Cytosorbents Corp
Form S-1/A
January 28, 2014

As filed with the Securities and Exchange Commission on December 23, 2013

Registration No. 333-193053

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Amendment Number 1 to

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CYTOSORBENTS CORPORATION

(Exact name of registrant as specified in its charter)

Nevada	**3841**	**98-0373793**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

7 Deer Park Drive, Suite K

Monmouth Junction, New Jersey 08852

(732) 329-8885

(Address, including zip code, and telephone number,

including area code, of registrant's principal executive offices)

(Name, address, including zip code, and telephone number,

including area code, of agent for service)

Copies to:

Gregg Jaclin, Esq.

Szaferman Lakind Blumstein & Blader, PC

101 Grovers Mill Road, Second Floor

Lawrenceville, NJ 08648

Tel No.: (609) 275-0400

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective. If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration Statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.¨

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

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	¨	Smaller reporting company	x

CALCULATION OF REGISTRATION FEE

Title of Each Class Of Securities to be Registered	Amount to Be Registered	Proposed Maximum Aggregate Offering Price per share	Proposed Maximum Aggregate Offering Price	Amount of Registration fee (1)
Units of Common Stock and Warrants (immediately separable) (2)				
Common Stock, $0.001 par value per share		$	$	$
Warrants to purchase Common Stock		$	$	$
Common Stock issuable upon exercise of Warrants (3)		$	$	$
Total Registration Fee	51,000,000	$	$ 8,500,000	$ 1,094.80

(1) Calculated pursuant to Rule 457(o) on the basis of the maximum aggregate offering price of all of the securities to be registered.

(2) These units consist of the Common Stock and Warrants listed in the above fee table. Such Common Stock and Warrants are immediately separable upon the closing of the offering. The Units will consist of 1 share of common stock and a warrant to purchase a half share of common stock.

(3) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable upon exercise of warrants registered hereunder as a result of stock splits, stock dividends, or similar transactions.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SECTION 8(a), MAY DETERMINE.

PRELIMINARY PROSPECTUS

Subject to completion, dated _____, 2014

CYTOSORBENTS CORPORATION

UP TO 34,000,000 UNITS, EACH CONSISTING OF

ONE (1) SHARE OF COMMON STOCK AND

A WARRANT TO PURCHASE ..5 SHARES OF COMMON STOCK

We are offering up to 34,000,000 units, each unit consisting of one (1) share of our common stock and one (1) warrant to purchase 0.50 shares of common stock at an exercise price of $[__] per share issued as part of this Unit. The warrants will be exercisable on or after the closing date of this offering through and including close of business on [ ], 2019. The units will not be certificated and the common stock and warrants will be immediately separable and will be separately transferable immediately upon issuance.

Our common stock is presently quoted on the OTC Bulletin Board, under the symbol “CTSO.” We do not intend to apply for listing of the warrants on any securities exchange. On December 19, 2013, the last reported sale price of our common stock on the OTC Bulletin Board was $0.1319 per share.

Investing in the offered securities involves risks, including those set forth in the “Risk Factors” section of this prospectus beginning on page 5 as well as those set forth in any prospectus supplement.

Brean Capital, LLC has agreed to act as our placement agent in connection with this offering. The placement agent is not required to sell any specific number or dollar amount of securities but will use their best efforts to sell the securities offered. This is a best efforts, no minimum offering and we may not sell the entire amount of securities being offered pursuant to this prospectus. We expect the offering to end on [_____], there are no minimum purchase requirements and there are no arrangements to place funds in an escrow, trust or similar account. The units being offered may be priced at a discount to the market price of our common stock, although as of the date hereof, there has been no definitive pricing of the units. We have agreed to pay the placement agent a cash fee equal to 6% of the gross proceeds of the offering. Subject to compliance with FINRA Rule 5110(f)(2)(D), we have also agreed to pay the placement agent for out-of-pocket expenses related to the Offering. We have also agreed to issue the placement agent common stock purchase warrants equal to 3% of the aggregate number of shares of common stock sold in the Offering.

We may complete the offering even if we do not raise the entire maximum offering amount. The amount raised may be substantially less than the total maximum offering amount and any investor funds not placed in escrow may be used by the Company prior to the maximum offering being sold. If we are voluntarily or involuntarily placed into bankruptcy or receivership, any investor funds may be property of the estate and used for the benefit of creditors and not recoverable by the investors.

The delivery of the shares and warrants is expected to be made on or about [_____], 2014.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is _____, 2014.

BREAN CAPITAL, LLC

TABLE OF CONTENTS

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all the information that you should consider before investing in the common stock. You should carefully read the entire prospectus, including "Risk Factors", "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Financial Statements, before making an investment decision. In this Prospectus, the terms "Cytosorbents," "Company," "we," "us" and "our" refer to Cytosorbents Corporation.

Overview

The Company

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, 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 finalized the name change of MedaSorb Technologies Corporation to CytoSorbents Corporation. Unless otherwise indicated, all references in this prospectus to "MedaSorb,", "CytoSorbents", "us" or "we" with respect to events prior to June 30, 2006 are references to CytoSorbents, Inc. and its predecessors.

We have experienced substantial operating losses since inception. As of September 30, 2013, we had a deficit accumulated during the development stage of approximately $104,469,233, which included losses of approximately $4,009,000 and $3,126,000 for the nine month periods ended September 30, 2013 and 2012, 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 approximately $3,608,000 and $2,770,000 for the nine month periods ended September 30, 2013 and 2012. We may continue to incur losses in the future. In part due to these losses, our 2012 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 executive offices are located at 7 Deer Park Drive, Suite K, Monmouth Junction, New Jersey 08852. Our telephone number is (732) 329-8885.

Summary of Our Business

CytoSorbents is a development stage critical care focused company using blood purification to treat disease. The technology is based upon biocompatible, highly porous polymer sorbent beads that are capable of extracting unwanted substances from blood and other bodily fluids. The technology is protected by 32 issued U.S. patents with multiple applications pending.

There are three major components of our business. The first is the manufacturing and sale of our flagship product, CytoSorb®, now approved and available for commercial sale throughout the entire European Union (E.U.). The second is the generation of clinical data on CytoSorb® as well as research and development of new products and technologies, partially funded through government contracts. The third is business development and out-licensing of our product pipeline and technology portfolio.

Commercialization of CytoSorb®

In March 2011, we received E.U. regulatory approval under the CE Mark and Medical Devices Directive for our flagship product, CytoSorb®, as an extracorporeal cytokine filter indicated for use in clinical situations where cytokines are elevated. The goal of the CytoSorb® is to prevent or treat organ failure by reducing cytokine storm and the potentially deadly systemic inflammatory response syndrome in life threatening conditions such as sepsis, trauma, burn injury, acute respiratory distress syndrome, pancreatitis, liver failure, and many others. Organ failure is the leading cause of death in the intensive care unit, and remains a major unmet medical need, with little more than supportive care therapy (e.g. mechanical ventilation, dialysis, vasopressors, fluid support, etc) as treatment options. By potentially preventing or treating organ failure, CytoSorb® may improve clinical outcome, including survival, while reducing the need for costly intensive care unit treatment, thereby potentially saving significant healthcare costs.

Our CE Mark enables CytoSorb® to be sold throughout the entire European Union. In addition, many countries outside the E.U. accept CE Mark approval for medical devices, but may also require registration with or without additional clinical studies. The broad approved indication enables CytoSorb® to be used “on-label” in diseases where cytokines are elevated including, but not limited to, critical illnesses such as those mentioned above, autoimmune disease flares, and many other conditions where cytokine-induced inflammation plays a detrimental role.

As part of the CE Mark approval process, we completed our randomized, controlled, European Sepsis Trial amongst fourteen trial sites in Germany in 2011, with enrollment of one hundred (100) patients with sepsis and respiratory failure. The trial established that CytoSorb® was safe in this critically-ill population, and that it was able to control cytokine storm, and broadly reduce key cytokines. In a post-hoc subgroup analysis, CytoSorb® was associated with a 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

- Age ≥ 65 (14-day mortality: 0% treated vs 36% control, p=0.04, n=21).

The Company plans to do larger, prospective studies in septic patients in the future to confirm the European Sepsis Trial findings.

In addition to CE Mark approval, CytoSorbents also achieved ISO 13485 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. CytoSorbents manufactures CytoSorb® at its manufacturing facilities in New Jersey for sale in the E.U. and for additional clinical studies. The Company also established a reimbursement path for CytoSorb® in Germany and Austria.

From September 2011 through June 2012, the Company began a controlled market release of CytoSorb® in select geographic territories in Germany with the primary goal of preparing for commercialization of CytoSorb® in Germany in terms of manufacturing, reimbursement, logistics, infrastructure, marketing, contacts, and other key issues.

In late June 2012, following the establishment of our European subsidiary, CytoSorbents Europe GmbH, CytoSorbents began the commercial launch of CytoSorb® for the treatment of critical care illnesses such as sepsis, burn injury, trauma, acute respiratory distress syndrome, pancreatitis and other conditions where inflammation plays a detrimental role, such as cardiac surgery. We hired Dr. Christian Steiner as Vice President of Sales and Marketing and three additional sales representatives who joined the Company and completed their sales training in Q3 2012. Q4 2012 represented the first quarter of direct sales with the full sales team in place. During this period, we expanded our direct sales efforts to include both Austria and Switzerland and have established reimbursement in Germany and Austria. At the end of the third quarter of 2013, we had more than 100 key opinion leaders (KOLs) in critical care and blood purification who were either using CytoSorb® or committed to using CytoSorb® in the near future, with 26 investigator initiated studies either underway or in the planning phase.

We have also begun to complement our direct sales efforts with sales to distributors and corporate partners. In 2013, we reached agreement with distributors in the United Kingdom, Ireland, Turkey, Russia, and the Netherlands, and we are currently in negotiations with and/or evaluating other potential distributor networks in other major countries where we are approved to market the device. In September 2013, we entered into a strategic partnership with Biocon Ltd., India's largest biotechnology company with an initial distribution agreement for India and select emerging markets, under which Biocon will have the exclusive commercialization rights for CytoSorb®.

We are currently conducting a dose ranging trial in Germany amongst eight clinical trial sites to evaluate the safety and efficacy of CytoSorb® when used for longer periods of time. Data from this dosing study are intended to help clinicians with additional treatment options for CytoSorb®, help support the positive clinical data from the Company's first European Sepsis Trial, and help shape the trial protocol for a U.S. based pivotal study.

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.

Research and Development of New Products and Technologies

The Company's proprietary hemocompatible porous polymer bead technology forms the basis of a broad technology portfolio. Some of our products include:

- CytoSorb® - an extracorporeal hemoperfusion cartridge approved in the E.U. for cytokine removal, with the goal of reducing SIRS and preventing or treating organ failure

- HemoDefend™ – a development-stage blood purification technology designed to remove contaminants in blood transfusion products. Goal is to reduce transfusion reactions and improve the safety of older blood

- ContrastSorb – a development-stage extracorporeal hemoperfusion cartridge designed to remove IV contrast from the blood of high risk patients undergoing CT imaging with contrast, or interventional radiology procedures such as cardiac catheterization. The goal is to prevent contrast-induced nephropathy

- DrugSorb – a development-stage extracorporeal hemoperfusion cartridge designed to remove toxic chemicals from the blood (e.g. drug overdose, high dose regional chemotherapy, etc.)

- BetaSorb™ – a development-stage extracorporeal hemoperfusion cartridge designed to remove mid-molecular weight toxins, such as b2-microglobulin, that standard high-flux dialysis cannot remove effectively. The goal is to improve the efficacy of dialysis or hemofiltration

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.

The Company has been successful in obtaining technology development contracts and support from agencies in the U.S. Department of Defense, including DARPA, U.S. Army, and the U.S. Air Force.

In June 2013, we announced that the U.S. Air Force will fund a 30 patient, single site, randomized controlled human pilot study in the United States amongst trauma patients with rhabdomyolysis. The FDA has approved our Investigational Device Exemption (IDE) application for this study, and the study is anticipated to commence shortly.

Following successful contract negotiations in June 2013, the Company began work on its previously announced $1 million Phase II SBIR U.S. Army contract to further develop its technology for the treatment of burn injury and trauma in animal models. This work is supported by the U.S. Army Medical Research and Material Command under an amendment to Contract W81XWH-12-C-0038 and has now received committed funding of $1.15 million to date.

In August 2012, the Company was awarded a $3.8 million contract by the Defense Advanced Research Projects Agency (DARPA) for its "Dialysis-Like Therapeutics" program to treat sepsis. This five-year contract is for advanced technology development of our hemocompatible porous polymer technologies to remove cytokines and a number of pathogen and biowarfare toxins from blood. CytoSorbents has begun work on Year 2 milestones and is currently working with the recently announced systems integrator, Battelle Laboratories, and its subcontractor, NxStage Medical, who are responsible for integrating the technology developed by CytoSorbents and others into a final medical device design prototype, and evaluation this device in septic animals and eventually in human clinical trials in sepsis. CytoSorbents' work is supported by DARPA and SSC Pacific under Contract No. N66001-12-C-4199.

In September 2013, the National Heart, Lung, and Blood Institute (NHLBI), a division of the National Institutes of Health ("NIH"), awarded the Company a Phase I SBIR (Small Business Innovation Research) contract to further advance its HemoDefend™ blood purification technology for packed red blood cell (pRBC) transfusions. The project, entitled "Elimination of blood contaminants from pRBCs using HemoDefend™ hemocompatible porous polymer beads," is valued at $203,351 over six months, with funding to start immediately. The overall goal of this new program is to reduce the risk of potential side effects of blood transfusions, and help to extend the useful life of pRBCs.

Business Development

We seek strategic partnerships or distributorships to help further develop or commercialize our technology portfolio. Because of the breadth of clinical applications that we attempt to address, the types of corporate partners are many. Examples of potential partners include companies focused on: medical devices, renal/dialysis, pharmaceuticals and biotechnology, critical-care, blood purification, advanced biomaterials, and others. No assurance can be given that we will be successful in our business development activities.

Where You Can Find Us

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

The Offering

Common stock offered	Up to 34,000,000 units. Each unit consists of 1 (one) share of our common stock and 1 (one) warrant to purchase 0.50 shares of our common stock issued as part of the unit. The units will not be certificated and the common stock and warrants will be immediately separable and will be separately transferable immediately upon issuance.
Common stock outstanding before the offering	As of November 30, 2013 there were 246,972,191 shares of the issuer's common stock, par value $0.001, outstanding.
Common stock outstanding after the offering	[_____] shares, assuming all of the Units are sold, which includes [_____] shares of common stock issuable upon exercise of the warrants included in the offered units or the shares of common stock issuable upon the exercise of the placement agent warrants.
Use of proceeds	We expect to use the proceeds received from the offering to further develop our products, to support our sales and marketing efforts, to help fund clinical studies, and for general working capital purposes. Specifically, of the $8,500,000 raised we expect to net proceeds of approximately $7,900,000 which will be used as follows: (i) 2,000,000 to further develop our products; (ii) 500,000 for sales and marketing efforts; (iii) $2,800,000 for clinical studies; and (iv) $2,600,000 for general working capital purposes. We may also receive additional funds from the exercise of the warrants, if they are in the money and the investors exercise the warrants for cash. However, the warrants will have a cashless component and we do not expect to receive any additional proceeds from the exercise of the warrants.
Risk Factors	The Common Stock offered hereby involves a high degree of risk and should not be purchased by investors who cannot afford the loss of their entire investment. See "Risk Factors" beginning on page 5.

RISK FACTORS

The shares of our common stock being offered are highly speculative in nature, involve a high degree of risk and should be purchased only by persons who can afford to lose the entire amount invested in the common stock. Before purchasing any of the shares of common stock, you should carefully consider the following factors relating to our business and prospects. If any of the following risks actually occurs, our business, financial condition or operating results could be materially adversely affected. In such case, you may lose all or part of your investment. You should carefully consider the risks described below and the other information in this process before investing in our common stock.

Risks Related to our Industry and our Business

We require additional capital to continue operations.

As of September 30, 2013 we had cash on hand of approximately $2,350,000 and current liabilities of approximately $3,066,000 (which includes approximately $1,562,000 of notes payable which are convertible into common shares). 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 expiring in August 2014 generally in amounts of up to $50,000 every two business days, which amounts may be increased under certain circumstances. At November 30, 2013, we had $3,200,000 of proceeds remaining under this Agreement.

The extent to which 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 $3,200,000 remaining 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 in other countries, such as the U.S., 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 September 30, 2013, we had an accumulated deficit of approximately $104,469,000, which included net losses of approximately $4,009,000 for the nine months ended September 30, 2013, approximately $3,664,000 for the year ended December 31, 2012 and approximately $5,482,000 for the year ended December 31, 2011. 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 November 30, 2013 we currently have twenty-five full-time employees and we also utilize consultants and temporary help who are not employees of the Company, as necessary. 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; Kathleen P Bloch, 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.

CytoSorb® is currently reimbursable in Germany and Austria. We plan to seek reimbursement for our product in other E.U. and non-E.U. 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" settlement 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 improperly 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.

CytoSorb® has already achieved European Union regulatory approval under the CE Mark and the Medical Devices Directive. It is manufactured at our manufacturing facility in New Jersey under ISO 13485 Full Quality Systems certification. 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 non E.U. 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 Devices 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 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® 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 clearance 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 or technologies, 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 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. CytoSorbents also achieved ISO 13485 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. CytoSorbents manufactures CytoSorb® at its manufacturing facilities in New Jersey for sale in the E.U. and for additional clinical studies. We will need to 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.

CytoSorb® is currently reimbursable in Germany and Austria. We plan to seek reimbursement for our product in other E.U. and non-E.U. countries to help further adoption. There can be no assurance when, or if, this additional reimbursement might be approved.

Investment Risks Connected to our Securities

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 a significant percentage of the voting control of the Common Stock on a fully diluted basis. One of our Directors represents an institutional investor that holds approximately 47% 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 5,776,329 shares of Series A Preferred Stock through September 30, 2013 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 September 30, 2013, the Company has a total of 1,716,743 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 47,254.51 shares of Series B Preferred Stock through September 30, 2013 to additional investors, and as dividends. Net of cumulative conversions into Common Stock through September 30, 2013, the Company has a total of 77,401.49 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 B 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 B 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 comments 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 re-file 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.

Redemption Provisions Of The Series B Preferred Stock

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.

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”) in December 2011, 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. Through September 30, 2013, 84,634,615 shares of common stock have been registered pursuant to S-1 registration statements 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. Currently, our certificate of incorporation authorizes the issuance of up to 800,000,000 shares of common stock, of which as of November 30, 2013, 553,027,809 shares remain available for issuance and may be issued by us or issued through conversions of preferred stock or convertible notes without stockholder approval. Pursuant to N.R.S. 78.315, the Board of Directors and a majority of the shareholders of the Company have approved the filing of an Amended Articles of Incorporation of the Company increasing the number of authorized shares of common stock to eight hundred million (800,000,000) shares of common stock, par value $0.001 per share. The filing was effective in April 2013.

On January 3, 2013, pursuant to Nevada Revised Statutes ("N.R.S.") 78.320, the Company received written consents in lieu of a meeting of Stockholders from twenty-one (21) Stockholders holding 12,517,118 shares of Common Stock and 71,834.74 shares of Series B Preferred Stock representing 51.5% of the 480,747,190 possible votes outstanding after dilution of the Series B Preferred Stock (the "Majority Stockholders"), approving the Amended Articles of Incorporation of the Company.

On March 12, 2013, the Company filed a Preliminary 14C Information Statement with the SEC. The Company filed a Definitive 14C Information Statement on March 22, 2013, and the Amended Articles of Incorporation of the Company became effective 20 days thereafter.

The increase in authorized shares does not mean that the Company is issuing additional shares in connection with the Amendment. As with all public companies, the authorized share amount sets a maximum number of shares that the Company may issue. 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.

As of September 30, 2013, our management determined that certain disclosure controls and procedures were ineffective, which could result in material misstatements of our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. As of September 30, 2013, our management determined that some of our disclosure controls and procedures were ineffective due to weaknesses in our financial closing process. Specifically, we lack a functioning Audit Committee to provide oversight and guidance.

While we do believe that our financial statements accurately reflect our financial results, it is possible that our ineffective controls and procedures may result in us failing to meet our future reporting obligations on a timely basis, our consolidated financial statements may contain material misstatements, and we may be required to restate our prior period financial results.

We can give no assurance that any measures we plan to take in the future will remediate the ineffectiveness of our disclosure controls and procedures or that any material weaknesses will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or adequate disclosure controls and procedures. In addition, even if we are successful in strengthening our disclosure controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

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 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The information contained in this report, including in the documents incorporated by reference into this report, includes some statement that are not purely historical and that are “forward-looking statements.” Such forward-looking statements include, but are not limited to, statements regarding management’s expectations, hopes, beliefs, intentions or strategies regarding the future, including our financial condition, results of operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipates,” “believes,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “might,” “plans,” “possible,” “potential,” “predicts,” “projects,” “seeks,” “should,” “would” and s expressions, or the negatives of such terms, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

The forward-looking statements contained in this report are based on current expectations and beliefs concerning future developments and the potential effects on the parties and the transaction. There can be no assurance that future developments actually affecting us will be those anticipated. These that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements, including the following forward-looking statements involve a number of risks, uncertainties (some of which are beyond the parties’ control) or other assumptions.

USE OF PROCEEDS

We estimate that we will receive up to $8,500,000 in gross proceeds from the sale of units in this offering. After deducting estimated placement agent fees and estimated offering expenses payable by us, we expect net proceeds of approximately $7,900,000. We will use the net proceeds from this offering to further develop our products, to support our sales and marketing efforts, clinical studies, and for working capital and other general corporate purposes.

We may also receive additional funds from the exercise of the warrants, if they are in the money and the investors exercise the warrants for cash. However, the warrants will have a cashless component. If a warrant holder elects to pay the exercise price, rather than exercising the warrants on a “cashless” basis, we may also receive proceeds from the exercise of warrants. We do not, however, expect to receive any additional proceeds from the exercise of the warrants. We cannot predict when or if the warrants will be exercised. It is possible that the warrants may expire and may never be exercised.

DILUTION

Our reported net tangible book value as of September 30, 2013 was $496,848, or $0.00 per share of common stock, based upon 245,140,613 shares outstanding as of that date. Net tangible book value per share is determined by dividing such number of outstanding shares of common stock into our net tangible book value, which are our total tangible assets less total liabilities. After giving effect to the sale of the units offered in this offering at an estimated offering price of $0.10 per unit, (and excluding shares of common stock issued and any proceeds received upon exercise of the warrants), after deducting placement agent fees and other estimated offering expenses payable by us, our net tangible book value at September 30, 2013 would have been approximately $5,169,000, or $(0.02) per share. This represents an immediate increase in net tangible book value of approximately $(0.02) per share to our existing stockholders, and an immediate dilution of $(0.00) per share to investors purchasing units in the offering.

The following table illustrates the per share dilution to investors purchasing units in the offering:

Public offering price per unit, estimated	$ 0.10
Net tangible book value per share as of September 30, 2013	$ 0.00
Increase per share attributable to sale of units to investors	$ 0.03
As adjusted net tangible book value per share after the offering	$ 0.03
Dilution per share to investors	$ 0.00
Dilution as a percentage of the offering price	0.0 %

The foregoing illustration does not reflect potential dilution from the exercise of outstanding options or warrants to purchase shares of our common stock.

DESCRIPTION OF BUSINESS

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, 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. In the past, the Company has raised money that 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 $1,706,000 and $1,854,000 for the periods ended September 30, 2013 and 2012, respectively. From our inception date January 22, 1997, through to September 30, 2013 the Company’s research and development costs totaled approximately $55,636,000. We have recently been awarded approximately $5 million in contracts from DARPA ($3.8M over 5 years) and the U.S. Army ($100,000 Phase I SBIR; $50,000 Phase I Option, and $1 million Phase II SBIR) to further develop our technologies for sepsis, trauma and burn injury. Payments are based on achieving certain technology milestones.

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 polymer adsorbent technology can remove drugs, bioactive lipids, inflammatory mediators such as cytokines, free hemoglobin, toxins, and immunoglobulin 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, but not limited to, 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.

CytoSorbents' flagship product, CytoSorb® and other products under development, including BetaSorb™, ContrastSorb, and DrugSorb consist of a cartridge containing adsorbent polymer beads, although the polymers used in these devices are physically different. The cartridges incorporate industry standard connectors at either end of the device, which connect directly to the extracorporeal circuit (bloodlines) in series with a dialyzer, in the case of the BetaSorb™ device, or as a standalone device in the case of the CytoSorb®, ContrastSorb, and DrugSorb devices. The extra-corporeal circuit consists of plastic blood tubing, our blood filtration cartridges 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. All of these devices are expected to be compatible with standard blood pumps or hemodialysis machines used commonly in hospitals and will therefore not require hospitals to purchase additional expensive equipment, and will require minimal training.

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 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, which 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 or trauma. It is commonly seen in the intensive care unit, accounting for approximately 10-20% of all ICU admissions. 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 25-35%. 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 40-50%.

23

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 multiple organ dysfunction syndrome (MODS) and multiple organ failure (MOF), 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 first-in-class, clinically-proven broad-spectrum extracorporeal cytokine filter currently approved for sale in the E.U. The goal of CytoSorb® is to prevent or treat organ failure by reducing cytokine storm and controlling a "run-away" immune response, while antibiotics work to control the actual infection. CytoSorb® has been evaluated in the randomized, controlled European Sepsis Trial in 43 patients in Germany with predominantly septic shock and acute respiratory distress syndrome or acute lung injury. The therapy was safe in more than 300 human treatments and generally well tolerated. CytoSorb demonstrated the statistically significant ability to reduce cyotkine storm and key cytokines by 30-50%. In a post-hoc analysis, this was associated with improvements in clinical outcome in two high-risk patient populations – those with very high cytokine levels and patients 65 years of age and older.

The Company estimates that the market potential in Europe for its products is larger than that in the U.S. For example, in the U.S. and Europe, there are an estimated one million and 1.5 million new cases, respectively, of severe sepsis and septic shock annually. In Germany alone, according to the German Sepsis Society (GSS), there are approximately 154,000 cases of severe 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.

The only treatment that had been approved to treat sepsis in the U.S. or E.U. was Xigris (Eli Lilly). Because of concerns of cost, limited efficacy, and potentially dangerous side effects including the increased risk of fatal bleeding events such as intracranial bleeding for those at risk, and also because of problems with reimbursement, worldwide sales of Xigris decreased from $160M in 2009 to $104M in 2010. In October 2011, following its PROWESS SHOCK trial that demonstrated no benefit in mortality in septic shock patients, Lilly voluntarily withdrew Xigris from all markets worldwide, and is no longer available as a treatment.

Development of most other experimental therapies has been discontinued, including Eritoran from Eisai, CytoFab from BTG/Astra Zeneca, Talactoferrin from Agennix, and others. Currently, there are two late stage trials ongoing. In November 2012, an 800 patient Phase III randomized controlled study began for Recomodulin (ART 123, Artisan/Asahi Kasei), a recombinant human thrombomodulin, for the treatment of septic patients with coagulopathy. Recomodulin has been approved in Japan since 2009 for the treatment of disseminated intravascular coagulation (DIC), a late complication of sepsis, at a cost of $5,800 per treatment. Although it has other activity, it works primarily by a similar anticoagulant mechanism to Xigris. Because of this, it has only demonstrated a limited mortality benefit (~9%: 34.6% control vs 26% treatment), similar to that seen in Xigris' initial PROWESS Trial (~6%: 31% control vs 25% treatment) and is unlikely to have greater benefit in larger scale studies. Spectral Diagnostics is collaborating with Toray on the EUPHRATES trial, combining an endotoxin assay with extracorporeal endotoxin

removal by Toraymyxin, a polymyxin-B immobilized polystyrene fiber cartridge. The study began in June 2010 and is still enrolling patients. Endotoxemia is a result of Gram negative sepsis, which only accounts for 45% of cases of sepsis. It is a potent stimulator of cytokine storm. However, all anti-endotoxin strategies have failed pivotal studies to date, believed to be the result of intervening too late in the sepsis cascade. Because of the lack of available therapies, there remains a significant medical need for improved treatments for sepsis.

Severe sepsis and septic shock patients are amongst the most expensive patients to treat in a hospital. For example, a typical severe sepsis or septic shock patient in the U.S. costs approximately $45,000-60,000 to treat. 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. CytoSorb® is approved in the E.U. and is being sold directly in Germany, Austria, and Switzerland. CytoSorbents has ongoing discussions with potential corporate partners and independent distributors to market CytoSorb® in other select E.U. countries and in other countries outside the E.U. that accept CE Mark approval. CytoSorb® is currently reimbursed in Germany and Austria at more than $500 per unit. A typical seven day treatment costs ~$3,500, approximately the cost of 1-2 days in the ICU. The cost of therapy represents a fraction of what is currently spent on the treatment of patients with sepsis. Based upon this price point, and an combined incidence of severe sepsis and septic shock of approximately 2.5 million patients in the U.S. and E.U. each year, the total addressable market for CytoSorb® for the treatment of sepsis in the U.S. and E.U. is approximately $6-8 billion.

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, oxygen toxicity, 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 (e.g. 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 where in a post-hoc analysis in patients with very high cytokine levels, we observed faster ventilator weaning in CytoSorb® treated patients that showed a statistical trend to benefit. Future, prospectively defined, larger studies are required to confirm these findings. Although a number of therapies have been tried such as corticosteroids, nitric oxide, surfactant therapy, and others, there are currently no approved treatments for ARDS. Only low tidal volume ventilation has been demonstrated to improve mortality (31.0 vs 39.8% control) in this patient population. However, even with this intervention, mortality is still unacceptably high. The total addressable market for CytoSorb® to treat ARDS/ALI in the E.U. is estimated to be between $500 million to $1.25 billion, and $1-2 billion in the U.S. and E.U.

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. The total addressable market in the E.U. for CytoSorb® to address burn and smoke inhalation injury is estimated at $150-350 million and $300-600 million in the U.S and E.U.

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 and myoglobin reduction by CytoSorb® and related technologies may have benefit in trauma, potentially improving clinical outcome. In December 2011, September 2012, and April 2013, CytoSorbents was awarded a Phase I, Phase II SBIR, and Phase I option award, respectively, from the U.S. Army Medical Research and Materiel Command to develop its technology for the treatment of trauma and burn injury. The total addressable market for CytoSorb® for the treatment of trauma is estimated to be $1.5-2.0 billion in the U.S. and E.U.

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. 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, generalized edema, and multiple organ failure that is correlated with high levels of cytokines and digestive enzymes in the blood. Little can be done to treat severe acute pancreatitis today, except for pancreatic duct decompression with endoscopic techniques, supportive care therapy, pain control and fluid support. ICU stay is frequently measured in weeks and although overall ICU mortality is approximately 10%, patients with multiple organ failure have a much higher risk of death. CytoSorb® may potentially benefit overall outcomes in episodes of acute pancreatitis by removing a diverse set of toxins from blood. The total addressable market for CytoSorb® for the treatment of severe acute pancreatitis in the U.S. and E.U. is estimated to be between $400-600 million.

Cardiopulmonary Bypass Procedures

There are approximately 400,000 cardiopulmonary bypass (CPB) and cardiac surgery procedures performed annually in the U.S. and approximately 1.5 million procedures worldwide. Many patients suffer from post-operative complications of cardiopulmonary bypass surgery, including complications from infection, pneumonia, pulmonary, renal, and neurological dysfunction. 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. A common characteristic of these post-operative complications is the presence of high amounts of cytokines in the blood. The use of CytoSorb® to reduce cytokines and other inflammatory mediators during and after the surgical procedure may prevent or mitigate post-operative complications. During the procedure, the CytoSorb® filter can be incorporated in the CPB blood circuit. After the surgery, CytoSorb® can be used similarly to dialysis, on patients that develop complications. CytoSorb® has the opportunity to replace leukoreduction filters that are commonly used during the CPB procedure to try to reduce the production of cytokines by white blood cells. The peri-procedural total addressable market for CytoSorb® in the U.S. and E.U in cardiothoracic surgery procedures is estimated at approximately $1 billion.

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. In addition, CytoSorb® treatment in a porcine animal model of brain death demonstrated a reduction in cytokines as well as a preservation of cardiac function compared to untreated controls.

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 such as free hemoglobin and antibodies. 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. The total addressable market for HemoDefend™ is more than $500M for pRBCs alone.

Radiocontrast Removal

ContrastSorb is a development-stage blood purification technology that is being optimized for the removal of IV contrast from blood in order to prevent contrast-induced nephropathy (CIN). Contrast-induced nephropathy is the acute loss of renal function within the first 48 hours following IV contrast administration. IV contrast is widely administered to patients undergoing CT scans, to enhance the images and make it easier to identify anatomic structures. IV contrast is also administered during vascular interventional radiology procedures and angiography of blood vessels in the brain, heart, limbs, and other parts of the body to diagnose and treat atherosclerosis (narrowing of blood vessels due to cholesterol deposits), vascular injury, aneurysms, etc. For example, an estimated 10 million coronary angiograms are performed worldwide each year to diagnose and treat coronary artery disease by placing coronary stents, performing balloon angioplasty, or atherectomy (removal of plaque in arteries). Overall, there are an estimated 80 million doses of IV contrast administered worldwide each year, split between approximately 65 million contrast-enhanced CT scans, 10 million coronary angiograms, and 5 million conventional angiograms. There are an estimated 30 million doses administered each year in the U.S. alone. The reported risk of CIN in patients undergoing contrast enhanced CT scans has been reported to be 2-13%. For coronary intervention, the risk has been estimated to be as high as 20-30% in high risk patients with pre-existing renal insufficiency, long-term diabetes, hypertension, congestive heart failure, and older age. The use of low osmolar IV contrast, hydration of patients pre-procedure, orally administration of N-acetylcysteine, and other agents to prevent CIN have demonstrated modest benefit in some clinical studies, but in many cases, the results across studies have been equivocal and inconsistent. In high risk patients, the direct removal of IV contrast from the blood with ContrastSorb to prevent CIN represents a potentially more effective alternative. The worldwide market opportunity for ContrastSorb in this high risk group is approximately $1-2 billion.

DrugSorb

DrugSorb is a development-stage blood purification technology that is capable of removing a wide variety of drugs and chemicals from blood, as a potential treatment for drug overdose, drug toxicity, toxic chemical exposure, use in high-dose regional chemotherapy, and other applications. It has demonstrated extremely high single pass removal efficiency of a number of different drugs that exceeds the extraction capability of hemodialysis or other filtration technologies. It is similar in action to activated charcoal hemoperfusion cartridges that have been available for many years, but has the advantage of having inherent biocompatibility and hemocompatibility without coatings, and can be easily customized for specific agents.

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; 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; the prevention of kidney injury from IV contrast; 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) critically ill patients with predominantly septic shock and respiratory failure. The trial successfully demonstrated CytoSorb®'s ability to reduce circulating levels of key cytokines from whole blood by 30-50% in treated patients, and that treatment was safe in these critically-ill patients with multiple organ failure. 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 continue 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 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 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 25% to greater than 50%. 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. Eli Lilly has voluntarily

withdrawn Xigris from all markets worldwide due to a lack of efficacy and is no longer commercially available.

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. CytoSorb® has demonstrated the ability to safely reduce key cytokines by 30-50% in septic patients with multiple-organ failure in our European Sepsis Trial.

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. Safety data collected from more than 300 treatments in septic patients, where there have been no serious device related adverse events, provide additional evidence that CytoSorb® treatment is safe in this patient population.

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: In 2011, the CytoSorb® filter received European Union regulatory approval under the CE Mark as an extracorporeal cytokine filter to be used in clinical situations where cytokines are elevated. CytoSorbents' manufacturing facility has also achieved ISO 13485 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 commercial sale in the European Union. CytoSorbents is currently selling CytoSorb® in Germany, Austria, and Switzerland with a direct sales force. Based on its CE Mark approval, CytoSorb® can also be sold throughout the rest of the European Union and countries outside the E.U. that will accept European regulatory approval. With sufficient resources and continued positive clinical data, 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 as well as pursue U.S. clinical trials to seek FDA regulatory approval for CytoSorb® in the United States.

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: CytoSorb®'s E.U. CE Mark approval as an extracorporeal cytokine filter and its broad approved indication to be used in any clinical situation where cytokines are elevated, allows it to be used "on label" in critical care applications such as acute respiratory distress syndrome, severe burn injury, trauma, liver failure, and pancreatitis, and in other conditions 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 currently have 26 such studies in Europe either enrolling patients or being planned. 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. For example, we recently announced that the U.S. Air Force is funding an FDA approved 30-patient randomized controlled human pilot study using CytoSorb to treat trauma patients with rhabdomyolysis to begin this year. 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.

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 post-operative complications such as ARDS, acute kidney injury, post-perfusion syndrome;
- 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 often difficult 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. Currently, a number of cardiac surgeons in Germany and Austria are using CytoSorb® both intra-operatively and post-operatively to control inflammation in their surgical patients.

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. CytoSorb® treatment in a porcine animal model of brain death demonstrated a reduction in cytokines as well as a preservation of cardiac function compared to untreated controls.

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.

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. CytoSorbents was recently was recently awarded a $203,351 Phase I SBIR contract by the NIH and NHLBI to further develop the HemoDefend platform towards commercialization.

ContrastSorb (Radiology and Interventional Radiology)

APPLICATION: Removal of IV contrast in blood administered during CT imaging, an angiogram, or during a vascular interventional radiology procedure, in order to reduce the risk of contrast-induced nephropathy.

Potential Benefits: IV contrast can lead to contrast-induced nephropathy (CIN) in susceptible patients. Risk factors include chronic kidney disease and renal insufficiency caused by age, diabetes, congestive heart failure, long-standing hypertension, and others co-morbid illnesses. CIN can lead to increased risk of patient morbidity and mortality. Removal of IV contrast by ContrastSorb may

- reduce the risk of acute kidney injury
- improve the safety of these procedures and reduce the risk of morbidity and mortality

Background and Rationale: Contrast-induced nephropathy is the acute loss of renal function within the first 48 hours following IV contrast administration. IV contrast is widely administered to patients undergoing CT scans, to enhance the images and make it easier to identify anatomic structures. IV contrast is also administered during vascular interventional radiology procedures and angiography of blood vessels in the brain, heart, limbs, and other parts of the body to diagnose and treat atherosclerosis (narrowing of blood vessels due to cholesterol deposits), vascular injury, aneurysms, etc. The reported risk of CIN undergoing contrast enhanced CT scans has been reported to be 2-13%. For coronary intervention, the risk has been estimated to be as high as 20-30% in high risk patients with pre-existing renal insufficiency, and other risk factors. The use of low osmolar IV contrast, hydration of patients pre-procedure, orally administration of N-acetylcysteine, and other agents to prevent CIN have demonstrated modest benefit in some clinical studies, but in many cases, the results across studies have been equivocal and inconsistent. In high risk patients, the direct removal of IV contrast from the blood with ContrastSorb to prevent CIN represents a potentially more effective alternative.

Projected Timeline: ContrastSorb has demonstrated the high efficiency single pass removal of IV contrast and is in the process of optimization. The underlying polymer is made of the same ISO 10993 biocompatible polymer as CytoSorb®, but with different structural characteristics. The ContrastSorb device is a hemoperfusion device similar in construction to CytoSorb® and BetaSorb. Assuming successful optimization of the ContrastSorb polymer, safety and efficacy of IV contrast removal will need to be established in human clinical studies. The Company seeks to out-license this technology to a potential strategic partner.

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 Professor of Critical Care Medicine, and Vice Chair of Research for Critical Care at the University of Pittsburgh Medical Center**,** has authored more than 100 publications and has received numerous research grants from foundations and industry.

DARPA

In August 2012, the Defense Advanced Research Projects Agency (DARPA) awarded CytoSorbents a five-year technology development contract valued at $3.8 million as part of its "Dialysis-Like Therapeutics" (DLT) program to treat sepsis. DARPA has been instrumental in funding many of the major technological and medical advances since its inception in 1958, including development of the Internet, the global positioning system (GPS), and robotic surgery. The DLT program in sepsis seeks to develop a therapeutic blood purification device that is capable of identifying the cause of sepsis (e.g. cytokines, toxins, pathogens, activated cells) and remove these substances in an intelligent, automated, and efficient manner. DARPA is funding CytoSorbents to further develop its technologies to remove both cytokines and a variety of toxins (e.g. pathogen-derived, naturally occurring, or biowarfare generated). In 2012, CytoSorbents recognized approximately $1.1 million in grant income following the successful completion of milestones under its contract.

United States Army

In December 2011 and September 2012, The US Army Medical Research and Material Command awarded CytoSorbents a $100,000 Phase I SBIR (Small Business Innovation Research), and a $1 million Phase II SBIR contract, respectively, to develop our technologies for the treatment of trauma and burn injury. During 2012, we received the full amount of the Phase I SBIR contract. In 2013, we were awarded a $50,000 Phase I Option.

United States Air Force

In June 2013, we announced that the U.S. Air Force will fund a 30 patient, single site, randomized controlled human pilot study in the United States using CytoSorb® to treat trauma patients with rhabdomyolysis. The FDA has approved our Investigational Device Exemption (IDE) application for this study, with the study anticipated to commence soon.

NIH/NHLBI

In September 2013, CytoSorbents was awarded $203,351 Phase I SBIR by the National Institutes of Health (NIH) - National Heart, Lung, and Blood Institute (NHLBI) to evaluate our HemoDefend™ technology for the removal biological based contaminants associated with the storage of blood such as hemoglobin, bioactive lipids, cytokines, and others substances as a result of processing and storage over time. CytoSorbents will collaborate with Dr. Larry Dumont, MBA, PhD, Director of the Center for Transfusion Medicine Research, and Associate Professor of Pathology at the Geisel School of Medicine at Dartmouth University, and Chairman of the BEST (Blood Evaluation for Safe Transfusion) Collaborative, Funding has commenced.

Fresenius Medical Care AG

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

Fresenius Medical Care is the world's largest, integrated provider of products and services for individuals with chronic kidney failure. Through its network of more than 2,100 dialysis clinics in North America, Europe, Latin America and Asia-Pacific, Fresenius Medical Care provides dialysis treatment to more than 163,000 patients around the globe. Fresenius Medical Care is also the world's largest provider of dialysis products, such as hemodialysis machines, dialyzers and related disposable products.

Advisory Boards

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

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

Our Medical Advisory Board for Severe Sepsis / Inflammatory Disease consists of 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 Trauma Advisory Board consists of five critical care specialists with expertise in trauma, inflammation, and burn injury.

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.

With Purolite

In 2003, Purolite filed a lawsuit against us asserting, among other things, co-ownership and co-inventorship of certain of our patents. On September 1, 2006, the United States District Court for the Eastern District of Pennsylvania approved a Stipulated Order and Settlement Agreement under which we and Purolite agreed to the settlement of the action. The Settlement Agreement provides us with the exclusive right to use our patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. In particular, the Settlement Agreement relates to several of our issued patents and several of our pending patent applications covering our biocompatible polymeric resins, our methods of producing these polymers, and the methods of using the polymers to remove impurities from physiological fluids, such as blood.

Under the terms of the Settlement Agreement, we have agreed to pay Purolite royalties of 2.5% to 5% on the sale of those of our products, if and when those products are sold commercially, that are used in direct contact with blood. However, if the first product we offer for commercial sale is a biocompatible polymer to be used in direct contact with a physiological fluid other than blood, royalties will be payable with respect to that product as well. The royalty payments provided for under the Settlement Agreement would apply to our 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 CytoSorb® reimbursement has been established. Reimbursement has also been established in Austria. 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 continue to gain traction of 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 technology to treat patients suffering from sepsis. These techniques are unable to effectively remove middle molecular weight toxins, which leading researchers have shown to cause and complicate sepsis. The same experts believe that a blood purification technique that efficiently removes, or significantly reduces, the circulating concentrations of such toxins might represent a successful therapeutic option. We believe that the CytoSorb® device may have the ability to remove middle molecular weight toxins from circulating blood.

Medical research during the past two decades has focused on drug interventions aimed at chemically blocking or suppressing the function of one or two inflammatory agents. In hindsight, some researchers now believe this approach has little chance of significantly improving patient outcomes because of the complex pathways and multiple chemical factors at play. Clinical studies of these drug therapies have been largely unsuccessful. An Eli Lilly drug, Xigris®, cleared by the FDA in November 2001, was 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. But 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 it from the market 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 AstraZeneca/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. In August 2012, AstraZeneca and partner BTG discontinued development of CytoFab after a failed Phase IIb study.

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. Approximately 100 patients have enrolled to date. The endpoint of the trial is 28-day all-cause mortality and interim data is expected at 184 patients. 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 cytapheresis, or the inactivation or removal of activated leukocytes. It is currently enrolling a 344 patient pivotal trial that began in August 2011 and is expected to be completed by December 2014 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. ExThera Medical Corporation has developed its Seraph™ (Selective Removal by Apheresis) platform that consists of heparin coated, solid polyethylene beads. Heparin has the ability to bind some, but not all viruses, bacteria, toxins and cytokines. In *in vitro* studies using 1 mL of human septic blood, there was no statistically different change in IL-6 or Interferon-gamma compared to control, but effected a ~50% reduction in TNF-alpha. This inability to remove a broad range of cytokines will likely limit its efficacy as a treatment in sepsis. 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 and Phase II SBIR grant awarded to CytoSorbents in December 2011 and September 2012, respectively.

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 Haemonetics 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.

In December 2013, the Company issued a press release relating to the dosing study that is underway. The dosing study was designed to evaluate the safety and preliminary efficacy of extended CytoSorb® treatment in septic patients with respiratory failure using the same inclusion and exclusion criteria as the European Sepsis Trial. The major goals of the study were to:

- Obtain safety data on extended CytoSorb® treatment
- Confirm CytoSorb® cytokine removal over an extended period of usage
- Provide clinicians with more flexibility on how to treat critically ill patients with CytoSorb®
- Obtain data to help optimize treatment and support the design of a US pivotal sepsis trial to prove effectiveness. This Dosing study was not intended to produce statistically significant data on clinical endpoints.

There are two CytoSorb® treatment protocols being evaluated in the Dosing study: 1) 24 hours per day for 7 days and 2) 6 hours per day for up to 14 days, each day using a new device. Currently, only the 24-hour treatment arm is enrolling patients. The intent is to compare these two arms against clinical outcomes from control and treated patients in the EST (6 hours a day for 7 days) using a matched pairs analysis strategy. In this analysis, all patients in the Dosing study are treated with CytoSorb®, and then are later matched and compared to patients from the EST trial using variables in common such as age ≥ 65 years old, need for dialysis, APACHE 2 score, cytokines, and other factors.

There have been 28 patients enrolled into the first arm (24 hours of treatment for 7 days) of the trial to date. Preliminary analysis of the available data suggests the following:

- CytoSorb® treatment is well tolerated at flow rates up to 300 mL/min, with no serious device related adverse events in the trial to date. 24-hour treatment increases platelet reduction compared to 6-hour treatment in the EST, but with no reported complications.

- CytoSorb® is compatible with a variety of antibiotics including aminoglycosides and broad-spectrum antibiotics, such as the carbepenem class, which require only modest dose adjustments. Additional antibiotic testing is underway.

- CytoSorb® is concentration dependent and continues to actively remove IL-6 during the entire 24-hour treatment period, higher at the beginning of treatment when IL-6 levels are highest, and with an overall average instantaneous IL-6 reduction of 8% per pass. For each patient, approximately 60-70 total blood volumes, the equivalent of approximately 300 liters or 75 gallons of blood, are treated per day. In an *in vitro* blood perfusion system with no cytokine production, this equates to a rapid and greater than 99% reduction of IL-6. In the body, however, with active ongoing cytokine production, the overall reduction is less.

- Safety data obtained from this study on continuous 24-hour treatment will be used to provide additional examples in the "Instructions for Use" document that accompanies the product for commercial usage. This will provide additional flexibility in how physicians use CytoSorb® in sepsis and other critical care applications.

- The first treatment arm continues to enroll patients. In this preliminary analysis, the overall 28-day all-cause mortality and 28-day all-cause mortality in patients 65 years and older is statistically similar to the treatment data reported in the EST (electronic randomized cohort). Severity of illness in the overall treatment groups were comparably high, with 50% or more of the treated patients (dosing > EST) having an APACHE 2 severity of illness score > 25 at the time of enrollment, predicting very high mortality of 55% or more. In comparison, the overall control patients reported in the EST (electronic randomization cohort) had a lower severity of illness with only 20% having an APACHE 2 score > 25.

Cytokine analysis and matched pairs analysis is currently ongoing and 60-day mortality data is still pending on many recently enrolled patients.

In 2011, the CytoSorb® filter received European Union regulatory approval under the CE Mark as an extracorporeal cytokine filter to be used in clinical situations where cytokines are elevated. As part of the CE Mark approval process, we completed our randomized, controlled, European Sepsis Trial amongst fourteen trial sites in Germany, with enrollment of one hundred (100) patients with sepsis and respiratory failure. The purpose of the trial was to demonstrate safety and the broad reduction of key cytokines such as IL-6 in critically-ill patients. 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. Although the trial was not powered to demonstrate significant reduction in other clinical endpoints such as mortality, these were also included as secondary and exploratory endpoints 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
- Age ≥ 65 (14-day mortality: 0% treated vs 36% control, p=0.04, n=21).

In patients aged ≥ 65 years old, however, seven days of treatment with CytoSorb® was not adequate to extend the observed 14-day mortality benefit out to 28-days (40% vs 45% control, p=0.6, n=21). These critically ill patients carried two major mortality risk factors: multiple organ failure and age ≥ 65 years old, which itself confers a 2.3-fold relative risk of death. Treatment of life-threatening infections with antibiotics often requires 7-14 days of treatment. We hypothesize that treatment of the "run-away" immune response should mirror treatment with antibiotics. We are currently conducting a dose ranging study in Germany amongst seven clinical trial sites to evaluate the safety and efficacy of CytoSorb® when used continuously for 7 days, or for 6 hours per day for more than 7 days. Patients are being stratified for age, cytokine levels, and co-morbid illnesses in this matched pairs analysis. Data from this dosing study are intended to help clinicians with additional treatment options for CytoSorb®, help support the positive clinical data from the Company's first European Sepsis Trial, and help shape the trial protocol for a U.S. based pivotal study. 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 while pursuing US regulatory approval.

In 2007, CytoSorbents received FDA approval of its investigational device exemption (IDE) application to run a single center sepsis study in the United States. The Company has since generated safety data in approximately 300 human treatments in patients with septic shock and multiple organ failure in its European Sepsis Trial. Following completion of our current dose ranging study, we plan to re-initiate discussions with the FDA to leverage our existing open IDE approval, and review our plans for the United States to determine whether to conduct clinical trials in the U.S. in support of a PMA filing for the indication of sepsis. 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 U.S. 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.

In June 2013, we announced that the U.S. Air Force will fund a 30 patient, single site, randomized controlled human pilot study in the United States using CytoSorb® to treat trauma patients with rhabdomyolysis. The FDA has approved our Investigational Device Exemption (IDE) application for this study, which is anticipated to commence shortly.

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 August 2012, the Defense Advanced Research Projects Agency (DARPA) awarded CytoSorbents a five-year technology development contract valued at $3.8 million as part of its “Dialysis-Like Therapeutics” (DLT) program to treat sepsis. DARPA is funding CytoSorbents to further develop its technologies to *remove* both cytokines and a variety of toxins (e.g. pathogen-derived, naturally occurring, or biowarfare generated).

In September 2012 CytoSorbents was awarded a $1 million Phase II SBIR (Small Business Innovation Research) contract by the US Army Medical Research and Materiel Command to evaluate our technology for the treatment of trauma and burn injury in large animal models. We are in the process of finalizing the Phase II SBIR contract with the granting agency.

In April 2013, CytoSorbents was awarded an additional $50,000 Phase I Option SBIR award by the US Army Medical Research and Materiel Command as part of the previously announced burn injury and trauma SBIR award.

In June 2013, CytoSorbents announced that the U.S. Air Force will fund a 30 patient, single site, randomized controller human pilot study in the United States amongst trauma patients with rhabdomyolysis. The FDA has approved our Investigational Device Exemption (IDE) application for this study, which is anticipated to commence this year.

In September 2013, CytoSorbents was awarded $203,351 Phase I SBIR by the National Institutes of Health (NIH) - National Heart, Lung, and Blood Institute (NHLBI) to evaluate our HemoDefend™ technology for the removal biological based contaminants associated with the storage of blood such as hemoglobin, bioactive lipids, cytokines, and others substances as a result of processing and storage over time. CytoSorbents will collaborate with Dr. Larry Dumont, MBA, PhD, Director of the Center for Transfusion Medicine Research, and Associate Professor of Pathology at the Geisel School of Medicine at Dartmouth University, and Chairman of the BEST (Blood Evaluation for Safe Transfusion) Collaborative, Funding has commenced.

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 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. Recently, hemoperfusion devices for drug detoxification were downregulated to Class II devices. 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

In 2012, we established our European subsidiary, CytoSorbents Europe GmbH, in Berlin, Germany which serves as the center of our sales activities in Europe. Following the completion of a controlled market release in late June 2012, CytoSorb® was formally launched in Germany with reimbursement established at more than $500 per cartridge. We recruited Dr. Christian Steiner, MD as our Vice President of Sales and Marketing and hired three additional sales representatives who completed training in Q3 2012. The fourth quarter of 2012 was the first full quarter of direct CytoSorb® sales with our sales force in place. We began expansion of our direct sales efforts into both Austria, where reimbursement for CytoSorb® is now available, and Switzerland. From the beginning of the controlled market release in Q4 2011 through the end of September 30, 2013, we achieved cumulative sales of approximately $695,000 in sales of CytoSorb in Europe. At the end of the second quarter of 2013, we had more than 100 key opinion leaders (KOL) who were either using CytoSorb® or interested in using it in clinical practice and/or in clinical studies. These KOL relationships are an essential step in our goal of driving usage, adoption and reorders of CytoSorb® as they facilitate ordering and reimbursement within the hospital, have a strong influential role within their department and amongst their peers and colleagues outside the hospital, and have the ability to conduct studies and generate data, papers and conference presentations that could drive awareness and demand.

We are approved to sell CytoSorb® in all 28 countries in the European Union, including Germany, United Kingdom, Italy, France and Spain. In 2013, we reached agreement with distributors in the United Kingdom, Turkey, Russia, and the Netherlands, and we are in negotiations with and evaluating other potential distributor networks in other major countries where we are approved to market the device. .. In September 2013, we entered into a strategic partnership with Biocon Ltd., Asia’s largest biotech company with an initial distribution agreement for India and select emerging markets, under which Biocon will have the exclusive commercialization rights for CytoSorb®.

We plan to expand to other countries in the E.U., and with registration, other countries outside the E.U. that will accept CE Mark approval with a mixed direct and independent distributor strategy, that can be augmented through strategic partnerships. Registration and reimbursement in other countries may or may not require additional clinical data. We plan to continue our commercialization plans in Europe provided we receive adequate and timely funding to support our planned activities and that our products continue to perform as expected in clinical studies.

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 32 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 November 30, 2013, we had twenty-five full-time employees and utilize consultants and temporary help 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.

DESCRIPTION OF PROPERTY

We currently operate a facility near Princeton, New Jersey with approximately 9,800 sq. ft., housing research laboratories, clinical manufacturing operations and administrative offices, under a lease agreement, which expires in May 2014. 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.

We also operate a small office facility in Berlin, Germany housing sales and administrative offices. We entered into a lease for this office on March 1, 2012. The lease expires on February 28, 2014. We rent this space for €1,200 per month or US$1,560 per month.

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.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS.

The information contained in Item 2 contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Actual results may materially differ from those projected in the forward-looking statements as a result of certain risks and uncertainties set forth in this report. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual results will not be different from expectations expressed in this report.

This filing contains a number of forward-looking statements which reflect management's current views and expectations with respect to our business, strategies, products, future results and events, and financial performance. All statements made in this filing other than statements of historical fact, including statements addressing operating performance, events, or developments which management expects or anticipates will or may occur in the future, including statements related to distributor channels, volume growth, revenues, profitability, new products, adequacy of funds from operations, statements expressing general optimism about future operating results, and non-historical information, are forward looking statements. In particular, the words "believe," "expect," "intend," "anticipate," "estimate," "m variations of such words, and similar expressions identify forward-looking statements, but are not the exclusive means of identifying such statements, and their absence does not mean that the statement is not forward-looking. These forward-looking statements are subject to certain risks and uncertainties, including those discussed below. Our actual results, performance or achievements could differ materially from historical results as well as those expressed in, anticipated, or implied by these forward-looking statements. We do not undertake any obligation to revise these forward-looking statements to reflect any future events or circumstances.

Readers should not place undue reliance on these forward-looking statements, which are based on management's current expectations and projections about future events, are not guarantees of future performance, are subject to risks, uncertainties and assumptions (including those described below), and apply only as of the date of this filing. Our actual results, performance or achievements could differ materially from the results expressed in, or implied by, these forward-looking statements. Factors which could cause or contribute to such differences include, but are not limited to, the risks to be discussed in our Annual Report on Form 10-K and in the press releases and other communications to shareholders issued by us from time to time which attempt to advise interested parties of the risks and factors which may affect our business. We undertake no obligation to publicly update or revise any forward-looking statements,

whether as a result of new information, future events, or otherwise.

Overview

CytoSorbents Corporation (the “Company”) is a development stage critical care focused company using blood purification to treat disease. The technology is based upon biocompatible, highly porous polymer sorbent beads that are capable of extracting unwanted substances from blood and other bodily fluids. The technology is protected by 32 issued U.S. patents with multiple applications pending.

In March 2011, we received E.U. regulatory approval under the CE Mark and Medical Devices Directive for our flagship product, CytoSorb®, as an extracorporeal cytokine filter indicated for use in clinical situations where cytokines are elevated. The goal of the CytoSorb® is to prevent or treat organ failure by reducing cytokine storm and the potentially deadly systemic inflammatory response syndrome in diseases such as sepsis, trauma, burn injury, acute respiratory distress syndrome, pancreatitis, liver failure, and many others. Organ failure is the leading cause of death in the intensive care unit, and remains a major unmet medical need, with little more than supportive care therapy (e.g. mechanical ventilation, dialysis, vasopressors, fluid support, etc.) as treatment options. By potentially preventing or treating organ failure, CytoSorb® may improve clinical outcome, including survival, while reducing the need for costly intensive care unit treatment, thereby potentially saving significant healthcare costs.

Our CE Mark enables CytoSorb® to be sold throughout the entire European Union. In addition, many countries outside the E.U. accept CE Mark approval for medical devices, but may also require registration with or without additional clinical studies. The broad approved indication enables CytoSorb® to be used “on-label” in diseases where cytokines are elevated including, but not limited to, critical illnesses such as those mentioned above, autoimmune disease flares, and many other conditions where cytokine-induced inflammation plays a detrimental role.

As part of the CE Mark approval process, we completed our randomized, controlled, European Sepsis Trial amongst fourteen trial sites in Germany in 2011, with enrollment of one hundred (100) patients with sepsis and respiratory failure. The trial established that CytoSorb® was safe in this critically-ill population, and that it was able to control cytokine storm,and broadly reduce key cytokines.

Plan of Operations

The Company plans to do larger, prospective studies in septic patients in the future to confirm the European Sepsis Trial findings.

In addition to CE Mark approval, CytoSorbents 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. CytoSorbents manufactures CytoSorb® at its manufacturing facilities in New Jersey for sale in the E.U. and for additional clinical studies. In September 2013, the company was granted a 2 year renewal for the CytoSorb® CE Mark. The Company also established a reimbursement path for CytoSorb® in Germany and Austria.

From September 2011 through June 2012, the Company began a controlled market release of CytoSorb® in select geographic territories in Germany with the primary goal of preparing for commercialization of CytoSorb® in Germany in terms of manufacturing, reimbursement, logistics, infrastructure, marketing, contacts, and other key issues.

In late June 2012, following the establishment of our European subsidiary, CytoSorbents Europe GmbH, CytoSorbents began the commercial launch of CytoSorb® for the treatment of critical care illnesses such as sepsis, burn injury, trauma, acute respiratory distress syndrome, pancreatitis and other conditions where inflammation plays a detrimental role, such as cardiac surgery. We hired Dr. Christian Steiner as Vice President of Sales and Marketing and three additional sales representatives who joined the Company and completed their sales training in Q3 2012. Q4 2012 represented the first quarter of direct sales with the full sales team in place. During this period, we expanded our direct sales efforts to include both Austria and Switzerland and have established reimbursement in Austria. At the end of Q3 2013, we had more than 100 key opinion leaders (KOLs) in critical care and blood purification who were either using CytoSorb® or committed to using CytoSorb® in the near future.

We seek to further complement our direct sales efforts with sales to distributors or corporate partners. In 2013, we reached an agreement with distributors in the United Kingdom and Turkey and we are in negotiation with and evaluating other potential distributor networks in other major countries where we are approved to market the device. In September 2013, we entered into a strategic partnership with Biocon Ltd., Asia’s largest biotech company with an

initial distribution agreement for India and select emerging markets, under which Biocon will have the exclusive commercialization rights for CytoSorb®.

We are currently conducting a dose ranging trial in Germany amongst eight clinical trial sites to evaluate the safety and efficacy of CytoSorb® when used for longer periods of time. Data from this dosing study are intended to help clinicians with additional treatment options for CytoSorb®, help support the positive clinical data from the Company's first European Sepsis Trial, and help shape the trial protocol for a U.S. based pivotal study.

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.

The initial major market focus for CytoSorb® is the adjunctive treatment of sepsis, a systemic inflammatory response to a serious infection. 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 that are 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 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's proprietary hemocompatible porous polymer bead technology forms the basis of a broad technology portfolio. Some of our products include:

- CytoSorb® - an extracorporeal hemoperfusion cartridge approved in the E.U. for cytokine removal, with the goal of reducing SIRS and preventing or treating organ failure.

- HemoDefend™ – a development-stage blood purification technology designed to remove contaminants in blood transfusion products. The goal is to reduce transfusion reactions and improve the safety of older blood

- ContrastSorb – a development-stage extracorporeal hemoperfusion cartridge designed to remove IV contrast from the blood of high risk patients undergoing CT imaging with contrast, or interventional radiology procedures such as cardiac catheterization. The goal is to prevent contrast-induced nephropathy

- DrugSorb – a development-stage extracorporeal hemoperfusion cartridge designed to remove toxic chemicals from the blood (e.g. drug overdose, high dose regional chemotherapy, etc.)

- BetaSorb – a development-stage extracorporeal hemoperfusion cartridge designed to remove mid-molecular weight toxins, such as b2-microglobulin, that standard high-flux dialysis cannot remove effectively. The goal is to improve the efficacy of dialysis or hemofiltration

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.

The Company has been successful in obtaining technology development contracts and support from agencies in the U.S. Department of Defense, including DARPA, the U.S. Army, and the U.S. Air Force.

In June 2013, we announced that the U.S. Air Force will fund a 30 patient, single site, randomized controlled human pilot study in the United States amongst trauma patients with rhabdomyolysis most commonly associated with trauma. The FDA has approved our Investigational Device Exemption (IDE) application for this study, which is anticipated to commence shortly.

Following successful contract negotiations in June 2013, the Company began work on its previously announced $1 million Phase II SBIR U.S. Army contract to further develop its technology for the treatment of burn injury and trauma in animal models. This work is supported by the U.S. Army Medical Research and Material Command under an amendment to Contract W81XWH-12-C-0038 and has now received committed funding of $1.15 million to date.

In August 2012, the Company was awarded a $3.8 million contract by the Defense Advanced Research Projects Agency (DARPA) for its “Dialysis-Like Therapeutics” program to treat sepsis. This five-year contract is for advanced technology development of our hemocompatible porous polymer technologies to remove cytokines and a number of pathogen and biowarfare toxins from blood. CytoSorbents has begun work on Year 2 milestones and is currently working with the recently announced systems integrator, Battelle Laboratories, and its subcontractor NxStage Medical, who are responsible for integrating the technology developed by CytoSorbents and others into a final medical device design prototype, and evaluating this device in septic animals and eventually in human clinical trials in sepsis. CytoSorbents’ work is supported by DARPA and SSC Pacific under Contract No. N66001-12-C-4199.

In September 2013, the National Heart, Lung, and Blood Institute (NHLBI), a division of the National Institutes of Health (“NIH”), awarded the Company a Phase I SBIR (Small Business Innovation Research) contract to further advance its HemoDefend™ blood purification technology for packed red blood cell (pRBC) transfusions. The project, entitled “Elimination of blood contaminants from pRBCs using HemoDefend™ hemocompatible porous polymer beads,” is valued at $203,351 over six months, with funding to start immediately. The overall goal of this new program is to reduce the risk of potential side effects of blood transfusions, and help to extend the useful life of pRBCs.

Results of Operations

Comparison for the nine months ended September 30, 2013 and 2012:

Revenues:

For the nine months ended September 30, 2013, the Company generated revenue of approximately $1,544,000 as compared to revenues of approximately $739,000, for the nine months ended September 30, 2012, an increase of 109%. Revenue from product sales was approximately $508,000 for the nine months ended September 30, 2013, as compared to approximately $64,000 in the nine months ended September 30, 2012, an increase of 698%. This increase in sales is a result of the establishment in August 2012 of a four person direct sales force covering Germany, Austria and Switzerland, as well as sales to distributors in other parts of Europe and the Middle East. Product gross margins were approximately 64% for the nine months ended September 30, 2013. Revenue from grants was approximately $1,036,000 in the nine months ended September 30, 2013, as compared to approximately $675,000 in the nine months ended September 30, 2012.

Expenses:

For the nine months ended September 30, 2013, our research and development expenses were approximately $1,706,000 as compared to research and development expenses of approximately $1,854,000 for the nine months ended September 30, 2012. The decrease of approximately $148,000 was primarily due to direct labor being deployed toward grant-funded activities, and as a result, salaries and other costs normally charged to research and development were included in cost of goods sold.

Legal, financial and other consulting expenses were approximately $570,000 for the nine months ended September 30, 2013 as compared to approximately $386,000 for the nine months ended September 30, 2012. The increase of approximately $184,000 was primarily due to approximately $70,000 of increases related to auditing and legal fees associated with 2013 filings with the Securities and Exchange Commission and other government entities, increases in accounting consulting fees of approximately $49,000, legal fees associated with patent review related costs of approximately $11,000 and consulting fees related to new systems and employment related fees totaling approximately $48,000.

Selling, general, and administrative expenses were approximately $1,902,000 for the nine months ended September 30, 2013 as compared to approximately $915,000 for the nine months ending September 30, 2012. The increase in

selling, general, and administrative expenses of approximately $987,000 was primarily due to the addition of our German sales and support team in August 2012 resulting in increased payroll expenses totaling approximately $410,000, increases in advertising of approximately 170,000, other selling, general, and administrative expenses of $180,000, as well as increased royalty expense of approximately $27,000 and increased option expenses of approximately $155,000.

For the nine months ended September 30, 2013, our interest expense was approximately $300,000 as compared to interest expense of approximately $448,000 for the nine months ended September 30, 2012. The decrease was principally due to the maturity of convertible notes in February 2013 and the related reduction in non-cash charges associated with the amortization of debt discount on the convertible notes.

We have experienced substantial operating losses since inception. As of September 30, 2013, we had a deficit accumulated during the development stage of approximately $104,469,000 which included losses of approximately $4,009,000 and $3,126,000 for the nine month periods ended September 30, 2013 and 2012 respectively. Historically, our losses have resulted principally from costs incurred in the research and development of our polymer technology, clinical studies, and general and administrative expenses.

Comparison for the three months ended September 30, 2013 and 2012:

Revenues:

CytoSorbents generated revenues of approximately $881,000 and $605,000 for the three months ending September 30, 2013 and September 30, 2012, respectively. Product revenues were approximately $204,000 for the quarter ended September 30, 2013, as compared to product revenues of approximately $14,000 for the three months ended September 30, 2012. This increase in product revenues was a result of our direct sales effort to hospitals in Germany, Austria and Switzerland, as well as sales to distributors. For the three months ended September 30, 2013, product sales of CytoSorb were the highest quarterly sales achieved to date, and were approximately 59.1% higher than product sales for the previous quarter ended June 30, 2013. Additionally, grant revenue and other income approximated $677,000 and $591,000 for the three month periods ended September 30, 2013 and 2012 respectively. Product gross margins were approximately 71% for the quarter ended September 30, 2013. Overall gross margins were approximately 29.5% for the quarter ended September 30, 2013, as a result of the higher cost of materials and labor associated with grant income.

Expenses:

For the three months ending September 30, 2013, our research and development costs were approximately $294,000, as compared to research and development costs of approximately $554,000, for the three months ended September 30, 2012. The decrease of approximately $260,000 was primarily due to direct labor being deployed toward grant-funded activities, and as a result, salaries and other costs normally charged to research and development were included in cost of goods sold.

Legal, financial and other consulting costs were approximately $158,000 for the three months ending September 30, 2013 as compared to legal financial and other consulting costs of approximately $151,000 for the three months ended September 30, 2012. This increase of approximately $7,000 was primarily due to increased accounting fees from consultants.

Our general and administrative costs were approximately $688,000 for the three months ended September 30, 2013 compared to approximately $360,000, an increase of approximately $328,000. This was primarily due to increases in costs related to salaries of approximately $170,000, increases in advertising of approximately $96,000, and increases in other selling, general, and administrative costs of approximately $65,000.

For the three months ending September 30, 2013, the Company’s net interest expense was approximately $85,000, as compared to net interest expense of approximately $51,000 for the three months ended September 30, 2012. The increase in net interest expense is primarily due to interest expense on convertible notes issued in June 2013.

Liquidity and Capital Resources

Since inception, our operations have been financed through the private placement of the Company’s debt and equity securities. As of September 30, 2013, we had cash on hand of approximately $2,350,000 and current liabilities of approximately $3,066,000. An additional $580,000 in cash was received in early October 2013 in connection with the issuance of convertible notes which closed on September 30, 2013. At December 31, 2012, we had cash of approximately $1,729,000 and current liabilities of approximately $2,077,000.

We believe that we have sufficient cash to fund our operations into the second quarter of 2014, following which we will need additional funding to permit us to complete additional clinical studies and to continue to commercialize our products. We will need to rely on additional funding to support our operations into the future. We expect to receive such required funding from grant revenue, issuance of new debt and/or equity securities, and sales of our shares to Lincoln Park Capital Fund LLC (“LPC”). (See Note 9 to the Company’s Annual Report on Form 10-K filed with the

Commission on April 03, 2013).

Lincoln Park Capital Fund LLC Purchase Agreement

Under the terms of its Purchase Agreement with LPC, in the first nine months of 2013, the Company sold approximately 14,529,000 shares of Common Stock to LPC at an average selling price of $0.110 and in return, the Company received proceeds of approximately $1,600,000. Per the terms of the Purchase Agreement the Company also issued an additional approximately 308,000 shares of Common Stock as additional Commitment Fee shares. As of September 30, 2013, under its current Purchase Agreement with LPC, the Company has the ability to sell up to an additional $3,400,000 of shares of Common Stock.

U.S. Army Medical Research Grant

In June 2013, the Company finalized contract negotiations of a $1 million Phase 2 SBIR award from the U.S. Army Medical Research and Materiel Command to fund the further development of the Company's technologies to treat trauma and burn injury. As of September 30, 2013, the Company has received approximately $599,000 out of a total of $651,000 awarded to CytoSorbents. For the nine months ended September 30, 2013, the Company has recognized approximately $163,000 of income from this grant.

DARPA Funding

In the nine months ended September 30, 2013, the Company received approximately $823,000 from the Defense Advanced Research Projects Agency (DARPA) following achievement of initial milestones of a five year technology development contract valued at $3.8 million that was awarded in August 2012. In addition, the Company is eligible, pending achievement of certain development milestones in this “Dialysis-Like Therapeutics” initiative to treat sepsis, to receive up to an additional approximately $1,120,000 (of the $3.8 million contract) in payments over the next ten months.

The Company is exploring potential eligibility in several other government sponsored grant programs which could, if approved, represent a substantial source of non-dilutive funds for our research programs.

Convertible Note and Warrant Private Offering

On September 30, 2013 (the “Closing Date”), the Company issued convertible notes to certain accredited investors (the “Purchasers”), whereby the Company agreed to sell and the Purchasers agreed to purchase the convertible notes in the aggregate principal amount of $745,000 (the “Notes”). The Notes mature one (1) year from the Closing Date (the “Maturity Date”), bear interest at an annual rate of 8%, and automatically convert into shares of the Company’s common stock, $0.001 par value per share (the “Common Stock”), at a conversion price of $0.10 at maturity or earlier at the option of the Purchaser. Full conversion of the principal value of the Notes would result in the issuance of 7,450,000 shares of Common Stock. In connection with the issuance of the Notes, the Company issued warrants to purchase shares of Common Stock, providing 50% coverage, exercisable at $0.125 per share (the “Warrants”).

On June 21, 2013 (the “Closing Date”), the Company issued convertible notes to certain accredited investors (the “Purchasers”), whereby the Company agreed to sell and the Purchasers agreed to purchase the convertible notes in the aggregate principal amount of $1,098,000 (the “Notes”). The Notes mature one (1) year from the Closing Date (the

"Maturity Date"), bear interest at an annual rate of 8%, and automatically convert into shares of the Company's common stock, $0.001 par value per share (the "Common Stock"), at a conversion price of $0.125 at maturity or earlier at the option of the Purchaser. Full conversion of the principal value of the Notes would result in the issuance of 8,784,000 shares of Common Stock. In connection with the issuance of the Notes, the Company issued warrants to purchase shares of Common Stock, providing 50% coverage, exercisable at $0.15 per share (the "Warrants").

The Notes stipulate that in the event at any time during the term of the Note, the Company closes on any debt or equity financing in an aggregate amount greater than or equal to $750,000, the noteholder will have the right to exchange the note for the equivalent dollar amount of securities sold in the new financing. The Company is not required to repay the Notes in cash, and there are no registration rights on the common stock underlying the Notes or Warrants.

We will also continue to seek other funding sources 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.

Off-balance Sheet Arrangements

We have no off-balance sheet arrangements.

Going Concern

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 September 30, 2013 of approximately $104,469,000. 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. These matters raise substantial doubt about the Company's ability to continue as a going concern. 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. The consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

Name	Age	Position
Phillip Chan, MD, PhD	43	President and Chief Executive Officer, Director
Al W. Kraus	69	Chairman of the Board
Joseph Rubin, Esq.	75	Director
Edward R. Jones, MD, MBA	65	Director
James Gunton	47	Director
Vincent Capponi	55	Chief Operating Officer
Kathleen Bloch	58	Chief Financial Officer
Robert Bartlett, MD	74	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 commercializing its HydraSolve™ lipoplasty system 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 Medical School. He also holds a BS in Cell and Molecular Biology from Cornell University.

Al W. 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, MBA. 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, Mr. Gunton 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. Mr. Gunton earned a BS from Stanford University and an MBA with distinction from Duke University.

Vincent Capponi, ***MS.*** 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.

Ronald Berger, CPA. Mr. Berger has been a financial consultant to the Company since 2005 and became Interim Chief Financial Officer in 2012 upon the departure of the previous CFO. He has over 40 years of business experience and has been a financial consultant to various Companies during the past 20 years. Prior to that, he was Controller for Singer Supermarkets and VP Finance and Administration for Quick Chek Corporation. His appointment to Interim Chief Financial Officer terminated with the commencement of employment of Kathleen P. Bloch.

Kathleen P. Bloch, MBA, CPA. Ms. Bloch has more than 20 years of executive financial experience in both public and private companies. She replaced Interim CFO, Mr. Ronald Berger, effective May 29, 2013. Most recently, she was Chief Financial Officer of Laureate Biopharmaceutical Services, Inc., a leader in biopharmaceutical contract development and manufacturing. Previously, Ms. Bloch was Chief Operating Officer and CFO of PC Group, Inc., a $70 million in revenue, NASDAQ-listed, publicly traded company with a diverse group of holdings, including several medical device subsidiaries. Prior to that, Ms. Bloch was CFO of Silver Line Building Products Corporation, one of the world's largest manufacturer of vinyl windows. Previously, Ms. Bloch was CFO of ERD Waste Corporation, a NASDAQ-listed, publicly-traded environmental services provider, operating in 16 states with more than $60 million in sales. She began her career at the accounting firm of Peat Marwick International. Ms. Bloch holds a Master of Business Administration degree and a Bachelor of Science Accounting degree from LaSalle University, and is a Certified Public Accountant.

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.

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.

Code of Business Conduct and Ethics

In October, 2013, the Company adopted a Code of Business Conduct and Ethics. All CytoSorbents employees, including our Chief Executive Officer and other senior executives, are required to comply with the Code of Business Conduct and Ethics to help ensure that our business is conducted in accordance with the highest standards of ethical behavior. Our Code of Conduct covers all areas of professional conduct, including customer relationships, conflicts of interest, insider trading, intellectual property and confidential information, as well as requiring strict adherence to all laws and regulations applicable to our business. Employees are required to bring any violations and suspected violations of the Code of Conduct to the attention of the Company, through management, the Board of Directors, or our legal counsel. At the current time, the Code of Business Conduct has been signed by all employees in the United States and is being translated into German. Upon completion of the translation, we will secure the signatures of our Germany-based employees.

EXECUTIVE COMPENSATION

The following summary compensation table sets forth all compensation awarded to, earned by, or paid to the named executive officers paid by us during the periods ended December 31, 2013 and 2012.

Summary Compensation Table

The following table shows for the fiscal years ended December 31, 2013 and 2012, compensation awarded to or paid to, or earned by, our Chief Executive Officer, our Chief Operating Officer, our Chief Financial Officer, and our Chief Medical Officer (the "Named Executive Officers").

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards (1) ($)	All Other Compensation	Total ($)
Phillip Chan						
Chief Executive Officer	2013	233,811 (2)	-0-	-0-	-0-	233,811
	2012	231,496	-0-	-0-	8,000	239,496
Vincent Capponi,						
Chief Operating Officer	2013	222,969 (3)	200	-0-	-0-	223,169
	2012	219,674	30,200	-0-	-0-	249,874
Kathleen P. Bloch,						
Chief Financial Officer (5)	2013	118,974	200	5,375 (4)	-0-	124,549
	2012	-0-	-0-	-0-	-0-	-0-
David Lamadrid						
Chief Financial Officer (5)	2013	-0-	-0-	-0-	-0-	-0-
	2012	108,706	-0-	-0-	-0-	108,706
Ronald Berger						
Interim Chief Financial Officer (5)	2013	-0-	200	9,800 (6)	100,526	110,562
	2012	-0-	200	1,030 (7)	102,472	103,702
Dr. Robert Bartlett						
Chief Medical Officer	2013	-0-	-0-	-0-	52,000	52,000
	2012	-0-	-0-	-0-	52,000	52,000

(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, 2012.

(2) Dr. Chan's salary for 2013 was $245,368, of which he deferred payment on $11,575 until 2014.

(3) Mr. Capponi's salary for 2013 was $239,445, of which he deferred payment on $16,476 until 2014.

(4) In connection with her employment, Ms. Bloch received options to purchase 1,000,000 shares on May 29, 2013 at an exercise price of $0.116. These options vest as follows: (1) 500,000 on May 9, 2014; and (2) 500,000 on May 9, 2015 and expire in ten years.

(5) Mr. Lamadrid resigned as our Chief Financial Officer effective July 11, 2012. Mr. Berger assumed the position of Interim CFO on July 11, 2012. On May 29, 2013, Ms. Bloch became Chief Financial Officer of the Company. Her annual salary is $200,000.

(6) On February 6, 2013, Mr. Berger received options to purchase 350,000 shares of stock at an exercise price of $0.106. These options vested on February 6, 2013, and expire in five years.

(7) On January 18, 2012, Mr. Berger received options to purchase 30,000 shares of stock at an exercise price of $0.168. 20% of the options vested immediately upon issuance and the remainder vest evenly over five years and expire in five years.

Outstanding Equity Awards at Fiscal Year End

The following table shows for the fiscal year ended December 31, 2013, certain information regarding outstanding equity awards at fiscal year-end for the Named Executive Officers.

Outstanding Equity Awards At December 31, 2013

Name

	Option Awards				
	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
	400,000	100,000	0.173	(2)	1/4/20
	2,227,500		0.138	(1)	5/5/20
Vincent Capponi	50,000		1.65	(1)	12/31/16
	1,100,000		0.25	(1)	01/16/18
	2,250,000		0.035	(1)	06/25/18
	400,000		0.168	(1)	01/28/19
	400,000	100,000	0.173	(3)	1/4/20
	2,032,500		0.138	(1)	5/5/20
Kathleen P. Bloch	0	1,000,000	0.116	(4)	5/7/23
David Lamadrid	150,000		1.90	(1)	01/16/17
	1,400,000		0.25	(1)	01/16/18
	1,946,724		0.035	(1)	06/25/18
	400,000		0.168	(1)	01/28/19
	240,000		0.173	(5)	1/4/20
	1,530,000		0.138	(1)	5/5/20
Robert Bartlett	50,000		0.084	(1)	01/08/14
	140,000	35,000	0.173	(5)	1/4/20
	515,000	0	0.138	(1)	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 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.

(4) Vests and becomes exercisable as to (i) 500,000 shares on May 9, 2014; and (ii) 500,000 shares on May 9, 2015.

(5) 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.

Director Compensation

The following table shows for the fiscal year ended December 31, 2013 certain information with respect to the compensation of all non-employee directors of the Company.

Director Compensation for Fiscal 2013

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)		Total ($)
Joseph Rubin	8,500	1,125	(2)	9,625
Edward R. Jones	10,000	1,125	(3)	11,125
James Gunton (5)	—	1,125	(4)	1,125
Al Kraus	25,000	2,250	(5)	27,250
Phillip Chan (6)	—	—	(6)	—

(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, 2012.

(2) In connection with his service as a director in 2013 we issued Mr. Rubin options to purchase 150,000 shares of our Common Stock at an exercise price of $0.115 per share, which were granted on April 4, 2013 and expire on April 4, 2023. All 150,000 shares vest and become exercisable on April 4, 2014.

(3) In connection with his service as a director in 2013 we issued Dr. Jones options to purchase 150,000 shares of our Common Stock at an exercise price of $0.115 per share, which were granted on April 4, 2013 and expire on April 4, 2023. All 150,000 shares vest and become exercisable on April 4, 2014.

(4) In connection with Mr. Gunton's service as a director in 2013, the NJTC Venture Fund was issued options to purchase 150,000 shares of our Common Stock at an exercise price of $0.115 per share, which were granted on April 4, 2013 and expire on April 4, 2023. All 150,000 shares vest and become exercisable on April 4, 2014.

(5) Pursuant to an agreement and in connection with Mr. Kraus' service as a director in 2013 we issued options to purchase 300,000 shares of our Common Stock at an exercise price of $0.115 per share, which were granted on April 4, 2013 and expire on April 4, 2023. All 300,000 shares vest and become exercisable on April 4, 2014.

(6) 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. Dr. Chan officially became CEO and President in 2010. During 2013, Dr. Chan was an employee 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 2013, these fees were increased to $2,500 for in person participation and $1,000 for conference call participation in each quarterly meeting. In addition, each non-employee director will be eligible to be issued options to purchase our Common Stock. 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 February 2013, Mr Kraus entered into another agreement with the Company to remain Chairman of the Board for the fiscal 2013 year, compensated at $25,000 per annum, with the issuance of a ten year option to purchase 300,000 shares of our Common Stock at a price of $0.115 per share.

Employment Agreements with Named Executive Officers

Phillip Chan

Effective December 31, 2013, we renewed the employment agreement by and between Dr. Phillip Chan and the Company as Chief Executive Officer retroactive to January 1, 2013. Per the terms of the agreement, we agree to pay Phillip Chan an annual base compensation of $245,386 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 December 31, 2013, we renewed the employment agreement by and between Vincent Capponi and the Company as Chief Operating Officer retroactive to January 1, 2013. Per the terms of the agreement, we agree to pay Vincent Capponi an annual base compensation of $239,445 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.

Robert Bartlett

Effective December 31, 2013, 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 $53,000 payable in equal monthly installments of $4,416.67 per month. He is eligible for stock options, which will be adjusted on the same basis as all other shareholders to account for any stock split, stock dividends, combination or recapitalization.

Kathleen P. Bloch

Effective May 29, 2013, we entered into the employment agreement with Ms. Kathleen P. Bloch. Pursuant to this employment agreement, Ms. Bloch will perform the services and duties that are normally and customarily associated with these positions as well as other associated duties as our Board reasonably determines. The agreement commences on May 29, 2013 and expires on May 31, 2014 and calls for an initial base salary of $200,000 payable in equal semi-monthly installments in accordance with the Company's usual practice. As a signing bonus, Ms. Bloch was also given a ten-year option to purchase 1,000,000 shares of the Company's common stock. This option vests in equal installments over the next two years: 500,000 options at the 12 month anniversary, and 500,000 options at 24 month anniversary of the signing of this employment agreement, provided that Ms. Bloch remains a full-time employee of the Company.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Joseph Rubin is a director of ours and performs legal services for us from time to time. At September 30, 2013, we owed Mr. Rubin's firm approximately $10,500 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, and Phillip Chan, our Chief Executive Officer, are independent under the standards set forth in Nasdaq Marketplace Rule 4200(a)(15).

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding our shares of common stock beneficially owned as of November 30, 2013, for (i) each stockholder known to be the beneficial owner of 5% or more of our outstanding shares of common stock, (ii) each named executive officer and director, and (iii) all executive officers and directors as a group. A person is considered to beneficially own any shares: (i) over which such person, directly or indirectly, exercises sole or shared voting or investment power, or (ii) of which such person has the right to acquire beneficial ownership at any time within 60 days through an exercise of stock options or warrants. Unless otherwise indicated, voting and investment power relating to the shares shown in the table for our directors and executive officers is exercised solely by the beneficial owner or shared by the owner and the owner's spouse or children.

For purposes of this table, a person or group of persons is deemed to have "beneficial ownership" of any shares of common stock that such person has the right to acquire within 60 days of November 30, 2013. For purposes of computing the percentage of outstanding shares of our common stock held by each person or group of persons named above, any shares that such person or persons has the right to acquire within 60 days of November 30, 2013 is deemed to be outstanding, but is not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. The inclusion herein of any shares listed as beneficially owned does not constitute an admission of beneficial ownership. Unless otherwise specified, the address of each of the persons set forth below is care of the company at the address of: 7 Deer Park Drive, Suite K, Monmouth Junction, New Jersey 08852.

	SHARES BENEFICIALLY OWNED(1)		
	Number	Percent (%)	
Directors and Executive Officers			
Al Kraus(2), *Chairman of the Board of Directors*	11,057,001	2.0	%
Phillip Chan (3), *President and Chief Executive Officer, Director*	8,763,191	1.6	%
Vince Capponi (4) *Chief Operating Officer*	8,250,586	1.5	%
Joseph Rubin (5) *Director*	1,634,187	*	
Robert Bartlett (6) *Chief Medical Officer*	1,140,000	*	
James Gunton (7) *Director*	103,650,906	18.9	%
Edward R. Jones (8) *Director*	532,500	*	
Thomas Bocchino**	0	*	
Ronald Berger (9) *Former Interim Chief Financial Officer****	1,165,595	*	
Kathleen Bloch(10) Chief Financial Officer***	1,500,000	*	
All directors and executive officers as a group (ten persons) (11)	137,693,966	25.1	%
Beneficial Owners of more than 5% of Common Stock (other than directors and executive officers)			
Robert Shipley(12)	58,591,111	10.7	%
NJTC Venture Fund SBIC, LP(13)	103,650,906	18.9	%

*Less than 1%.

** On February 8, 2013, Mr. Thomas Bocchino, the Company's Chief Financial Officer, gave notice of his resignation, effective immediately, due to personal reasons. Mr. Ronald Berger, a certified public accountant and the Company's controller for the past eight years, was appointed by the Board of Directors as Interim Chief Financial Officer and assumed Mr. Bocchino's duties as of February 8, 2013. Mr. Bocchino agreed to stay on in a part-time capacity.

*** On May 29, 2013, the Company replaced Mr. Ronald Berger with Kathleen P. Bloch as the Company's new Chief Financial Officer.

1 Based on 540,069,603 fully-diluted shares of Common Stock and common stock equivalents as of August 30, 2012. Shares of Common Stock subject to options or warrants currently exercisable or expected to be exercisable with the passage of time, are deemed outstanding for purposes of computing the percentage of the person holding such options or warrants, but are not deemed outstanding for purposes of computing the percentage of any other person.

2 Includes 9,663,370 shares of Common Stock issuable upon exercise of stock options.

60

3 Includes 874,144 shares of Common Stock issuable upon conversion of Series B Preferred Stock, 306,022 shares of Common Stock, 6,896,358 shares of Common Stock issuable upon exercise of stock options and 286,667 shares of Common Stock issuable upon exercise of warrants.

4 Includes 7,832,500 shares of Common Stock issuable upon exercise of stock options.

5 Includes 3,995 shares of Common Stock issuable upon conversion of Series A Preferred Stock, 605,525 shares of Common Stock issuable upon conversion of Series B Preferred Stock, and 857,454 shares of Common Stock issuable upon exercise of warrants and stock options, and 84,949 shares of Common Stock beneficially owned by Mr. Rubin's spouse, as to which he disclaims beneficial ownership.

6 These shares are issuable upon exercise of stock options.

7 Includes 103,161,906 shares of Common Stock issuable upon conversion of Series B Preferred Stock, and 489,000 shares of Common Stock issuable upon exercise of stock options. These securities are held directly by NJTC Venture Fund SBIC, LP, of which Mr. Gunton is a partner. Mr. Gunton disclaims beneficial ownership.

8 These shares are issuable upon exercise of stock options.

9 Includes 204,751 shares of Common Stock issuable upon conversion of Series B Preferred Stock, 886,333 shares of Common Stock issuable upon exercise of stock options, and 10,000 shares of Common Stock issuable upon conversion of Series B Preferred Stock. This amount includes 6,500 shares of Common Stock beneficially owned by Mr. Berger's spouse, as to which he disclaims beneficial ownership.

10 These shares are issuable upon exercise of stock options.

11 Includes an aggregate of 3,995 shares of Common Stock issuable upon conversion of Series A Preferred Stock, 104,846,326 shares of Common Stock issuable upon conversion of Series B Preferred Stock, 400,000 shares of Common Stock issuable upon conversion of Convertible Notes, 29,557,390 shares of Common Stock issuable upon exercise of stock options, and 536,792 shares of Common Stock issuable upon exercise of warrants.

12 Includes 639,661 shares of Common Stock issuable upon conversion of Series A Preferred Stock and 52,459,006 shares of Common Stock issuable upon conversion of Series B Preferred Stock.

13 Includes 103,161,906 shares of Common Stock issuable upon conversion of Series B Preferred Stock, and 489,000 shares of Common Stock issuable upon exercise of stock options. These securities are held directly by NJTC Venture Fund SBIC, LP, and indirectly through James Gunton, a partner at NJTC.

Auditors; Code of Ethics; Audit Committee

We do not have an audit committee and we do not have a financial expert. We do not have an audit committee or a financial expert, because we believe the costs related to retaining an Audit Committee and a financial expert at this time is prohibitive.

In October, 2013, the Company adopted a Code of Business Conduct and Ethics. All CytoSorbents employees, including our Chief Executive Officer and other senior executives, are required to comply with the Code of Business Conduct and Ethics to help ensure that our business is conducted in accordance with the highest standards of ethical behavior. Our Code of Conduct covers all areas of professional conduct, including customer relationships, conflicts of interest, insider trading, intellectual property and confidential information, as well as requiring strict adherence to all laws and regulations applicable to our business. Employees are required to bring any violations and suspected violations of the Code of Conduct to the attention of the Company, through management, the Board of Directors, or our legal counsel. At the current time, the Code of Business Conduct has been signed by all employees in the United States and is being translated into German. Upon completion of the translation, we will secure the signatures of our Germany-based employees.

EQUITY COMPENSATION PLAN INFORMATION

The following table summarizes outstanding options as of December 31, 2012, 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	36,827,616		$ 0.23		166,562	(2)
Total	36,827,616	(3)	$ 0.23	(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) 402 shares of Common Stock at a price of $41.47 per share, (ii) 5,574 shares of Common Stock at a price of $21.57 per share, (iii) 439,740 shares of Common Stock at a price of $6.64 per share, (iv) 170,000 shares of Common Stock at a price of $1.90 per share, (v) 306,000 shares of Common Stock at a price of $1.65 per share, (vi) 400,000 shares of Common Stock at a price of $1.26 per share, (vii) 166,756 shares of Common Stock at a price of $1.25 per share, (viii) 3,014,000 shares of Common Stock at a price of $0.25, (vix) 137,622 shares of Common Stock at a price of $0.22, (x) 2,530,000 shares of Common Stock at a price of $0.173, (xi) 2,25,000 shares of Common Stock at a price of $0.168, (xii) 25,000 shares of Common Stock at a price of $0.167, (xiii) 408,000 shares of Common Stock at a price of $0.166, (xiv) 408,000 shares of Common Stock at a price of $0.165, (xiv)25,000 shares of Common Stock at a price of $0.164, (xvi) 5,000 shares of Common Stock at a price of $0.159, (xvii) 25,000 shares of Common Stock at a price of $0.156, (xviii) 52,000 shares of Common Stock at a price of $0.154, (xix) 500,000 shares of Common Stock at a price of $0.148, (xx) 35,000 shares of Common Stock at a price of $0.143, (xxi) 100,000 shares of Common Stock at a price of $0.14, (xxii) 9,020,000 shares of Common Stock at a price of $0.138, (xxiii) 90,000 shares of Common Stock at a price of $0.136 per share, (xxiiv) 302,000 shares of Common Stock at a price of $0.134, (xxv) 50,000 shares of Common Stock at a price of $0.133, (xxvi) 525,000 shares of

Common Stock at a price of $0.13, (xxvii) 200,000 shares of Common Stock at a price of $0.129, (xxviii) 30,000 shares of Common Stock at a price of $0.097, (xxix) 2,000 shares of Common Stock at a price of $0.09, (xxx) 7,000 shares of Common Stock at a price of $0.089, (xxxi) 2,753,858 shares of Common Stock at a price of $0.084, (xxxii) 115,000 shares of Common Stock at a price of $0.08, and (xxxiii) 12,554,664 shares of Common Stock at a price of $0.035.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports and other information with the SEC. You may read and copy any reports, statements or other information we file at the SEC's public reference rooms in Washington D.C., New York, New York and Chicago, Illinois. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our filings are also available to the public from commercial document retrieval services and at the web site maintained by the SEC at http://www.sec.gov.

We have filed a registration statement on Form S-1 under the Securities Act with the SEC covering the Common Stock to be offered by the selling stockholders. As permitted by the rules and regulations of the SEC, this document does not contain all information set forth in the registration statement and exhibits thereto, all of which are available for inspection as set forth above. For further information, please refer to the registration statement, including the exhibits thereto. Statements contained in this document relating to the contents of any contract or other document referred to herein are not necessarily complete, and reference is made to the copy of that contract or other document filed as an exhibit to the registration statement or other document, and each statement of this type is qualified in all respects by that reference.

No person is authorized to give any information or make any representation not contained in this document. You should not rely on any information provided to you that is not contained in this document. This prospectus does not constitute an offer to sell or a solicitation of an offer to purchase the securities described herein in any jurisdiction in which, or to any person to whom, it is unlawful to make the offer or solicitation. Neither the delivery of this document nor any distribution of shares of Common Stock made hereunder shall, under any circumstances, create any implication that there has not been any change in our affairs as of any time subsequent to the date hereof.

DESCRIPTION OF SECURITIES

General

We are authorized to issue an aggregate number of 812,200,000 shares of capital stock, of which 800,000,000 shares are common stock, $0.001 par value per share, and 12,000,000 shares of our preferred stock as Series A 10% Cumulative Convertible Preferred Stock, and 200,000 shares of our preferred stock as Series B 10% Cumulative Convertible Preferred Stock. As of November 30, 2013, there were 246,972.191 shares of our Common Stock, 77,401.49 shares of our Series B Preferred Stock and 1,716,743 shares of Series A Preferred Stock outstanding.

Common Stock

Holders of our Common Stock are entitled to receive dividends out of assets legally available therefore at such times and in such amounts as the Board of Directors from time to time may determine. Holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. Cumulative voting with respect to the election of directors is not permitted by our Articles of Incorporation. Our Common Stock is not entitled to preemptive rights and is not subject to conversion or redemption. Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to stockholders are distributable ratably among the holders of the Common Stock after payment of liquidation preferences, if any, on any outstanding stock having prior rights on such distributions and payment of other claims of creditors.

Preferred Stock

Our Articles of Incorporation authorize the issuance of shares of preferred stock in one or more series. Our Board of Directors has the authority, without any vote or action by the stockholders, to create one or more series of preferred stock up to the limit of our authorized but unissued shares of preferred stock and to fix the number of shares constituting such series and the designation of such series, the voting powers (if any) of the shares of such series and the relative participating, option or other special rights (if any), and any qualifications, preferences, limitations or restrictions pertaining to such series which may be fixed by the Board of Directors pursuant to a resolution or resolutions providing for the issuance of such series adopted by the Board of Directors. Our Board of Directors authorized the creation of both Series A and Series B preferred stock. Each Series is further described herein.

Series A 10% Cumulative Convertible Preferred Stock

We have designated 12,000,000 shares of our preferred stock as Series A 10% Cumulative Convertible Preferred Stock (the "Series A Preferred Stock"), of which 1,716,743 shares were issued and outstanding as of November 30, 2013. Each share of Series A Preferred Stock has a stated value of $1.00. For the period from January 22, 1997 (date of inception) to November 30, 2013, 9,558,112 Series A Preferred Shares were converted into 43,728,457 Common Shares.

Dilution and Subordination

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") on June 25, 2008. 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.

Dividends

The holders of outstanding shares of Series A Preferred Stock shall be entitled to receive preferential dividends in cash out of any funds of the company together with the holders of the Series B Preferred Stock, before any dividend or other distribution will be paid or declared and set apart for payment on any shares of any Common Stock, or other class of junior stock at the rate of 10% per annum on the Series A Stated Value from the date of issue of such shares. Such dividends shall be payable on the last day of each calendar quarter. The rate of such preferential dividends shall be increased to 20% per annum upon the occurrence of any "Event of Default" as defined in Section 6 of the Certificate of Amendment to Certificate of Designation.

Voting Rights

Holders of Series A Preferred Stock do not have the right to vote on matters submitted to the holders of our Common Stock. However, consent of the holders of at least 80% of the shares of Series A preferred Stock, voting as a separate class, shall be required for amending the rights related to Series A Preferred Stock in our certificate of incorporation.

Liquidation

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to stockholders are distributable ratably among the holders of the Series A Preferred Stock after payment of liquidation to the Series B Preferred Stock, if any.

Redemption

Commencing on June 30, 2009, if an “Event of Default” as defined in the Certificate of Designation of Series A Preferred Stock has not occurred and is not then continuing, we have the option to redeem the Obligation Amount of the Series A Preferred Stock, in whole or in part, by paying to the holders of the Series A Preferred Stock a sum of money equal to 120% of the Obligation Amount to be redeemed. An Event of Default has not occurred as of the date of this prospectus.

Series B 10% 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 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. For the period from January 22, 1997 (date of inception) to November 30, 2013, 22,774.45 Series B Preferred Shares were converted into 62,912,304 Common Shares.

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.

We received waivers from the holders of Series B Preferred Stock with regard to the requirement to register the shares. The original Form S1 December 12, 2008 Registration Statement was withdrawn on May 7, 2010. 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 shall be required on matters related to the rights of the Series B Preferred Stock.

Registration Rights

We 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. We also granted the investors demand and piggyback registration rights with respect to such Common Stock. The investors in the Series B Financing are entitled to liquidated damages in an amount equal to two percent (2%) of the purchase price of the Series B Preferred Stock if we fail to timely file that registration statement with, or have it declared effective by, the SEC.

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

Redemption Rights

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

Dividends

We have not paid any cash dividends to our shareholders. The declaration of any future cash dividends is at the discretion of our board of directors and depends upon our earnings, if any, our capital requirements and financial position, our general economic conditions, and other pertinent conditions. It is our present intention not to pay any cash dividends in the foreseeable future, but rather to reinvest earnings, if any, in our business operations.

Warrants

As of November 30, 2013, 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
397,825	$ 0.04	September 30, 2014
1,750,000	$ 0.10	August 16, 2015
1,600,000	$ 0.13	August 16, 2015
1,333,333	$ 0.15	August 16, 2015
490,000	$ 0.10	October 22, 2015
196,000	$ 0.13	October 22, 2015
163,333	$ 0.15	October 22, 2015
625,000	$ 0.10	November 2, 2015
250,000	$ 0.13	November 2, 2015
208,334	$ 0.15	November 2, 2015
500,000	$ 0.10	November 19, 2015
200,000	$ 0.13	November 19, 2015
166,667	$ 0.15	November 19, 2015
5,000,000	$ 0.10	February 15, 2016
2,200,000	$ 0.13	February 15, 2016
1,833,333	$ 0.15	February 15, 2016
240,125	$ 1.25	October 24, 2016
1,166,667	$ 0.18	February 10, 2017
4,392,000	$ 0.15	June 21, 2018
3,725,000	$ 0.12	September 30, 2018
26,437,617		

Unit Warrants

The Warrants offered in this offering will be issued in a form substantially similar to the form that is filed as an exhibit to the registration statement of which this prospectus is a part. You should review a copy of the form of warrant for a complete description of the terms and conditions applicable to the Warrants. The following is a brief summary of the Warrants and is subject in all respects to the provisions contained in the form of warrant.

The warrants issued to each investor shall represent the right to purchase up to 0.5 shares of common stock equal at an exercise price equal to 125% of the exercise price of the common shares, subject to adjustment as described below.

The Warrants will have a term of five (5) years. We will not issue fractional shares of common stock. All fractional shares shall either be rounded up or we will pay cash in lieu of fractional shares of common stock. The warrant holders will not have any voting or other rights as a stockholder of our company. The exercise price and the number of shares underlying the Warrants are subject to standard adjustment provisions.

The Warrants will not be listed on any securities exchange or automated quotation system and we do not intend to arrange for any exchange or quotation system to list or quote the Warrants.

Placement Agent Warrants

We have also agreed to issue to Brean Capital, LLC, a warrant to purchase a number of shares equal to 3% of the shares of common stock sold in this financing. The shares issuable upon exercise of this warrant are identical to those offered by this prospectus. This warrant is exercisable at any time expiring five years after the effective date of the registration statement of which this prospectus is a part. The warrant may also be exercised on a cashless basis. The warrant and the shares of common stock underlying the warrant have been deemed compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The placement agent (or permitted assignees under the Rule) will not sell, transfer, assign, pledge, or hypothecate this warrant or the securities underlying this warrant, nor will it engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of this warrant or the underlying securities for a period of 180 days from the effective date of the registration statement of which this prospectus is a part. The exercise price and number of shares issuable upon exercise of the warrant will not contain any anti-dilution protection and will not be adjusted in the event of an extraordinary cash dividend, or any issuances of common stock at a price below the warrant exercise price.

Options

As of September 30, 2013, the Company had the following options outstanding:

# of Options Outstanding	Exercise Price	Expiration Date
15,070	$ 6.640	December 28, 2013
3,765	$ 21.570	December 28, 2013
50,000	$ 0.084	January 8, 2014
15,000	$ 0.168	January 28, 2014
1,809	$ 21.570	June 19, 2014
10,750	$ 6.640	December 29, 2014
15,000	$ 0.173	January 4, 2015
5,000	$ 0.159	March 31, 2015
35,000	$ 0.143	April 12, 2015
5,000	$ 0.089	June 30, 2015
30,000	$ 0.097	November 30, 2015
90,000	$ 0.136	January 6, 2016
166,756	$ 1.250	June 12, 2016
332,094	$ 6.640	September 29, 2016
103,000	$ 1.650	December 31, 2016
81,826	$ 6.640	December 31, 2016
203,000	$ 0.165	January 1, 2017
170,000	$ 1.900	January 16, 2017
60,000	$ 0.168	January 18, 2017
400,000	$ 1.260	February 8, 2017
500,000	$ 0.130	March 6, 2017
200,000	$ 0.129	June 1, 2017

100,000	$ 0.140	August 30, 2017
200,000	$ 0.148	September 1, 2017
300,000	$ 0.148	October 1, 2017
137,622	$ 0.220	December 31, 2017
3,005,000	$ 0.250	January 16, 2018
100,000	$ 0.115	February 6, 2018
9,455,000	$ 0.115	April 4, 2018
12,012,927	$ 0.035	June 25, 2018
100,000	$ 0.080	December 31, 2018
2,703,858	$ 0.084	January 8, 2019
2,150,000	$ 0.168	January 28, 2019
300,000	$ 0.166	December 31, 2019
108,000	$ 0.166	January 1, 2020
2,355,000	$ 0.173	January 4, 2020
2,000	$ 0.154	March 31, 2020
7,920,000	$ 0.138	May 5, 2020
2,000	$ 0.089	June 30, 2020
2,000	$ 0.090	September 30, 2020
302,000	$ 0.134	December 31, 2020
200,000	$ 0.138	January 6, 2021
50,000	$ 0.133	November 17, 2021
25,000	$ 0.167	January 2, 2022
408,000	$ 0.165	January 18, 2022
25,000	$ 0.156	