Cytosorbents Corp
Form POS AM
December 12, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 3 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:

Gregg Jaclin, Esq.

Eric Stein, Esq.

Anslow Jaclin LLP

195 Route 9 South, Suite 204

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

EXPLANATORY NOTE

On February 10, 2012, the Securities and Exchange Committee declared effective the registration statement on Form S-1 (File No. 333-178654) (the "Registration Statement") filed by Cytosorbents Corporation. (the "Company"). The Company is filing this post effective amendment to the Registration Statement for the purpose of including XBRL detail tagging for our financial statements.

The information included in this filing updates and supplements this Registration Statement and the Prospectus contained therein. **No additional securities are being registered under this Post-Effective Amendment No. 3.** All applicable registration fees were paid at the time of the original filing of the Registration Statement.

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. This registration statement covers the 39,634,615 shares of our common stock previously registered in the S-1/A registration statement filed on February 6, 2012. No new shares are being registered.

(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 December 12, 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 December 12, 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.

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 2011 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. In late June 2012, we completed the controlled-market release and began the commercial launch of CytoSorb® in Germany with the hiring of Dr. Christian Steiner as Vice President of Sales and Marketing and three additional sales people, one of whom started immediately and the other two expected to start by August 2012. Because of this timing, the third quarter of 2012 is expected to be a transitional quarter in terms of revenues as the sales force increases its training and sales activities, particularly in Germany.

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 are focusing our efforts on the commercialization of CytoSorb® and have now concluded a controlled-market release program in select territories in Germany that we initiated in late 2011. The purpose of this program was to prepare the Company for commercialization of CytoSorb in Germany in terms of manufacturing, logistics, infrastructure, marketing, contacts, and other key issues. Following the establishment of our European subsidiary, CytoSorbents Europe GmbH, we commenced a direct sales effort in Germany at the end of the second quarter of 2012 with the hiring of a four person direct sales force including a Vice President of Sales and Marketing, two of which started immediately, and two that began at the beginning of August. We are also evaluating potential distributor networks in other major countries where we are approved to market the device.

We are required to obtain required regulatory approvals from the United States Food and Drug Administration (“FDA”) before we can sell our products in the United States.

We have completed the targeted enrollment in our European Sepsis clinical trial of one hundred (100) patients with sepsis and respiratory failure with the participation of fourteen trial sites. The purpose of the trial was to demonstrate safety and the broad, and statistically significant reduction of key cytokines such as IL-6 in these patients. Although the trial was not powered to demonstrate significant reduction in clinical endpoints such as mortality, these were included as secondary and exploratory endpoints in the trial. Taking into account all 100 patients, the treatment was well-tolerated with no serious device related adverse events reported in more than 300 human treatments in the trial. The first 22 patients in the study represented a sepsis pilot study. In the next 31 patients, a compromise of the manual randomization schedule at two trial sites led to an imbalance in the severity of illness between the control and treatment patient groups of the study. After a thorough review, the Scientific Advisory Board (SAB) and the

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

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 beta-2-microglobulin from the blood of patients suffering from chronic kidney failure who rely on long term dialysis therapy to sustain their life. BetaSorb™ utilizes an adsorbent polymer packed into 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

This Post-effective S-1 is designed only to update operations and financials. There are no new shares being registered. The 39,634,615 shares mentioned below have already been registered in the S1/A filing dated February 6, 2012.

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 November 5, 2012 there were 211,912,915 shares of our common stock outstanding. 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. As of November 5, 2012, 25,580,789 shares of our common stock have been sold to LPC and there are 11,784,619 shares remain to be sold, notwithstanding the 1,634,615 commitment shares that are issuable to LPC as we sell shared to LPC under the Purchase Agreement.

Securities Offered

Common stock offered by selling stockholder:	39,634,615 shares. There are no new shares being registered.
Offering Price:	Market Price
Common Stock Currently Outstanding:	211,912,915 shares as of December 3, 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, 2012 we had cash on hand of $2,061,132 and current liabilities of $2,075,758. 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, 2012, we had an accumulated deficit of $97,554,274, which included net losses of $651,980 and $3,125,886 for the three and nine month periods ended September 30, 2012. 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 sixteen 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; 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.

CytoSorb is currently eligible for reimbursement in Germany and Austria. We plan to seek reimbursement in other European countries to help further adoption. Additional approvals from other regulatory authorities (such as the FDA) will be required before we can market our device in countries not covered by the CE Mark. There is no guarantee that the Company will be able to achieve additional regulatory approvals, and even if we do, our products may not achieve market acceptance in the countries covered by such approvals. The degree of market acceptance will depend upon a number of factors, including:

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

Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our products. Approval of our CytoSorb® device as a cytokine filter as well as the data we have gathered in our clinical studies to support device usage in this indication may not be sufficient for market acceptance in the medical community. We may also need to conduct additional clinical studies to gather additional data for marketing purposes. If we are unable to obtain regulatory approval or commercialize and market our products when planned, we may not achieve any market acceptance or generate revenue.

Even with our approval to apply the CE Mark to our CytoSorb® device as a cytokine filter, there can be no assurance that the data from our limited clinical studies will be viewed as sufficient by the medical community to support the purchase of our products in substantial quantities or at all.

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

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

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

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

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

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

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

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

Our products will be subject to international regulation as medical devices under the Medical Device Directive. In Europe, which we expect to provide the initial market for our products, the Notified Body and Competent Authority govern, where applicable, development, clinical studies, labeling, manufacturing, registration, notification, clearance or approval, marketing, distribution, record keeping, and reporting requirements for medical devices. Different regulatory requirements may apply to our products depending on how they are categorized by the Notified Body under these laws. Current international regulations classify our CytoSorb® device (the first product we intend to seek international approval for) as a Class IIb device. Even though we have received CE Mark certification of the

CytoSorb® device, there can be no assurance that we will be able to continue to comply with the required annual auditing requirements or other international regulatory requirements that may be applicable. In addition, there can be no assurance that government regulations applicable to our products or the interpretation of those regulations will not change. The extent of potentially adverse government regulation that might arise from future legislation or administrative action cannot be predicted. There can be no assurances that reimbursement will be granted or that additional clinical data may be required to establish reimbursement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

INVESTMENT RISKS

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

Our directors, executive officers and principal stockholders together beneficially own approximately 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

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