

Cytosorbents Corp  
Form POS AM  
October 08, 2015

As filed with the Securities and Exchange Commission on October 8, 2015

Registration No. 333-194394

Registration No. 333-193053

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 1 TO

FORM S-1

ON FORM S-3

REGISTRATION STATEMENT UNDER

THE SECURITIES ACT OF 1933

CYTOSORBENTS CORPORATION

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction

of incorporation or

organization)

**3841**

(Primary Standard Industrial (I.R.S. Employer

Classification Code Number) Identification Number)

**98-0373793**

7 Deer Park Drive, Suite K

Edgar Filing: Cytosorbents Corp - Form POS AM

Monmouth Junction, New Jersey 08852

(732) 329-8885

(Address, including zip code, and telephone number,  
including area code, of registrant's principal executive offices)

Dr. 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:

David C. Schwartz, Esq.

DLA Piper LLP (US)

51 John F. Kennedy Parkway, Suite 120

Short Hills, New Jersey 07078

**APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC:** From time to time after the effective date of this registration statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

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.

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

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.

## EXPLANATORY NOTE

This Post-Effective Amendment No. 1 on Form S-3 relates to the registration statement on Form S-1 (File No. 333-193053) of Cytosorbents Corporation (the “Company”) which was declared effective by the Securities and Exchange Commission on February 14, 2014 (the “Registration Statement”) and an additional registration statement on Form S-1 (File No. 333-194394) to register an additional amount of securities, the final prospectus of which was filed on March 7, 2014. The Company is filing this post-effective amendment to the Registration Statement (the “Post-Effective Amendment”) for the purpose of 1) updating the associated financial statements, including information from the Company’s Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015 and from the Company’s Annual Report on Form 10-K for the year ended December 31, 2014, including the financial statements for those corresponding periods, and 2) converting the Registration Statement on Form S-1 into a Form S-3. **NO NEW OR ADDITIONAL SECURITIES ARE BEING REGISTERED UNDER THIS POST-EFFECTIVE AMENDMENT.**

The Company became eligible in December 2014 to utilize Form S-3 for this purpose as a result of the listing of its shares of common stock on the NASDAQ Capital Market. Pursuant to Rule 429 under the Securities Act, the prospectus included in this Post-Effective Amendment relates to units of the Registrant, each consisting of one (1) share of common stock of the Registrant and one (1) warrant to purchase common stock of the Registrant, previously registered upon the original filing of this Registration Statement on Form S-1, and constitutes a post-effective amendment to such Registration Statement. This Post-Effective Amendment shall hereafter become effective concurrently with the effectiveness of this Registration Statement in accordance with Section 8 of the Securities Act.

This Post-Effective Amendment should be read in conjunction with the Registration Statement. This Post-Effective Amendment does not reflect events that may have occurred after the date of the Registration Statement and does not modify or update in any way the disclosures made in the Registration Statement, except as required to reflect the revisions discussed above.

The information included in this filing updates and supplements this Registration Statement and the Prospectus contained therein. All applicable registration fees were paid at the time of the original filing of the Registration Statement.

**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 October 8, 2015*

## **PROSPECTUS**

### **CYTOSORBENTS CORPORATION**

#### **UP TO 40,800,000 UNITS, EACH CONSISTING OF**

#### **ONE (1) SHARE OF COMMON STOCK AND**

#### **A WARRANT TO PURCHASE .5 SHARES OF COMMON STOCK**

This prospectus is registering an aggregate of up to 40,800,000 units at a per unit price of \$0.25, each unit consisting of one (1) share of our common stock and one (1) warrant to purchase 0.50 shares of common stock at an exercise price of \$0.3125 per share issued as part of this Unit. On December 3, 2014 we effected a twenty-five-for-one (25:1) reverse split of our common stock. Taking into effect the twenty-five-for-one (25:1) reverse stock split, the Prospectus relates to the offer and sale of an aggregate of up to 1,632,000 units at a per unit price of \$6.25, each unit consisting of one (1) share of our common stock and one (1) warrant to purchase 0.02 shares of common stock at an exercise price of \$7.8125 per share issued as a part of this Unit.

Our common stock currently trades on the NASDAQ Capital Market under the symbol "CTSO." On September 30, 2015, the closing price of our common stock was \$6.31 per share.

**INVESTING IN OUR COMMON STOCK INVOLVES SUBSTANTIAL RISKS. SEE THE SECTION TITLED "RISK FACTORS" BEGINNING ON PAGE [·] 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                      , 2015**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS</u>	1
<u>PROSPECTUS SUMMARY</u>	2
<u>RISK FACTORS</u>	9
<u>USE OF PROCEEDS</u>	16
<u>PLAN OF DISTRIBUTION</u>	17
<u>DESCRIPTION OF SECURITIES</u>	17
<u>EXPERTS</u>	19
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	19
<u>INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE</u>	19

## CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and documents incorporated by reference into this prospectus and any prospectus supplement or free writing prospectus may contain “forward-looking statements” within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as “may,” “should,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “potential,” “project,” “continue” and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements included herein represent management’s current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. The following documents, among others, describe these assumptions, risks, uncertainties, and other factors. You should read and interpret any forward-looking statements together with the following documents:

our most recent Annual Report on Form 10-K, as amended, including the sections entitled “Business”, “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”;

- the risk factors contained in this prospectus under the caption “Risk Factors”;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015; and
- our other filings with the Securities and Exchange Commission.

Any forward-looking statement speaks only as to the date on which that statement is made. We assume no obligation to update any forward-looking statement to reflect events or circumstances that occur after the date on which the statement is made.



## 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 9 of this prospectus and our financial statements and related notes incorporated by reference 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 19 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 9 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. On October 28, 2014, we changed the name of our operating subsidiary from CytoSorbents, Inc. to CytoSorbents Medical, Inc. On December 3, 2014 we changed our state of incorporation from the State of Nevada to the State of Delaware.

On December 3, 2014, we effected a twenty-five-for-one (25:1) reverse split of our common stock. As a result of the reverse stock split shares of our common stock outstanding were reduced by approximately 96%. Based on the 582,097,092 shares of common stock outstanding as of December 3, 2014, the total number of shares of common stock outstanding after the reverse stock split, including accounting for fractional shares which were rounded up to the next whole number, were 23,284,040. All share, option and warrant information included in this prospectus has been retroactively adjusted to reflect the reduced number of shares resulting from this action.

We have experienced substantial operating losses since inception. As of June 30, 2015, we had an accumulated deficit of approximately \$127,677,000, which included losses of approximately \$3,283,000 and \$2,829,000 for the six month periods ended June 30, 2015 and 2014, respectively. Historically, our losses have resulted principally from costs incurred in the research and development of our polymer technology, and general and administrative expenses. We may continue to incur losses in the future. In part due to these losses, our 2014 audited consolidated financial statements have been prepared assuming we will continue as a going concern, and the auditors' report on those financial statements express substantial doubt about our ability to continue as a going concern.

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

## **Summary of Our Business**

CytoSorbents is a critical care focused immunotherapy company using blood purification to modulate inflammation—with the goal of preventing or treating multiple organ failure in life-threatening illnesses and cardiac surgery. Organ failure is the cause of nearly half of all deaths in the intensive care unit, with little to improve clinical outcome. CytoSorb®, the Company's flagship product, is approved in the European Union, or EU, as a safe and effective extracorporeal cytokine filter, designed to reduce the "cytokine storm" that could otherwise cause massive inflammation, organ failure and death in common critical illnesses such as sepsis, burn injury, trauma, lung injury, and pancreatitis. These are conditions where the mortality is extremely high, yet no effective treatments exist. In addition, CytoSorb® can be used in other inflammatory conditions such as cardiac surgery, autoimmune disease flares, and potentially for cancer, cytokine release syndrome in cancer immunotherapy, and cancer cachexia where cytokines play a major role in the cause of inflammation. CytoSorbents' purification technologies are based on biocompatible, highly porous polymer beads that can actively remove toxic substances from blood and other bodily fluids by pore capture and surface adsorption. CytoSorbents has numerous products under development based upon this unique blood purification technology, protected by 32 issued U.S. patents and multiple applications pending, including HemoDefend™, ContrastSorb, DrugSorb, and others.

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

Our CE Mark enables CytoSorb® to be sold throughout all 28 countries of the EU. In addition, many countries outside the EU accept CE Mark approval for medical devices, but may also require registration with or without additional clinical studies. The broad approved indication enables CytoSorb® to be used “on-label” in diseases where cytokines are elevated including, but not limited to, critical illnesses such as those mentioned above, autoimmune disease flares, cancer cachexia, and many other conditions where cytokine-induced inflammation plays a detrimental role.

Cytokines are small proteins that normally stimulate and regulate the immune response. However, in certain diseases, particularly life-threatening conditions commonly seen in the intensive care unit, or ICU, such as sepsis and infection, trauma, acute respiratory distress syndrome (ARDS), severe burn injury, liver failure, and acute pancreatitis, cytokines are often produced in vast excess – a condition often called cytokine storm. Left unchecked, this cytokine storm can lead to a severe maladaptive systemic inflammatory response syndrome, or SIRS, that can then cause cell death, multiple organ dysfunction syndrome or MODS, and multiple organ failure, MOF. Failure of vital organs such as the heart, lungs, and kidneys, accounts for nearly half of all deaths in the intensive care unit. This is despite the wide availability of supportive care therapies, or “life support”, such as dialysis, mechanical ventilation, extracorporeal membrane oxygenation, and vasopressors. By replacing the function of failed organs, these supportive care therapies can initially help to keep patients alive, but do not help patients recover faster, and in many cases can increase the risk of dangerous complications. Unlike these supportive care therapies, the goal of the CytoSorb® cytokine filter is to pro-actively prevent or treat organ failure by reducing cytokine storm and reducing the maladaptive SIRS response. In doing so, CytoSorb® targets the reduction in the severity of patient illness and the need for intensive care, while potentially improving clinical outcome and saving healthcare costs.

As part of the CE Mark approval process, we completed our randomized, controlled, European Sepsis Trial amongst 14 trial sites in Germany in 2011, with enrollment of 100 patients with sepsis and respiratory failure. The trial established that CytoSorb® was safe in this critically-ill population. Taking into account all 100 patients, the treatment was well-tolerated with no serious device related adverse events reported in more than 300 human treatments in the trial. Although the trial was not powered to demonstrate significant reduction in other clinical endpoints such as mortality, these were also included as secondary and exploratory endpoints in the trial.

## Edgar Filing: Cytosorbents Corp - Form POS AM

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, or SAB, and the independent Data Safety Monitoring Board, or 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 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. An independent CRO, RCRI, Inc., analyzed these 43 patients the European Sepsis Trial and showed 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 seven-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

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

We plan to conduct larger, prospective studies in septic patients in the future to confirm these findings. According to a recent study by the U.S. Centers for Disease Control and Prevention, or CDC, those older than age 65 account for approximately two-thirds of patients hospitalized in the United States for sepsis, and were responsible for the doubling in the incidence of sepsis over the past decade. Without effective therapies to treat sepsis, the incidence of sepsis and sepsis-related deaths are expected to continue to increase significantly over the course of the next decade, particularly as the baby boomer generation, which began turning 65 in 2011, continues to get older.

In addition to CE Mark approval, CytoSorbents also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the European Union. We manufacture CytoSorb® at our manufacturing facilities in New Jersey for commercial sales abroad and for additional clinical studies. In September 2013, we were granted a two-year renewal for the CytoSorb® CE Mark. We also established a reimbursement path for CytoSorb® in Germany and Austria.

From September 2011 through June 2012, we began a controlled market release of CytoSorb® in select geographic territories in Germany. The purpose of this program was to prepare the Company for commercialization of CytoSorb® in Germany in terms of manufacturing, reimbursement, logistics, infrastructure, marketing, contacts, and other key issues.

In late June 2012, following the establishment of our European subsidiary, CytoSorbents Europe GmbH, a wholly-owned operating subsidiary of CytoSorbents Corporation, we 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 representatives who joined us and completed their sales training in Q3 2012. The fourth quarter of 2012 represented the first quarter of direct sales with the full sales team in place. During this period, we expanded our direct sales efforts to include both Austria and Switzerland.

Fiscal 2013 represented the first full year of CytoSorb® commercialization. We focused our direct sales efforts in Germany, Austria and Switzerland with four sales representatives. The focus of the team was to encourage acceptance and usage by key opinion leaders, or KOLs, throughout these countries. By the end of 2014, we had more than 150 KOLs in critical care, cardiac surgery, and blood purification who were either using CytoSorb® or committed to using CytoSorb® in the near future. We believe these KOL relationships will be essential to drive adoption and recurrent usage of CytoSorb by the department, facilitate purchases by the hospital administration, arrange reimbursement, and generate data for papers and presentations. In addition, we now currently have more than 40 investigator initiated studies being planned in Germany, Austria, and the United Kingdom in multiple applications including sepsis, cardiac surgery, lung injury, trauma, pancreatitis, liver failure, kidney failure, and others, with many already enrolling patients. These studies are being supported by our European Director of Scientific Affairs. As of June 30, 2015, we have increased our sales force to includes six direct sales people, two contract sales people, and eight sales and distributor support staff.

We have complemented our direct sales efforts with sales to distributors and corporate partners. In 2013, we reached agreement with distributors in the United Kingdom, Ireland, the Netherlands, Russia and Turkey. In April 2014, we announced distribution of CytoSorb® in the Middle East, including Saudi Arabia, the United Arab Emirates, Kuwait, Qatar, Bahrain, and Oman (the Gulf Cooperative Council, or GCC) and Yemen, Iraq, and Jordan through an exclusive agreement with TechnoOrbits. In December 2014, we entered into an exclusive agreement with Smart Medical Solutions S.R.L. to distribute CytoSorb® for critical care applications in Romania and the neighboring Republic of Moldova. In January 2015, we announced our exclusive distribution agreement with Aferetica SRL to distribute CytoSorb® in Italy for critical care applications.

We have been expanding the number and scope of its strategic partnerships. In September 2013, we entered into a strategic partnership with Biocon Ltd., Asia's largest biotech company, with an initial distribution agreement for India and select emerging markets, under which Biocon has the exclusive commercialization rights for CytoSorb® initially focused on sepsis. In September 2014, the Biocon partnership was expanded to include all critical care applications and cardiac surgery. In addition, Biocon committed to higher annual minimum purchases of CytoSorb® to maintain distribution exclusivity and committed to conduct and publish results from multiple investigator initiated studies and patient case studies.

In addition, in November 2014, we entered into an initial partnership agreement with a leading global medical device company in cardiac surgery and other cardiovascular diseases, to use CytoSorb® intra-operatively during cardiac surgery in France. Under the terms of the agreement, the partnership will commence with an initial six-month market evaluation period to determine various market parameters, to obtain clinical data, and to build key opinion leader support in France. Following a successful evaluation, the parties plan to jointly determine how to expand upon both the size and geographic footprint of its partnership.

In February 2015, we entered into a multi-country strategic partnership with Fresenius Medical Care AG & Co KGaA, or Fresenius, to commercialize the CytoSorb® therapy. Under the terms of this agreement, Fresenius has exclusive rights to distribute CytoSorb® for critical care applications in France, Poland, Sweden, Denmark, Norway, and Finland. The partnership will allow Fresenius to offer an innovative and easy way to use blood purification therapy for removing cytokines in patients that are treated in the intensive care unit. To promote the success of CytoSorb®, Fresenius will also engage in the ongoing clinical development of the product. This includes the support and publication of a number of small case series and patient case reports as well as the potential for future larger, clinical collaborations.

Overall, we have established either direct sales (as above) or distribution (via distributors or strategic partners) of CytoSorb in 29 countries worldwide. Registration of CytoSorb is typically required in each of these countries prior to active commercialization. With CE Mark approval, this can be typically achieved within several months in EU countries. Outside of the EU, the process is more variable and can take months to more than a year due to different requirements for documentation and clinical data. Variability in the timing of registration affects the initiation of active commercialization in these countries, which affects the timing of expected CytoSorb sales. We actively support all of our distributors and strategic partners in the product registration process. Outside of the EU, CytoSorb is actively being commercialized in Turkey and India. CytoSorb is registered in Saudi Arabia, but is currently awaiting Saudi FDA approval, a proxy for the rest of the Gulf Cooperation Council, or GCC, countries. CytoSorb and its distribution partner in Russia have submitted all requested documentation for registration, and await a response from the Russian authorities. We cannot generally predict the timing of these registrations, and there can be no guarantee that we will ultimately achieve registration in countries where we have established distribution. For example, in August 2014 we announced exclusive distribution of CytoSorb® in Taiwan with Hemoscien Corporation. However, in March 2015, due to the complexity we encountered with Taiwanese product registration, we elected to terminate our agreement with Hemoscien. We also cannot guarantee that we will generate meaningful sales in the countries where we have established registration, due to other factors such as market adoption and reimbursement. We are currently actively evaluating other potential distributor and strategic partner networks in other major countries that accept CE Mark approval.

The market focus for CytoSorb® is the prevention or treatment of organ failure in life-threatening conditions, including commonly seen illnesses in the intensive care unit such as infection and sepsis, trauma, burn injury, ARDS, and others. Severe sepsis and septic shock, a potentially life-threatening systemic inflammatory response to a serious infection, accounts for approximately 10-20% of all ICU admissions and is one of the largest target markets for CytoSorb®. Sepsis is a major unmet medical need with no approved products in the United States or Europe to treat it. As with other critical care illnesses, multiple organ failure is the primary cause of death in sepsis. When used with standard of care therapy, that includes antibiotics, the goal of CytoSorb® in sepsis is to reduce excessive levels of cytokines and other inflammatory toxins, to help reduce the SIRS response and either prevent or treat organ failure.

In addition to the sepsis indication, we intend to conduct or support additional clinical studies in sepsis, cardiac surgery, and other critical care diseases where CytoSorb® could be used, such as ARDS, trauma, severe burn injury, acute pancreatitis, and in other acute conditions that may benefit by the reduction of cytokines in the bloodstream. Some examples 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 intend 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.

We are currently conducting a matched pairs analysis, dose ranging trial in Germany amongst eight clinical trial sites to evaluate the safety and efficacy of CytoSorb® when used continuously for seven days, each day with a new device. Data from this dosing study are intended to help clinicians with additional treatment options for CytoSorb®, help support the positive clinical data from our first European Sepsis Trial, and help shape the trial protocol for a pivotal sepsis study.

In addition to the dosing study, we will rely on data generated in the more than 40 ongoing investigator initiated studies and company sponsored trials currently planned or enrolling in Germany, Austria and the United Kingdom, India, and the United States. Approximately 12 of these studies are currently enrolling patients. These trials, which are funded and supported by well-known university hospitals and KOLs, are the equivalent of Phase 2 clinical studies. They will provide invaluable information regarding the success of the device in the treatment of sepsis, cardio-pulmonary bypass surgery, trauma, and many other indications, and if successful, will be integral in helping to drive additional usage and adoption of CytoSorb®.

In addition to sepsis and other critical care applications, cardiac surgery is emerging as an important potential application for CytoSorb® in the European market. There are approximately one million cardiac surgery procedures performed annually in the United States and EU including, for example, coronary artery bypass graft surgery, valve replacement surgery, heart and lung transplant, congenital heart defect repair, and left ventricular assist device, or LVAD, implantation. Cardiac surgery can result in inflammation and the production of high levels of inflammatory cytokines, as well as hemolysis, causing the release of free hemoglobin. These can lead to post-operative complications such as respiratory failure and acute kidney injury. CytoSorb® has a unique competitive advantage as the only cytokine and free hemoglobin removal technology that can be used during the operative procedure and can be easily installed in a bypass circuit in a heart-lung machine without the need for an additional pump. Direct cytokine and hemoglobin removal with CytoSorb® enables it to replace the existing market for leukoreduction filters in cardiac surgery that attempt to indirectly reduce cytokines by capturing cytokine-producing leukocytes – an inefficient and suboptimal approach.

In February 2015, the U.S. Food and Drug Administration, or FDA, approved our Investigational Device Exemption, or IDE, application to commence a planned cardiac surgery feasibility study in the United States. This single-arm study in 20 patients and three U.S. clinical sites represents the first part of a larger clinical trial strategy intended to support the U.S. approval of CytoSorb® for intra-operative use during cardiac surgery. The study is designed to evaluate the safety of CytoSorb® when used intra-operatively in a heart-lung machine to reduce plasma free hemoglobin and cytokines in patients undergoing complex cardiac surgery. The length, complexity and invasiveness of these procedures cause hemolysis and inflammation, leading to high levels of plasma free hemoglobin, cytokines, activated complement, and other substances. These inflammatory mediators directly correlate with the incidence of serious post-operative complications such as kidney injury and failure. The goal of CytoSorb® is to actively remove these inflammatory and toxic substances as they are being generated during the surgery and reduce complications.



Concurrently, we are funding a non-interventional study amongst a broader array of U.S. cardiac surgery centers that will assess adverse event rates (e.g., incidence of acute kidney injury and respiratory failure) and levels of free hemoglobin and other inflammatory mediators in patients undergoing complex cardiac surgery. These patients will be selected using similar inclusion and exclusion criteria to the feasibility study. The data from these two studies will help to rapidly validate assumptions in this surgical patient population and help to appropriately power a pivotal cardiac surgery trial in the United States.

Even though we have obtained CE Mark approval, no guarantee or assurance can be given that our CytoSorb® product will work as intended or that we will be able to obtain FDA approval to sell CytoSorb® in the United States or approval in any other country or jurisdiction. Because of the limited studies we have conducted, we are subject to substantial risk that our technology will have little or no effect on the treatment of any indications that we have targeted.

We have been successful in obtaining technology development contracts from agencies in the U.S. Department of Defense, including the Defense Advanced Research Projects Agency, or DARPA, the U.S. Army, and the U.S. Air Force.

In June 2013, we announced that the U.S. Air Force will fund a 30 patient, single site, randomized controlled human pilot study in the United States amongst trauma patients with rhabdomyolysis. The primary endpoint is myoglobin removal. The FDA approved our Investigational Device Exemption (IDE) application for this study and we also received ethics committee approval, allowing the study to commence. However, because of the stringency of our inclusion criteria, and because of the patient mix seen at our single center, we have experienced difficulty in enrolling patients. We have subsequently modified one of the key inclusion criteria and have expanded the number of clinical trial sites to three in a revised protocol which has been submitted to the FDA. Though CytoSorbents does not expect to receive material direct funding from this \$3 million budgeted program, the study may generate valuable data that can be used commercially or in future trauma studies.

In September 2012, we were awarded a Phase II Small Business Innovation Research, or SBIR, contract by the U.S. Army Medical Research and Material Command to evaluate our technology for the treatment of trauma and burn injury in large animal models. In 2013, we finalized the Phase II SBIR contract which provided for a maximum funding of approximately \$753,000 with the granting agency. This work is supported by the U.S. Army Medical Research and Material Command under an amendment to Contract W81XWH-12-C-0038. As of December 31, 2014, we received approximately \$649,000 in funding under this contract and no further amounts are expected from this contract.

In August 2012, we were awarded a \$3.8 million, five-year contract by DARPA for its “Dialysis-Like Therapeutics” program to treat sepsis. DARPA has been instrumental in funding many of the major technological and medical

advances since its inception in 1958, including development of the Internet, the global positioning system, or GPS, and robotic surgery. The DLT program in sepsis seeks to develop a therapeutic blood purification device that is capable of identifying the cause of sepsis (e.g. cytokines, toxins, pathogens, activated cells) and remove these substances in an intelligent, automated, and efficient manner. Our contract is for advanced technology development of its hemocompatible porous polymer technologies to remove cytokines and a number of pathogen and biowarfare toxins from blood. We are in Year 3 of the program and are currently working with the systems integrator, Battelle Laboratories, and its subcontractor NxStage Medical, who are responsible for integrating the technology developed by CytoSorbents and others into a final medical device design prototype, and evaluating this device in septic animals and eventually in human clinical trials in sepsis. Our work is supported by DARPA and SSC Pacific under Contract No. N66001-12-C-4199. As of December 31, 2014, we have received approximately \$2,818,000 to date and have approximately \$1,007,000 not yet billed under this contract.

In September 2013, the National Heart, Lung, and Blood Institute, or NHLBI, a division of the National Institutes of Health (“NIH”), awarded us a Phase I SBIR contract valued at \$203,351 to further advance our HemoDefend™ blood purification technology for packed red blood cell, or pRBC, transfusions. The University of Dartmouth collaborated with us as a subcontractor on the project, entitled “Elimination of blood contaminants from pRBCs using HemoDefend™ hemocompatible porous polymer beads. The overall goal of this program is to reduce the risk of potential side effects of blood transfusions, and help to extend the useful life of pRBCs. As of December 31, 2014, we completed the Phase I program and have been invited to apply for the Phase II SBIR, which has now been submitted.

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

In addition to CytoSorb®, we are developing other products utilizing our adsorbent polymer technology that have not yet received regulatory approval including HemoDefend™, ContrastSorb, DrugSorb, BetaSorb™, and others. The HemoDefend™ technology platform is a development-stage blood purification system that can remove contaminants in transfused blood products, with the goal of reducing potentially fatal transfusion reactions and improving the quality of blood. ContrastSorb is designed to remove intravenous radiocontrast, or “IV contrast”, that is administered during interventional radiology procedures (e.g., coronary angiograms for heart disease) and computed tomography or computer axial tomography imaging (i.e., CT or “CAT” scans) that can cause kidney failure in high risk patients (e.g. those with pre-existing kidney disease, diabetes, hypertension, congestive heart failure, and old age). DrugSorb is designed to remove toxic drugs from blood, as in drug overdose. The BetaSorb™ filter was designed for use with renal replacement therapy in end-stage renal disease patients, to remove mid-molecular weight toxins that are not adequately removed by hemodialysis or hemofiltration. BetaSorb™ is not the current focus of our near term commercialization plans. With the exception of HemoDefend™, all of these products are known medically as hemoperfusion devices. Hemoperfusion, along with hemodialysis and hemofiltration, are the three major forms of blood purification. During hemoperfusion, blood is removed from the body via a catheter or other blood access device, perfused through a filter medium where toxic compounds are removed, and returned to the body.

HemoDefend™ 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, 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 these contaminants in transfused blood products to reduce transfusion reactions, to keep new blood fresh, and to improve the quality and safety of blood.

The HemoDefend™ beads are intended to be used in multiple configurations, including as a 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.

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

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

Our BetaSorb™ device is intended to remove beta<sub>2</sub>-microglobulin and other mid-molecular weight toxins from the blood of patients suffering from chronic kidney failure who rely on long term dialysis therapy to sustain their life. Standard high-flux hemodialysis is very effective in removing small uremic toxins, but much less effective in removing these mid-molecular weight toxins that functional kidneys normally remove. BetaSorb™ utilizes an adsorbent polymer packed into a similarly shaped and constructed cartridge as utilized for our CytoSorb® product, although the polymers used in the two devices are physically different with one optimized for short-term critical care use and the other specifically designed for the needs of long-term chronic usage. The BetaSorb™ device also incorporates industry standard connectors at either end of the device, which connect directly into the extra-corporeal circuit (bloodlines) in series with a dialyzer. To date, we have manufactured the BetaSorb™ device on a limited basis for testing purposes, including for use in clinical studies.

We had initially identified end stage renal disease, or 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 may pursue our BetaSorb™ product in the future after the commercialization of the CytoSorb® device. 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 United States 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.

## **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 may require additional capital in the future to fund our operations*

As of June 30, 2015, we had current assets of approximately \$13,041,000, including cash on hand of approximately \$8,017,000 and short-term investments of approximately \$3,188,000 and current liabilities of approximately \$2,858,000. On January 14, 2015, we received approximately \$9,409,000 in net proceeds in connection with a registered offering of our common stock. Our cash burn was approximately \$5,400,000 for the six months ended June 30, 2015. Our current and historical cash burn is not necessarily indicative of our future use of cash and cash equivalents.

We may require additional financing in the future in order to complete additional clinical studies and to support the commercialization of our proposed products. There can be no assurance that we will be successful in our capital raising efforts. Our long-term capital requirements are expected to depend on many factors, including:

- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical studies;
- the time and costs involved in obtaining regulatory clearance in other countries and/or for other indications;
- costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- costs of developing sales, marketing and distribution channels;
- market acceptance and reimbursement of our products; and
- cost for training physicians and other health care personnel.

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 have been engaged primarily in research and development activities and have generated limited revenues to date. There can be no assurance that we will be able to successfully manage the transition to a commercial enterprise. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by an enterprise in the early stage of development, which include unanticipated problems relating to development of proposed products, testing, regulatory compliance, manufacturing, competition, market adoption, product registration, reimbursement, marketing problems and additional costs and expenses that may exceed current estimates. Our proposed products will require significant additional research and testing, and we will need to overcome significant regulatory burdens prior to commercialization in other countries, such as the United States, 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 June 30, 2015, we had an accumulated deficit of \$127,676,744, which included net losses of \$3,282,624 for the six months ended June 30, 2015 and \$2,828,685 for the six months ended June 30, 2014. 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. We intend to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for the establishment of manufacturing arrangements and a marketing and distribution presence, and other general and administrative expenses, are expected to result in continuing operating losses for the foreseeable future. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our technology and commercial products, obtaining additional requisite regulatory approvals in markets not covered by the CE Mark and for potential label extensions of our current CE Mark, establishing manufacturing and sales and marketing arrangements with third parties, and raising sufficient funds to finance our activities. No assurance can be given that our product development efforts will be successful, that our current CE Mark will enable us to achieve profitability, that additional regulatory approvals in other countries will be obtained, that any of our products will be manufactured at a competitive cost and will be of acceptable quality, or that

the we will be able to achieve profitability or that profitability, if achieved, can be sustained.



***We depend upon key personnel who may terminate their employment with us at any time.***

As of August 1, 2015, we currently have 52 full-time employees and several full-time temporary 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; Kathleen P. Bloch, our Chief Financial Officer; Vincent Capponi, our Chief Operating Officer; and Dr. Robert Bartlett, our Chief Medical Officer, who works with us on a consulting basis. While we currently have long-term employment agreements in place with Dr. Chan, Ms. Bloch and Mr. Capponi, Dr. Bartlett does not have a long term consulting agreement in place. Although we are discussing formalizing our consulting agreement with Dr. Bartlett, there can be no assurance that Dr. Bartlett or other members of our management team under contract 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. As a result of this consulting arrangement, Dr. Bartlett works with us on a part-time basis and may not be available to us on an immediate basis.

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

Our future financial performance will depend, at least in part, upon the introduction and customer acceptance of our polymer products. Even with our approval to apply the CE Mark to our CytoSorb® device as a cytokine filter, our products may not achieve market acceptance in the European countries that recognize and accept the CE Mark. Additional approvals from other regulatory authorities (such as the U.S. Food and Drug Administration, or FDA) will be required before we can market our device in countries not covered by the CE Mark. There is no guarantee that we will be able to achieve additional regulatory approvals, and even if we do, our products may not achieve market acceptance in the countries covered by such approvals. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration of the advantages, safety and efficacy of the our polymer technology;

pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;  
our ability to attract corporate partners, including medical device companies, to assist in commercializing our products; and  
our ability to market our products.

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

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

CytoSorb® is currently reimbursable in Germany and Austria. We plan to seek reimbursement for our product in other EU and non-EU 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 improperly assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing rights.

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

More than a decade 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 within our control. The failure to obtain government approvals, internationally or domestically, for our polymer products, or to comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of our products and result in the failure to achieve***

*revenues or maintain our operations.*

CytoSorb® has already achieved regulatory approval in the EU under the CE Mark and the Medical Devices Directive. It is manufactured at our manufacturing facility in New Jersey under ISO 13485 Full Quality Systems certification. The manufacturing and marketing of our products will be subject to extensive and rigorous government regulation in the European market, the United States, in various states and in other foreign countries. In the United States and other countries, the process of obtaining and maintaining required regulatory approvals is lengthy, expensive, and uncertain. There can be no assurance that we will ever obtain the necessary additional approvals to sell our products in the United States or other non-EU countries. Even if we do ultimately receive FDA approval for any of our products, we will be subject to extensive ongoing regulation. While we have received approval from our Notified Body to apply the CE Mark to our CytoSorb® device, we will be subject to extensive ongoing regulation and auditing requirements to maintain the CE Mark.

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

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

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

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

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

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

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

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

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

Dr. John Kellum and other critical care advisors and consultants of ours 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.***

In March 2011, we received approval from our Notified Body to apply the CE Mark to our CytoSorb® device for commercial sale as a cytokine filter. CytoSorbents also achieved ISO 13485:2003 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 EU. CytoSorbents manufactures CytoSorb® at its manufacturing facilities in New Jersey for sale in the EU and for additional clinical studies. We will need to maintain compliance on an ongoing basis. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we or the third-party manufacturers of our products fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products.

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

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

We expect to enter into agreements with third parties for the commercial marketing, 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.

***Our results of operations can be significantly affected by foreign currency fluctuations and regulations.***

A significant portion of our revenues is currently derived in the local currencies of the foreign jurisdictions in which our products are sold. Accordingly, we are subject to risks relating to fluctuations in currency exchange rates. In the future, and especially as we further expand our sales efforts in international markets, our customers will increasingly make payments in non-U.S. currencies. Fluctuations in foreign currency exchange rates could affect our revenues, operating costs and operating margins. In addition, currency devaluation can result in a loss to us if we hold deposits of that currency. We cannot predict the effect of future exchange rate fluctuations on our operating results.

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

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

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

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

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

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

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



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

### **Risks Connected to our Securities and this Offering**

*The price of our common stock has been highly volatile due to factors that will continue to affect the price of our stock.*

Our common stock closed as high as \$8.75 and as low as \$3.00 per share between January 1, 2014 and December 2, 2014 on the OTCQB. On December 3, 2014, we effected a twenty-five-for-one (25:1) reverse split of our common stock. Immediately after the reverse stock split, on December 3, 2014 we changed our state of incorporation from the State of Nevada to the State of Delaware pursuant to an Agreement and Plan of Merger, dated December 3, 2014, whereby we merged with and into our then recently formed, wholly-owned Delaware subsidiary. On December 17, 2014, CytoSorbents received approval for up-listing to The NASDAQ Capital Market and our common stock began trading on the NASDAQ Capital Market on December 23, 2014. Our common stock closed as high as \$14.99 and as low as \$5.20 per share between December 23, 2014 and September 30, 2015. On September 30, 2015, the closing price of our common stock, as reported on the NASDAQ Capital Market was \$6.31. Historically, the over-the-counter markets for securities such as our common stock have experienced extreme price fluctuations. Some of the factors leading to this volatility include, but are not limited to:

- fluctuations in our operating results;
- announcements of product releases by us or our competitors;
- announcements of acquisitions and/or partnerships by us or our competitors; and
- general market conditions.

Although share of our common stock currently trade on the NASDAQ Capital Market under the symbol “CTSO”, there is no assurance that our stock will not continue to be volatile while listed on NASDAQ in the future.

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

Our directors, executive officers and principal stockholders together beneficially own a significant percentage of the voting control of our common stock on a fully diluted basis. 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 Board of Directors may, without stockholder approval, issue and fix the terms of shares of preferred stock and issue additional shares of common stock, which will adversely affect the rights of holders of our common stock.***

On December 3, 2014, we effected a twenty-five-for-one (25:1) reverse split of our common stock. Immediately after the reverse stock split, on December 3, 2014 we changed our state of incorporation from the State of Nevada to the State of Delaware pursuant to an Agreement and Plan of Merger, dated December 3, 2014, whereby we merged with and into our then recently formed, wholly-owned Delaware subsidiary. Pursuant to the Agreement and Plan of Merger effecting the merger, we adopted the certificate of incorporation, as amended and restated, and bylaws of our Delaware subsidiary as our certificate of incorporation and bylaws at effective time of the merger. As a result, our certificate of incorporation, as amended and restated, authorizes the issuance of up to 5,000,000 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. Currently, our certificate of incorporation, as amended and restated, which became effective on December 3, 2014, authorizes the issuance of up to 50,000,000 shares of common stock, of which as of June 30, 2015, approximately 25,109,000 shares remain available for issuance and may be issued by us without stockholder approval.

***Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that our stockholders may favor and may prevent stockholders from changing the direction of our business or our management.***

After giving effect to our merger into our wholly-owned Delaware subsidiary, provisions of our certificate of incorporation, as amended and restated, and our bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares, and may also frustrate or prevent any attempt by stockholders to change our direction or management. For example, these provisions:

- authorize the issuance of “blank check” preferred stock without any need for action by stockholders;
- eliminate the ability of stockholders to call special meetings of stockholders;

prohibit stockholder action by written consent; and  
establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

***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, and any new SEC regulations will require an increased amount of management attention and external resources. 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 NASDAQ Capital Market exchange, and no assurances can be made about stock performance, liquidity, or maintenance of our NASDAQ listing.***

Historically, our common stock was quoted on the OTCQB, which provided significantly less liquidity than a securities exchange (such as the New York Stock Exchange or the Nasdaq Stock Market). On December 17, 2014, our common stock was approved for trading on the NASDAQ Capital Market, or NASDAQ. Beginning on December 23, 2014, our common stock began trading on NASDAQ under the symbol “CTSO.” Although currently listed on NASDAQ, there can be no assurance that we will continue to meet NASDAQ’s minimum listing requirements or that of any other national exchange. In addition, there can be no assurances that a liquid market will be created for our common stock. If we are unable to maintain listing on the NASDAQ or if a liquid market for our common stock does not develop, our common stock may remain thinly traded.

***Our use of the offering proceeds may not yield a favorable return on your investment.***

We currently anticipate that the net proceeds from this offering will be used primarily to fund clinical studies, expand production capacity, support our sales and marketing efforts, to develop our products and for general corporate purposes. Pending the application of the net proceeds, we intend to invest the net proceeds in investment-grade or government, interest-bearing securities. Our management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree. Pending the use of the proceeds in this offering, we will invest them. However, the proceeds may not be invested in a manner that yields a favorable or any return.



**USE OF PROCEEDS**

We received \$10,200,000 in gross proceeds from the sale of units in this offering. After deducting estimated placement agent fees and estimated offering expenses payable by us, we received net proceeds of approximately \$9,451,000. We are using the net proceeds from this offering to further develop our products, to support our sales and marketing efforts, clinical studies, and for working capital and other general corporate purposes. The following is a table that shows our use of proceeds based on the amount of funds we received.

Use of Proceeds	\$ 10,200,000
Expenses associated with the offering (including Commissions)	\$ 600,000
Further develop our products	\$ 2,000,000
To support sales and marketing efforts	\$ 500,000
To fund clinical studies	\$ 2,800,000
General working capital purposes	\$ 4,300,000

We may also receive additional funds from the exercise of the warrants, if they are in the money and the investors exercise the warrants for cash. The warrants will have a cashless component only if there is not an effective registration statement covering the shares underlying the warrant. We may also receive proceeds from the exercise of warrants. The exercise price of the warrants will be out of the money, however, and, therefore, we do not expect that the warrants will be immediately exercised. If the warrants are exercised, we will receive additional proceeds from the exercise of the warrants which will be used for general working capital purposes. We cannot predict when or if the warrants will be exercised. It is possible that the warrants may expire and may never be exercised.

## PLAN OF DISTRIBUTION

We offered 40,800,000 units, each unit consisting of one share of common stock and one warrant to purchase one-half (1/2) shares of common stock issued as part of this unit at an exercise price of \$0.3125 per share, with aggregate gross proceeds of up to \$10.2 million. Pursuant to an engagement letter agreement, we engaged Brean Capital, LLC as our placement agent for this offering. Brean Capital, LLC did not purchase or sell any units, nor were they required to arrange for the purchase and sale of any specific number or dollar amount of units, other than to use their “reasonable best efforts” to arrange for the sale of units by us. Therefore, we entered into a purchase agreement directly with investors in connection with this offering. The units may be priced a discount to the market price but such determination of the offering price was negotiated between the Company, Brean Capital, LLC and the investors.

We agreed to pay the placement agent a cash fee equal to 6% of the gross proceeds of the offering. We also agreed to issue the placement agent common stock purchase warrants equal to 3% of the aggregate number of shares of common stock sold in this offering. The placement agent warrants are not covered by this prospectus. The warrants issued to the placement agent will be substantially identical to the warrants offered by this prospectus, and the expiration date of such warrants shall be the five year anniversary of the effective date of the registration statement of which this prospectus is a part. Additionally, the Company will reimburse the placement agent for all reasonable expenses incurred in connection with the offering.

Because there was no minimum offering amount required as a condition to the closing in this offering, the actual total offering commissions, were not determinable at the time of the offering, and could have been substantially less than the maximum amount set forth above.

Our obligations to issue and sell units to the purchasers were subject to the conditions set forth in the securities purchase agreement, which may be waived by us at our discretion. A purchaser’s obligation to purchase units were subject to the conditions set forth in the securities purchase agreement as well, which may also be waived by the purchaser.

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

We agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act of 1933, as amended or the Securities Act. We may also be required to contribute to payments the placement agent may

be required to make in respect of such liabilities.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any commissions received by it and any profit realized on the sale of the securities by them while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent would be required to comply with the requirements of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock and warrants to purchase shares of common stock by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

## **DESCRIPTION OF SECURITIES**

Our total authorized capital stock consists of 50,000,000 shares of Common Stock, par value \$.001 per share and 5,000,000 shares of preferred stock, par value \$0.001 per share. As of September 30, 2015, there were 25,177,005 shares of our Common Stock outstanding, and no shares of our Preferred Stock 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 Delaware 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 Certificate 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 Certificate 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.

### **Anti-Takeover Provisions**

Certain anti-takeover provisions in our Certificate of Incorporation may make a change in control 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.



## **EXPERTS**

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 consolidated financial statements of CytoSorbents Corporation appearing in CytoSorbents Corporation's Annual Report (Form 10-K) for the year ended December 31, 2014 have been audited by WithumSmith+Brown, PC, independent registered public accounting firm, as set forth in their reports thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firm as experts in accounting and auditing.

## **WHERE YOU CAN FIND MORE INFORMATION**

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

We have filed a registration statement on Form S-3 under the Securities Act with the SEC covering the Common Stock offered hereby. As permitted by the rules and regulations of the SEC, this document does not contain all information set forth in the registration statement and exhibits thereto, all of which are available for inspection as set forth above. For further information, please refer to the registration statement, including the exhibits thereto. Statements contained in this document relating to the contents of any contract or other document referred to herein are not necessarily complete, and reference is made to the copy of that contract or other document filed as an exhibit to the registration statement or other document, and each statement of this type is qualified in all respects by that reference.

No person is authorized to give any information or make any representation not contained in this document. You should not rely on any information provided to you that is not contained in this document. This prospectus does not constitute an offer to sell or a solicitation of an offer to purchase the securities described herein in any jurisdiction in

which, or to any person to whom, it is unlawful to make the offer or solicitation. Neither the delivery of this document nor any distribution of shares of Common Stock made hereunder shall, under any circumstances, create any implication that there has not been any change in our affairs as of any time subsequent to the date hereof.

## **INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The SEC allows us to “incorporate by reference” much of the information we file with them under Commission File No. 000-31719, which means that we can disclose important information to you by referring you to those publicly available documents. All of the information that we incorporate by reference is considered to be part of this prospectus, and any of our subsequent filings with the SEC will automatically update and supersede this information. This prospectus incorporates by reference the documents listed below and any future filings made by CytoSorbents Corporation with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, except for information furnished under Items 2.02 or 7.01 of Current Report on Form 8-K, or exhibits related thereto, until the filing of a post-effective amendment to this prospectus which indicates that all securities registered have been sold or which deregisters all securities then remaining unsold:

our annual report on Form 10-K for the fiscal year ended December 31, 2014, filed on March 31, 2015, pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), in which there is set forth the audited financial statements for the Registrant’s fiscal year ended December 31, 2014;

- our proxy statement for our annual meeting of stockholders, filed on April 22, 2015
- our quarterly report on Form 10-Q for the quarter ended March 31, 2015, filed on May 11, 2015;
- our quarterly report on Form 10-Q for the quarter ended June 30, 2015, filed on August 13, 2015;

our current reports on Form 8-K, filed on January 14, 2015, April 3, 2015, April 8, 2015 (responsive to Items 8.01 and 9.01), April 14, 2015, June 4, 2015, July 15, 2015, and July 23, 2015;

our description of our common stock contained in the Registration Statement on Form 8-A12B filed with the Securities and Exchange Commission on December 17, 2014; and

all other reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act after the date of this registration statement and prior to the effectiveness of the registration statement.

We will provide, upon written or oral request, to each person to whom a prospectus is delivered, a copy of any or all of the information that has been incorporated by reference in the prospectus but not delivered with the prospectus. You may request a copy of these filings, at no cost, by writing us at CytoSorbents Corporation, 7 Deer Park Drive, Suite K, Monmouth Junction, New Jersey 08852. Our telephone number is (732) 329-8885.

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. We will not make an offer of these shares in any jurisdiction where the offer is not permitted. You should not assume that information in this prospectus or any supplement is accurate as of any date other than the date on the front of these documents.

**PART II**

**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 14. Other Expenses of Issuance and Distribution.**

The expenses of this offering in connection with the issuance and distribution of the securities being registered, all of which were paid by the Registrant, are as follows:

Securities and Exchange Commission Registration Fee <sup>(1)</sup>	\$ 1,779.05
Federal Taxes	\$-
State Taxes and Fees	\$-
Placement Agent Fees and Expenses <sup>(2)</sup>	\$510,000
Accounting Fees and Expenses	\$4,000
Legal Fees and Expense	\$60,000
Blue Sky Fees and Expenses	\$2,500
Miscellaneous	\$4,000
Total	\$ 582,279.05

<sup>(1)</sup> Previously paid.

<sup>(2)</sup> Estimated.

All amounts are estimates other than the Commission's registration fee. We are paying all expenses of the offering listed above.

**Item 15. Indemnification of Directors and Officers.**

Our directors and officers are indemnified as provided by the Delaware General Corporation Law, our certificate of incorporation and our bylaws. We have been advised that in the opinion of the Securities and Exchange Commission indemnification for liabilities arising under the Securities Act of 1933 is against public policy as expressed in the Securities Act of 1933, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities is asserted by one of our directors, officers, or controlling persons in connection with the securities being registered, we will, unless in the opinion of our legal counsel the matter has been settled by controlling precedent,

submit the question of whether such indemnification is against public policy to a court of appropriate jurisdiction. We will then be governed by the court's decision.

**Item 16. Exhibits.**

The following exhibits are filed as part of, or incorporated by reference into this document:

**Exhibit**

<b>No.</b>	<b>Description</b>
3.1(a)	First Amended and Restated Certificate of Incorporation, dated December 3, 2014 (1)
3.1(b)	Bylaws of the Company (2)
4.1	Form of Placement Agent Warrant (3)
4.2	Form of Warrant (3)
5.1	Legal Opinion of Szaferman, Lakind, Blumstein & Blader, P.C. (previously filed)
10.1	Employment Agreement with Dr. Phillip P. Chan Effective January 1, 2015 (4)
10.2	Employment Agreement with Vincent Capponi Effective January 1, 2015 (4)
10.3	Employment Agreement with Kathleen Bloch Effective January 1, 2015 (4)
10.4	Consulting Agreement with Robert Bartlett Effective December 3, 2012 (5)
10.4	Placement Agency Agreement, dated March 7, 2014, between CytoSorbents Corporation and Brean Capital, LLC (3)
10.5	Form of Subscription Agreement (3)
23.1	Consent of WithumSmith + Brown, PC (filed herewith)
24.1	Power of Attorney (included on signature page)

(1) Filed as an Exhibit to the Current Report on Form 8-K filed with the SEC on December 4, 2014.

(2) Filed as an Exhibit to the Current Report on Form 8-K filed with the SEC on December 4, 2014.

(3) Filed as an Exhibit to the Current Report on Form 8-K filed with the SEC on March 12, 2014.

(4) Filed as an Exhibit to the Current Report on Form 8-K filed with the SEC on July 9, 2015.

- (5) Filed as an Exhibit to the Current Report on Form 8-K filed with the SEC on June 17, 2011.

**Item 17. Undertakings.**

The undersigned registrant hereby undertakes:

(1) To file, during any period in which it offers or sells securities, a post-effective amendment to this registration statement to:

(i) Include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) Reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of the securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of a prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) Include any additional or changed material information on the plan of distribution;

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the bona fide offering thereof.

(3) To file a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

Insofar as indemnification arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Monmouth Junction, New Jersey, on October 8, 2015.

**CYTOSORBENTS CORPORATION**

By: /s/ Dr. Phillip P. Chan  
Dr. Phillip P. Chan  
President and Chief Executive Officer



KNOW BY ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Phillip P. Chan and Kathleen P. Bloch, and each of them, the undersigned's true and lawful attorneys-in-fact and agents, with full power of substitution and revocation, for and in the undersigned's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and any registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratify and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1933, as amended, this registration statement has been signed below by the following persons on behalf of the registrant and in the capacities indicated on the date listed below.

<b>Name</b>	<b>Capacity</b>	<b>Date</b>
/s/ Dr. Phillip P. Chan <b>Dr. Phillip P. Chan</b>	Chief Executive Officer (Principal Executive Officer) and Director	October 8, 2015
/s/ Kathleen P. Bloch <b>Kathleen P. Bloch</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	October 8, 2015
/s/ Al Kraus <b>Al Kraus</b>	Chairman of the Board	October 8, 2015
/s/ Michael G. Bator <b>Michael G. Bator</b>	Director	October 8, 2015
/s/ Edward R. Jones <b>Edward R. Jones</b>	Director	October 8, 2015
/s/ Alan D. Sobel <b>Alan D. Sobel</b>	Director	October 8, 2015



## INDEX TO EXHIBITS

### Exhibit

No.	Description
3.1(a)	First Amended and Restated Certificate of Incorporation, dated December 3, 2014 (1)
3.1(b)	Bylaws of the Company (2)
4.1	Form of Placement Agent Warrant (3)
4.2	Form of Warrant (3)
5.1	Legal Opinion of Szaferman, Lakind, Blumstein & Blader, P.C. (previously filed)
10.1	Employment Agreement with Dr. Phillip P. Chan Effective January 1, 2015 (4)
10.2	Employment Agreement with Vincent Capponi Effective January 1, 2015 (4)
10.3	Employment Agreement with Kathleen Bloch Effective January 1, 2015 (4)
10.4	Consulting Agreement with Robert Bartlett Effective December 3, 2012 (5)
10.4	Placement Agency Agreement, dated March 7, 2014, between CytoSorbents Corporation and Brean Capital, LLC (3)
10.5	Form of Subscription Agreement (3)
23.1	Consent of WithumSmith + Brown, PC (filed herewith)
24.1	Power of Attorney (included on signature page)

- (1) Filed as an Exhibit to the Current Report on Form 8-K filed with the SEC on December 4, 2014.
- (2) Filed as an Exhibit to the Current Report on Form 8-K filed with the SEC on December 4, 2014.
- (3) Filed as an Exhibit to the Current Report on Form 8-K filed with the SEC on March 12, 2014.
- (4) Filed as an Exhibit to the Current Report on Form 8-K filed with the SEC on July 9, 2015.
- (5) Filed as an Exhibit to the Current Report on Form 8-K filed with the SEC on June 17, 2011.