41	Chief Financial Officer
Robert Bartlett, MD	71	Chief Medical Officer

Phillip Chan, MD, PhD. Dr. Chan became a director of the Company in 2008 and since January 2009 is also Chief Executive Officer. Prior to CytoSorbents, 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. 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 the Company 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 the Company in 1997. Mr. Rubin is a founder and Senior Partner of, Rubin & Bailin, LLP an international and domestic corporate and commercial law firm in New York City, where he has practiced law since 1986. Mr. Rubin also taught at the Columbia University School of International and Public Affairs, where he is also Executive Director of the International Technical Assistance Program for Transforming Economies (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 the Company 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 is a past President of the Renal Physicians Association.

James Gunton. Mr. Gunton became a director of the Company 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 the Company 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 CytoSorbents 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 joined the Company as Vice President of Finance in 2000 and became its Chief Financial Officer in 2002. He has over 19 years of business experience in finance and operations. Prior to joining CytoSorbents, Mr. Lamadrid was a financial analyst at Chase Manhattan Bank working in the Middle Market Banking Group and also worked for several high growth product distribution companies. Mr. Lamadrid received his MBA in Management and Finance from New York University, a BS in Finance from St. John’s University, and an AAS in Accounting from S.U.N.Y. Rockland.

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 2011 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, 2011, 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").

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Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards (1) ($)		Total ($)
Phillip Chan						
Chief Executive Officer	2011	239,496(14)	—0-	—0-		239,496
	2010	216,351	-0-	201,307	(2)	417,658
	2009	216,351	-0-	12,971	(3)	229,322
Vincent Capponi,						
Chief Operating Officer	2011	219,674	250	—0-		219,924
	2010	205,303	200	184,448	(4)	389,951
	2009	205,303	200	510	(5)	206,013
	2008	195,527	150	155,795	(6)	351,472
David Lamadrid,						
Chief Financial Officer	2011	201,942(15)	250	-0-		202,192
	2010	189,086(12)	200	164,418	(7)	353,704
	2009	189,992(13)	200	510	(8)	190,702
	2008	157,630	150	196,555	(9)	354,335
Dr. Robert Bartlett						
Chief Medical Officer	2011	51,083	—0-	—0-		51,083
	2010	50,000	-0-	57,331	(10)	107,331
	2009	50,000	-0-	73	(11)	50,073

(1) The value of option awards granted to the Named Executive Officers has been estimated pursuant to recognition requirements of accounting standards for accounting for stock-based compensation 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, 2010.

(2) Reflects options to purchase 500,000 shares of Common Stock at an exercise price of $0.173 per share, which were granted on January 4, 2010 and expire on January 4, 2020. This option vested and became exercisable as to 100,000 shares on the date of grant, vested and became exercisable as to 100,000 shares on January 4, 2011, vested and became exercisable as to 100,000 shares on January 4, 2012, vests and becomes exercisable as to 100,000 shares on January 4, 2013, and vests and becomes exercisable as to 100,000 shares on January 4, 2014. Reflects options to purchase 3,350,000 shares of Common Stock at an exercise price of $0.138 per share, which were granted on May 5, 2010. The options granted on May 5, 2010 vest at the discretion of the Board of Directors based on criteria including (but not limited to) a timely completion of the sepsis trial, raising capital, and partnering and business development. As of the date of this filing, 882,500 of the options granted on May 5, 2010 have been approved for vesting by the Board of Directors.

(3) Reflects options to purchase 2,503,858 shares of Common Stock at an exercise price of $0.084 per share, which were granted on January 8, 2009 and expire on January 8, 2019. This option vested and became exercisable as to 1,251,929 shares on the date of grant, and vested and became exercisable as to 1,251,929 shares on January 8, 2010.

(4) Reflects options to purchase 500,000 shares of Common Stock at an exercise price of $0.173 per share, which were granted on January 4, 2010 and expire on January 4, 2020. This option vested and became exercisable as to 100,000 shares on the date of grant, vested and became exercisable as to 100,000 shares on January 4, 2011, vested and became exercisable as to 100,000 shares on January 4, 2012, vests and becomes exercisable as to 100,000 shares on January 4, 2013, and vests and becomes exercisable as to 100,000 shares on January 4, 2014.

(5) Reflects options to purchase 3,000,000 shares of Common Stock at an exercise price of $0.138 per share, which were granted on May 5, 2010. The options granted on May 5, 2010 vest at the discretion of the Board of Directors based on criteria including (but not limited to) a timely completion of the sepsis trial, raising capital, and partnering and business development. As of the date of this filing, 910,000 of the options granted on May 5, 2010 have been approved for vesting by the Board of Directors.

(6) Reflects options to purchase 400,000 shares of Common Stock at an exercise price of $0.168 per share, which were granted on January 28, 2009 and expire on January 28, 2019. This option vested and became exercisable as to 100,000 shares on the date of grant, vested and became exercisable as to 100,000 shares on January 28, 2010, vested and became exercisable as to 100,000 shares on January 28, 2011, and vested and became exercisable as to 100,000 shares on January 28, 2012.

(7) 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 vested and became 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, vested and became exercisable as to 562,500 shares on June 25, 2009, vested and became exercisable as to 562,500 shares on June 25, 2010, and vested and became exercisable as to 562,500 shares on June 25, 2011.

(8) Reflects options to purchase 400,000 shares of Common Stock at an exercise price of $0.173 per share, which were granted on January 4, 2010 and expire on January 4, 2020. This option vested and became exercisable as to 80,000 shares on the date of grant, vested and became exercisable as to 80,000 shares on January 4, 2011, vested and became exercisable as to 80,000 shares on January 4, 2012, vests and becomes exercisable as to 80,000 shares on January 4, 2013, and vests and becomes exercisable as to 80,000 shares on January 4, 2014. Reflects options to purchase 2,750,000 shares of Common Stock at an exercise price of $0.138 per share, which were granted on May 5, 2010. The options granted on May 5, 2010 vest at the discretion of the Board of Directors based on criteria including (but not limited to) a timely completion of the sepsis trial, raising capital, and partnering and business development. As of the date of this filing, 830,000 of the options granted on May 5, 2010 have been approved for vesting by the Board of Directors.

(9) Reflects options to purchase 400,000 shares of Common Stock at an exercise price of $0.168 per share, which were granted on January 28, 2009 and expire on January 28, 2019. This option vested and became exercisable as to 100,000 shares on the date of grant, vested and became exercisable as to 100,000 shares on January 28, 2010, vested and became exercisable as to 100,000 shares on January 28, 2011, and vested and became exercisable as to 100,000 shares on January 28, 2012.

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 vested and became 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, vested and became exercisable as to 687,500 shares on June 25, 2009, vested and became exercisable as to 687,500 shares on June 25, 2010, and vested and became exercisable as to 687,500 shares on June 25, 2011.

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(10) Reflects options to purchase 175,000 shares of Common Stock at an exercise price of $0.173 per share, which were granted on January 4, 2010 and expire on January 4, 2020. This option vested and became exercisable as to 35,000 shares on the date of grant, vested and became exercisable as to 35,000 shares on January 4, 2011, vested and became exercisable as to 35,000 shares on January 4, 2012, vests and becomes exercisable as to 35,000 shares on January 4, 2013, and vests and becomes exercisable as to 35,000 shares on January 4, 2014. Reflects options to purchase 900,000 shares of Common Stock at an exercise price of $0.138 per share, which were granted on May 5, 2010. The options granted on May 5, 2010 vest at the discretion of the Board of Directors based on criteria including (but not limited to) a timely completion of the sepsis trial, raising capital, and partnering and business development. As of the date of this filing, 200,000 of the options granted on May 5, 2010 have been approved for vesting by the Board of Directors.

(11) Reflects options to purchase 50,000 shares of Common Stock at an exercise price of $0.084 per share, which were granted on January 8, 2009 and expire on January 8, 2014. This option vested and became exercisable as to 12,500 shares on January 8, 2010, vested and became exercisable as to 12,500 shares on January 8, 2011; vested and became exercisable as to 12,500 shares on January 8, 2012, and vests and becomes exercisable as to 12,500 shares on January 8, 2013.

(12) Amount includes payments in the approximate amount of $14,086 for certain other expenses pursuant to an employment agreement.

(13) Amount includes payments in the approximate amount of $14,992 for certain other expenses pursuant to an employment agreement.

(14) Amount includes the approximate amount of $8,000 for certain other expenses pursuant to an employment agreement.

(15) Amount includes the approximate amount of $14,692 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, 2011, certain information regarding outstanding equity awards at fiscal year end for the Named Executive Officers.

Outstanding Equity Awards At December 31, 2011

	Option Awards				
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)		Option Expiration Date
Phillip Chan	15,000		0.08	(1)	12/31/18
	2,503,858		0.084	(1)	1/8/19
	200,000	300,000	0.173	(2)	1/4/20
	882,500	2,467,500	0.138	(3)	5/5/20
Vincent Capponi	50,000		1.65	(1)	12/31/16
	1,100,000		0.25	(1)	01/16/18
	2,200,000		0.035	(4)	06/25/18
	300,000	100,000	0.168	(5)	01/28/19
	200,000	300,000	0.173	(6)	1/4/20
	910,000	2,090,000	0.138	(12)	5/5/20
David Lamadrid	150,000		1.90	(1)	01/16/17
	1,400,000		0.25	(1)	01/16/18
	2,737,500		0.035	(7)	06/25/18
	300,000	100,000	0.168	(8)	01/28/19
	160,000	240,000	0.173	(9)	1/4/20
	830,000	1,920,000	0.138	(13)	5/5/20
Robert Bartlett	25,000	25,000	0.084	(10)	01/08/14
	70,000	105,000	0.173	(11)	1/4/20
	200,000	700,000	0.138	(14)	5/5/20

(1) Fully vested

(2) Vests and becomes exercisable as to (i) 100,000 shares on January 4, 2010; (ii) 100,000 shares on January 4, 2011; (iii) 100,000 shares on January 4, 2012; (iv) 100,000 shares on January 4, 2013; and (v) 100,000 shares on January 4, 2014.

(3) Vests and becomes exercisable at the discretion of the Board of Directors based on criteria including (but not limited to) a timely completion of the sepsis trial, raising capital, and partnering and business development. As of the date of this filing, 882,500of these options have been approved for vesting by the Board of Directors.

(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) 100,000 shares on January 28, 2009; (ii) 100,000 shares on January 28, 2010; (iii) 100,000 shares on January 28, 2011; and (iv) 100,000 shares on January 28, 2012.

(6) Vests and becomes exercisable as to (i) 100,000 shares on January 4, 2010; (ii) 100,000 shares on January 4, 2011; (iii) 100,000 shares on January 4, 2012; (iv) 100,000 shares on January 4, 2013; and (v) 100,000 shares on January 4, 2014.

(7) Vests and becomes exercisable as to (i) 687,500 shares on June 25, 2008; (ii) 687,500 shares on June 25, 2009; (iii) 687,500 shares on June 25, 2010; and (iv) 687,500 shares on June 25, 2011.

(8) Vests and becomes exercisable as to (i) 100,000 shares on January 28, 2009; (ii) 100,000 shares on January 28, 2010; (iii) 100,000 shares on January 28, 2011; and (iv) 100,000 shares on January 28, 2012.

(9) Vests and becomes exercisable as to (i) 80,000 shares on January 4, 2010; (ii) 80,000 shares on January 4, 2011; (iii) 80,000 shares on January 4, 2012; (iv) 80,000 shares on January 4, 2013; and (v) 80,000 shares on January 4, 2014.

(10) Vests and becomes exercisable as to (i) 12,500 shares on January 8, 2010; (ii) 12,500 shares on January 8, 2011; (iii)12,500 shares on January 8, 2012 and (iv) 12,500 shares on January 8, 2013.

(11) Vests and becomes exercisable as to (i) 35,000 shares on January 4, 2010; (ii) 35,000 shares on January 4, 2011; (iii) 35,000 shares on January 4, 2012; (iv) 35,000 shares on January 4, 2013; and (v) 35,000 shares on January 4, 2014.

(12) Vests and becomes exercisable at the discretion of the Board of Directors based on criteria including (but not limited to) a timely completion of the sepsis trial, raising capital, and partnering and business development. As of the date of this filing, 910,000 of these options have been approved for vesting by the Board of Directors.

(13) Vests and becomes exercisable at the discretion of the Board of Directors based on criteria including (but not limited to) a timely completion of the sepsis trial, raising capital, and partnering and business development. As of the date of this filing, 830,000 of these options have been approved for vesting by the Board of Directors.

(14) Vests and becomes exercisable at the discretion of the Board of Directors based on criteria including (but not limited to) a timely completion of the sepsis trial, raising capital, and partnering and business development. As of the date of this filing, 200,000 of these options have been approved for vesting by the Board of Directors.

Director Compensation

The following table shows for the fiscal year ended December 31, 2011 certain information with respect to the compensation of all non-employee directors of the Company.

Director Compensation for Fiscal 2011

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)		Total ($)
Joseph Rubin	8,000	6,732	(2)(3)	14,732
Edward R. Jones	8,000	6,732	(2)(4)	14,732
James Gunton (5)	—	—		—
Al Kraus	20,000	12,461	(6)	32,461
Phillip Chan (7)	—	—		—

(1) The value of option awards granted to directors has been estimated pursuant to the recognition requirements of accounting standards for accounting for stock-based compensation 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, 2011.

(2) Fully vested

(3) In connection with his service as a director in 2011 we issued Mr. Rubin options to purchase 100,000 shares of our Common Stock at an exercise price of $0.165per share, which were granted on January 18, 2012 and expire on January 18, 2022.

(4) In connection with his service as a director in 2011 we issued Dr. Jones options to purchase 100,000 shares of our Common Stock at an exercise price of $0.165 per share, which were granted on December 31, 2010 and expire on December 31, 2020.

(5) In connection with Mr. Gunton’s service as a director in 2011, the NJTC Venture Fund was issued options to purchase 108,000 shares of our Common Stock at an exercise price of $0.165 per share, which were granted on January 18, 2012 and expire on January 18, 2022.

(6) Pursuant to an agreement and in connection with Mr. Kraus’ service as a director in 2011 we issued options to purchase 200,000 shares of our Common Stock at an exercise price of $0.138 per share, which were granted on January 21, 2011 and expire on January 21, December 31, 2021.

(7) 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. During 2011 Dr. Chan was an employee Director and was not eligible to receive compensation for Director services.

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 2008. Such options will be exercisable in accordance with the Company's option pricing policy 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 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. In December 2009 we issued Mr. Kraus an additional option to purchase 100,000 shares of Common Stock at an exercise price of $0.166 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 January 2011, we renewed the agreement with Al Kraus, as Chairman of the Board of Directors for an additional two year term period.

In 2010, 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 to be issued on December 31, 2010 based on attendance at quarterly Board meetings held during 2010. For the Chairman, the Board approved the issuance of options to purchase up to 125,000 shares of Common Stock to be issued on December 31, 2010 based on attendance at quarterly Board meeting held during 2010.

In 2011, non-employee Directors compensation terms remained the same as they were during 2010. Our Chairman of the Board, Mr. Kraus, was compensated per the terms of his renewal agreement entered into in January 2011.

Employment Agreements with Named Executive Officers

Phillip Chan

Effective June 15, 2011, we renewed the employment agreement by and between Dr. Phillip Chan and the Company as Chief Executive Officer retroactive to January 1, 2011. Per the terms of the agreement, we agree to pay Phillip Chan an annual base compensation of $231,496 payable in equal semimonthly installments in accordance with our usual practice. This base compensation shall be subject to 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.

Vincent Capponi

Effective June 15, 2011, we renewed the employment agreement by and between Vincent Capponi and the Company as Chief Operating Officer retroactive to January 1, 2011. Per the terms of the agreement, we agree to pay Vincent Capponi an annual base compensation of $219,674 payable in equal semimonthly installments in accordance with our usual practice. This base compensation shall be subject to 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

Effective June 15, 2011, we renewed the employment agreement by and between David Lamadrid and the Company as Chief Financial Officer retroactive to January 1, 2011. Per the terms of the agreement, we agree to pay David Lamadrid an initial annual base compensation of $187,250 payable in equal semimonthly installments in accordance with our usual practice. This base compensation shall be subject to 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 June 15, 2011, we renewed the consulting agreement with Dr. Bartlett. Pursuant to this consulting agreement, we agree to pay Dr. Robert Bartlett consulting fees at an annualized rate of $52,000 payable in equal monthly installments of $4,333.33 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 28, 2012, 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)			
	—	—	
Directors and Executive Officers			
Al Kraus(2)	10,357,001	5.2	%
Phillip Chan (3)	4,623,384	2.4	%
David Lamadrid (4)	5,773,734	3.0	%
Vince Capponi (5)	4,665,586	2.4	%
Joseph Rubin (6)	1,113,514	*	
Robert Bartlett (7)	95,000	*	
James Gunton (8)	15,000	*	
Edward R. Jones (9)	282,500	*	
All directors and executive officers as a group (eight persons)(10)	27,221,463	12.7	%

*Less than 1%.

1 Gives effect to the shares of Common Stock issuable upon the exercise of all options exercisable within 60 days of March 30, 2012 and other rights beneficially owned by the indicated stockholders on that date. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting and investment power with respect to shares. Unless otherwise indicated, the persons named in the table have sole voting and sole investment control with respect to all shares beneficially owned. Percentage ownership is calculated based on 189,107,064 shares of Common Stock outstanding as of March 28, 2012.

2 Includes 8,963,370 shares of Common Stock issuable upon exercise of stock options.

3 Includes 735,359 shares of Common Stock issuable upon conversion of Series B Preferred Stock, 100,000 shares of Common Stock issuable upon conversion of Convertible Note, and 3,788,025 shares of Common Stock issuable upon exercise of warrants and stock options.

4 Includes 5,770,000 shares of Common Stock issuable upon exercise of stock options.

5 Includes 4,247,500 shares of Common Stock issuable upon exercise of stock options.

6 Includes 3,360 shares of Common Stock issuable upon conversion of Series A Preferred Stock, 509,392 shares of Common Stock issuable upon conversion of Series B Preferred Stock, and 566,742 shares of Common Stock issuable upon exercise of warrants and stock options. Does not include shares of Common Stock beneficially owned by Mr. Rubin’s spouse, as to which he disclaims beneficial ownership.

7 These shares are issuable upon exercise of stock options.

8 These shares are issuable upon exercise of stock options.

9 These shares are issuable upon exercise of stock options.

10 Includes an aggregate of 3,360 shares of Common Stock issuable upon conversion of Series A Preferred Stock, 1,244,751 shares of Common Stock issuable upon conversion of Series B Preferred Stock, 100,000 shares of Common Stock issuable upon conversion of Convertible Notes, and 23,975,637 shares of Common Stock issuable upon exercise of warrants and stock options.

Item 13. Certain Relationships and Related Transactions and Director Independence.

Joseph Rubin is a director of ours and performs legal services for us from time to time. At December 31, 2011, we owed Mr. Rubin's firm approximately $10,625 in respect of legal services provided by his firm to us.

Director Independence

All members of our Board of Directors, other than Joseph Rubin, who performs legal services for us as disclosed above, Al Kraus, formerly an employee, and Phillip Chan, our Chief Executive Officer, are independent under the standards set forth in Nasdaq Marketplace Rule 4200(a)(15).

Item 14. Principal Accountant Fees and Services.

The following table presents fees for professional audit services rendered by WithumSmith+Brown, PC for the audit of our annual financial statements for the years ended December 31, 2011 and 2010, and fees billed for other services rendered by WithumSmith+Brown, PC during those years.

	2011	2010
Audit fees (1)	$96,835	$105,300
Audit related fees	—	—
Tax fees	5,500	9,710
All other fees	—	—
Total fees	$102,335	$115,010

(1) Includes fees paid for professional services rendered in connection with the audit of annual financial statements and the review of quarterly financial statements, and the review of such financial statements in the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Registration Statement on Form S-1 and S-8, and Current Reports on Form 8-K.

Pre-Approval Policies And Procedures

We do not have an audit committee or a formal pre-approval process for the performance for us by our independent auditor of non-audit services. For the year ended December 31, 2011 our independent auditor performed non-attest tax services. We anticipate that any non-audit services to be performed for us by our independent auditor, subject to the de minimis exceptions for non-audit services described in Section 10A(i)(1)(B) of the Securities Exchange Act of 1934, as amended, will be approved prior to our auditor's engagement for such services by our Board of Directors, acting in the capacity of an audit committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

Exhibit No.	Description
10.1	Employment Agreement with Dr. Phillip P. Chan Effective June 15, 2011.*
10.2	Employment Agreement with David Lamadrid Effective June 15, 2011.*
10.3	Employment Agreement with Vincent Capponi Effective June 15, 2011.*
10.4	Consulting Agreement with Dr. Robert Bartlett Effective June 15, 2011.*
10.5	Purchase Agreement, dated as of December 8, 2011 by and between the Company and Lincoln Park Capital Fund, LLC.**
10.6	Registration Rights Agreement, dated as of December 8, 2011, by and between the Company and Lincoln Park Capital Fund, LLC.**
10.7	Termination Agreement, dated as of December 7, 2011, by and between the Company and Lincoln Park Capital Fund, LLC.**
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data File (Form 10-K for the quarterly period ended October 31, 2011 furnished in XBRL).

*- As filed as an exhibit to the Form 8-K filed with the SEC on June 17, 2011 and herein incorporated by reference.

**- As filed as an exhibit to the Form 8-K filed with the SEC on December 9, 2011 and herein incorporated by reference.

In accordance with SEC Release 33-8238, Exhibits 32.1 and 32.2 are being furnished and not filed.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, CytoSorbents Corporation has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 30th day of March 2012.

CYTOSORBENTS
CORPORATION

By: /s/ Phillip Chan
Phillip Chan
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Phillip Chan Phillip Chan	Chief Executive Officer (Principal Executive Officer) and Director	March 30, 2012
/s/ David Lamadrid David Lamadrid	Chief Financial Officer (Principal Accounting and Financial Officer)	March 30, 2012
/s/ Al Kraus Al Kraus	Chairman of the Board	March 30, 2012
/s/ Joseph Rubin Joseph Rubin, Esq.	Director	March 30, 2012
/s/ Edward R. Jones Edward R. Jones	Director	March 30, 2012
/s/ James Gunton James Gunton	Director	March 30, 2012

FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders,

CytoSorbents Corporation:

We have audited the accompanying consolidated balance sheets of CytoSorbents Corporation (a development stage company), as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity (deficiency) and cash flows for the years then ended and the cumulative period from January 22, 1997 (date of inception) to December 31, 2011. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We did not audit the consolidated financial statements of CytoSorbents Corporation for the period from January 22, 1997 (date of inception) to December 31, 2000. Such statements are included in the cumulative total from inception to December 31, 2011 on the consolidated statements of operations and cash flows and reflect a net loss of 22.6% of the related cumulative total. Those statements were audited by other auditors whose report has been furnished to us and our opinion, insofar as it relates to the amounts for the period from January 22, 1997 (date of inception) to December 31, 2000 included in the cumulative totals, is based solely upon the report of the other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of CytoSorbents Corporation as of December 31, 2011 and 2010 and the consolidated results of their operations and their cash flows for the years then ended and the cumulative period from January 22, 1997 (date of inception) to December 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring net

losses and negative cash flows from operations. These matters raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ WithumSmith+Brown, PC

New Brunswick, New Jersey

March 30 2012

********** **This report is a copy of a previously issued report and has not been reissued by Arthur**

Andersen pursuant to rule 2-02(e) of Regulation SX ********

Report of Independent Public Accountants

To the Board of Directors and Stockholders,

CytoSorbents Corporation:

We have audited the accompanying balance sheets of CytoSorbents Corporation (a development stage company), as of December 31, 2000 and 1999, and the related statements of operations, changes in members' equity and cash flows for the period from inception (January 22, 1997) through December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of CytoSorbents Corporation as of December 31, 2000 and 1999, and the results of its operations and its cash flows for the period from inception (January 22, 1997) to December 31, 2000, in conformity with accounting principles generally accepted in the United States.

Arthur Andersen, LLP

New York, New York

December 27, 2001

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CYTOSORBENTS CORPORATION

(a development stage company)

CONSOLIDATED BALANCE SHEETS

December 31,	2011	2010
ASSETS		
Current Assets:		
Cash and cash equivalents	$1,186,653	$1,055,669
Accounts receivable, net of allowance for doubtful accounts of $-0-	36,078	—
Inventories	431,022	—
Prepaid expenses and other current assets	43,728	344,536
Total current assets	1,697,481	1,400,205
Property and equipment – net	155,067	144,146
Other assets	269,994	267,575
Total long-term assets	425,061	411,721
Total Assets	$2,122,542	$1,811,926
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current Liabilities:		
Accounts payable	$675,160	$817,701
Accrued expenses and other current liabilities	558,466	401,418
Convertible notes payable, net of debt discount in the amount of $53,677	294,323	—
Total current liabilities	1,527,949	1,219,119
Notes Payable:		
Convertible notes payable, net of debt discount in the amount of $508,750	276,250	1,077,388
Total Long Term Liabilities	276,250	1,077,388

Total liabilities	1,804,199	2,296,507
Commitments and Contingencies		
Stockholders Equity/(Deficiency):		
10% Series B Convertible Preferred Stock, Par Value $0.001, 200,000 shares authorized at December 31, 2011 and 2010, respectively; 65,433.34and 60,973.11 issued and outstanding , respectively	65	61
10% Series A Convertible Preferred Stock, Par Value $0.001, 12,000,000 shares authorized at December 31, 2011 and 2010, respectively; 1,447,159and 5,826,409 shares issued and outstanding, respectively	1,447	5,826
Common Stock, Par Value $0.001, 500,000,000 shares authorized at December 31, 2011 and 2010, respectively; 177,626,058 and 122,838,411 shares issued and outstanding, respectively	177,626	122,838
Additional paid-in capital	92,696,747	83,375,544
Deficit accumulated during the development stage	(92,557,542)	(83,988,850)
Total stockholders’ equity/(deficiency)	318,343	(484,581)
Total Liabilities and Stockholders' Equity (Deficiency)	$2,122,542	$1,811,926

The Notes to Consolidated Financial Statements are an integral part of these statements.

CYTOSORBENTS CORPORATION

(a development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Period from January 22,1997 (date of inception) to December 31, 2011	Year ended December 31, 2011	Year ended December 31, 2010
Revenue	$ 36,078	$36,078	$—
Cost of goods sold	11,760	11,760	—
Gross profit	24,318	24,318	
Other expenses			
Research and development	50,899,338	2,888,245	1,757,370
Legal, financial and other consulting	7,957,890	342,651	307,262
General and administrative	25,056,473	1,230,189	759,387
Change in fair value of management and incentive units	(6,055,483)	—	—
Total expenses	77,858,218	4,461,085	2,824,019
Loss from Operations	77,833,900	4,436,767	2,824,019
Other (income) expenses:			
Gain on disposal of property and equipment	(21,663)	—	—
Gain on extinguishment of debt	(216,617)		—
Interest (income) expense, net	6,737,122	1,044,881	84,846
Penalties associated with non-registration of Series A Preferred Stock	361,495	—	—
Total other (income) expense, net	6,860,337	1,044,881	84,846
Loss before benefit from income taxes	84,694,237	5,481,648	2,908,865
Benefit from income taxes	(547,318)	—	—

Net loss	(84,146,919)	(5,481,648)	(2,908,865)
Preferred stock dividend	8,410,623	3,087,044	2,177,464
Net loss available to common shareholders	$ (92,557,542)	$ (8,568,692)	$ (5,086,329)
Basic and diluted net loss per common share		$ (0.05)	$ (0.05)
Weighted average number of common stock outstanding		160,235,291	98,094,768

The Notes to Consolidated Financial Statements are an integral part of these statements.

CYTOSORBENTS CORPORATION

(a development stage company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(DEFICIENCY)

Period from January 22, 1997 (date of inception) to December 31, 2011

	Members Equity (Deficiency)	Deferred Compensation	Common Stock Shares	Common Stock Par value	Preferred Stock B Shares	Preferred Stock B Par Value	Preferred Stock A Shares	Preferred Stock A Par Value	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
Balance at January 22, 1997 (date of inception)	$—	$—	—	$ —	$ —	$ —	$ —	$ —	$ —	$—	$—
Equity contributions	1,143,487	—	—	—	—	—	—	—	—	—	1,143,487
Subscriptions receivable	440,000	—	—	—	—	—	—	—	—	—	440,000
Technology contribution	4,550,000	—	—	—	—	—	—	—	—	—	4,550,000
Net loss	—	—	—	—	—	—	—	—	—	(5,256,012)	(5,256,012)
Balance at December 31, 1997	6,133,487	—	—	—	—	—	—	—	—	(5,256,012)	877,475
Equity contributions	2,518,236	—	—	—	—	—	—	—	—	—	2,518,236
Options issued to consultants	1,671	—	—	—	—	—	—	—	—	—	1,671

Subscriptions receivable	50,000	—	—	—	—	—	—	—	—	—	50,000
Net loss	—	—	—	—	—	—	—	—	—	(1,867,348)	(1,867,348)
Balance at December 31, 1998	8,703,394	—	—	—	—	—	—	—	—	(7,123,360)	1,580,034
Equity contributions	1,382,872	—	—	—	—	—	—	—	—	—	1,382,872
Equity issued to consultants	88,363	—	—	—	—	—	—	—	—	—	88,363
Recognition of deferred compensation	47,001	(47,001)	—	—	—	—	—	—	—	—	—
Amortization of deferred compensation	—	15,667	—	—	—	—	—	—	—	—	15,667
Subscriptions receivable	100,000	—	—	—	—	—	—	—	—	—	100,000

Net loss	—	—	— — — — — — —	(3,066,388)	(3,066,388)
Balance at December 31, 1999	10,321,630	(31,334)	— — — — — — —	(10,189,748)	100,548
Equity contributions	14,407,916	—	— — — — — — —	—	14,407,916
Equity issued to consultants	1,070,740	—	— — — — — — —	—	1,070,740
Warrants issued to consultants	468,526	—	— — — — — — —	—	468,526
Recognition of deferred compensation	27,937	(27,937)	— — — — — — —	—	—
Amortization of deferred compensation	—	46,772	— — — — — — —	—	46,772
Net loss	—	—	— — — — — — —	(10,753,871)	(10,753,871)
Balance at December 31, 2000	26,296,749	(12,499)	— — — — — — —	(20,943,619)	5,340,631
Equity contributions	13,411,506	—	— — — — — — —	—	13,411,506
Equity issued to consultants	161,073	—	— — — — — — —	—	161,073
Stock options issued to employee	2,847	—	— — — — — — —	—	2,847
Fees incurred in raising capital	(1,206,730)	—	— — — — — — —	—	(1,206,730)
Amortization of deferred compensation	—	12,499	— — — — — — —	—	12,499
Net loss	—	—	— — — — — — —	(15,392,618)	(15,392,618)
Balance at December 31, 2001	38,665,445	—	— — — — — — —	(36,336,237)	2,329,208
Equity contributions	6,739,189	—	— — — — — — —	—	6,739,189
Equity issued to consultants	156,073	—	— — — — — — —	—	156,073
Options issued to consultant	176,250	—	— — — — — — —	—	176,250
Options issued to employee	2,847	—	— — — — — — —	—	2,847
Fees incurred in raising capital	(556,047)	—	— — — — — — —	—	(556,047)
Forgiveness of loan receivable in exchange for equity	(1,350,828)	—	— — — — — — —	—	(1,350,828)
Net loss	—	—	— — — — — — —	(11,871,668)	(11,871,668)
Balance at December 31, 2002	43,832,929	—	— — — — — — —	(48,207,905)	(4,374,976)

Equity contributions	4,067,250	—	—	—	—	—	—	—	—	—	4,067,250
Equity issued to consultants	16,624	—	—	—	—	—	—	—	—	—	16,624
Change in fair value of management units	2,952,474	—	—	—	—	—	—	—	—	—	2,952,474
Options issued to consultant	65,681	—	—	—	—	—	—	—	—	—	65,681
Fees incurred in raising capital	(343,737)	—	—	—	—	—	—	—	—	—	(343,737)
Forgiveness of loan receivable in exchange for equity	(281,340)	—	—	—	—	—	—	—	—	—	(281,340)
Net loss	—	—	—	—	—	—	—	—	—	(6,009,283)	(6,009,283)
Balance at December 31, 2003	50,309,881	—	—	—	—	—	—	—	—	(54,217,188)	(3,907,307)
Equity contributions	512,555	—	—	—	—	—	—	—	—	—	512,555
Change in fair value of management units	(2,396,291)	—	—	—	—	—	—	—	—	—	(2,396,291)

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Fees incurred in raising capital	(80,218)	—	—	—	—	—	—	—	(80,218
Net Loss	—	—	—	—	—	—	—	(1,096,683)	(1,096,683
Balance at December 31, 2004	48,345,927	—	—	—	—	—	—	(55,313,871)	(6,967,944
Equity contributions	92,287	—	—	—	—	—	—	—	92,287
Settlement of accounts payable in exchange for equity	836,319	—	—	—	—	—	—	—	836,319
Conversion of convertible notes payable and accrued interest for equity	51,565	—	—	—	—	—	—	—	51,565
Change in fair value of management units	(14,551)	—	—	—	—	—	—	—	(14,551
Fees incurred in raising capital	(92,287)	—	—	—	—	—	—	—	(92,287
Reorganization from LLC to "C" Corporation	(49,219,260)	—	4,829,120	4,829	—	—	—	49,214,431	—	—
Net loss	—	—	—	—	—	—	—	(3,665,596)	(3,665,596
Balance at December 31, 2005	—	—	4,829,120	4,829	—	—	—	49,214,431	(58,979,467)	(9,760,207

Issuance of common stock for stock subscribed	—	—	240,929	241	—	—	—	—	799,644	—	799,885
Issuance of common stock to investor group for price protection	—	—	100,000	100	—	—	—	—	(100)	—	—
Issuance of stock options to employees, consultants and directors	—	—	—	—	—	—	—	—	143,352	—	143,352
Issuance of 10% Series A Preferred Stock for cash	—	—	—	—	—	—	5,300,000	5,300	5,530,143	(235,443)	5,300,000
Cost of raising capital associated with issuance of preferred stock	—	—	—	—	—	—	—	—	(620,563)	—	(620,563
Shares held by original stockholders of Parent immediately prior to merger	—	—	3,750,000	3,750	—	—	—	—	(3,750)	—	—
Conversion of convertible debt, related accrued interest and shares to induce conversion into common stock	—	—	5,170,880	5,171	—	—	—	—	11,376,939	—	11,382,11
Issuance of common stock in consideration	—	—	10,000,000	10,000	—	—	—	—	990,000	—	1,000,000

for funding $1,000,000 convertible note payable per terms of merger transaction													
Issuance of common stock in exchange for accounts payable and services rendered	—	—	778,274	779	—	—	—	—	587,035	—		587,814	
Conversion of common stock issued prior to reverse merger for 10% Series A Preferred Stock	—	—	(240,929)	(241)	—	—	799,885	800	30,194	(30,753)		—	
Non-cash stock dividends on 10% Series A Preferred Stock	—	—	—	—	—	—	303,700	303	303,397	(303,700)		—	
Issuance of preferred stock for redemption of convertible note	—	—	—	—	—	—	1,000,000	1,000	1,204,640	(205,640)		1,000,000	

Issuance of warrants to consultants for services	—	—	—	—	—	—	—	—	—	9,883	—	9,883
Issuance of warrants in exchange for accounts payable	—	—	—	—	—	—	—	—	—	192,311	—	192,3
Net loss	—	—	—	—	—	—	—	—	—	—	(7,671,580)	(7,67
Balance at December 31, 2006	—	—	24,628,274	24,629	—	—	7,403,585	7,403	69,757,556	(67,426,583)	2,363
Issuance of stock options to employees, consultants and directors	—	—	—	—	—	—	—	—	—	498,955	—	498,9
Issuance of common stock in settlement of accounts payable	—	—	11,501	11	—	—	—	—	22,991	—	23,00
Conversion of preferred stock into common stock	—	—	405,157	405	—	—	(506,446)	(506)	101	—	—
Issuance of Series A Preferred Stock as dividends and settlement of dividends/penalties payable in connection with non-registration event	—	—	—	—	—	—	1,122,369	1,122	1,121,246	(760,872)	361,4
Net loss	—	—	—	—	—	—	—	—	—	—	(3,350,754)	(3,350
Balance at December 31, 2007	—	—	25,044,932	25,045	—	—	8,019,508	8,019	71,400,849	(71,538,209)	(104,2
Stock based compensation -	—	—	—	—	—	—	—	—	—	363,563	—	363,5

employees, consultants and directors											
Issuance of Series A Preferred Stock as dividends	—	—	—	—	—	—	830,384	831	277,087	(277,918)	—
Issuance of Series B Preferred Stock for cash and conversion of $175,000 of convertible debt	—	—	—	—	52,931.47	53	—	—	5,657,842	(364,747)	5,293
Cost of raising capital associated with issuance of Series B Preferred Stock	—	—	—	—	—	—	—	—	(215,398)	—	(215,3
Issuance of Series B Preferred Stock as dividends	—	—	—	—	2,627.17	2	—	—	262,715	(262,717)	—
Issuance of warrants upon conversion of convertible notes payable into Series B Preferred Stock	—	—	—	—	—	—	—	—	40,354	—	40,35
Conversion of Series A Preferred stock into common	—	—	218,585	219	—	—	(56,832)	(57)	(162)	—	—
Net loss	—	—	—	—	—	—	—	—	—	(3,017,890)	(3,017
Balance at December 31, 2008	—	—	25,263,517	25,264	55,558.64	55	8,793,060	8,793	77,786,850	(75,461,481)	2,359
Stock based compensation - employees, consultants and directors	—	—	—	—	—	—	—	—	236,705	—	236,7
Issuance of Series A Preferred Stock as dividends	—	—	—	—	—	—	789,610	789	110,809	(111,598)	—

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Issuance of Series B Preferred Stock as dividends	—	—	—	—	5,860.22	6	—	—	586,017	(586,023
Exercise of warrants	—	—	—	—	13,357.52	13	—	—	1,335,741	—
Warrant modification as inducement to exercise	—	—	—	—	—	—	—	—	14,885	—
Conversion of notes payable and accrued interest to Series B Preferred Shares	—	—	—	—	576.05	1	—	—	64,308	(6,704
Conversion of Series A and B Preferred stock into common	—	—	41,111,339	41,111	(6,628.55)	(6)	(3,326,857)	(3,326)	(37,779)	—
Net loss	—	—	—	—	—	—	—	—	—	(2,736,715
Balance December 31, 2009	—	—	66,374,856	66,375	68,723.88	69	6,255,813	6,256	80,097,536	(78,902,52
Stock based compensation - employees, consultants and directors	—	—	—	—	—	—	—	—	149,325	—
Issuance of Series A Preferred Stock as dividends	—	—	—	—	—	—	590,159	590	167,992	(168,582
	—	—	—	—	6,232.81	6	—	—	2,008,876	(2,008,882

Issuance of Series B Preferred Stock as dividends											
Conversion of Series A and Series B Preferred into Common	—	—	47,824,298	47,824	(13,983.58)	(14)	(1,019,563)	(1,020)	(46,790	)	—
Issuance of common stock for cash	—	—	7,174,186	7,174	—	—	—	—	742,825		—
Cost of raising capital	—	—	1,465,071	1,465	—	—	—	—	(51,025	)	—
Relative fair value of warrants and beneficial conversion feature in connection with issuance of convertible notes	—	—	—	—	—	—	—	—	306,805		—
Net loss	—	—	—	—	—	—	—	—	—		(2,908,865
Balance at December 31, 2010	-	-	122,838,411	122,838	60,973.11	61	5,826,409	5,826	83,375,544		(83,988,85
Stock based compensation - employees, consultants and directors	—	—	—	—	—	-	—		865,535		—
Issuance of Series A Preferred Stock as dividends	—	—	—	—	—	—	266,161	266	71,755		(72,021
Issuance of Series B Preferred	—	—	—	—	6,283.41	6	—	—	3,015,017		(3,015,023

Stock as dividends										
Conversion of Series A and Series B Preferred into Common	—	—	16,115,042	16,116	(1,823.18)	(2)	(4,645,411)	(4,645)	(11,469)	—
Issuance of common stock for cash	—	—	17,335,942	17,336	—	—	—	—	2,626,430	-
Conversion of convertible notes to common	-		15,151,310	15,151					1,499,979	
Relative fair value of warrants and beneficial conversion feature in connection with issuance of convertible notes	—	—	—	—	—	—	—	—	1,250,000	—
Cashless exercise of warrants			6,013,478	6,013					(6,013)	
Exercise of stock options			146,875	147					4,994	
Issuance Of common stock in settlement of accounts payable			25,000	25					4,975	
Net loss	—	—	—	—	—	—	—	—	—	(5,481,648
Balance at December 31, 2011	$ -	$ -	177,626,058	$ 177,626	65,433.34	$ 65	1,447,159	$ 1,447	$ 92,696,747	$ (92,557,54

The Notes to Consolidated Financial Statements are an integral part of these statements.

CYTOSORBENTS CORPORATION

(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Period from January 22, 1997 (date of inception) to December 31, 2011	Year ended December 31, 2011	Year ended December 31, 2010
Cash flows from operating activities:			
Net loss	$ (84,146,919)	$ (5,481,648)	$ (2,908,865)
Adjustments to reconcile net loss to net cash used by operating activities:			
Common stock issued as inducement to convert convertible notes payable and accrued interest	3,351,961	—	—
Issuance of common stock to consultants for services	30,000	—	—
Depreciation and amortization	2,449,415	39,150	17,804
Amortization of debt discount	1,994,377	945,434	48,943
Gain on disposal of property and equipment	(21,663)	-	—
Gain on extinguishment of debt	(216,617)	—	—
Interest expense paid with Series B Preferred Stock in connection with conversion of notes payable	3,147	—	—
Abandoned patents	183,556	—	—
Bad debts	255,882	—	—
Contributed technology expense	4,550,000	—	—
Consulting expense	237,836	—	—
Management unit expense	1,334,285	—	—
Expense for issuance of warrants	533,648	—	—
Expense for issuance of options	2,505,060	865,535	149,325
Amortization of deferred compensation	74,938	—	—
Penalties in connection with non-registration event	361,496	—	—
Changes in operating assets and liabilities:			
Accounts Receivable	(36,078)	(36,078)	
Inventories	(431,022)	(431,022)	

Prepaid expenses and other current assets	(315,276)	300,808	24,555
Other assets	(56,394)	—	—
Accounts payable and accrued expenses	2,957,856	(30,706)	190,980
Accrued interest	1,823,103	—	—
Net cash used by operating activities	(62,577,409)	(3,828,527)	(2,477,258)
Cash flows from investing activities:			
Proceeds from sale of property and equipment	32,491	—	—
Purchases of property and equipment	(2,400,960)	(34,672)	(139,356)
Patent costs	(479,558)	(17,818)	(26,093)
Purchases of short-term investments	(393,607)		
Proceeds from sale of short-term investments	393,607	—	—
Loan receivable	(1,632,168)	—	—
Net cash (used) provided by investing activities	(4,480,195)	(52,490)	(165,449)
Cash flows from financing activities:			
Proceeds from issuance of common stock	400,490	—	—
Proceeds from issuance of preferred stock, net of related issuance costs	9,579,040	—	—
Equity contributions - net of fees incurred	46,571,310	2,756,860	767,498
Proceeds from borrowing	11,188,881	1,250,000	1,335,250
Proceeds from subscription receivables	499,395	—	—
Proceeds from exercise of stock options	5,141	5,141	
Net cash provided by financing activities	68,244,257	4,012,001	2,102,748

The Notes to Consolidated Financial Statements are an integral part of these statements.

CYTOSORBENTS CORPORATION

(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Period from January 22, 1997 (date of inception) to December 31, 2011	Year ended December 31, 2011	Year ended December 31, 2010
Net increase (decrease) in cash and cash equivalents	1,186,653	130,984	(539,959)
Cash and cash equivalents at beginning of period	—	1,055,669	1,595,628
Cash and cash equivalents at end of period	$ 1,186,653	$ 1,186,653	$ 1,055,669
Supplemental disclosure of cash flow information:			
Cash paid during the period for interest	$ 590,189	$ —	$ —
Supplemental schedule of noncash financing activities:			
Debt discount in connection with issuance of convertible debt	$ 1,556,805	$ 1,250,000	306,805
Fair value of shares issued as costs of raising capital	$ 335,950	$ 106,344	229,606
Note payable principal and interest conversion to equity	$ 11,949,449	$ 1,515,130	$ —
Issuance of member units for leasehold improvements	$ 141,635	$ —	$ —
Issuance of management units in settlement of cost of raising capital	$ 437,206	$ —	$ —
Change in fair value of management units for cost of raising capital	$ 278,087	$ —	$ —
Exchange of loan receivable for member units	$ 1,632,168	$ —	$ —
Issuance of equity in settlement of accounts payable	$ 1,614,446	$ 5,000	$ —
Issuance of common stock in exchange for stock subscribed	$ 399,395	$ —	$ —
Costs paid from proceeds in conjunction with issuance of preferred stock	$ 768,063	$ —	$ —
Preferred stock dividends	$ 8,410,623	$ 3,087,044	$ 2,177,464
Net effect of conversion of common stock to preferred stock prior to merger	$ 559	$ —	$ —

During the years ended December 31, 2011 and 2010, 1,823.18 and 13,983.58 Series B Preferred Shares were converted into 5,036,408 and 38,628,675 Common Shares, respectively. During the years ended December 31, 2011 and 2010, 4,645,411 and 1,019,563 Series A Preferred Shares were converted into 11,078,634 and 9,195,623 Common Shares, respectively. For the period from January 22, 1997 (date of inception) to December 31, 2011, 22,435.31 Series B Preferred Shares and 9,555,109 Series A Preferred Shares were converted into 61,975,994 and 43,698,427 Common Shares, respectively.

During the years ended December 31, 2011 and 2010, no shares of Series B Preferred Shares were issued in connection with non-registration events as settlement of dividends/penalties payable. For the period from January 22, 1997 (date of inception) to December 31, 2011, 553,629 Series A Preferred Shares and -0- Series B Preferred Shares were issued in connection with non-registration events as settlement of dividends/penalties payable.

The Notes to Consolidated Financial Statements are an integral part of these statements.

CYTOSORBENTS CORPORATION

(a development stage company)

Notes to Consolidated Financial Statements

1. BASIS OF PRESENTATION

The accompanying consolidated financial statements include the results of CytoSorbents Corporation (the “Parent”), and CytoSorbents, Inc. its wholly-owned operating subsidiary (the “Subsidiary”), collectively referred to as “the Company.”

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has experienced negative cash flows from operations since inception and has a deficit accumulated during the development stage at December 31, 2011 of $92,557,542. The Company is not currently generating significant revenue and is dependent on the proceeds of present and future financings to fund its research, development and commercialization program. The Company is continuing its fund-raising efforts. Although the Company has historically been successful in raising additional capital through equity and debt financings, there can be no assurance that the Company will be successful in raising additional capital in the future or that it will be on favorable terms. Furthermore, if the Company is successful in raising the additional financing, there can be no assurance that the amount will be sufficient to complete the Company's plans. These matters raise substantial doubt about the Company’s ability to continue as a going concern. These consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

The Company is a development stage company and has not yet generated significant revenues. Since inception, the Company's expenses relate primarily to research and development, organizational activities, clinical manufacturing, regulatory compliance and operational strategic planning. Although the Company has made advances on these matters, there can be no assurance that the Company will continue to be successful regarding these issues, nor can there be any assurance that the Company will successfully implement its long-term strategic plans.

The Company has developed an intellectual property portfolio, including 29 issued and multiple pending patents, covering materials, methods of production, systems incorporating the technology and multiple medical uses.

2. PRINCIPAL BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Nature of Business

The Company, through its subsidiary, is engaged in the research, development and commercialization of medical devices with its platform blood purification technology incorporating a proprietary adsorbent polymer technology. The Company is focused on developing this technology for multiple applications in the medical field, specifically to provide improved blood purification for the treatment of acute and chronic health complications associated with blood toxicity. As of December 31, 2011, the Company has not commenced full commercial operations and, accordingly, is in the development stage. The Company has yet to generate any significant revenue and has no assurance of future revenue.

Principles of Consolidation

The consolidated financial statements include the accounts of the Parent, CytoSorbents Corporation, and its wholly-owned subsidiary, CytoSorbents, Inc. All significant intercompany transactions and balances have been eliminated in consolidation.

Development Stage Corporation

The accompanying consolidated financial statements have been prepared in accordance with the provisions of accounting and reporting by development stage enterprises.

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents.

Inventories

Inventories are valued at the lower of cost or market. At December 31, 2011 and December 31, 2010 the Company's inventory was comprised of finished goods, which amounted to $191,340 and $-0-, respectively, and work in process which amounted to $239,682 and $-0-, respectively.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation of property and equipment is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the lesser of their economic useful lives or the term of the related leases. Gains and losses on depreciable assets retired or sold are recognized in the statements of operations in the year of disposal. Repairs and maintenance expenditures are expensed as incurred.

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.

Impairment or Disposal of Long-Lived Assets

The Company assesses the impairment of patents and other long-lived assets under accounting standards for the impairment or disposal of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. For long-lived assets to be held and used, the Company recognizes an impairment loss only if its carrying amount is not recoverable through its undiscounted cash flows and measures the impairment loss based on the difference between the carrying amount and fair value.

Research and Development

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

For the years ended December 31, 2011 and December 31, 2010,the Company's operating results include grant income of approximately $-0- and $604,000, which were recorded as a reduction of research and development expenses during each year. Grant income received during the year ended December 31, 2010 was primarily composed of approximately $489,000 in Qualified Therapeutic Discovery Project grants ("QTDP") under Section 48D of the Internal Revenue Code, as enacted under the Patient Protection and Affordable Care Act of 2010.

Revenue Recognition

The Company recognizes revenue when it is earned. Delivery of the goods generally completes the criteria for revenue recognition.

Income Taxes

Income taxes are accounted for under the asset and liability method prescribed by accounting standards for accounting for income taxes. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax asset will not be realized. Under Section 382 of the Internal Revenue Code the net operating losses generated prior to the reverse merger may be limited due to the change in ownership. Additionally, net operating losses generated subsequent to the reverse merger may be limited in the event of changes in ownership.

The Company follows the accounting standards associated with uncertain tax provisions. The Company had no unrecognized tax benefits at December 31, 2011 or 2010. The Company files tax returns in the U.S. federal and state jurisdictions. The Company currently has no open years prior to December 31, 2008 and has no income tax related penalties or interest for the periods presented in these financial statements.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities. Actual results could differ from these estimates. Significant estimates in these financials are the valuation of options granted and the valuation of preferred shares issued as stock dividends.

Concentration of Credit Risk

The Company maintains cash balances, at times, with financial institutions in excess of amounts insured by the Federal Deposit Insurance Corporation. Management monitors the soundness of these institutions in an effort to minimize its collection risk of these balances.

Financial Instruments

The carrying values of cash and cash equivalents, short-term investments, accounts payable and other debt obligations approximate their fair values due to their short-term nature.

Net Loss per Common Share

Basic EPS is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period. The computation of diluted EPS does not assume conversion, exercise or contingent exercise of securities that would have an anti-dilutive effect on earnings. (See Note 10).

Stock-Based Compensation

The Company accounts for its stock-based compensation under the recognition requirements of accounting standards for 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 these accounting standards, 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 of accounting standards for 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

There have been no recently issued accounting standards which would have an impact on the Company's financial statements.

3. PROPERTY AND EQUIPMENT, NET:

Property and equipment - net, consists of the following:

December 31,	2011	2010	Depreciation/ Amortization Period
Furniture and fixtures	$130,015	$130,015	7 years
Equipment and computers	1,901,995	1,867,323	3 to 7 years
Leasehold improvements	462,980	462,980	Term of lease
	2,494,990	2,460,318	
Less accumulated depreciation and amortization	2,339,923	2,316,172	
Property and Equipment, Net	$155,067	$144,146	

Depreciation expense for the years ended December 31, 2011 and 2010 amounted to $23,751and $4,378, respectively. Depreciation expense from inception to December 31, 2011 amounted to $2,367,012

4. OTHER ASSETS:

Other assets consist of the following:

December 31,	2011	2010
Intangible assets, net	$213,600	$211,181
Security deposits	56,394	56,394
Total	$269,994	$267,575

Intangible assets consist of the following:

December 31,	2011		2010	
	Gross Amount	Accumulated Amortization	Gross Amount	Accumulated Amortization
Patents	$296,002	$ 82,402	$278,183	$ 67,002

Amortization expense amounted to $15,399 and $13,426 for the years ended December 31, 2011 and 2010, respectively. Amortization expense from inception to December 31, 2011 amounted to $82,401.

Amortization expense is anticipated to be approximately $15,000 for the next five years ended December 31, 2016.

5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES:

Accounts Payable and accrued expenses consist of the following:

	2011	2010
Other payable	$374,758	$186,170
Legal, financial and consulting	123,650	117,841
Research and development	735,218	915,108
	$1,233,626	$1,219,119

6. CONVERTIBLE NOTES:

During the third and fourth quarters of 2010 the Company issued 24-month Promissory Notes in the aggregate principal amount of $1,335,250, which accrue interest at the rate of 8% per annum. This amount includes principal and accrued interest of Promissory Notes that were originally issued in January 2010 that, through the option of the Note holder, were cancelled and exchanged for the new Notes issued in August 2010. Upon this exchange, the investor who originally owned the January Notes also received an additional five year warrant to purchase 886,250 shares of Common Stock at an exercise price of $0.10 per share. Per the terms of the Notes issued in August, the investors will be repaid in equity of the Company, not cash. During the term of the Notes, investors may at any time convert outstanding principal and interest into Common Stock of the Company at a rate of $0.10 per share. In addition, during the term of the Note, should the Company complete any subsequent financing, debt or equity, in an aggregate amount greater or equal to $750,000, which includes any equity component or the right to convert into equity, the investor shall have the option to exchange any outstanding principal and interest of the Note into the new financing. Pursuant to the terms of the Promissory Note, the note holder will receive warrant coverage in the form of five year warrants to purchase that number of shares of common stock as follows: that number of shares of Common Stock equal to the quotient obtained by dividing (x) 50% of the Principal, by (y) $0.10, with the resulting number of shares having an exercise price equal to $0.10 per share of Common Stock, plus that number of shares of Common Stock equal to the quotient obtained by dividing (x) 25% of the Principal, by (y) $0.125, with the resulting number of shares having an exercise price equal to $0.125 per share of Common Stock, plus that number of shares of Common Stock equal to the quotient obtained by dividing (x) 25% of the Principal, by (y) $0.15, with the resulting number of shares having an exercise price equal to $0.15 per share of Common Stock. The warrants have a cashless exercise provision. If during the term of the Note, and as long as the Note investor continues to own an outstanding balance of the Note, the Company has an equity financing of less than $750,000 that values the Company on a pre-money basis at or below $35 million on a fully-diluted basis, the Note investor will have a right of first refusal to participate in the financing per the terms of the Note. The Promissory Notes do not have registration rights for the shares underlying the notes or warrants.

During February 2011 the Company issued 24-month Promissory Notes in the aggregate principal amount of $1,250,000, which accrue interest at the rate of 8% per annum. Per the terms of the Promissory Notes issued in February, the investors will be repaid in equity of the Company, not cash. During the term of the Notes, investors may at any time convert outstanding principal and interest into Common Stock of the Company at a rate of $0.10 per share. In addition, during the term of the Note, should the Company complete any subsequent financing, debt or equity, in an aggregate amount greater or equal to $750,000, which includes any equity component or the right to convert into equity, the investor shall have the option to exchange any outstanding principal and interest of the Note into the new financing. Pursuant to the terms of the Promissory Note, the note holder will receive warrant coverage in the form of five year warrants to purchase that number of shares of common stock as follows: that number of shares of Common Stock equal to the quotient obtained by dividing (x) 50% of the Principal, by (y) $0.10, with the resulting number of shares having an exercise price equal to $0.10 per share of Common Stock, plus that number of shares of Common Stock equal to the quotient obtained by dividing (x) 25% of the Principal, by (y) $0.125, with the resulting number of shares having an exercise price equal to $0.125 per share of Common Stock, plus that number of shares of Common Stock equal to the quotient obtained by dividing (x) 25% of the Principal, by (y) $0.15, with the resulting number of shares having an exercise price equal to $0.15 per share of Common Stock. The warrants have a cashless exercise provision. If during the term of the Note, and as long as the Note investor continues to own an outstanding balance of the Note, the Company has an equity financing of less than $750,000 that values the Company on a pre-money basis

at or below $35 million on a fully-diluted basis, the Note investor will have a right of first refusal to participate in the financing per the terms of the Note. The Promissory Notes do not have registration rights for the shares underlying the notes or warrants.

The Company allocates the proceeds associated with the issuance of promissory notes based on the relative fair value of the promissory notes and warrants. Additionally, the Company evaluates if the embedded conversion option results in a beneficial conversion feature by comparing the relative fair value allocated to the promissory notes to the market value of the underlying common stock subject to conversion. In connection with the promissory note issuances during the years ended December 31, 2011 and 2010 the Company received proceeds of $1,250,000 and $1,335,250, respectively. The Company allocated the proceeds in accordance with FASB Codification Topic 470 based on the related fair value as follows for the years ended December 31, 2011 and 2010: ($0) and $1,028,445 was allocated to the promissory notes, respectively, and $466,432 and $188,031 to the warrants, respectively. Additionally, the embedded conversion feature resulted in a beneficial conversion feature in the amount of $783,568 and $118,774 for the years ended December 31, 2011 and 2010, respectively. The value assigned to the warrants resulting from the relative fair value calculation as well as the value of the beneficial conversion feature is recorded as a debt discount and is presented in the consolidated balance sheets. The debt discount is being amortized to interest expense over the term of the promissory notes and amounted to $425,427 and $48,943 for the years ended December 31, 2011 and 2010, respectively. During the years ended December 31, 2011 and 2010 Convertible Notes in the principal and accrued interest amount of $1,515,131 and $-0- were converted into 15,151,310 and -0- Common shares resulting in a reduction of debt discount and charge to interest expense in the amount of $516,258 and $-0-.

7. INCOME TAXES:

Tax losses amounted to approximately $4,500,000 and $2,700,000 for the years ended December 31, 2011 and December 31, 2010, respectively. The Company’s Federal net operating loss carryforward amounts to approximately $18,006,000 and expires through 2031. The Company’s remaining New Jersey net operating loss carryforward amounts to approximately $9,888,000 and expires through 2018. These loss carryforwards are subject to limitation in future years should certain ownership changes occur. A full valuation allowance equal to the deferred tax asset has been recorded due to the uncertainty that the Company will have the ability to utilize such asset.

For the years ended December 31, 2011 and December 31, 2010, respectively, the Company's effective tax rate differs from the federal statutory rate principally due to net operating losses offset by certain non-deductible expenses for which no benefit has been recorded.

A reconciliation of the Federal statutory rate to the Company's effective tax rate for the years ended December 31, 2011 and December 31, 2010 is as follows:

	2011	2010
Federal statutory rate	(34.0)%	(34.0)%
Decrease resulting from:		
Non-deductible expenses	5.9	—
Timing differences	—	1.3
Change in valuation allowance	25.0	31.6
Net operating losses	3.1	1.1
Effective tax rate	— %	— %

8. COMMITMENTS AND CONTINGENCIES:

The Company is obligated under non-cancelable operating leases for office space expiring at various dates through March 2013. The aggregate minimum future payments under these leases are approximately as follows:

Year ending December 31,	
2012	$131,500
2013	32,900
Total	$164,400

The preceding data reflects existing leases through the date of this report and does not include replacements upon their expiration. In the normal course of business, operating leases are normally renewed or replaced by other leases.

Rent expense for the years ended December 31, 2011 and 2010 amounted to approximately $249,000 and $241,000, respectively.

Employment Agreements

The Company has employment agreements with certain key executives through December 2011. The agreements provide for annual base salaries of varying amounts. The Company is currently in the process of renewing these agreements.

Litigation

The Company is currently not involved, but may at times be involved in various claims and legal actions. Management is currently of the opinion that these claims and legal actions would have no merit, and any ultimate outcome will not have a material adverse impact on the consolidated financial position of the Company and/or the results of its operations.

Royalty Agreements

Pursuant to an agreement dated August 11, 2003 an existing investor agreed to make a $4 million equity investment in the Company. These amounts were received by the Company in 2003. In connection with this agreement the Company granted the investor a future royalty of 3% on all gross revenues received by the Company from the sale of its CytoSorb™ device. For the year ended December 31, 2011 the Company has accrued royalty costs of $1,082.

License Agreements

In an agreement dated September 1, 2006, the Company entered into a license agreement which provides the Company the exclusive right to use its patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the agreement, the Company has agreed to pay royalties of 2.5% to 5% on the sale of certain of its products if and when those products are sold commercially for a term not greater than 18 years commencing with the first sale of such product. For the year ended December 31, 2011 per the terms of the license agreement the Company has recorded royalty costs of $731.

Warrant Agreement

As inducement to invest additional funds in the private placement of Series B Preferred Stock, additional consideration was granted to the participants of the Series B Preferred Stock offering in the event that litigation is commenced against CytoSorbents prior to June 30, 2018, claiming patent infringement on certain of the Company’s issued patents. In the event this litigation arises the Company may be required to issue warrants to purchase in the aggregate up to a maximum of ten million shares of Common Stock subject to certain adjustments. Through December 31, 2011 no such litigation has arisen and due to the deemed low probability of this potential outcome, the Company has not booked a contingent liability for this agreement.

9. STOCKHOLDERS' EQUITY

Preferred 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 below. 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.

10% Series A Preferred Stock

Each share of Series A Preferred Stock has a stated value of $1.00, and is convertible at the holder's option into that number of shares of Common Stock equal to the stated value of such share of Series A Preferred Stock divided by an initial conversion price of $1.25. 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 the Company's assets, the conversion rate will be adjusted so that the conversion rights of the Series A Preferred Stock stockholders will be equivalent to the conversion rights of the Series A Preferred Stock stockholders prior to such event. In addition, in the event the Company sells shares of Common Stock (or the equivalent thereof) at a price of less than $1.25 per share, the conversion price of the shares of Series A Preferred Stock will be reduced to such lower price. In addition, in the event the Company sells shares of Common Stock (or the equivalent thereof) at a price of less than $2.00 per share, the exercise price of the warrants issued to the holders of the Series A Preferred Stock will be reduced to such 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.

Pursuant to agreements with the June 30, 2006 purchasers of Series A Preferred Stock that waived rights to anti-dilution price protection upon the completion of the Series B offering, the Company reduced the conversion price for these holders of Series A Preferred Stock from $1.25 per share of Common to prices ranging from $0.10 to $0.45 per share of Common. The June 30, 2006 purchasers of Series A Preferred Stock also received reductions in their corresponding warrant exercise prices from $2.00 per share of Common Stock to exercise prices ranging from $0.40 to $0.90 per share of Common Stock.

The Series A Preferred Stock bears a dividend of 10% per annum payable quarterly, at the Company's election in cash or additional shares of Series A Preferred Stock valued at the stated value thereof; provided, however, that the Company must pay the dividend in cash if an "Event of Default" as defined in the Certificate of Designation designating the Series A Preferred Stock has occurred and is then continuing. In addition, upon an Event of Default, the dividend rate increases to 20% per annum. An Event of Default includes, but is not limited to, the following:

- the occurrence of "Non-Registration Events";
- an uncured breach by the Company 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 the Company for more than $100,000.

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

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The Series A Preferred Stock is not redeemable at the option of the holder but may be redeemed by the Company at its 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 Common Stock into which such Preferred is convertible and an Event of Default is not then continuing.

Holders of Series A Preferred Stock do not have the right to vote on matters submitted to the holders of Common Stock.

The registration rights provided for in the subscription agreements entered into with the purchasers of the Series A Preferred Stock: 1) required that the Company 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 within 240 days following the closing; and 2) 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 the Company fails to timely file that registration statement with, or have it declared effective by, the SEC.

The transaction documents entered into with the purchasers of the Series A Preferred Stock 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 upon conversion of the Series A Preferred Stock or exercise of the warrants, 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.

The Company has recorded non-cash stock dividends in connection with the issuance of Series A Preferred Stock as a stock dividend to its preferred shareholders as of December 31, 2011. Prior to February 26, 2007 and after May 7, 2007, the dividend rate was 10% per annum. Effective February 26, 2007 due to the Company’s failure to have the registration statement it filed declared effective by the Commission within the time required under agreements with the June 30, 2006 purchasers of the Series A Preferred Stock (i) dividends on the shares of Series A Preferred Stock issued to those purchasers were required to be paid in cash, (ii) the dividend rate increased from 10% per annum to 20% per annum, and (iii) such purchasers were entitled to liquidated damages of 2% of their principal investment payable in cash per 30 day period until the registration statement was declared effective. In connection with such cash dividend and penalty obligations, as modified by the Settlement Agreement described below, the Company’s financial statements for the year ending December 31, 2007 also reflect an aggregate charge of $361,495. On May 7, 2007 the Company’s registration statement filed in connection with the Company’s obligations to the June 30, 2006 purchasers of its Series A Preferred Stock was declared effective by the Commission.

Pursuant to a settlement agreement entered into in August 2007 with the June 30, 2006 purchasers of the Series A Preferred Stock, cash dividends stopped accruing on the Series A Preferred Stock effective on the date the Company’s

registration statement was declared effective (May 7, 2007) and all cash dividends and penalties due through that date were paid with additional shares of Series A Preferred Stock at its stated value of $1.00 per share in lieu of cash. The settlement did not result in a gain or loss on extinguishment of debt for the year ended December 31, 2007. Additionally, as part of the settlement, the dividend rate on the Series A Preferred Stock issued to these purchasers was reset to 10% effective as of May 7, 2007.

During the years ended December 31, 2011 and 2010, the Company issued 266,161 and 590,159 shares of Series A Preferred Stock respectively as payment of stock dividends at the stated value of $1.00 per share. The fair value of the non-cash stock dividends for the years ended December 31, 2011 and 2010 amounted to $72,021 and $168,582, respectively.

10 % Series B Cumulative Convertible Preferred Stock

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 stated value of such share of Series B Preferred Stock divided by an initial conversion price of $0.035, 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 the Company's assets, the conversion rate will be adjusted so that the conversion rights of the Series B Preferred Stock stockholders will be equivalent to the conversion rights of the Series B Preferred Stock stockholders prior to such event.

The Series B Preferred Stock bears a dividend of 10% per annum payable quarterly; provided, that if an "Event of Default" as defined in the Certificate of Designation designating the Series B Preferred Stock has occurred and is then continuing, the dividend rate increases to 20% per annum. An Event of Default includes, but is not limited to, the following:

- the occurrence of "Non-Registration Events";
- an uncured breach by the Company 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 the Company for more than $100,000.

Dividends on the Series B Preferred Stock will be made in additional shares of Series B Preferred Stock, valued at the stated value thereof. 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 ("NJTC"), if it then owns 25% of the shares of Series B Preferred Stock initially purchased by it (the "Required Amount"), the Company 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 Required Amount, may require that such payments be made in cash.

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 thereon.

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.

The Company has agreed to file a registration statement under the Securities Act covering the Common Stock issuable upon conversion of the Series B Preferred Stock within 180 days following the initial closing and to cause it to become effective within 240 days of such closing. The Company also granted the investors demand and piggyback registration rights with respect to such Common Stock. The investors in the private placement are entitled to liquidated damages in an amount equal to two percent (2%) of the purchase price of the Series B Preferred Stock if the Company fails 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.

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 the Company 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, provided the market price of the Company’s Common Stock is then below the conversion price of the Series B Preferred Stock.

Pursuant to the Certificate of Designation designating the Series B Preferred Stock, for so long as NJTC holds the Required Amount, NJTC is entitled to elect (i) two directors to the Company’s Board of Directors, which shall initially consist of six members, and (ii) two members to the Company’s compensation committee, which shall consist of at least three members. Within twelve months following the initial closing, the Company agreed to reduce the number of Directors on the Company’s Board of Directors to five members. Following the initial closing, two affiliates of NJTC joined the Company’s Board of Directors and compensation committee pursuant to the foregoing provision.

The transaction documents entered into with the purchasers of the Series B Preferred Stock 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 upon conversion of the Series B Preferred Stock or exercise of the warrants, and obtaining and maintaining an effective registration statement with respect to the shares of Common Stock underlying the Series B Preferred Stock and warrants sold in the offering.

In accordance with accounting standards governing debt with conversion and other options, the Company allocates the proceeds associated with the issuance of preferred stock based on the relative fair value of the preferred stock and warrants. Additionally, the Company evaluates if the embedded conversion option results in a beneficial conversion feature by comparing the relative fair value allocated to the preferred stock to the market value of the underlying common stock subject to conversion. The value assigned to the warrants resulting from the relative fair value calculation as well as the value of the beneficial conversion feature is recorded as a preferred stock dividend and is presented in the consolidated statements of operations. In addition, the Company considers the guidance of accounting for derivative financial instruments indexed to, and potentially settled in, a company's own common stock, and accounting for derivative instruments and hedging activities and concluded that the conversion feature embedded in the preferred stock only provides for physical settlement and there are no net settlement features. Accordingly, the Company has concluded that the conversion feature is not considered a derivative.

During the years ended December 31, 2011 and 2010, the Company issued 6,283.41 and 6,232.81 shares of Series B Preferred Stock respectively as payment of stock dividends at the stated value of $100.00 per share. The fair value of the non-cash stock dividends for the years ended December 31, 2011 and 2010 amounted to $3,015,020 and $2,008,882, respectively.

Determination of Stock Dividend Fair Value

Effective January 1, 2010 the Company has changed its basis for estimating the fair value of the preferred stock dividends from the underlying conversion prices of the Series A and Series B Preferred Stock, to a five day volume weighted average price of actual closing market prices for the Company's Common Stock.

Common Stock

Our certificate of incorporation authorizes the issuance of up to 500,000,000 shares of common stock with a par value of $0.001 per share of common ("Common Stock").

In May 2010, the Company executed a purchase agreement, or the Purchase Agreement, and a registration rights agreement, or the Registration Rights Agreement, with Lincoln Park Capital Fund, LLC ("LPC"). Under the Purchase Agreement, LPC is obligated, under certain conditions, to purchase from the Company up to $6 million of our Common Stock, from time to time over a 750 day (twenty-five (25) monthly) period.

The Company has the right, but not the obligation, to direct LPC to purchase up to $6,000,000 of its Common Stock in amounts up to $50,000 as often as every two business days under certain conditions. The Company can also accelerate the amount of its common stock to be purchased under certain circumstances. No sales of shares may occur at a purchase price below $0.10 per share or without a registration statement having been declared effective. The purchase price of the shares will be based on the market prices of our shares at the time of sale as computed under the Purchase Agreement without any fixed discount. The Company may at any time at its sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business days notice.

The Company issued 1,153,846 shares of our Common Stock to LPC as a commitment fee for entering into the agreement, and is obligated to issue up to an additional 1,153,846 shares pro rata as LPC purchases up to $6,000,000 of its Common Stock as directed by the Company. LPC may not assign any of its rights or obligations under the Purchase Agreement. During the years ended December 31, 2011 and 2010 the Company sold a total of 16,325,814 and 7,174,186 shares of Common Stock per the terms of the Purchase Agreement with LPC at an average price of approximately $0.179 and $0.105 per share of Common respectively. Per the terms of the Purchase Agreement the Company also issued an additional 561,600 and 144,200 shares of Common Stock as additional Commitment Fee shares during the years ended December 31, 2011 and 2010, respectively. The fair value of the Commitment shares have been recorded as a cost of raising capital.

In December 2011, the Company terminated the Purchase Agreement and executed a new purchase agreement, or the New Purchase Agreement, and a registration rights agreement, or the New Registration Rights Agreement, with Lincoln Park Capital Fund, LLC ("LPC"). Under the New Purchase Agreement, LPC is obligated, under certain conditions, to purchase from the Company up to $8.5 million of our Common Stock, from time to time over a thirty-two (32) month) period.

The Company has the right, but not the obligation, to direct LPC to purchase up to $8,500,000 of its Common Stock in amounts up to $50,000 as often as every two business days under certain conditions. The Company can also accelerate the amount of its common stock to be purchased under certain circumstances. No sales of shares may occur at a purchase price below $0.10 per share or without a registration statement having been declared effective. The purchase price of the shares will be based on the market prices of our shares at the time of sale as computed under the Purchase Agreement without any fixed discount. The Company may at any time at its sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business days notice.

There was no up front commitment fee paid to LPC for entering into the new agreement, however the Company is obligated to issue up to an additional 1,634,615 shares pro rata as LPC purchases up to $8,500,000 of its Common Stock as directed by the Company. LPC may not assign any of its rights or obligations under the Purchase Agreement. As of December 31, 2011 there were no sales of Common Stock made under the new Purchase Agreement.

Stock Option Plans

As of December 31, 2011, the Company had a Long Term Incentive Plan (“2006 Plan”) to attract, retain, and provide incentives to employees, officers, directors, and consultants. The Plan generally provides for the granting of stock, stock options, stock appreciation rights, restricted shares, or any combination of the foregoing to eligible participants.

A total of 40,000,000 shares of common stock are reserved for issuance under the 2006 Plan. As of December 31, 2011 there were outstanding options to purchase approximately 38,943,000 shares of common stock reserved under the plan. Additionally, as of December 31, 2011 there were options to purchase approximately 890,000 shares of Common Stock that were issued outside of the 2006 Plan. The Company may increase the shares in the 2006 Plan as needed to maintain the pool with 15% of the shares outstanding on a fully diluted basis.

The 2006 Plan as well as grants issued outside of the Plan are administered by the Board of Directors. The Board is authorized to select from among eligible employees, directors, advisors and consultants those individuals to whom incentives are to be granted and to determine the number of shares to be subject to, and the terms and conditions of the options. The Board is also authorized to prescribe, amend and rescind terms relating to options granted under the Plans. Generally, the interpretation and construction of any provision of the Plans or any options granted hereunder is within the discretion of the Board.

The Plan provides that options may or may not be Incentive Stock Options (ISOs) within the meaning of Section 422 of the Internal Revenue Code. Only employees of the Company are eligible to receive ISOs, while employees and non-employee directors, advisors and consultants are eligible to receive options, which are not ISOs, i.e. “Non-Qualified Options.” Because the Company has not yet obtained shareholder approval of the 2006 Plan, all options granted thereunder to date are “Non-Qualified Options” and until such shareholder approval is obtained, all future options issued under the 2006 Plan will also be “Non-Qualified Options.”

Stock-based Compensation

Total share-based employee, director, and consultant compensation for the years ended December 31, 2011 and 2010 amounted to approximately $865,500 and $149,000 respectively. These amounts are included in the statement of operations under the captions research and development ($444,200 and $65,000) and general and administrative ($421,300 and $84,000), respectively.

The summary of the stock option activity for the years ended December 31, 2011 and 2010 is as follows:

	Shares	Weighted Average Exercise per Share	Weighted Average Remaining Contractual Life (Years)
Outstanding January 1, 2010	23,577,704	$ 0.84	8.3
Granted	16,321,000	$ 0.143	9.3
Cancelled	(143,591)	$ 31.48	—
Exercised	—	—	—
Outstanding, December 31, 2010	39,755,113	$ 0.44	8.2
Granted	290,000	$ 0.137	7.5
Cancelled	(64,800)	$ 31.52	—
Exercised	(146,875)	$ 0.035	—
Outstanding, December 31, 2011	39,833,438	$ 0.39	7.2

The weighted-average grant date fair value for options granted during the years ended December 31, 2011 and 2010 amounted to approximately $0.055 and $0.053 per share, respectively. As of December 31, 2011 the Company’s outstanding options had exercise prices ranging from $0.035 to $41.47 per share of Common Stock.

At December 31, 2011, the aggregate intrinsic value of options outstanding and options currently exercisable amounted to approximately $ 2,265,000. As of December 31, 2011, the Company had options currently exercisable into an aggregate total of 27,923,438 shares of common stock which have a weighted average exercise price of $0.54 per share.

The summary of the status of the Company’s non-vested options for the year ended December 31, 2011 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2011	17,795,144	$ 0.047
Granted	290,000	0.055
Cancelled	—	—
Vested	(6,175,144)	0.038
Exercised	—	—
Non-vested, December 31, 2011	11,910,000	$ 0.051

As of December 31, 2011, there was approximately $2,756 of total unrecognized compensation cost related to stock options. Due to the uncertainty over whether certain options granted during the year ended December 31, 2010 will vest based on performance milestones in the Company's long term incentive plan, no charge for these options has been recorded in the consolidated statements of operations for the year ended December 31, 2011. The Company will evaluate on an ongoing basis the probability and likelihood of any of these performance milestones being achieved and will accrue charges as it becomes likely that they will be achieved.

The Company has reserved a separate pool of 15.6 million shares of restricted stock that may be issued to employees and directors as part of a long term incentive plan tied to corporate objectives. As of December 31, 2011, none of these shares have been issued and due to the uncertainty over whether they will be issued, no charge for these shares has been recorded in the consolidated statement of operations for the year ended December 31, 2011.

As of December 31, 2011, the Company has the following warrants to purchase common stock outstanding:

Number of Shares To be Purchased	Warrant Exercise Price per Share	Warrant Expiration Date
3,986,429	$ 0.035	June 25, 2013
397,825	$ 0.0362	September 30, 2014
1,750,000	$ 0.10	August 16, 2015
1,600,000	$ 0.125	August 16, 2015
1,333,333	$ 0.15	August 16, 2015
490,000	$ 0.10	October 22, 2015
196,000	$ 0.125	October 22, 2015
163,333	$ 0.15	October 22, 2015
625,000	$ 0.10	November 2, 2015
250,000	$ 0.125	November 2, 2015
208,334	$ 0.15	November 2, 2015
500,000	$ 0.10	November 19, 2015
200,000	$ 0.125	November 19, 2015
166,667	$ 0.15	November 19, 2015
240,125	$ 1.25	October 24, 2016
5,500,000	$ 0.10	February 15, 2016
2,200,000	$ 0.125	February 15, 2016
1,833,333	$ 0.15	February 15, 2016
21,640,379		

10. NET LOSS PER SHARE

Basic earnings per share and diluted earnings per share for the years ended December 31, 2011 and 2010 have been computed by dividing the net loss for each respective period by the weighted average number of shares outstanding during that period. All outstanding warrants and options representing approximately 61,473,817 and 60,546,634 incremental shares at December 31, 2011 and 2010, respectively, as well as shares issuable upon conversion of Series A & B Convertible Preferred Stock and Preferred Stock Warrants representing 182,041,312 and 185,838,147 incremental shares at December 31, 2011 and 2010, respectively, as well as potential shares issuable upon Promissory Note conversion into Common Stock representing approximately 11,330,000 and 13,352,500 shares at December 31, 2011 and 2010, respectively, and have been excluded from the computation of diluted loss per share as they are anti-dilutive.

11. SUBSEQUENT EVENTS

The Company has evaluated subsequent events occurring after the balance sheet date which include the following:

During February 2012 a total of 131.56 shares of Series B Preferred Stock were converted into 363,425 shares of Common Stock.

During February and March 2012 a total of $395,154 of principal and accrued interest of Convertible Notes were converted into 3,951,540 shares of Common Stock.

In February 2012 the Company issued 12 month Promissory Notes in the principal amount of $700,000, which accrue interest at the rate of 8% per annum. Per the terms of the Note, the investors will be repaid in equity of the Company, not cash. During the term of the Notes, investors may at any time convert outstanding principal and interest into Common Stock of the Company at a rate of $0.15 per share. In addition, during the term of the Note, should the Company complete any subsequent financing, debt or equity, in an aggregate amount greater or equal to $750,000, which includes any equity component or the right to convert into equity, the investor shall have the option to exchange any outstanding principal and interest of the Note into the new financing. Pursuant to the terms of the Promissory Note, the note holder will receive 25% warrant coverage in the form of five year warrants to purchase that number of shares of common stock as follows: that number of shares of Common Stock equal to the quotient obtained by dividing (x) 25% of the Principal, by (y) $0.15, with the resulting number of shares having an exercise price equal to $0.175 per share of Common Stock. The warrants have a cashless exercise provision. The Promissory Notes do not have registration rights for the shares underlying the notes or warrants.

In January 2012 the Company issued 630,993 shares of Common Stock to complete payment of cost of raising capital incurred in 2011.

During February and March 2012, the Company received approximately $900,000 as proceeds from the sale of 6,361,976 shares of Common Stock per the terms of the Purchase Agreement with LPC (See Note 9) at an average price of approximately $0.142 per share of Common. Per the terms of the Purchase Agreement the Company also issued an additional 173,072 shares of Common Stock as additional Commitment Fee shares.