Cytosorbents Corp
Form S-1/A
January 20, 2012

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

AMENDMENT NO. 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)

Phillip Chan President and Chief Executive Officer
CytoSorbents Corporation

(Name, Address, Including Zip Code, and Telephone Number,
Including Area Code, of Agent for Service)

Copies to:
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Eric Stein, Esq.
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Manalapan, NJ 07726

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: From time to time after the effective date of this registration statement, as determined by the selling stockholder.

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, 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, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one):

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 (1)	Proposed Maximum Offering Price Per Security (2)	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee
Shares of Common Stock, par value $0.001 per share	39,634,615 Shares	$ 0.14	$ 5,548,846	$ 635.90
Total	39,634,615 Shares	$ 0.14	$ 5,548,846	$ 635.90

(1) This registration statement covers 39,634,615 shares of our common stock. Pursuant to and in accordance with Rule 416 under the Securities Act, there are also registered hereunder such indeterminate number of securities as may be issued to prevent dilution resulting from stock splits, stock dividends, or similar transactions.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) of the Securities Act. The proposed maximum offering price per share and proposed maximum aggregate offering price are based upon the closing price of $0.14 of our common stock on December 19, 2011, as reported by the OTCBB. It is not known how many shares of our common stock will be sold under this registration statement or at what price or prices such shares will be sold.

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, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), SHALL DETERMINE.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale of these securities is not permitted.

Subject to Completion, Dated January 20, 2012

PROSPECTUS

CytoSorbents Corporation

39,634,615 SHARES OF COMMON STOCK

This prospectus is registering an aggregate of 39,634,615 shares of common stock, par value $0.001, of CytoSorbents Corporation, a Nevada corporation, and relates to the sale of such shares by Lincoln Park Capital Fund, LLC. Lincoln Park Capital Fund, LLC is sometimes referred to in this prospectus as the selling stockholder or LPC. The prices at which LPC may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. See "Plan of Distribution" on page 18 for a description of how the selling stockholder may dispose of the shares covered by this prospectus. We do not know when or in what amount the selling stockholder may offer the shares for sale. We will not receive proceeds from the sale of our shares by LPC. We have agreed to pay certain expenses related to the registration of the shares of common stock pursuant to the registration statement of which this prospectus forms a part.

Our common stock currently trades on the over-the-counter market and is quoted on the OTC Bulletin Board under the symbol "CTSO." On January 19, 2012, the last reported sale price of our Common Stock was $0.16 per share.

The selling stockholder is an "underwriter" within the meaning of the Securities Act of 1933, as amended.

INVESTING IN OUR COMMON STOCK INVOLVES SUBSTANTIAL RISKS. SEE THE SECTION TITLED "RISK FACTORS" BEGINNING ON PAGE 6 OF THIS PROSPECTUS TO READ ABOUT FACTORS YOU SHOULD CONSIDER BEFORE BUYING SHARES OF OUR COMMON STOCK.

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

The date of this prospectus is January 20, 2012.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before making an investment decision with respect to our securities. You should read this entire prospectus, including all documents incorporated by reference, carefully, especially the "Risk Factors" section beginning on page 6 of this prospectus and our financial statements and related notes contained in this prospectus before making an investment decision with respect to our securities. Please see the section titled, "Where You Can Find More Information," beginning on page 64 of this prospectus. Unless the context indicates otherwise, references to "CytoSorbents," "the Company," "we," "us," or "our," refers to CytoSorbents Corporation and our wholly-owned subsidiary, CytoSorbents, Inc.

You should rely only on the information contained in this prospectus or any related prospectus supplement, including the content of all documents incorporated by reference into the registration statement of which this prospectus forms a part. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in this prospectus or incorporated by reference herein is accurate only on the date of this prospectus. Our business, financial condition, results of operations and prospects may have changed since such date. Other than as required under the federal securities laws, we undertake no obligation to publicly update or revise such information, whether as a result of new information, future events or any other reason.

Some of the industry data contained in this prospectus is derived from data from various third-party sources. We have not independently verified any of this information and cannot assure you of its accuracy or completeness. While we are not aware of any misstatements regarding any industry data presented herein, such data is subject to change based on various factors, including those discussed under the "Risk Factors" section beginning on page 6 of this prospectus.

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 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.

We have incurred operating losses since inception through September 30, 2011 equal to $90,627,971. Losses have been primarily attributable to expenses incurred for research and development, general and administrative costs, and legal and accounting fees. We may continue to incur losses in the future. In part due to these losses, our 2010 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

We are a critical care focused therapeutic medical device company that is currently in the development stage, headquartered in Monmouth Junction, New Jersey (near Princeton). We have developed and are seeking to commercialize a blood purification technology that we believe will be able to efficiently remove middle molecular weight toxins from circulating blood and physiologic fluids. We are required to obtain required regulatory approvals from a Notified Body for the European Community (CE Mark) and the United States Food and Drug Administration ("FDA") before we can sell our products in Europe and the United States, respectively.

In March 2011, we received European Union (E.U.) regulatory approval under the CE Mark and Medical Devices Directive for our flagship product, CytoSorb™, as an extracorporeal cytokine filter to be used in clinical situations where cytokines are elevated. In mid-September we started to exhibit the CytoSorb™ device at conferences in Germany as part of our product marketing under a controlled-market release in select geographic territories in Germany. Because of the limited nature of this initial release, we anticipate only modest sales until we expand our marketing efforts into the broader market.

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

We have completed the targeted enrollment in our European Sepsis clinical trial of one hundred (100) patients with sepsis and respiratory failure with the participation of fourteen trial sites. The purpose of the trial was to demonstrate safety and the broad, and statistically significant reduction of key cytokines such as IL-6 in these patients. Although the trial was not powered to demonstrate significant reduction in clinical endpoints such as mortality, these were included as secondary and exploratory endpoints in the trial. Taking into account all 100 patients, the treatment was well-tolerated with no serious device related adverse events reported in more than 300 human treatments in the trial. The first 22 patients in the study represented a sepsis pilot study. In the next 31 patients, a compromise of the manual randomization schedule at two trial sites led to an imbalance in the severity of illness between the control and treatment patient groups of the study. After a thorough review, the Scientific Advisory Board (SAB) and the independent Data Safety Monitoring Board (DSMB) both recommended that due to this enrollment bias, these 31 patients should only be used for safety evaluation purposes and that new patients should be enrolled into the trial using electronic web-based randomization to randomly assign patients into either the control or treatment arms. Excluding four patients that withdrew, the remaining forty three (43) patients enrolled under electronic randomization were relatively balanced in terms of the severity of illness in treatment and control patients, confirming the findings of the SAB and DSMB. In these forty three (43) patients the European Sepsis Trial successfully demonstrated, on a statistically significant basis ($p<0.05$), CytoSorb™'s ability to reduce circulating levels of key cytokines from whole blood in treated patients on the average of 30-50% over the 7 day treatment period. Additionally, post-hoc subgroup analyses of the clinical outcome data from patients enrolled under electronic randomization demonstrated statistically significant reduction in mortality in patients at high risk of death in sepsis, specifically in patients with very high cytokine levels (IL-6 $\geq$ 1,000 pg/mL and/or IL-1ra $\geq$ 16,000 pg/mL) where 28-day mortality was 0% treated vs 63% control, p=0.03, n=14 and patients $\geq$ age 65 (14-day mortality: 0% treated vs 36% control, p=0.04, n=21).

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

In addition to the sepsis indication, we intend to continue to foster research in other critical care illnesses where CytoSorb™ could be used, such as ARDS, trauma, severe burn injury and severe acute pancreatitis, or in other acute conditions that have demonstrated potential in preliminary studies to prevent or reduce the accumulation of cytokines

in the bloodstream. These other conditions include the prevention of post-operative complications of cardiac surgery (cardiopulmonary bypass surgery) and damage to organs donated for transplant prior to organ harvest. We are also exploring the potential benefits our technology may have in removing drugs and other substances from blood and physiologic fluids.

The Company is currently manufacturing CytoSorb™ under ISO 13485:2003 Full Quality Systems certification for sale in the E.U. and for additional clinical studies. Concurrent with its commercialization plans, the Company intends to conduct additional clinical studies in sepsis and other critical care diseases to generate additional clinical data to expand the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. Assuming availability of adequate and timely funding, and continued positive results from our clinical studies, the Company intends to continue commercializing its product in Europe.

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

We have developed two products, CytoSorb™ and BetaSorb™, and a technology platform called HemoDefend, utilizing our adsorbent polymer technology. CytoSorb™ has received CE Mark regulatory approval in the European Union (E.U.) and is commercially available for sale throughout the E.U. The BetaSorb has not been approved for CE Mark and is not the current focus of our near term commercialization plans. The HemoDefend technology platform is a development-stage blood purification system that targets blood transfusions, and has not yet received regulatory approval. CytoSorb™ and BetaSorb™ are known medically as hemoperfusion devices. During hemoperfusion, blood is removed from the body via a catheter or other blood access device, perfused through a filter medium where toxic compounds are removed, and returned to the body.

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

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

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

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

We have conducted clinical studies using our BetaSorb™ device in patients with chronic kidney failure, which have provided valuable data that underpin the development of the critical care applications for our technology. The BetaSorb™ device has been used in a total of four human pilot studies, involving 20 patients, in the U.S. and Europe. The studies included approximately 345 treatments, with some patients using the device for up to 24 weeks (in multiple treatment sessions lasting up to four hours, three times per week) in connection with the application of our products to patients suffering from chronic kidney failure.

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

certain infectious agents.

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

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

THE OFFERING

On May 5, 2010, the Company and LPC entered into a purchase agreement and a registration rights agreement (the "May 2010 LPC Agreements") whereby the Company had the right to sell, at its sole discretion, to LPC up to $6,000,000 of the Company's common stock, over a 25-month period.

On December 7, 2011, the May 2010 LPC Agreements between the Company and LPC were terminated by mutual agreement (the "Termination Agreement").

On December 8, 2011, we executed a new purchase agreement (the "Purchase Agreement") and a new registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC. ("LPC") Under the Purchase Agreement, LPC is obligated to purchase from us up to $8.5 million of our common stock, from time to time over a 960 day (thirty-two (32) months) period.

Pursuant to the Registration Rights Agreement, we were required to file a registration statement that includes this prospectus with the U.S. Securities and Exchange Commission ("SEC") covering the shares that have been issued or may be issued to LPC under the Purchase Agreement. We do not have the right to commence any sales of our shares to LPC until the SEC has declared effective the registration statement of which this prospectus is a part. Thereafter, over approximately 960 days, or, 32 months, generally we have the right, but not the obligation, to direct LPC to purchase up to $8,500,000 of our common stock in amounts up to $50,000 as often as every two business days under certain conditions. We can also accelerate the amount of our common stock to be purchased under certain circumstances. No sales of shares may occur at a purchase price below $0.10 per share. The price of our stock as of December 9, 2011 was $0.135. The purchase price of the shares will be based on the market prices of our shares at the time of sale as computed under the Purchase Agreement without any fixed discount. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business days notice. We are obligated to issue up to an additional 1,634,615 shares pro rata as LPC purchases up to $8,500,000 of our common stock as directed by us. For example, if we elect, at our sole discretion, to require LPC to purchase $50,000 of our stock then we would issue 9,615 shares of the pro rata commitment fee which is the product of $50,000 (the amount we have elected to sell) divided by $8,500,000 (the total amount we can sell LPC under the Purchase Agreement multiplied by 1,634,615 (the total number of pro rata commitment shares). The pro rata commitment shares will only be issued pursuant to this formula as and when we elect at our discretion to sell stock to LPC. LPC may not assign or transfer its rights and obligations under the Purchase Agreement.

As of January 20, 2012 there were 177,626,058 shares of our common stock outstanding of which 175,728,343 shares are held by non-affiliates. 39,634,615 shares are offered hereby, all of which we may sell to LPC pursuant to the Purchase Agreement. If all of the 39,634,615 shares offered by LPC hereby were issued and outstanding as of December 20, 2011, such shares would represent approximately 18.3% of the total common stock outstanding or approximately 18.4% of the non-affiliates shares outstanding, as of the date hereof.

Securities Offered

Common stock offered by selling stockholder:	39,634,615 shares
Offering Price:	Market Price
Common Stock Currently Outstanding:	177,626,058 shares as of January 20, 2012

Use of proceeds:	We will not receive any proceeds from the sale by the selling stockholder of our common stock covered by this prospectus. However, we will receive proceeds from sales of our common stock under the Purchase Agreement. The proceeds from the Purchase Agreement will be used for working capital and general corporate purposes. See "Use of Proceeds" on page 18.
Risk Factors:	See "Risk Factors" beginning on page 6 and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in the shares.
OTCBB Ticker Symbol:	CTSO.OB

RISK FACTORS

An investment in our Common Stock involves a high degree of risk. You should carefully consider the risks described below before deciding to purchase shares of our Common Stock. If any of the events, contingencies, circumstances or conditions described in the risks below actually occur, our business, financial condition or results of operations could be seriously harmed. The trading price of our Common Stock could, in turn, decline and you could lose all or part of your investment.

RISKS RELATED TO OUR INDUSTRY AND OUR BUSINESS

We require additional capital to continue operations.

As of September 30, 2011 we had cash on hand of $2,296,147 and current liabilities of $1,588,584. We will need additional financing in the future in order to complete our clinical studies and the commercialization of our proposed products. There can be no assurance that we will be successful in our capital raising efforts.

Our long-term capital requirements are expected to depend on many factors, including:

- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical studies;
- the time and costs involved in obtaining regulatory clearance 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 LPC to purchase up to $8,500,000 worth of shares of our common stock under our agreement over a 32 month period generally in amounts of up to $50,000 every two business days, which amounts may be increased under certain circumstances. Assuming a purchase price of $0.135 per share (the closing sale price of the common stock on December 9, 2011) and the purchase by LPC of the full 38,000,000 purchase shares and along with issuance of 1,634,615 additional pro rata commitment shares registered under this offering, proceeds to us would be $5,130,000.

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

In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, we may have to relinquish economic and/or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourselves.

We currently are in the process of commercializing our products, but there can be no assurance that we will be successful in developing commercial operations.

We are a development stage company and have been engaged primarily in research and development activities and have not generated any significant revenues to date. There can be no assurance that we will be able to successfully manage the transition to a commercial enterprise. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by an enterprise in the early stage of development, which include unanticipated problems relating to development of proposed products, testing, regulatory compliance, manufacturing, competition, market adoption, marketing problems and additional costs and expenses that may exceed current estimates. Our proposed products will require significant additional research and testing, and we will need to overcome significant regulatory burdens prior to commercialization and for ongoing compliance for our CE Mark. We will also need to raise significant additional funds to complete additional clinical studies and obtain regulatory approvals in other countries before we can begin selling our products in markets not covered by the CE Mark. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any products, generate any significant revenues or ever achieve and maintain a substantial level of sales of our products.

We have a history of losses and expect to incur substantial future losses, and the report of our auditor on our consolidated financial statements expresses substantial doubt about our ability to continue as a going concern.

We have experienced substantial operating losses since inception. As of September 30, 2011, we had an accumulated deficit of $90,627,971, which included net losses of $1,728,927 and $4,284,693 for the three and nine month periods ended September 30, 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 achieving adequate adoption of CytoSorb™ by hospitals and physicians, 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.

We currently have eight full-time employees and several full-time interim employees. Our success will depend to a significant degree upon the continued services of our key management and advisors, including, Dr. Phillip Chan, our Chief Executive Officer; David Lamadrid, our Chief Financial Officer; Vincent Capponi, our Chief Operating Officer and Dr. Robert Bartlett our Chief Medical Officer, who works with us on a consulting basis. These individuals do not have long-term employment agreements, and there can be no assurance that they will continue to provide services to us. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. We may be

unable to recruit such personnel on a timely basis, if at all. Management and other employees may voluntarily terminate their employment with us at any time. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources.

Our Chief Medical Officer works with us on a consulting basis.

Our Chief Medical Officer, Dr. Robert Bartlett, works with us on a consulting basis. Because of the part time nature of his consulting agreement, Dr. Bartlett may not always be available to provide us with his services when needed by us in a timely manner.

Acceptance of our medical devices in the marketplace is uncertain, and failure to achieve market acceptance will prevent or delay our ability to generate revenues.

Our future financial performance will depend, at least in part, upon the introduction and customer acceptance of our polymer products. Even with our approval to apply the CE Mark to our CytoSorbTM 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 CytoSorbTM 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 CytoSorbTM device as a cytokine filter, there can be no assurance that the data from our limited clinical studies will be viewed as sufficient by the medical community to support the purchase of our products in substantial quantities or at all.

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

We may face litigation from third parties claiming that our products infringe on their intellectual property rights, or seek to challenge the validity of our patents.

Our future success is also dependent on the strength of our intellectual property, trade secrets and know-how, which have been developed from years of research and development. In addition to the “Purolite” litigation discussed below, we may be exposed to additional future litigation by third parties seeking to challenge the validity of our rights based on claims that our technologies, products or activities infringe the intellectual property rights of others or are invalid,

or that we have misappropriated the trade secrets of others.

Since our inception, we have sought to contract with large, established manufacturers to supply commercial quantities of our adsorbent polymers. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers. We believe that these disclosures, while necessary for our business, have resulted in the attempt by potential suppliers to assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing rights.

We have previously engaged in discussions with the Brotech Corporation and its affiliate, Purolite International, Inc. (collectively "Purolite"), which had demonstrated a strong interest in being our polymer manufacturer. For a period of time beginning in December 1998, Purolite engaged in efforts to develop and optimize the manufacturing process needed to produce our polymer products on a commercial scale. However, the parties eventually decided not to proceed. In 2003, Purolite filed a lawsuit against us asserting, among other things, co-ownership and co-inventorship of certain of our patents. On September 1, 2006, the United States District Court for the Eastern District of Pennsylvania approved a Stipulated Order and Settlement Agreement under which we and Purolite agreed to the settlement of the action. The Settlement Agreement provides us with the exclusive right to use our patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the Settlement Agreement, we have agreed to pay Purolite royalties of 2.5% to 5% on the sale of certain of our products if and when those products are sold commercially.

Several years ago we engaged in discussions with the Dow Chemical Company, which had indicated a strong interest in being our polymer manufacturer. After a Dow representative on our Advisory Board resigned, Dow filed and received several patents naming our former Advisory Board member as an inventor. In management's view the Dow patents improperly incorporate our technology and should not have been granted to Dow. The existence of these Dow patents could result in a potential dispute with Dow in the future and additional expenses for us.

We have commenced the process of seeking regulatory approvals of our products, but the approval process involves lengthy and costly clinical studies and is, in large part, not in the control of the Company. The failure to obtain government approvals, internationally or domestically, for our polymer products, or to comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of our products and result in the failure to achieve revenues or maintain our operations.

The manufacturing and marketing of our products will be subject to extensive and rigorous government regulation in the European market, the United States, in various states and in other foreign countries. In the United States and other countries, the process of obtaining and maintaining required regulatory approvals is lengthy, expensive, and uncertain. There can be no assurance that we will ever obtain the necessary additional approvals to sell our products in the United States or other countries. Even if we do ultimately receive FDA approval for any of our products, we will be subject to extensive ongoing regulation. While the Company has received approval from its Notified Body to apply the CE Mark to our CytoSorbTM device, we will be subject to extensive ongoing regulation and auditing requirements to maintain the CE Mark.

Our products will be subject to international regulation as medical devices under the Medical Device Directive. In Europe, which we expect to provide the initial market for our products, the Notified Body and Competent Authority govern, where applicable, development, clinical studies, labeling, manufacturing, registration, notification, clearance or approval, marketing, distribution, record keeping, and reporting requirements for medical devices. Different regulatory requirements may apply to our products depending on how they are categorized by the Notified Body under these laws. Current international regulations classify our CytoSorb™ device (the first product we intend to seek international approval for) as a Class IIb device. Even though we have received CE Mark certification of the CytoSorb™ device, there can be no assurance that we will be able to continue to comply with the required annual auditing requirements or other international regulatory requirements that may be applicable. In addition, there can be no assurance that government regulations applicable to our products or the interpretation of those regulations will not change. The extent of potentially adverse government regulation that might arise from future legislation or administrative action cannot be predicted. There can be no assurances that reimbursement will be granted or that additional clinical data may be required to establish reimbursement.

We have conducted limited clinical studies of our CytoSorb™ and BetaSorb™ device. Clinical and pre-clinical data is susceptible to varying interpretations, which could delay, limit or prevent additional regulatory clearances.

To date, we have conducted limited clinical studies on our products. There can be no assurance that we will successfully complete additional clinical studies necessary to receive additional regulatory approvals in markets not covered by the CE Mark. While studies conducted by us and others have produced results we believe to be encouraging and indicative of the potential efficacy of our products and technology, data already obtained, or in the future obtained, from pre-clinical studies and clinical studies do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical studies. Moreover, pre-clinical and clinical data are susceptible to varying interpretations, which could delay, limit or prevent additional regulatory approvals. A number of companies in the medical device and pharmaceutical industries have suffered significant setbacks in advanced clinical studies, even after promising results in earlier studies. The failure to adequately demonstrate the safety and effectiveness of an intended product under development could delay or prevent regulatory clearance of the device, resulting in delays to commercialization, and could materially harm our business. Even though we have received approval to apply the CE Mark to our CytoSorb device as a cytokine filter, there can be no assurance that we will be able to receive approval for other potential applications of CytoSorb™, or that we will receive regulatory clearances from other targeted regions or countries.

We rely extensively on research and testing facilities at various universities and institutions, which could adversely affect us should we lose access to those facilities.

Although we have our own research laboratories and clinical facilities, we collaborate with numerous institutions, universities and commercial entities to conduct research and studies of our products. We currently maintain a good working relationship with these parties. However, should the situation change, the cost and time to establish or locate alternative research and development could be substantial and delay gaining CE Mark for other potential applications and/or FDA approval and commercializing our products.

We are and will be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon us should we be sued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of medical devices. We cannot be sure that claims will not be asserted against us. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We cannot give assurances that we will be able to continue to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against potential liabilities. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition and results of operations.

Certain university and other relationships are important to our business and may potentially result in conflicts of interests.

Dr. John Kellum and others, are critical care advisors and consultants of ours and are associated with institutions such as the University of Pittsburgh Medical Center. Their association with these institutions may currently or in the future involve conflicting interests in the event they or these institutions enter into consulting or other arrangements with competitors of ours.

We have limited manufacturing experience, and once our products are approved, we may not be able to manufacture sufficient quantities at an acceptable cost, or without shut-downs or delays.

We are in the research and development and clinical study phase of product commercialization. We have received approval from our Notified Body to apply the CE Mark to our CytoSorbTM device for commercial sale as a cytokine filter, but we will need to establish the capability to commercially manufacture our products in accordance with international regulatory requirements and maintain compliance on an ongoing basis. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we or the third-party manufacturers of our products fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products.

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

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

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

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

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

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

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

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

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

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

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

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

INVESTMENT RISKS

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

Our directors, executive officers and principal stockholders together beneficially own approximately 13.7% of our outstanding shares of Common Stock. Accordingly, these stockholders could have a significant influence over the outcome of any corporate transaction or other matter submitted to stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets and also could prevent or cause a change in control. The interests of these stockholders may differ from the interests of our other stockholders. Third parties may be discouraged from making a tender offer or bid to acquire us because of this concentration of ownership.

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

Immediately following our June 30, 2006 merger, we issued 5,250,000 shares of Series A 10% Cumulative Convertible Preferred Stock with an aggregate stated value of $5,250,000. We issued an additional 5,716,975 shares of Series A Preferred Stock through September 30, 2011 to additional investors, as dividends and in connection with the settlement of amounts owed to certain investors due to our failure to timely register shares of Common Stock issuable upon conversion of Series A Preferred Stock. Net of cumulative conversions into Common Stock through September 30, 2011, the Company has a total of 1,411,864 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 33,341.22 shares of Series B Preferred Stock through September 30, 2011 to additional investors, and as dividends. Net of cumulative conversions into Common Stock through September 30, 2011, the Company has a total of 65,647.38 shares of Series B Preferred Stock issued and outstanding. We will likely issue additional shares of this series of preferred stock in the future as dividends. The Certificate of Designation designating the Series B Preferred Stock provides that upon the following events, among others, the dividend rate with respect to the Series A Preferred Stock increases to 20% per annum:

- the occurrence of “Non-Registration Events”;
- an uncured breach by us of any material covenant, term or condition in the Certificate of Designation or any of the related transaction documents; and
- any money judgment or similar final process being filed against us for more than $100,000.

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

- required us to file a registration statement with the SEC on or before 180 days from the Initial Closing to register the shares of Common Stock issuable upon conversion of the Series B Preferred Stock, and cause such registration statement to be effective by February 21, 2009 (240 days following the Initial Closing) or March 23, 2009 if the reasons for delay are solely due to SEC delay; and
- entitles each of these investors to liquidated damages in an amount equal to two percent (2%) of the purchase price of the Series A Preferred Stock if we fail to timely file that registration statement with, or have it declared effective by, the SEC.

The Company submitted an original S-1 registration statement to the SEC on December 12, 2008. The SEC replied with questions and a request to reduce the number of shares to be registered. In May 2010 the Company filed to withdraw this registration statement. The Company intends to amend and refile the registration statement. The

Company has received a waiver from a majority of the Series B holders for the non-registration event and the timing of the Series B registration does not create a cross-default of the Series A Preferred Series. There can be no assurance that the Company will receive such waiver from investors for any future items and no assurance the Company will still not incur penalties or prevent an Event of Default from occurring.

The Certificate of Designation, Subscription Agreement and related transaction documents also provide for various penalties and fees for breaches or failures to comply with provisions of those documents, such as the timely payment of dividends, delivery of stock certificates, and obtaining and maintaining an effective registration statement with respect to the shares of Common Stock underlying the Series B Preferred Stock sold in the offering. We may in the future default in our contractual obligations to the holders of our Series B Preferred Stock, and in such event we may be required to pay liquidated damages in cash or additional shares of Preferred Stock.

Anti-Dilution Provisions Of The Series B Preferred Stock

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

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

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

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

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

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

In connection with entering into the agreement, 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 number of shares ultimately offered for sale by LPC under this prospectus is dependent upon the number of shares purchased by LPC under the agreement. 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. All 39,634,615 shares registered in this offering are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 32 months from the date of this prospectus. Depending upon market liquidity at the time, a sale of shares under this offering 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 this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to LPC and the agreement may be terminated by us at any time at our discretion without any cost to us.

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

Our certificate of incorporation authorizes the issuance of up to 100,000,000 shares of "blank check" preferred stock, with such designation rights and preferences as may be determined from time to time by the Board of Directors. We have designated 12,000,000 shares of Series A Preferred Stock and 200,000 shares of Series B Preferred Stock as described above. Subject to the rights of the holders of the Series A and Series B Preferred Stock, our Board of Directors is empowered, without stockholder approval, to issue up to 87,800,000 additional shares of preferred stock with dividend, liquidation, conversion, voting or other rights, which could adversely affect the rights of the holders of our common stock. In addition, our certificate of incorporation authorizes the issuance of up to 500,000,000 shares of common stock, of which approximately 322,373,942 shares remain available for issuance and may be issued by us or issued through conversions of preferred stock or convertible notes without stockholder approval. Issuances of additional shares of common stock and/or preferred stock may be utilized as a method of discouraging, delaying or preventing a change in control of our company.

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

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

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

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

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

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

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the selling stockholder. We will receive no proceeds from the sale of shares of common stock in this offering. However, we may receive proceeds of up to $8,500,000 under the Purchase Agreement. Any proceeds from LPC that we receive under the Purchase Agreement will be used for working capital and for other general corporate purposes.

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by Lincoln Park Capital Fund, LLC, or LPC, the selling stockholder. The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;

- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

Brokers, dealers, underwriters or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions.

LPC is an "underwriter" within the meaning of the Securities Act.

Neither we nor LPC can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between LPC or any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters or dealers and any compensation from the selling stockholder, and any other required information.

We will pay all of the expenses incident to the registration, offering and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers or agents. We have also agreed to indemnify LPC and related persons against specified liabilities, including liabilities under the Securities Act.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

LPC and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the Purchase Agreement.

We have advised LPC that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered by this prospectus.

DESCRIPTION OF SECURITIES

Our total authorized capital stock consists of 500,000,000 shares of Common Stock, par value $.001 per share and 100,000,000 shares of preferred stock, par value $0.001 per share. We have designated 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 January 20, 2012, there were 177,626,058 shares of our Common Stock outstanding, 65,433.34 shares of our Series B Preferred Stock and 1,447,159 shares of Series A Preferred outstanding.

The following description of our capital stock does not purport to be complete and is subject to and qualified by our Articles of Incorporation and By-laws, and by the provisions of applicable Nevada law.

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 1,447,159 shares were issued and outstanding as of January 20, 2012. 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 September 30, 2011, 9,555,109 Series A Preferred Shares were converted into 43,698,427 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 September 30, 2011, 20,625.31 Series B Preferred Shares were converted into 56,975,994 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.

Anti-Takeover Provisions

Certain anti-takeover provisions in our Certificate of Incorporation may make a change in control of the Company more difficult, even if a change in control would be beneficial to our stockholders. In particular, our board of directors will be able to issue shares of preferred stock with rights and privileges that might be senior to our Common Stock, without the consent of the holders of our Common Stock, and has the authority to determine the price, rights, preferences, privileges and restrictions of the preferred stock. Although the ability to issue preferred stock may provide us with flexibility in connection with possible acquisitions and other corporate purposes, this issuance may make it more difficult for a third party to acquire a majority of our outstanding voting stock.

Transfer Agent

The transfer agent for our Common Stock is American Stock Transfer & Trust Company, located at 6201 15th Avenue, Brooklyn, New York 11219. American Stock Transfer & Trust Company's telephone number is 718-921-8143.

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THE TRANSACTION

General

In May 2010, we entered into a purchase agreement and registration rights agreement with LPC (the "May 2010 LPC Agreements") under which LPC was obligated, under certain conditions, to purchase up to $6 million of our common stock, from time to time over a twenty-five (25) month period. Under the May 2010 LPC Agreements the Company sold 23,500,000 shares of common stock for an aggregate investment from LPC of $3,670,377. On December 7, 2011, the May 2010 LPC Agreements were terminated, canceling LPC's remaining investment requirement, and on December 8, 2011 entered into a new purchase agreement, or the Purchase Agreement, and a registration rights agreement, or the Registration Rights Agreement, with LPC. Under the new Purchase Agreement, LPC is obligated, under certain conditions, to purchase from us up to $8.5 million of our common stock, from time to time over a 960 day (thirty-two (32) month) period.

Pursuant to the Registration Rights Agreement, we have filed a registration statement that includes this prospectus with the U.S. Securities and Exchange Commission or SEC covering the shares that have been issued or may be issued to LPC under the Purchase Agreement. We do not have the right to commence any sales of our shares to LPC until the SEC has declared effective the registration statement of which this prospectus is a part. Thereafter, over 960 days (32 months), generally we have the right, but not the obligation, to direct LPC to purchase up to $8,500,000 of our common stock in amounts up to $50,000 as often as every two business days under certain conditions. We can also accelerate the amount of our common stock to be purchased under certain circumstances. No sales of shares may occur at a purchase price below $0.10 per share. The price of our stock as of December 9, 2011 was $0.135. The purchase price of the shares will be based on the market prices of our shares at the time of sale as computed under the Purchase Agreement without any fixed discount. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business days notice. We are obligated to issue up to an additional 1,634,615 shares pro rata as LPC purchases up to $8,500,000 of our common stock as directed by us. For example, if we elect, at our sole discretion, to require LPC to purchase $50,000 of our stock then we would issue 9,615 shares of the pro rata commitment fee which is the product of $50,000 (the amount we have elected to sell) divided by $8,500,000 (the total amount we can sell LPC under the Purchase Agreement multiplied by 1,634,615 (the total number of pro rata commitment shares). The pro rata commitment shares will only be issued pursuant to this formula as and when we elect at our discretion to sell stock to LPC. LPC may not assign or transfer any of its rights or obligations under the Purchase Agreement.

Purchase Of Shares Under The Purchase Agreement

Under the Purchase Agreement, on any business day selected by us and as often as every two business days, we may direct LPC to purchase up to $50,000 of our common stock. The purchase price per share is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the average of the two (2) lowest closing sale prices of our common stock during the seven (7) consecutive business days prior to the date of a purchase by LPC.

The purchase price will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

In addition to purchases of up to $50,000, we may direct LPC as often as every two business days to purchase up to $75,000 of our common stock provided that our closing share price on the purchase date is not below $.15 per share. We may increase this amount: up to $150,000 of our common stock provided that our closing share price on

the purchase date is not below $.20 per share; up to $225,000 of our common stock provided that our closing share price on the purchase date is not below $.30 per share; up to $300,000 of our common stock provided that our closing share price on the purchase date is not below $.40 per share; and up to $750,000 of our common stock provided that our closing share price on the purchase date is not below $.60. The price at which LPC would purchase these accelerated amounts of our common stock will be the lesser of (i) the lowest sale price of our common stock on the purchase date or (ii) the lowest purchase price (as described in the first paragraph of this section above) during the three (3) consecutive business days prior to the purchase date.

Minimum Purchase Price

Under the Purchase Agreement, we have set a floor price of $0.10 per share. However, LPC shall not have the right nor the obligation to purchase any shares of our common stock in the event that the purchase price per share would be less than the floor price.

Events of Default

The following events constitute events of default under the Purchase Agreement:

- while any registration statement is required to be maintained effective pursuant to the terms of the Registration Rights Agreement, the effectiveness of the registration statement of which this prospectus is a part of lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to LPC for sale of our common stock offered hereby and such lapse or unavailability continues for a period of ten (10) consecutive business days or for more than an aggregate of thirty (30) business days in any 365-day period;

- suspension by our principal market of our common stock from trading for a period of three (3) consecutive business days;

- the de-listing of our common stock from our principal market provided our common stock is not immediately thereafter trading on the Nasdaq Global Market, the Nasdaq Global Select Market, the Nasdaq Capital market, the New York Stock Exchange or the NYSE AMEX;

- the transfer agent's failure for five (5) business days to issue to LPC shares of our common stock which LPC is entitled to under the Purchase Agreement;

- any material breach of the representations or warranties or covenants contained in the Purchase Agreement or any related agreements which has or which could have a material adverse effect on us subject to a cure period of five (5) business days;

    - any participation or threatened participation in insolvency or bankruptcy proceedings by or against us; or

- a material adverse change in the business, properties, operations, financial condition or results of operations of the Company and its Subsidiaries taken as a whole.

LPC does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party. During an event of default, all of which are outside the control of LPC, shares of our common stock cannot be sold by us or purchased by LPC under the terms of the Purchase Agreement.

Our Termination Rights

We have the unconditional right at any time for any reason to give notice to LPC terminating the Purchase Agreement without any cost to us.

No Short-Selling or Hedging by LPC

LPC has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

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Effect of Performance of the Purchase Agreement on Our Stockholders

All 38,000,000 shares registered in this offering which may be sold by us to LPC under the Purchase Agreement are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 960 days (32 months) from the date of this prospectus. The sale by LPC of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. LPC may ultimately purchase all, some or none of the 39,634,615 shares of common stock not yet issued but registered in this offering. After it 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. 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.

In connection with entering into the Purchase Agreement, we authorized the issuance to LPC of up to 39,634,615 shares of our common stock inclusive of the additional commitment shares to be issued. We have the right to terminate the agreement without any payment or liability to LPC at any time, including in the event that all $8,500,000 is sold to LPC under the Purchase Agreement. Subject to approval by our board of directors, we have the right but not the obligation to sell more than 38,000,000 shares to LPC. In the event we elect to issue more than the 38,000,000 shares (not including the commitment shares) offered hereby, we will be required to file a new registration statement and have it declared effective by the SEC. The number of shares ultimately offered for sale by LPC under this prospectus is dependent upon the number of shares purchased by LPC under the Purchase Agreement. The following table sets forth the amount of proceeds we would receive from LPC from the sale of shares at varying purchase prices:

Assumed Average Purchase Price		Number of Shares to be Issued if Full Purchase(1)	Percentage of Outstanding Shares After Giving Effect to the Issuance to LPC(2)		Proceeds from the Sale of Shares to LPC Under the Purchase Agreement (in millions)
$ 0.10	(3)	38,730,769	17.90	%	$ 3.80
$ 0.15		39,096,154	18.04	%	$ 5.70
$ 0.20		39,461,538	18.18	%	$ 7.60
$ 0.30		29,967,949	14.44	%	$ 8.50
$ 0.40		22,884,615	11.41	%	$ 8.50
$ 0.60		15,801,282	8.17	%	$ 8.50

(1) The number of shares to be issued includes the additional commitment shares issuable to LPC, and no proceeds will be attributable to such commitment shares.

(2) The denominator is based on 177,626,058 shares outstanding as of January 20, 2012, and the number of shares set forth in the adjacent column which includes the commitment fee issued pro rata as up to $8,500,000 of our stock is purchased by LPC. The numerator is based on the number of shares issuable under the Purchase Agreement at the corresponding assumed purchase price set forth in the adjacent column, including the additional commitment shares.

(3) Under the Purchase Agreement, we may not sell and LPC cannot purchase any shares in the event the purchase price thereof is below $0.10 per share.

THE SELLING STOCKHOLDER

The following table presents information regarding the selling stockholder. Neither the selling stockholder nor any of its affiliates has held a position or office, or had any other material relationship, with us. However, in May 2010, we entered into a prior purchase agreement with LPC, pursuant to which we sold an aggregate of 23,500,000 shares for total gross proceeds of $3,670,376.92. The agreement was terminated December 7, 2011.

Selling Stockholder	Shares Beneficially Owned Before Offering	Percentage of Outstanding Shares Beneficially Owned Before Offering	Shares to be Issued in the Offering Assuming The Company Issues The Maximum Number of Shares Under the Purchase Agreement	Percentage of Outstanding Shares Beneficially Owned After Offering
Lincoln Park Capital Fund, LLC (1)	2,731,886 (2)	1.54 %(2)	39,634,615 (3)	1.26 %

(1) Josh Scheinfeld and Jonathan Cope, the principals of LPC, are deemed to be beneficial owners of all of the shares of common stock owned by LPC. Messrs. Scheinfeld and Cope have shared voting and disposition power over the shares being offered under this Prospectus.

(2) Shares of our common stock previously issued to LPC pursuant to a purchase agreement executed in May 2010. The agreement was terminated December 7, 2011. We may at our discretion elect to issue to LPC up to an additional 39,634,615 shares of our common stock under the Purchase Agreement but LPC does not beneficially own any such shares that may be issued by us at our sole discretion and such shares are not included in determining the percentage of shares beneficially owned before the offering.

(3) This number includes 38,000,000 shares of common stock, the maximum number of shares to be sold in the offering, plus 1,634,615, the additional commitment shares to be issued assuming the Company offers the maximum number of shares under the Purchase Agreement.

INTERESTS OF NAMED EXPERTS AND COUNSEL

No expert or counsel named in this prospectus as having prepared or certified any part of this prospectus or having given an opinion upon the validity of the securities being registered or upon other legal matters in connection with the registration or offering of the common stock was employed on a contingency basis, or had, or is to receive, in connection with the offering, a substantial interest, direct or indirect, in the registrant or any of its parents or subsidiaries. Nor was any such person connected with the registrant or any of its parents or subsidiaries as a promoter, managing or principal underwriter, voting trustee, director, officer, or employee.

The December 31, 2010 financial statements included in this prospectus and the registration statement have been audited by WithumSmith+Brown, PC, independent registered public accounting firm, to the extent and for the periods set forth in their report appearing elsewhere herein and in the registration statement, and are included in reliance upon such report given upon the authority of said firm as experts in auditing and accounting.

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

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

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

Principal Terms of the Reverse Merger

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

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

For accounting purposes, the merger has been accounted for as a reverse merger, since MedaSorb Technologies Corporation (then Gilder Enterprises) was a shell company prior to the merger, the stockholders of MedaSorb prior to the merger own a majority of the issued and outstanding shares of our Common Stock after the merger, and the directors and executive officers of MedaSorb prior to the merger became our directors and executive officers.

Accordingly, pre-merger MedaSorb is treated as the acquiror in the merger, which is treated as a recapitalization of pre-merger MedaSorb, and the pre-merger financial statements of MedaSorb are now deemed to be our historical financial statements.

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

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

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

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

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

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

Because the registration statement we agreed to file was not declared effective within the time required under our agreements with the June 30, 2006 purchasers of the Series A Preferred Stock, dividends on the shares of Series A Preferred Stock issued to those purchasers accrued at the rate of 20% per annum from February 26, 2007 until May 7, 2007, the date the registration statement was declared effective. During this time period, we were obligated to pay those purchasers cash dividends and an aggregate of $105,000 per 30-day period from February 26, 2007 through the date such registration statement was declared effective (May 7,2007) in cash. Pursuant to a settlement agreement with the June 30, 2006 purchasers of Series A Preferred Stock, all cash dividends and damages were paid for in full with additional shares of Series A Preferred Stock.

Both the conversion price 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 $1,757,000 and $1,962,000 for the years ended December 31, 2010 and 2009, respectively.

Technology, Products and Applications

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

Our initial products, CytoSorb™ and BetaSorb™, are known in the medical field as hemoperfusion devices. During hemoperfusion, blood is removed from the body via a catheter or other blood access device, perfused through a filter medium where toxic compounds are removed, and returned to the body.

We believe that our polymer adsorbent technology may remove middle molecular weight toxins and toxic compounds, such as cytokines, from blood and physiologic fluids. We believe that our technology may have many applications in the treatment of common, chronic and acute healthcare conditions including the adjunctive treatment and/or prevention of sepsis; the treatment of other critical care illnesses such as severe burn injury, trauma, acute respiratory distress syndrome and pancreatitis, the treatment of chronic kidney failure; the prevention of post-operative complications of cardiopulmonary bypass surgery; and the prevention of damage to organs donated by brain-dead donors prior to organ harvest. These applications vary by cause and complexity as well as by severity but share a common characteristic i.e. high concentrations of inflammatory mediators and toxins in the circulating blood.

Both the CytoSorb™ and BetaSorb™ devices consist of a cartridge containing adsorbent polymer beads, although the polymers used in the two devices are physically different. The cartridges in both devices incorporate industry standard connectors at either end of the device, which connect directly to the extra-corporeal circuit (bloodlines) in series with a dialyzer, in the case of the BetaSorb™ device, or as a stand alone device in the case of the CytoSorb™ device. Both devices are compatible with standard blood pumps or hemodialysis machines used commonly in hospitals and will therefore not require additional expensive equipment, and will require minimal training.

The extra-corporeal circuit consists of plastic blood tubing, our CytoSorb™ or BetaSorb™ cartridge, as applicable, containing adsorbent polymer beads, pressure monitoring gauges, and a blood pump to maintain blood flow. The patient's blood is accessed through a catheter inserted into his or her veins. The catheter is connected to the extra-corporeal circuit and the blood pump draws blood from the patient, pumps it through the cartridge and returns it back to the patient in a closed loop system.

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, that is designed to keep the patient from dying while using careful patient management to tip the balance towards gradual recovery over time. Unfortunately, many supportive care therapies are only useful in supporting organ function and not designed to address the root cause of why multiple organ failure initially developed, which is typically multi-factorial. Because of this, the treatment course is often poorly defined and highly variable, leading to a higher risk of adverse outcomes from hospital acquired infections, medical errors, and other factors, as well as exorbitant costs. There is an urgent need for more effective "active" therapies that can help to reverse or prevent organ failure. CytoSorbents' main product, CytoSorb™ is a unique cytokine filter designed to try to address this void, by attempting to address the substantial role that an aberrant immune response and "cytokine storm" plays in the development of organ dysfunction.

Sepsis

Sepsis is characterized by a systemic inflammatory response in response to severe infection 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 30-35%. Septic shock, or severe sepsis with low blood pressure that is not responsive to fluid resuscitation, is the most serious form of sepsis with an expected mortality in excess of 50%.

In sepsis, the body produces large amounts of inflammatory mediators called cytokines in response to infection. In severe infection, many people suffer from a massive, unregulated overproduction of cytokines, often termed “cytokine storm” that can kill cells and damage organs, leading to multi-organ failure and in many cases death. CytoSorb™ is an investigational device designed to act as a broad spectrum cytokine filter. It is intended to play a critical role in treating patients with severe sepsis or septic shock by reducing cytokine storm, while antibiotics work to control the actual infection. CytoSorb™ has completed its European Sepsis Trial in patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis in a randomized, controlled clinical trial in Europe.

In the United States and Europe, there are more than one million and 1.5 million new cases, respectively, of severe sepsis and septic shock annually. Based on the reported incidence of sepsis in a number of developed countries, the worldwide incidence is estimated to be 18 million cases per year. The incidence of serious infection and sepsis has doubled in the past 20 years driven by a number of factors including the spread of antibiotic resistant bacteria like methicillin-resistant Staphylococcus aureus (MRSA), an aging population that is more prone to infection, an increase in co-morbid conditions like HIV, cancer and diabetes that increases the risk of infection, an increasing use of implantable devices like artificial hips and knees that are prone to colonization by bacteria, and the appearance of new highly virulent or contagious strains of common pathogens such as H1N1 influenza. The Company estimates that the market potential in Europe for its products is substantially equivalent to that in the U.S. In Germany alone, according to the German Sepsis Society (GSS), there are approximately 154,000 cases of sepsis each year. Patients are treated in the intensive care unit for 12-18 days on average and for a total of 20-25 days in the hospital.

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

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

Severe Burn Injury

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

Trauma

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