Cytosorbents Corp
Form S-1/A
January 06, 2015

As filed with the Securities and Exchange Commission on January 6, 2015

Registration No. 333-199762

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

AMENDMENT NO. 6 TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

CYTOSORBENTS CORPORATION

(Exact name of registrant as specified in its charter)

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

7 Deer Park Drive, Suite K
Monmouth Junction, New Jersey 08852
(732) 329-8885

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

(Name, address, including zip code, and telephone number,
including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o
Accelerated filer o
Non-accelerated filer o
Smaller reporting company x

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of

1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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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 it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

Subject to completion, dated January 6, 2015

CYTOSORBENTS CORPORATION

1,250,000 SHARES OF COMMON STOCK

We are offering 1,250,000 shares of our common stock. The offering price per share is $.

Beginning on December 23, 2014, our common stock is quoted on the NASDAQ Capital Market (NASDAQ) under the symbol CTSO. Prior to December 23, 2014, our common stock was quoted on the OTCQB Marketplace under the symbol CTSO. On December 29, 2014, the last reported sale price of our common stock on NASDAQ was $10.40 per share.

Investing in our common stock involves risks, including those set forth in the Risk Factors section of this prospectus beginning on page 8 as well as those set forth in any prospectus supplement.

The offering price to the public will be determined by negotiation between us and Brean Capital, LLC and H.C. Wainwright & Co., LLC (the Representatives) as representatives of the several underwriters (the Underwriters), but will be fixed prior to the commencement of the offering by the Underwriters. Please see the Underwriting section for more information.

We have agreed to issue warrants exercisable within five years after the effective date of the Registration Statement, representing 3% of the securities issued in the offering (the Underwriter Warrants) to the Representatives for nominal consideration. Resales of the Underwriter Warrants on a delayed or continuous basis pursuant to Rule 415 under the Securities Act are registered hereby. Resales of units, shares and warrants issuable upon exercise of the Underwriter Warrants or the component securities thereof are also being simultaneously registered on a delayed or continuous basis hereby.

	Per Share	Total
Public Offering Price	$	$
Underwriting Discounts and Commissions[(1)]	$	$
Proceeds to Us (Before Expenses)	$	$

(1) The underwriters will receive consideration in addition to the underwriting discounts and commissions. See Underwriting beginning on page 70.

The delivery of the shares and underwriter warrants is expected to be made on or about , 2015. We have

granted the underwriters an option for a period of 30 days to purchase up to a total of 187,500 additional shares.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2015.

Joint Book Running Managers

BREAN CAPITAL **H.C. WAINWRIGHT & CO.**

Co-Managers

MERRIMAN CAPITAL **MLV & CO.** **WBB SECURITIES**

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PROSPECTUS SUMMARY

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

Overview

Summary of Our Business

We are 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. The technology is based upon biocompatible, highly porous polymer sorbent beads that are capable of extracting unwanted substances from blood and other bodily fluids. The technology is protected by 32 issued U.S. patents with multiple applications pending both in the United States and internationally. Our intellectual property consists of composition of matter, materials, methods of production, systems incorporating the technology and multiple medical uses with expiration dates ranging from 3 to 12 years.

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

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

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

We plan to do larger, prospective studies in septic patients in the future to confirm the European Sepsis Trial findings.

In addition to CE Mark approval, CytoSorbents also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in

the E.U. CytoSorbents manufactures CytoSorb® at its manufacturing facilities in New Jersey for sale in the E.U. and for additional clinical studies. 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 with the primary goal of preparing for commercialization of CytoSorb® in Germany in terms of manufacturing, reimbursement, logistics, infrastructure, marketing, contacts, and other key issues.

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In late June 2012, following the establishment of our European subsidiary, CytoSorbents Europe GmbH, CytoSorbents 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 full 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. At the end of second quarter of 2014, we had more than 150 key opinion leaders (KOLs) in critical care, cardiac surgery, and blood purification who were either using CytoSorb® or planning to use CytoSorb® in the near future.

In addition, we now 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 Medical Director and our European Director of Scientific Affairs. As of September 30, 2014, the Company s sales force includes seven direct sales people and two sales support staff. We intend to add more staff to the direct sales and marketing team during 2014.

We have complemented our direct sales efforts with sales to distributors and/or corporate partners. In 2013, we reached agreement with distributors in the United Kingdom, Ireland, Turkey, Russia, and the Netherlands. In September 2013, we entered into a strategic partnership with Biocon, Ltd., Asia s largest biotechnology company with an initial distribution agreement for India and select emerging markets, under which Biocon will have the exclusive commercialization rights for CytoSorb®. 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 Cooperation Council or GCC) and Yemen, Iraq, and Jordan through an exclusive agreement with Techno Orbits. In August 2014, the Company announced exclusive distribution of CytoSorb® in Taiwan with HemoScien Corporation. We are currently evaluating other potential distributor networks in other major countries where we are either approved to market the device or where CE Mark approval is accepted.

We are currently conducting a dose ranging trial in Germany amongst eight clinical trial sites to evaluate the safety and efficacy of CytoSorb® when used for longer periods of time. Data from this dosing study is 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 U.S. based pivotal study. In addition, we will receive additional data from the results of more than thirty investigator-initiated studies in Europe which are either currently underway or planned.

Concurrent with our commercialization plans, we intend to conduct or support additional clinical studies in sepsis, cardiac surgery, and other critical care diseases to generate additional clinical data to expend the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. The Company is currently organizing a pivotal trial in the U.S. using CytoSorb® during cardiac surgery that is intended to be the basis of the Company s application seeking U.S. regulatory 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, acute respiratory distress syndrome, or ARDS , and others. Sepsis is a major unmet medical need with no approved products in the U.S. 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 continue to foster research in other critical care illnesses where CytoSorb® could be used, such as ARDS, trauma, severe burn injury and acute pancreatitis, or in other acute conditions that 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.

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Our proprietary hemocompatible porous polymer bead technology forms the basis of a broad technology portfolio. Some of our products include:

CytoSorb® an extracorporeal hemoperfusion cartridge approved in the E.U. for cytokine removal, with the goal of reducing SIRS and preventing or treating organ failure;
HemoDefend™ a development-stage blood purification technology designed to remove contaminants in blood transfusion products. Goal is to reduce transfusion reactions and improve the safety of older blood;
ContrastSorb a development-stage extracorporeal hemoperfusion cartridge designed to remove IV contrast from the blood of high risk patients undergoing CT imaging with contrast, or interventional radiology procedures such as cardiac catheterization. The goal is to prevent contrast-induced nephropathy;
DrugSorb a development-stage extracorporeal hemoperfusion cartridge designed to remove toxic chemicals from the blood (e.g., drug overdose, high dose regional chemotherapy, etc); and
BetaSorb™ a development-stage extracorporeal hemoperfusion cartridge designed to remove mid-molecular weight toxins, such as b2-microglobulin, that standard high-flux dialysis cannot remove effectively. The goal is to improve the efficacy of dialysis or hemofiltration.

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

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

In June 2013, we announced that the U.S. Air Force will fund a 30 patient, single site, randomized controlled human pilot study in the United States amongst trauma patients with rhabdomyolysis most commonly associated with trauma. The FDA has approved our Investigational Device Exemption (IDE) application for this study and we also have received ethics committee approval to proceed, and the study began in April 2014.

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

In August 2012, we were awarded a $3.8 million, five-year contract by the Defense Advanced Research Projects Agency, or DARPA , for our 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. CytoSorbents 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. CytoSorbents is in Year 3 of the program and is currently working with the recently announced systems integrator, Battelle Laboratories, and its subcontractor NxStage Medical, who are responsible for integrating the technology developed by CytoSorbents and others into a final medical device design prototype, and evaluating this device in septic animals and eventually in human clinical trials in sepsis. CytoSorbents work is supported by DARPA and SSC Pacific under Contract No. N66001-12-C-4199.

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Recent Corporate Actions

Our common stock has been approved for trading on the NASDAQ Capital Market. Beginning on December 23, 2014, our common stock trades on NASDAQ under the symbol CTSO. In order to facilitate that process, in October 2014, the stockholders representing over 88 percent (88%) of the then-issued and outstanding Series A 10% Cumulative Convertible Preferred Stock, or the Series A Preferred Stock, elected to convert all issued and outstanding Series A Preferred Stock into Common Stock at the then-effective conversion price. As a result of the election, effective October 9, 2014, 1,894,969 shares of Series A Preferred Stock, representing all issued and outstanding shares of Series A Preferred Stock, were converted into 2,583,289 shares of Common Stock. Similarly, the stockholders representing over 93 percent (93%) of the then-issued and outstanding Series B 10% Cumulative Convertible Preferred Stock, or the Series B Preferred Stock, elected to convert all issued and outstanding Series B Preferred Stock into Common Stock. As a result of the election, effective October 9, 2014, 84,283.99 shares of Series B Preferred Stock were issued a dividend of 10%, and then the 92,712.27 shares of Series B Preferred Stock, representing all issued and outstanding shares of Series B Preferred Stock, were converted into 256,111,243 shares of Common Stock.

On December 1, 2014, we received stockholder approval authorizing our Board of Directors to (i) amend our Articles of Incorporation, as amended, to effect a reverse split of our Common Stock, with a reverse split ratio of twenty-five-to-one (25:1); (ii) amend our Articles of Incorporation, as amended, to reduce the total number of authorized shares of Common Stock from 800,000,000 to 50,000,000, after giving effect to the reverse stock split; (iii) amend our Articles of Incorporation, as amended, to reduce the total number of authorized shares of undesignated preferred stock from 100,000,000 to 5,000,000, after giving effect to the reverse stock split; (iv) implement the form, terms and provisions of the CytoSorbents Corporation 2014 Long-Term Incentive Plan; and (v) change our domicile from the State of Nevada to the State of Delaware through our merger with and into a newly-organized subsidiary organized under the laws of 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 twenty-five-for-one (25:1) 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 shares. Immediately after the reverse 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 recently formed, wholly-owned Delaware subsidiary. Pursuant to the Agreement and Plan of 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. At the effective time of our merger, (i) we merged with and into our Delaware subsidiary, (ii) our separate corporate existence in Nevada ceased to exist, (iii) our Delaware subsidiary became the surviving corporation, and (iv) each share of our common stock, $0.001 par value per share outstanding immediately prior to the effective time was converted into one fully-paid and non-assessable share of common stock of CytoSorbents Corporation, a Delaware corporation, $0.001 par value per share. The reverse stock split, the merger and the Agreement and Plan of Merger were approved by the our Board of Directors and stockholders representing a majority of our outstanding common stock.

On December 15, 2014, we issued a press release announcing the entry into an exclusive Distribution Agreement, or Distribution Agreement, with Fresenius Medical Care Deutschland GmbH, or Fresenius, an operating division of Fresenius Medical Care AG & CO KGaA. Although the Distribution Agreement marks a continuation of our long-term distribution strategy, we do not deem it material to us at this time, but it may become material at some time in the future. In accordance with the disclosure rules of the Securities and Exchange Commission, when such

agreement becomes material to us, we shall appropriately disclose the terms and conditions of such agreement and file such agreement (with confidential treatment requested).

Under the terms of the Distribution Agreement, Fresenius was granted exclusive rights to distribute our CytoSorb product and other blood purification products, or the Products, for critical care medicine and intensive care unit applications in France, Poland, Sweden, Denmark, Norway, and Finland, or collectively, the Territory. Fresenius s exclusivity is subject to Fresenius achieving certain annual minimum guaranteed orders of the Products. If Fresenius does not achieve the annual minimum guaranteed orders, then we may terminate

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the Distribution Agreement or change the exclusive rights granted to non-exclusive rights. Fresenius is obligated to register the Products with the appropriate governmental agencies for marketing approval in the Territory within six (6) months. Pricing is generally fixed for the term of the Distribution Agreement, but Fresenius is able to achieve volume discounts on pricing. The parties agree to negotiate, in good faith, an increase in the purchase price of the Products in the event the average selling price to customers increases or, on the other hand, if the costs of production for the Products decreases, a reduction in the purchase price.

The Distribution Agreement expires upon the third anniversary of the first Product registration in the Territory, but, in any event, no later than June 15, 2018, and is subject to renewal or renegotiation with mutual agreement at that time. During the term of the Distribution Agreement and for a period of one (1) year afterwards, Fresenius has agreed not to compete with us regarding the production or distribution of a competitive product in the Territory.

In December 2014, we submitted an Investigational Device Exemption, or IDE, application to the FDA to conduct our U.S. cardiac surgery trial using CytoSorb intra-operatively in patients undergoing complex cardiac surgery requiring the use of a heart-lung machine. The goal of CytoSorb treatment is to reduce inflammatory mediators and proteins such as cytokines and plasma free hemoglobin generated during surgery that can lead to serious post-operative complications. All investigational medical devices require IDE approval before they can be used in U.S.-based clinical studies to evaluate safety and efficacy.

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. Unless otherwise indicated, all references in this prospectus to MedaSorb , CytoSorbents , us or we with respect to events prior to June 30, 2006 are references to CytoSorbents Medical, Inc. and its predecessors.

On December 3, 2014 we effected a twenty-five-for-one (25:1) reverse split of our common stock. As a result of the twenty-five-to-one (25:1) 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 shares. 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 recently formed, wholly-owned Delaware subsidiary. Pursuant to the Agreement and Plan of 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. At the effective time of our merger, (i) we merged with and into our Delaware subsidiary, (ii) our separate corporate existence in Nevada ceased to exist, (iii) our Delaware subsidiary became the surviving corporation, and (iv) each share of our common stock, $0.001 par value per share outstanding immediately prior to the effective time was converted into one fully-paid and non-assessable share of common stock of CytoSorbents Corporation, a Delaware corporation, $0.001 par value per share. The reverse stock split, the merger and

the Agreement and Plan of Merger were approved by the our Board of Directors and stockholders representing a majority of our outstanding common stock. All references to us, we or the Company, on or after December 3, 2014, refer to CytoSorbents Corporation, a Delaware corporation.

We have experienced substantial operating losses since inception. As of September 30, 2014, we had an accumulated deficit of $113,902,629, which included losses of approximately $4,327,000 and $4,009,000 for the nine months ended September 30, 2014 and 2013, respectively. Historically, our losses have resulted principally from costs incurred in the research and development of our polymer technology, and general and

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administrative expenses, which together were approximately $4,935,000 and $3,608,000 for the nine months ended September 30, 2014 and 2013, respectively. We may continue to incur losses in the future. In part due to these losses, our 2013 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.

Since inception, our operations have been primarily financed through the private placement of our debt and equity securities. At September 30, 2014, we had current assets of approximately $8,954,000, including cash on hand and short-term investments of approximately $7,780,000 and current liabilities of approximately $1,549,000. We believe we have sufficient cash to fund its operations into 2016; however, we may need to raise additional capital to fully fund pivotal trials in the United States and/or Germany. We will be better able to assess this need once the specific protocols are finalized.

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

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The Offering

The summary below describes some of the terms of the offering. For a more complete description of the Common Stock comprising the securities, see Description of Securities.

Issuer

CytoSorbents Corporation.

Common Stock offered

1,250,000 shares of our common stock (the Offering).

Price per share

$.

Over-allotment option

We have granted the underwriters an option to purchase up to a total of 187,500 additional shares of Common Stock. This option is exercisable, in whole or in part, for a period of 30 days from the date of this prospectus.

Common Stock outstanding before the offering

As of December 3, 2014 there were 23,284,040 shares of the issuer s common stock, par value $0.001 (the Common Stock), outstanding.

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 recently formed, wholly-owned Delaware subsidiary. As a result, all references to shares of common stock, options and warrants, as well as per share data and related information in this prospectus have been retroactively adjusted, where applicable, to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented and all references to us, on or after December 3, 2014, refer to CytoSorbents Corporation, a Delaware corporation.

Common Stock outstanding after the offering

24,508,801 shares will be outstanding after the Offering.

Use of proceeds

We expect to use the proceeds received from the Offering to support our sales and marketing efforts, to fund clinical studies, to increase production capacity, to further develop our products, and for general working capital and other general corporate purposes. See the section titled Use of Proceeds for additional information.

Risk factors

The Common Stock offered hereby involves a high degree of risk and should not be purchased by investors who cannot afford the loss of their entire investment. See Risk Factors beginning on page 8.

Joint Book-Running Managers

Brean Capital and H.C. Wainwright & Co.

Market and trading symbol

Beginning on December 23, 2014, our common stock is quoted on the NASDAQ Capital Market (NASDAQ) under the symbol CTSO. Prior to December 23, 2014, our common stock was quoted on the OTCQB Marketplace under the symbol CTSO. On December 29, 2014, the last reported sale price of our common stock on NASDAQ was $10.40 per share.

Unless otherwise indicated, all numbers in this prospectus, including information relating to the number of shares of common stock outstanding immediately after completion of this offering, assume the underwriters do not exercise their option to purchase additional shares of our common stock.

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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 our common stock. If any of the events, contingencies, circumstances or conditions described in the risks below actually occur, our business, financial condition or results of operations could be seriously harmed. The trading price of our Common Stock could, in turn, decline and you could lose all or part of your investment.

RISKS RELATED TO OUR INDUSTRY AND OUR BUSINESS

We require additional capital to continue operations.

As of September 30, 2014 we had current assets of approximately $8,954,000, including cash on hand of approximately $433,000, short-term investments of approximately $7,347,000 and current liabilities of approximately $1,549,000. On March 12, 2014, we received approximately $9,451,000 in net proceeds in connection with a registered offering of our Common Stock. Through September 30, 2014, our cash burn rate for fiscal year 2014 was approximately $4,143,000. Our current and historical cash burn rate 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 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, marketing problems and additional costs and expenses that may exceed current estimates. Our proposed products will require significant additional research and testing, and we will need to overcome significant regulatory burdens prior to commercialization in other countries, such as the U.S., and for ongoing compliance for our CE Mark. We will also need to raise significant additional funds to complete additional clinical studies and obtain regulatory approvals in other countries before we can begin selling our products in markets not covered by the CE Mark. There can be no assurance that after the expenditure of substantial

We currently are in the process of commercializing our products, but therecan be no assurance that we will be succ

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funds and efforts, we will successfully develop and commercialize any products, generate any significant revenues or ever achieve and maintain a substantial level of sales of our products.

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

We have experienced substantial operating losses since inception. As of September 30, 2014, we had an accumulated deficit of $113,902,629, which included net losses of $4,327,035 for the nine months ended September 30, 2014 and $4,008,720 for the nine months ended September 30, 2013. In part due to these losses, our audited consolidated financial statements have been prepared assuming we will continue as a going concern, and the auditors report on those financial statements express substantial doubt about our ability to continue as a going concern. Our losses have resulted principally from costs incurred in the research and development of our polymer technology and general and administrative expenses. Because our predecessor was a limited liability company until December 2005, substantially all of these losses were allocated to that company s members and will not be available for tax purposes to us in future periods. We intend to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for the establishment of manufacturing arrangements and a marketing and distribution presence and other general and administrative expenses, are expected to result in continuing operating losses for the foreseeable future. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our technology and commercial products, obtaining additional requisite regulatory approvals in markets not covered by the CE Mark and for potential label extensions of our current CE Mark, establishing manufacturing and sales and marketing arrangements with third parties, and raising sufficient funds to finance our activities. No assurance can be given that our product development efforts will be successful, that our current CE Mark will enable us to achieve profitability, that additional regulatory approvals in other countries will be obtained, that any of our products will be manufactured at a competitive cost and will be of acceptable quality, or that the we will be able to achieve profitability or that profitability, if achieved, can be sustained.

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

As of December 31, 2014 we had thirty-four full-time employees and eight 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. These individuals do not have long-term employment agreements, and in some cases, including with respect to Dr. Chan and Mr. Capponi, do not have current and effective employment agreements in place. Although we are discussing formalizing our employment and consulting arrangements, as applicable, with Dr. Chan, Mr. Capponi and Dr. Bartlett in connection with our reincorporation merger with and into a Delaware corporation, there can be no assurance that Dr. Chan, Mr. Capponi, Dr. Bartlett or other members of our management team and advisors will continue to provide services to us. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Management and other employees may voluntarily terminate their employment with us at any time. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources.

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

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

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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 E.U. and non-E.U. countries to help further adoption. There can be no assurance when, or if, this additional reimbursement might be approved.

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

Our future success is also dependent on the strength of our intellectual property, trade secrets and know-how, which have been developed from years of research and development. In addition to the Purolite 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

We may face litigation from third parties claiming that our products infringeon their intellectual property rights, or see

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United States District Court for the Eastern District of Pennsylvania approved a Stipulated Order and Settlement Agreement under which we and Purolite agreed to the settlement of the action. The Settlement Agreement provides us with the exclusive right to use our patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the Settlement Agreement, we have agreed to pay Purolite royalties of 2.5% to 5% on the sale of certain of our products if and when those products are sold commercially.

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

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

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

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

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

We have commenced the process of seeking regulatory approvals of our products, but the approval process involve

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

We have commenced the process of seeking regulatory approvals of our products, but the approval proces involve

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suffered significant setbacks in advanced clinical studies, even after promising results in earlier studies. The failure to adequately demonstrate the safety and effectiveness of an intended product under development could delay or prevent regulatory clearance of the device, resulting in delays to commercialization, and could materially harm our business. Even though we have received approval to apply the CE Mark to our CytoSorb® device as a cytokine filter, there can be no assurance that we will be able to receive approval for other potential applications of CytoSorb®, or that we will receive regulatory clearance from other targeted regions or countries.

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

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

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

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

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

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

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

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

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 European Union. CytoSorbents manufactures CytoSorb® at its manufacturing facilities in New Jersey for sale in the E.U. and for additional clinical studies. We will need to maintain compliance on an ongoing basis. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we or the third-party manufacturers of our products fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products.

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

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

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

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

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

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

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

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

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

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

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the

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

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations (HMOs). Third-party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as

If users of our products are unable to obtain adequate reimbursement fromthird-party payers, or if new restrictive le

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HMOs, which could control or significantly influence the purchase of health care services and medical devices, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for our products. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

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

RISKS RELATED TO THIS OFFERING, THE SECURITIES MARKETS AND OUR SECURITIES

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 $0.35 and as low as $0.12 per share between January 1, 2014 and December 2, 2014. 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 recently formed, wholly-owned Delaware subsidiary. As a result, on December 29, 2014 the closing price of our common stock, as reported on the NASDAQ Capital Market was $10.40. 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 we have been approved for listing 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.

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 support our sales and marketing efforts, to fund clinical studies, to increase production capacity, to further develop our products and for general working capital and other 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.

An investment in our Common Stock is extremely speculative and there can be no assurance of any return on any such investment.

An investment in our Common Stock is extremely speculative and there is no assurance that investors will obtain any return on their investment. Investors will be subject to substantial risks involved in an investment in us, including the risk of losing their entire investment.

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

Our directors, executive officers and principal stockholders together beneficially own a significant percentage of the voting control of the Common Stock on a fully diluted basis. 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

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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.

Penny stock regulations may affect your ability to sell 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 recently formed, wholly-owned Delaware subsidiary. Our common stock has been approved for trading on the NASDAQ Capital Market. Beginning on December 23, 2014, our common stock trades on NASDAQ under the symbol CTSO. As a result, on December 29, 2014 the closing price of our common stock, as reported on the NASDAQ Capital Market was $10.40. To the extent the price of our common stock trades below $5.00 per share, our common stock will be subject to Rule 15g-9 under the Exchange Act, which imposes additional sales practice requirements on broker dealers which sell these securities to persons other than established customers and accredited investors. Under these rules, broker-dealers who recommend penny stocks to persons other than established customers and accredited investors must make a special written suitability determination for the purchaser and receive the purchaser s written agreement to a transaction prior to sale. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our common stock and may make it more difficult for holders of our common stock to sell shares to third parties or to otherwise dispose of them.

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

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 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 was effective December 3, 2014, authorizes the issuance of up to 50,000,000 shares of common stock, of which approximately 26,715,960 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 bylaws may discourage, delay or prevent a merger or acquisition that our

Directors, executive officers and principal stockholders own a significantpercentage of the shares of our Common S

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 the direction or management of us. 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.

Anti-takeover provisions in our charter documents and under Delaware lawcould prevent or delay transactions that

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

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

As of September 30, 2014, our management determined that certain disclosure controls and procedures were ineffective, which could result in material misstatements of our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. As of September 30, 2014, our management determined that its disclosure controls and procedures were not effective because of the following material weakness: Lack of an independent audit committee or audit committee financial expert. The Company is currently remediating this weakness, but there can be no assurance that it will be completely remediated in the near future.

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

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

We have concluded that our disclosure controls and procedures are not effective. Additionally, we have determined that there are material weaknesses in our internal control over financial reporting. If this leads to us failing to meet our future reporting obligations on a timely basis or if our consolidated financial statements contain material misstatements it could negatively impact our business by requiring that we employ additional capital to restate our financial statements or cure any defects in our reporting which would result in us having less capital to use to develop our business. An untimely filing or material misstatement could also lead to a lack of confidence by our shareholders, potential investors and shareholders and could lead to our stock price significantly decreasing in value.

Historically, our Common Stock has been thinly traded and we may be unable to maintain listing of our Common Stock on a more liquid market.

Historically, our common stock was quoted on the OTCQB, which provides significantly less liquidity than a securities exchange (such as the New York Stock Exchange or the Nasdaq Stock Market). Our common stock has been approved for trading on the NASDAQ Capital Market (NASDAQ). Beginning on December 23, 2014, our common stock trades 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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, any prospectus supplement and the documents we incorporate by reference 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, predict, potential, 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, including the sections entitled Business , Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations ;

our most recent Quarterly Report on Form 10-Q;

the risk factors contained in this prospectus under the caption Risk Factors ; 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.

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USE OF PROCEEDS

We estimate that we will receive up to $13,000,000 in gross proceeds from the sale of Common Stock in this Offering. After deducting estimated discounts and commissions to the Underwriters and estimated offering expenses payable by us, we expect net proceeds of approximately $12,010,000. We will use the net proceeds from this Offering to support our sales and marketing efforts, to fund clinical studies, to increase production capacity, to further develop our products and for general working capital and other general corporate purposes. Each $1.00 increase (decrease) in the public offering price per ordinary share would increase (decrease) our net proceeds, after deducting estimated underwriting discounts and commissions and estimated offering expenses, payable by us, by approximately $1.175 million.

We intend to use the net proceeds as follows:

approximately $7,000,000 to fund clinical studies.
approximately $3,500,000 for expansion of production capacity.
approximately $500,000 to support our sales and marketing efforts.
approximately $500,000 for development of our products.
all other amounts will be used be used for general working capital purposes.

Our management will have broad discretion to allocate net proceeds to us from this Offering. We reserve the right to change the use of these proceeds as a result of certain contingencies such as competitive developments, the result of our sales and marketing efforts and other factors. Pending use of the proceeds as described above, we intend to invest the net proceeds of this Offering in short-term, interest-bearing, investment-grade securities or certificates of deposit.

In the event that we do not raise the expected capital of $13,000,000, we would apply the funds generally as stated above but may need to re-budget or shift expenses, or may need to raise additional funding to complete our business goals. We do not know the amounts or source of the funds and may need to attempt additional financing.

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DILUTION

Our reported net tangible book value as of September 30, 2014 was $7,654,599, or $0.33 per share of Common Stock, based upon 23,258,801 shares outstanding as of that date adjusted for the subsequent conversion of the preferred shares into common shares and the twenty-five-for-one reverse split. Net tangible book value per share is determined by dividing such number of outstanding shares of common stock into our net tangible book value, which are our total tangible assets less total liabilities. After giving effect to the sale of shares in this offering at an estimated offering price of $10.40 per share, after deducting payments of discounts and commissions to the Underwriters and other estimated offering expenses payable by us, our net tangible book value at September 30, 2014 would have been approximately $19,665,500, or $0.80 per share after giving effect to our December 3, 2014 twenty-five-for-one reverse spilt of our common stock and merger with and into our recently formed, wholly-owned Delaware subsidiary. This represents an immediate increase in net tangible book value of approximately $0.47 per share to our existing stockholders, and an immediate dilution of $(0.00) per share to investors purchasing shares in the Offering.

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

Public offering price per share, estimated	$ 10.40
Net tangible book value per share as of September 30, 2014	$ 0.33
Increase per share attributable to sale of units to investors	$ 0.47
As adjusted net tangible book value per share after the Offering	$ 0.80
Dilution per share to investors	$
Dilution as a percentage of the offering price	0.0 %

The dilution information discussed above is illustrative only and will change based on the actual offering price and other terms of this Offering determined at pricing.

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DESCRIPTION OF BUSINESS

Overview

We are 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. The technology is based upon biocompatible, highly porous polymer sorbent beads that are capable of extracting unwanted substances from blood and other bodily fluids. The technology is protected by 32 issued U.S. patents with multiple patent applications pending both in the United States and internationally. Our intellectual property consists of composition of matter, materials, methods of production, systems incorporating the technology and multiple medical uses with expiration dates ranging from 3 to 12 years.

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

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

As part of the CE Mark approval process, we completed our randomized, controlled, European Sepsis Trial among 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, and that it was able to control cytokine storm and broadly reduce key cytokines.

We plan to do larger, prospective studies in septic patients in the future to confirm the European Sepsis Trial findings.

In addition to CE Mark approval, CytoSorbents also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the European Union. CytoSorbents manufactures CytoSorb® at its manufacturing facilities in New Jersey for sale in the E.U. and for additional clinical studies. 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 with the primary goal of preparing for commercialization of CytoSorb® in Germany in terms of manufacturing, reimbursement, logistics, infrastructure, marketing, contacts, and other key issues.

In late June 2012, following the establishment of our European subsidiary, CytoSorbents Europe GmbH, CytoSorbents began the commercial launch of CytoSorb® 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 full 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. At the end of Q1 2014, we had more than 100 key opinion leaders, or KOLs, in critical care, cardiac surgery, and blood purification who were either using CytoSorb® or committed to using CytoSorb® in the near future.

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In addition, we now 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 September 30, 2014, our sales force includes seven direct sales people and two sales support staff. We intend to add more staff to the direct sales and marketing team in the future.

We have complemented our direct sales efforts with sales to distributors and/or corporate partners. In 2013, we reached agreement with distributors in the United Kingdom, Ireland, Turkey, Russia, and the Netherlands. In September 2013, we entered into a strategic partnership with Biocon Ltd., Asia s largest biotech company with an initial distribution agreement for India and select emerging markets, under which Biocon will have the exclusive commercialization rights for CytoSorb®. 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 Cooperation Council or GCC) and Yemen, Iraq, and Jordan through an exclusive agreement with Techno Orbits. In August 2014, the Company announced distribution in Taiwan with Hemoscien Corporation. We are currently evaluating other potential distributor networks in other major countries where we are either approved to market the device or where CE Mark approval is accepted.

We are currently conducting a dose ranging trial in Germany among eight clinical trial sites to evaluate the safety and efficacy of CytoSorb® when used for longer periods of time. Data from this dosing study is 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 U.S. based pivotal study. In addition, we will receive additional data from the results of more than forty investigator-initiated studies in Europe which are either currently underway or planned.

Concurrent with our commercialization plans, we intend to conduct or support additional clinical studies in sepsis, cardiac surgery, and other critical care diseases to generate additional clinical data to expend the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. We are currently organizing a pivotal trial in the U.S. using CytoSorb® during cardiac surgury that is intended to be the basis of our application seeking U.S. regulatory 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, acute respiratory distress syndrome, or ARDS, and others. Sepsis is a major unmet medical need with no approved products in the U.S. 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 severe inflammatory response syndrome, or SIRS, response and either prevent or treat organ failure.

In addition to the sepsis indication, we intend to continue to foster research in other critical care illnesses where CytoSorb® could be used, such as ARDS, trauma, severe burn injury and acute pancreatitis, or in other acute conditions that 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.

Our proprietary hemocompatible porous polymer bead technology forms the basis of a broad technology portfolio. Some of our products include:

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

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

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

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

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

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

In September 2013, the National Heart, Lung, and Blood Institute (NHLBI), a division of the National Institutes of Health (NIH), awarded us a Phase I Small Business Innovation Research (SBIR) contract to further advance our HemoDefend™ blood purification technology for RBC transfusions. The project, entitled Elimination of blood contaminants from pRBCs using HemoDefend™ hemocompatible porous polymer beads, was $203,351 over six months. The overall goal of the program was to reduce the risk of potential side effects of blood transfusions, and help to extend the useful life of pRBCs.

In June 2013, we announced that the U.S. Air Force will fund a 30 patient, single site, randomized controlled human pilot study in the United States amongst trauma patients with rhabdomyolysis most commonly associated with trauma. The FDA has approved our Investigational Device Exemption (IDE) application for this study, and the study began in April 2014.

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

In August 2012, we were awarded a $3.8 million contract by the Defense Advanced Research Projects Agency (DARPA) for our 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 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 our hemocompatible porous polymer technologies to remove cytokines and a number of pathogen and biowarfare toxins from blood. We are in Year 2 of the program and are currently working with the recently announced systems integrator, Battelle Laboratories, and its subcontractor NxStage Medical, who are responsible for integrating the technology developed by us 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.

Corporate History

CytoSorbents Corporation was incorporated in Nevada on April 25, 2002 as Gilder Enterprises, Inc. and was originally engaged in the business of installing and operating computer networks that provided high-speed access to the Internet. On June 30, 2006, we disposed of our original business, and pursuant to an Agreement and Plan of Merger, acquired all of the stock of MedaSorb Technologies, Inc., a Delaware corporation, in a merger, and its

business became our business. Following the merger, in July 2006 we changed our name to MedaSorb Technologies Corporation. In November 2008, we changed the name of our operating subsidiary from MedaSorb Technologies, Inc. to CytoSorbents, Inc. In May 2010, we 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. Unless otherwise indicated, all references in this prospectus to MedaSorb , CytoSorbents , us or we with respect to

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events prior to June 30, 2006 are references to CytoSorbents Medical, Inc. and its predecessors. Our executive offices are located at 7 Deer Park Drive, Suite K, Monmouth Junction, New Jersey 08852. Our telephone number is (732) 329-8885.

On December 3, 2014 we effected a twenty-five-for-one (25:1) reverse split of our common stock. As a result of the twenty-five-to-one (25:1) 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 shares. 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 recently formed, wholly-owned Delaware subsidiary. Pursuant to the Agreement and Plan of 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. At the effective time of our merger, (i) we merged with and into our Delaware subsidiary, (ii) our separate corporate existence in Nevada ceased to exist, (iii) our Delaware subsidiary became the surviving corporation, and (iv) each share of our common stock, $0.001 par value per share outstanding immediately prior to the effective time was converted into one fully-paid and non-assessable share of common stock of CytoSorbents Corporation, a Delaware corporation, $0.001 par value per share. The reverse stock split, the merger and the Agreement and Plan of Merger were approved by the our Board of Directors and stockholders representing a majority of our outstanding common stock. All references to us, we or the Company, on or after December 3, 2014, refer to CytoSorbents Corporation, a Delaware corporation.

CytoSorbents was originally organized as a Delaware limited liability company in August 1997 as Advanced Renal Technologies, LLC. The Company changed its name to RenalTech International, LLC in November 1998, and to MedaSorb Technologies, LLC in October 2003. In December 2005, MedaSorb converted from a limited liability company to a corporation.

CytoSorbents has been engaged in research and development since its inception, had raised approximately $86 million from investors. These proceeds have been used to fund the development of multiple product applications and to conduct clinical studies. These funds have also been used to establish in-house manufacturing capacity to meet clinical testing needs, expand our intellectual property through additional patents and to develop extensive proprietary know-how with regard to our products.

We have raised funds through various means including convertible note offerings and equity transactions. Our three most significant financing transactions are discussed below.

Principal Terms of the March 2014 $10,200,000 Equity Offering

On March 7, 2014, we entered into subscription agreements with certain investors providing for the issuance and sale by us (the March Offering) of 40,800,000 units (the Units) for an aggregate purchase price of $10,200,000. Each Unit is comprised of one share of our common stock, priced at $0.25 per share, par value $0.001 per share and a warrant to purchase 0.50 shares of common stock at an exercise price of $0.3125 per share. The warrants are convertible into a total of 20,400,000 shares of common stock. Each warrant is exercisable for a period of five (5) years beginning on March 11, 2014, the date of the closing of the sale of these securities, and are only exercisable for cash if at the time of exercise there is an effective registration statement registering the warrants and shares underlying the warrants. The exercise price of the warrants are subject to certain adjustment provisions, including adjustments for the issuance of stock dividends, subsequent equity sales below the then-current exercise price and fundamental transactions. Upon the sale, grant or other disposition or issuance of any Company Common Stock or equity equivalent securities at an

effective price per share less than the then-current exercise price of the warrants, the exercise price of the warrants shall be reduced to equal the price per share of such disposition or issuance. Upon the occurrence of any such issuance or disposition, the holder is entitled to receive a number of warrant shares based upon the price per share of such disposition or issuance.

We received net proceeds from the March Offering of approximately $9,451,000 million. The net proceeds received by us from the March Offering will be used for building additional sales and marketing infrastructure, clinical studies, working capital and general corporate purposes.

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We conducted the March Offering pursuant to a registration statement on Form S-1 (File No. 333-193053) which was declared effective by the Securities and Exchange Commission on February 14, 2014 and an additional registration statement on Form S-1 (File No. 333-194394) to register an additional amount of securities having a proposed maximum aggregate offering price of $2,762,500, which increased the total registered amount to $16,575,000 assuming the full cash exercise of the warrants for cash. We filed a final prospectus on March 7, 2014, disclosing the final terms of the March Offering.

In connection with the March Offering, on March 7, 2014, we entered into a placement agency agreement with Brean Capital, LLC pursuant to which the placement agent agreed to act as our exclusive placement agent for the March Offering and sale of the Units.

In connection with the successful completion of the March Offering, the placement agent received an aggregate cash placement agent fee equal to 6% of the gross proceeds of the sale of the Units in the March Offering and a warrant to purchase 1,224,000 shares of common stock at an exercise price of $0.30 per share exercisable for five years from the effective date of the placement agency agreement. The placement agent warrant contains piggy-back registration rights which expire on the fifth anniversary of the effective date of the registration statement. We have also agreed to reimburse the placement agent for actual out-of-pocket expenses up to a maximum of 2% of gross proceeds from the transaction. We also granted the placement agent a right of first refusal to participate in any subsequent offering or placement of our securities that takes place within twelve months following the effective date of the registration statement.

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

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

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

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

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

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

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

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Pursuant to a settlement agreement with the June 30, 2006 purchasers of Series A Preferred Stock, all cash dividends and damages were paid for in full with additional shares of Series A Preferred Stock.

Both the conversion price for the June 30, 2006 purchasers of the Series A Preferred Stock and the exercise price of the warrants were subject to full-ratchet anti-dilution provisions, so that upon future issuances of our common stock or equivalents thereof, subject to specified customary exceptions, at a price below the conversion price of the Series A Preferred Stock and/or exercise price of the warrants, the conversion price and/or exercise price will be reduced to the lower price. As of the Qualified Closing of our Series B Preferred Stock private placement in August of 2008, these investors agreed to a modification of their rights and pricing and gave up their anti-dilution protection.

In connection with the sale of the Series A Preferred Stock and warrants to the four institutional investors, to induce those investors to make the investment, Margie Chassman pledged to those investors securities of other publicly traded companies. The pledged securities consisted of a $400,000 promissory note of Xechem International, Inc. convertible into Xechem common stock at $.005 per share, and 250,000 shares of the common stock of Novelos Therapeutics, Inc. Based on the market value of the Xechem common stock ($0.07 per share) and the Novelos common stock ($1.03) per share, on June 30, 2006, the aggregate fair market value of the pledged securities at the date of pledge was approximately $5,857,500.

The terms of the pledge provided that in the event those investors suffered a loss on their investment in our securities as of June 30, 2007 (as determined by actual sales by those investors or the market price of our common stock on such date), the investors would be entitled to sell all or a portion of the pledged securities so that the investors receive proceeds from such sale in an amount equal to their loss on their investment in our securities. In consideration of her pledge to these investors, we paid Ms. Chassman (i) $525,000 in cash (representing 10% of the cash amount raised from the institutional investors), and (ii) five-year warrants to purchase:

525,000 shares of Series A Preferred Stock (representing 10% of the Series A Preferred Stock purchased by those investors); and
warrants to purchase 210,000 shares of common stock at an exercise price of $2.00 per share (representing 10% of the Series A Preferred Stock purchased by those investors), for an aggregate exercise price of $525,000.

As of the Qualified Closing of our Series B Preferred Stock private placement in August of 2008, Ms. Chassman agreed to a modification of her rights and pricing and gave up her anti-dilution protection.

Principal Terms of the Series B Financing Consummated in 2008

Each share of Series B Preferred Stock has a stated value of $100.00, and is convertible at the holder s option into that number of shares of common stock equal to the Series B stated value at a conversion price of $0.0362, subject to certain adjustments. Additionally, upon the occurrence of a stock split, stock dividend, combination of the common stock into a smaller number of shares, issuance of any of shares of common stock or other securities by reclassification of the common stock, merger or sale of substantially all of our assets, the conversion rate will be adjusted so that the conversion rights of the Series B Preferred Stock stockholders will remain equivalent to those prior to such event.

Dividend

The holders of Series B Preferred Stock are entitled to receive preferential dividends payable in shares of additional Series B Preferred Stock. Any dividends payable to both the Series A and Series B Preferred shareholders shall be paid before any dividend or other distribution will be paid to any common stock shareholder. The Series B Preferred Stock dividend is based payable at a rate of 10% per annum on the Series B Stated Value payable on the last day of

each calendar quarter after June 30, 2008. However, upon the occurrence of any Event of Default as defined in the Certificate of Designation of Series B Preferred Stock, the dividend rate increases to 20% per annum, and revert back to 10% after the Event of Default is cured. An Event of Default includes, but is not limited to,

the occurrence of Non-Registration Events ;

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an uncured breach by us of any material covenant, term or condition in the Certificate of Designation or any of the related transaction documents; and

any money judgment or similar final process being filed against us for more than $100,000.

Dividends must be delivered to the holder of the Series B Preferred Stock no later than five (5) business days after the end of each period for which dividends are payable. Dividends on the Series B Preferred Stock will be made in additional shares of Series B Preferred Stock, valued at the Series B Preferred Stock stated value. Notwithstanding the foregoing, during the first three-years following the initial closing, upon the approval of the holders of a majority of the Series B Preferred Stock, including the lead investor, NJTC Investment Fund, if it then owns 25% of the shares of Series B Preferred Stock initially purchased by it, we may pay dividends in cash instead of additional shares of Series B Preferred Stock, and after such three-year period, the holders of a majority of the Series B Preferred Stock, including NJTC if it then owns the 25% of the shares of the Series B Preferred Stock initially purchased by it, may require us to make such payments in cash.

Conversion of Series A and Series B Shares into Shares of Common Stock

On October 9, 2014, the Company filed with the Nevada Secretary of State an Amendment, or the Series A Amendment, to the Certificate of Designation, as amended, or the Series A Certificate of Designation, of the Series A Preferred Stock. The Series A Amendment, which became effective on October 9, 2014, (i) amends the Series A Certificate of Designation to allow the stockholders representing eighty percent (80%) of the issued and outstanding shares of Series A Preferred Stock to elect to convert all issued and outstanding shares of Series A Preferred Stock into Common Stock, at the then-effective Conversion Price, as defined in the Series A Certificate of Designation, and (ii) in consideration for such amendment, amends the Conversion Price from $1.25 per share to $0.77 per share, except with respect to the shares of Series A Preferred Stock covered by that certain Agreement and Consent dated as of June 25, 2008 by and among the Company and certain holders of Series A Preferred Stock. Immediately following effectiveness of the Series A Amendment, the stockholders representing over 88 percent (88%) of the then-issued and outstanding Series A Preferred Stock elected to convert all issued and outstanding Series A Preferred Stock into Common Stock at the Conversion Price, as amended. As a result of the election, 1,894,969 shares of Series A Preferred Stock have been converted into 2,583,289 shares of Common Stock.

The Series A Amendment was approved by the Board of Directors of the Company, as well as by over 88 percent (88%) of the Series A Preferred Stock.

On October 9, 2014, the Company also filed with the Nevada Secretary of State an Amendment, or the Series B Amendment, to the Certificate of Designation, or the Series B Certificate of Designation, of the Series B Preferred Stock. The Series B Amendment, which became effective on October 9, 2014, amends the Series B Certificate of Designation to allow the holders of a majority of the Series B Preferred Stock, including NJTC Investment Fund, LP, to elect to convert all issued and outstanding shares of Series B Preferred Stock into Common Stock.

Immediately following effectiveness of the Series B Amendment, the stockholders representing over 93 percent (93%) of the then-issued and outstanding Series B Preferred Stock elected to convert all issued and outstanding Series B Preferred Stock into Common Stock. Each share of Series B Preferred Stock has a stated value of $100.00, or the Series B Stated Value, and is convertible into that number of shares of Common Stock equal to the Series B Stated Value at a conversion price of $0.036 (which remained unchanged in this process). As more fully described below, as consideration for the Series B Amendment the holders of Series B Preferred Stock received a one-time dividend equal to ten percent (10%) of the shares of Series B Preferred Stock then held. As a result of the election by the holders of Series B Preferred Stock and the one-time dividend, 84,283.99 shares of Series B Preferred Stock have been converted into 256,111,243 shares of Common Stock.

The Series B Amendment was approved by the Board, as well as by over 93 percent (93%) of the Series B Preferred Stock.

The foregoing description of the amendment to the rights of the Series B Preferred Stock is qualified in its entirety by the provisions of the Series B Amendment, filed as Exhibit 3(i).10 hereto.

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After giving effect to the conversions of the Series A Preferred Stock and Series B Preferred Stock described above, there are no shares of Preferred Stock of the Company issued and outstanding.

Recent Corporate Actions

Our common stock has been approved for trading on the NASDAQ Capital Market. Beginning on December 23, 2014, our common stock trades on NASDAQ under the symbol CTSO. In order to facilitate that process, in October 2014, the stockholders representing over 88 percent (88%) of the then-issued and outstanding Series A 10% Cumulative Convertible Preferred Stock, or the Series A Preferred Stock, elected to convert all issued and outstanding Series A Preferred Stock into Common Stock at the then-effective conversion price. As a result of the election, effective October 9, 2014, 1,894,969 shares of Series A Preferred Stock, representing all issued and outstanding shares of Series A Preferred Stock, were converted into 2,583,289 shares of Common Stock. Similarly, the stockholders representing over 93 percent (93%) of the then-issued and outstanding Series B 10% Cumulative Convertible Preferred Stock, or the Series B Preferred Stock, elected to convert all issued and outstanding Series B Preferred Stock into Common Stock. As a result of the election, effective October 9, 2014, 84,283.99 shares of Series B Preferred Stock were issued a dividend of 10%, and then the 92,712.27 shares of Series B Preferred Stock, representing all issued and outstanding shares of Series B Preferred Stock, were converted into 256,111,243 shares of Common Stock.

On December 1, 2014, we received stockholder approval authorizing our Board of Directors to (i) amend our Articles of Incorporation, as amended, to effect a reverse split of our Common Stock, with a reverse split ratio of twenty-five-to-one (25:1); (ii) amend our Articles of Incorporation, as amended, to reduce the total number of authorized shares of Common Stock from 800,000,000 to 50,000,000, after giving effect to the reverse stock split; (iii) amend our Articles of Incorporation, as amended, to reduce the total number of authorized shares of undesignated preferred stock from 100,000,000 to 5,000,000, after giving effect to the reverse stock split; (iv) implement the form, terms and provisions of the CytoSorbents Corporation 2014 Long-Term Incentive Plan; and (v) change our domicile from the State of Nevada to the State of Delaware through our merger with and into a newly-organized subsidiary organized under the laws of 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 twenty-five-for-one (25:1) 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 shares. Immediately after the reverse 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 recently formed, wholly-owned Delaware subsidiary. Pursuant to the Agreement and Plan of 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. At the effective time of our merger, (i) we merged with and into our Delaware subsidiary, (ii) our separate corporate existence in Nevada ceased to exist, (iii) our Delaware subsidiary became the surviving corporation, and (iv) each share of our common stock, $0.001 par value per share outstanding immediately prior to the effective time was converted into one fully-paid and non-assessable share of common stock of CytoSorbents Corporation, a Delaware corporation, $0.001 par value per share. The reverse stock split, the merger and the Agreement and Plan of Merger were approved by the our Board of Directors and stockholders representing a majority of our outstanding common stock.

On December 15, 2014, we issued a press release announcing the entry into an exclusive Distribution Agreement, or Distribution Agreement, with Fresenius Medical Care Deutschland GmbH, or Fresenius, an operating division of Fresenius Medical Care AG & CO KGaA. Although the Distribution Agreement marks a continuation of our long-term distribution strategy, we do not deem it material to us at this time, but it may become material at some time

in the future. In accordance with the disclosure rules of the Securities and Exchange Commission, when such agreement becomes material to us, we shall appropriately disclose the terms and conditions of such agreement and file such agreement (with confidential treatment requested).

Under the terms of the Distribution Agreement, Fresenius was granted exclusive rights to distribute our CytoSorb product and other blood purification products, or the Products, for critical care medicine and intensive care unit applications in France, Poland, Sweden, Denmark, Norway, and Finland, or collectively, the

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Territory. Fresenius s exclusivity is subject to Fresenius achieving certain annual minimum guaranteed orders of the Products. If Fresenius does not achieve the annual minimum guaranteed orders, then we may terminate the Distribution Agreement or change the exclusive rights granted to non-exclusive rights. Fresenius is obligated to register the Products with the appropriate governmental agencies for marketing approval in the Territory within six (6) months. Pricing is generally fixed for the term of the Distribution Agreement, but Fresenius is able to achieve volume discounts on pricing. The parties agree to negotiate, in good faith, an increase in the purchase price of the Products in the event the average selling price to customers increases or, on the other hand, if the costs of production for the Products decreases, a reduction in the purchase price.

The Distribution Agreement expires upon the third anniversary of the first Product registration in the Territory, but, in any event, no later than June 15, 2018, and is subject to renewal or renegotiation with mutual agreement at that time. During the term of the Distribution Agreement and for a period of one (1) year afterwards, Fresenius has agreed not to compete with us regarding the production or distribution of a competitive product in the Territory.

In December 2014, we submitted an Investigational Device Exemption, or IDE, application to the FDA to conduct our U.S. cardiac surgery trial using CytoSorb intra-operatively in patients undergoing complex cardiac surgery requiring the use of a heart-lung machine. The goal of CytoSorb treatment is to reduce inflammatory mediators and proteins such as cytokines and plasma free hemoglobin generated during surgery that can lead to serious post-operative complications. All investigational medical devices require IDE approval before they can be used in U.S.-based clinical studies to evaluate safety and efficacy.

Research and Development

We have been engaged in research and development since inception. Our research and development costs were approximately $1,739,000 and $2,532,000 for the years ended December 31, 2013 and 2012, respectively. From our inception date January 22, 1997, through to December 31, 2013 our research and development costs totaled approximately $55,668,000. We have recently been awarded more than $5 million in contracts from DARPA ($3.8M over 5 years), the U.S. Army ($100,000 Phase I SBIR; $50,000 Phase I extension, $1 million Phase II SBIR), and a $203,000 Phase I SBIR contract from the National Heart, Lung and Blood Institute to further develop our technologies for sepsis, trauma and burn injury, and blood transfusions, respectively. Payments are based on achieving certain technology milestones. In addition, the U.S. Air Force is funding a 30-patient, randomized controlled human pilot study evaluating CytoSorb® in patients with severe trauma and rhabdomyolysis. The FDA approved the trial under an IDE application and enrollment began in 2014.

Technology, Products and Applications

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

Our polymer adsorbent technology can remove drugs, bioactive lipids, inflammatory mediators such as cytokines, free hemoglobin, toxins, and immunoglobulin from blood and physiologic fluids depending on the polymer construct. We believe that our technology may have many applications in the treatment of common, chronic and acute healthcare conditions including, but not limited to, the adjunctive treatment and/or prevention of sepsis; the treatment of other

critical care illnesses such as severe burn injury, trauma, acute respiratory distress syndrome and pancreatitis; the prevention of post-operative complications of cardiopulmonary bypass surgery; the treatment of cancer cachexia; the prevention of damage to organs donated by brain-dead donors prior to organ harvest; the prevention of transfusion reactions caused by contaminants in transfused blood products; the prevention of contrast induced nephropathy, the treatment of drug overdose, and the treatment of chronic kidney failure. These applications vary by cause and complexity as well as by severity but share a common characteristic i.e., high concentrations of inflammatory mediators and toxins in the circulating blood.

CytoSorbents flagship product, CytoSorb® and other products under development, including BetaSorb™, ContrastSorb, and DrugSorb consist of a cartridge containing adsorbent polymer beads, although the polymers

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used in these devices are physically different. The cartridges incorporate industry standard connectors at either end of the device, which connect directly to the extracorporeal circuit (bloodlines) in series with a dialyzer, in the case of the BetaSorb™ device, or as a standalone device in the case of the CytoSorb®, ContrastSorb, and DrugSorb devices. The extra-corporeal circuit consists of plastic blood tubing, our blood filtration cartridges containing adsorbent polymer beads, pressure monitoring gauges, and a blood pump to maintain blood flow. The patient s blood is accessed through a catheter inserted into his or her veins. The catheter is connected to the extra-corporeal circuit and the blood pump draws blood from the patient, pumps it through the cartridge and returns it back to the patient in a closed loop system. All of these devices are expected to be compatible with standard blood pumps or hemodialysis machines used commonly in hospitals and will therefore not require hospitals to purchase additional expensive equipment, and will require minimal training.

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

Markets

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

In many critical care illnesses, the mortality is often higher than 30%. A major cause of death is multiple organ failure, where vital organs such as the lungs, kidneys, heart and liver are damaged and no longer function properly. Such patients are kept alive with supportive care therapy, or life support , such as mechanical ventilation, dialysis and vasopressor treatment, that is designed to keep the patient from dying while using careful patient management to tip the balance towards gradual recovery over time. Unfortunately, most supportive care therapies only help to keep patients alive by supporting organ function but do not help reverse the underlying causes of organ failure and do not help patients recover more quickly. Because of this, the treatment course is often poorly defined and highly variable, leading to lengthy ICU stays, a higher risk of adverse outcomes from hospital acquired infections, medical errors, and other factors, as well as exorbitant costs. There is an urgent need for more effective active therapies that can help to reverse or prevent organ failure. CytoSorbents main product, CytoSorb® is a unique cytokine filter designed to try to address this void, by reducing cytokine storm and working to reduce the subsequent deadly inflammation that can lead to organ failure and death. Together the total addressable market to address these numerous critical care applications in the U.S. and E.U. with CytoSorb® is estimated at $10 15 billion.

Sepsis

Sepsis is characterized by a systemic inflammatory response triggered by a severe infection. It is commonly seen in the intensive care unit, accounting for approximately 10 20% of all ICU admissions. However, there are currently no approved products that are available to treat sepsis in the U.S. or E.U. Each year, there are more than one million and 1.5 million new cases of severe sepsis or septic shock in the United States and Europe, respectively. Based on the reported incidence of sepsis in a number of developed countries, the worldwide incidence is estimated to be 18 million

cases per year. According to the U.S. Centers of Disease Control and Prevention (CDC), the incidence of serious infection and sepsis has doubled in the U.S. in the past 10 years. The main driver of sepsis incidence is the aging demographic, specifically patients who are older than age 65 who are more prone to infection and now account for two-thirds of patients hospitalized for sepsis and the majority of sepsis deaths. Other factors contributing to the increase in sepsis incidence include the spread of antibiotic resistant bacteria like methicillin-resistant Staphylococcus aureus (MRSA), an increase in co-morbid conditions like HIV, cancer and diabetes that increases the risk of infection, an increasing use of implantable devices like artificial hips and knees that are prone to colonization by bacteria, and the appearance of new highly virulent or contagious strains of common pathogens such as H1N1 influenza.

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There are generally three categories of sepsis, including mild to moderate sepsis, severe sepsis and septic shock. Mild to moderate sepsis typically occurs with an infection that is responsive to antibiotics or antiviral medication. An example is a patient with self-limiting influenza or a treatable community acquired pneumonia. Mortality is generally very low. Severe sepsis is sepsis with evidence of organ dysfunction. An example is a patient who develops respiratory failure due to a severe pneumonia and requires mechanical ventilation in the intensive care unit. Severe sepsis has a mortality rate of approximately 25 35%. Septic shock, or severe sepsis with low blood pressure that is not responsive to fluid resuscitation, is the most serious form of sepsis with an expected mortality in excess of 40 50%.

In sepsis, there are two major problems: the infection and the body s immune response to the infection. Antibiotics are main therapy used to treat the triggering infection, and although antibiotic resistance is growing, the infection is often eventually controlled. However, it is the body s immune response to this infection that frequently leads to the most devastating damage. The body s immune system normally produces large amounts of inflammatory mediators called cytokines to help stimulate and regulate the immune response during an infection. In severe infection, however, many people suffer from a massive, unregulated overproduction of cytokines, often termed cytokine storm that can kill cells and damage organs, leading to multiple organ dysfunction syndrome (MODS) and multiple organ failure (MOF), and in many cases death. Until recently, there have been no available therapies in the U.S. or E.U. that can control the aberrant immune response and cytokine storm. Our CytoSorb® device is a first-in-class, clinically-proven broad-spectrum extracorporeal cytokine filter currently approved for sale in the E.U. The goal of CytoSorb® is to prevent or treat organ failure by reducing cytokine storm and controlling a run-away immune response, while antibiotics work to control the actual infection. CytoSorb® has been evaluated in the randomized, controlled European Sepsis Trial in 43 patients in Germany with predominantly septic shock and acute respiratory distress syndrome or acute lung injury. The therapy was safe in more than 300 human treatments and generally well tolerated. CytoSorb® demonstrated the statistically significant ability to reduce cytokine storm and key cytokines by 30 50%. In a post-hoc analysis, this was associated with improvements in clinical outcome in two high-risk patient populations those with very high cytokine levels and patients 65 years of age and older. CytoSorbents is currently conducting a Dosing study at 8 clinical trial sites in Germany, and has demonstrated the safety of continuous treatment over 7 days.

We estimate that the market potential in Europe for its products is larger than that in the U.S. For example, in the U.S. and Europe, there are an estimated one million and 1.5 million new cases, respectively, of severe sepsis and septic shock annually. In Germany alone, according to the German Sepsis Society (GSS), there are approximately 154,000 cases of severe sepsis each year. Patients are treated in the intensive care unit for 12 18 days on average and for a total of 20 25 days in the hospital. Germany is the largest medical device market in Europe and the third largest in the world.

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

Development of most other experimental therapies has been discontinued, including Eritoran from Eisai, CytoFab from BTG/Astra Zeneca, Talactoferrin from Agennix, and others. Currently, there are two late stage trials ongoing. In November 2012, an 800 patient Phase III randomized controlled study began for Recomodulin (ART 123, Artisan/Asahi Kasei), a recombinant human thrombomodulin, for the treatment of septic patients with coagulopathy. In mid-2013, following an interim analysis of safety data, the Data Safety Monitoring Board (DSMB) recommended that the trial continue. The primary completion date of the trial is expected to be March 2015. Recomodulin has been approved in Japan since 2009 for the treatment of disseminated intravascular coagulation (DIC), a late complication of

sepsis, at a cost of $5,800 per treatment. Although it has other activity, it works primarily by a similar anticoagulant mechanism to Xigris. Because of

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this, it has only demonstrated a limited mortality benefit (~9%: 34.6% control vs 26% treatment), similar to that seen in Xigris initial PROWESS Trial (~6%: 31% control vs 25% treatment) and is unlikely to have greater benefit in larger scale studies.

Spectral Diagnostics is collaborating with Toray on the EUPHRATES trial, combining an endotoxin assay with extracorporeal endotoxin removal by Toraymyxin, a polymyxin-B immobilized polystyrene fiber cartridge. The study began in June 2010 and is still enrolling patients. Endotoxemia is a result of Gram negative sepsis, which only accounts for 45% of cases of sepsis. It is a potent stimulator of cytokine storm. However, all anti-endotoxin strategies have failed pivotal studies to date, believed to be the result of intervening too late in the sepsis cascade. In a second interim analysis announced in January 2014, following the enrollment of 184 patients with 28-day follow-up, the DSMB has recommended that the trial continue, but has asked that further analysis be performed before recalculation of the trial s sample size is finalized. Because of the lack of available therapies, there remains a significant medical need for improved treatments for sepsis.

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

Cardiac Surgery

There are approximately 500,000 cardiopulmonary bypass (CPB) and cardiac surgery procedures performed annually in the U.S., 500,000 in the E.U., and approximately 1.5 million procedures worldwide. These include relatively common procedures including coronary artery bypass graft surgery, valve replacement surgery, heart and lung transplant, congenital heart defect repair, and left ventricular assist device implantation for the treatment of heart failure. 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 including infection, pulmonary, renal, and neurological dysfunction. Complications lead to longer ICU recovery times and hospital stays, increased morbidity and mortality, and higher costs. An average coronary artery bypass graft procedure already costs approximately $36,000 in the U.S. without complications. The use of CytoSorb® to reduce cytokines and other inflammatory mediators during and after the surgical procedure may prevent or mitigate these post-operative complications. During the procedure, the CytoSorb® filter can be incorporated in a bypass circuit in the heart-lung machine without the need for a separate pump, a unique competitive advantage over other technologies. After the surgery, CytoSorb® can be used similarly to dialysis on patients that develop a severe post-operative inflammatory response. 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. The peri-procedural total addressable market for CytoSorb® in the U.S. and E.U in cardiothoracic surgery procedures is estimated to be $500 million to $1 billion.

Acute Respiratory Distress Syndrome

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

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ventilator-induced lung injury, oxygen toxicity, ventilator-acquired pneumonias, and other hospital acquired infections, and outcome is significantly dependent on the presence of other organ dysfunction as well as co-morbid conditions such as pre-existing lung disease (e.g., emphysema or chronic obstructive pulmonary disease) and age. Because of this, mortality is typically greater than 30%, even with modern medicine and ventilation techniques. ALI and ARDS can be precipitated by a number of conditions including pneumonia and other infections, burn and smoke inhalation injury, aspiration, reperfusion injury and shock. Cytokine injury plays a major role in the vascular compromise and cell-mediated damage to the lung. Reduction of cytokine levels may either prevent or mitigate lung injury, enabling patients to wean from mechanical ventilation faster, potentially reducing numerous sequelae such as infection, pneumothoraces, and respiratory muscle deconditioning, and allow faster intensive care unit discharge, thereby potentially saving costs. CytoSorb® treatment of patients with either ALI or ARDS in the setting of sepsis was the subject of our European Sepsis Trial where in a post-hoc analysis in patients with very high cytokine levels, we observed faster ventilator weaning in CytoSorb® treated patients that showed a statistical trend to benefit. Future, prospectively defined, larger studies are required to confirm these findings. Although a number of therapies have been tried such as corticosteroids, nitric oxide, surfactant therapy, and others, there are currently no approved treatments for ARDS. Only low tidal volume ventilation has been demonstrated to improve mortality (31.0 vs 39.8% control) in this patient population. However, even with this intervention, mortality is still unacceptably high. The total addressable market for CytoSorb® to treat ARDS/ALI in the E.U. is estimated to be between $500 million to $1.25 billion, and $1 2 billion in the U.S. and E.U.

Severe Burn Injury

In the U.S., there are approximately 2.4 million burn injuries per year, with 650,000 treated by medical professionals and approximately 75,000 requiring hospitalization. Aggressive modern management of burn injury, including debridement, skin grafts, anti-microbial dressings and mechanical ventilation for smoke and chemical inhalation injury has led to significant improvements in survival of burn injury to approximately 95% on average in leading burns centers. However, there remains a need for better therapies to reduce the mortality in those patients with large burns and inhalation injury as well as to reduce complications of burn injury and hospital length of stay for all patients. According to National Burn Repository Data, the average hospital stay for burn patients is directly correlated with the percent total body surface area (TBSA) burned. Every 1% increase of TBSA burned equates to approximately 1 additional day in the hospital. A single patient with more than 30% TBSA burned who survives, is hospitalized for an average of 30 days and costs approximately $200,000 to treat. Major causes of death following severe burn and smoke inhalation injury are multi-organ failure (hemodynamic shock, respiratory failure, acute renal failure) and sepsis, particularly in patients with greater than 30% TBSA burns. Specifically, burns and inhalation injury lead to severe systemic and localized lung inflammation, loss of fluid, and cytokine overproduction. This cytokine storm causes numerous problems, including: hypovolemic shock and inadequate oxygen and blood flow to critical organs, acute respiratory distress syndrome preventing adequate oxygenation of blood, capillary leakage resulting in tissue edema and intravascular depletion, hypermetabolism leading to massive protein degradation and catabolism and yielding increased risk of infection, impaired healing, severe weakness and delayed recovery, immune dysfunction causing a higher risk of secondary infections (wound infections, pneumonia) and sepsis, and direct apoptosis and cell-mediated killing of cells, leading to organ damage. Up to a third of severe hospitalized burn patients develop multi-organ failure and sepsis that can often lead to complicated, extended hospital courses, or death. Broad reduction of cytokine storm has not been previously feasible and represents a novel approach to limiting or reversing organ failure, potentially enabling more rapid mechanical ventilation weaning, prevention of shock, reversal of the hypermetabolic state encouraging faster healing and patient recovery, reducing hospital costs, and potentially improving survival. The total addressable market in the E.U. for CytoSorb to address burn and smoke inhalation injury is estimated at $150 350 million and $300 600 million in the U.S and E.U.

Trauma

According to the National Center for Health Statistics, in the U.S., there are more than 31 million visits to hospital emergency rooms, with 1.9 million hospitalizations, and 167,000 deaths every year due to injury. The leading causes of injury are trauma from motor vehicle accidents, being struck by an object or other person, and falls. Trauma is a well-known trigger of the immune response and a surge of cytokine production or

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cytokine storm. In trauma, cytokine storm contributes to a systemic inflammatory response syndrome (SIRS) and a cascade of events that cause cell death, organ damage, organ failure and often death. Cytokine storm exacerbates physical trauma in many ways. For instance, trauma can cause hypovolemic shock due to blood loss, while cytokine storm causes capillary leak and intravascular volume loss, and triggers nitric oxide production that causes cardiac depression and peripheral dilation. Shock can lead to a lack of oxygenated blood flow to vital organs, causing organ injury. Severe systemic inflammation and cytokine storm can lead to acute lung injury and acute respiratory distress syndrome as is often seen in ischemia and reperfusion injury following severe bleeding injuries. Penetrating wound injury from bullets, shrapnel and knives, can lead to infection and sepsis, another significant cause of organ failure in trauma. Complicating matters is the breakdown of damaged skeletal muscle, or rhabdomyolysis, from blunt trauma that can lead to a massive release of myoglobin into the blood that can crystallize in the kidneys, leading to acute kidney injury and renal failure. Renal failure in trauma is associated with a significant increase in expected mortality. Cytokine and myoglobin reduction by CytoSorb® and related technologies may have benefit in trauma, potentially improving clinical outcome. In December 2011 and September 2012, CytoSorbents was awarded a Phase I and a Phase II SBIR award, respectively, from the U.S. Army Medical Research and Materiel Command to develop its technology for the treatment of trauma and burn injury. The total addressable market for CytoSorb® for the treatment of trauma is estimated to be $1.5 2.0 billion in the U.S. and E.U.

Severe Acute Pancreatitis

Acute pancreatitis is the inflammation of the pancreas that results in the local release of digestive enzymes and chemicals that cause severe inflammation, necrosis and hemorrhage of the pancreas and local tissues. Approximately 210,000 people in the U.S. are hospitalized each year with acute pancreatitis with roughly 20% requiring ICU care. It is caused most frequently by a blockage of the pancreatic duct or biliary duct with gallstones, cancer, or from excessive alcohol use. Severe acute pancreatitis is characterized by severe pain, inflammation, and edema in the abdominal cavity, as well as progressive systemic inflammation, generalized edema, and multiple organ failure that is correlated with high levels of cytokines and digestive enzymes in the blood. Little can be done to treat severe acute pancreatitis today, except for pancreatic duct decompression with endoscopic techniques, supportive care therapy, pain control, enteral feeding, and fluid support. ICU stay is frequently measured in weeks and although overall ICU mortality is approximately 10%, patients with multiple organ failure have a much higher risk of death. CytoSorb® may potentially benefit overall outcomes in episodes of acute pancreatitis by removing a diverse set of toxins from blood. The total addressable market for CytoSorb® for the treatment of severe acute pancreatitis in the U.S. and E.U. is estimated to be between $400 600 million.

Cancer Cachexia and Cancer Immunotherapy

Cancer cachexia is a progressive wasting syndrome characterized by rapid weight loss, anorexia, and physical debilitation that significantly contributes to death in the majority of cancer patients. Cancer cachexia is a systemic inflammatory condition, driven by excessive pro-inflammatory cytokines and other factors, that cripples the patient s physical and immunologic reserve to fight cancer. Despite afflicting millions of patients worldwide each year, there are no effective approved treatments for cancer cachexia, with only symptomatic treatments available. CytoSorb® blood purification may stop or reverse cancer cachexia through broad reduction of cytokines and other inflammatory mediators. For example, CytoSorb® efficiently removes TNF-alpha (originally called cachectin or cachexin when first isolated in cancer cachexia patients) and other major pro-inflammatory cytokines including IL-1, IL-6, and gamma interferon that can cause cachexia. This broad immunotherapy approach may lead to improved clinical outcomes while reducing patient suffering.

In February 2014, CytoSorbents announced a research collaboration with researchers at the University of Pennsylvania School of Veterinary Medicine to evaluate the use of CytoSorb® as a treatment for cancer cachexia in

animals. Demonstrating the potential benefit of CytoSorb® therapy in animals may provide the data to begin evaluating the therapy in human cancer patients in the U.S. and Europe. CytoSorb® is approved in the European Union with a broad indication for use, allowing it to be used in any clinical situation where cytokines are elevated, including the potential treatment today of cancer related issues such as cancer cachexia. Because of this, any positive data from this collaboration could potentially be translated to human studies relatively quickly.

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The collaboration will also explore the use of CytoSorb® as a primary immunotherapy to treat cancer, or in synergy with more traditional chemotherapy or immunotherapy agents. Cancer cells have evolved ways to proliferate while confusing and evading the immune response. Many of these mechanisms rely on immunologic messages relayed by cytokines and other soluble factors that CytoSorb® has the potential to remove. In doing so, CytoSorb® may help to restore the ability of the immune system to attack cancer cells.

The total addressable market for CytoSorb for the treatment of cancer cachexia and cancer in the U.S. and E.U. is estimated to be in excess of $3 billion.

Brain-Dead Organ Donors

There are in excess of 6,000 brain dead organ donors each year in the United States; worldwide, the number of these organ donors is estimated to be at least double the U.S. brain dead organ donor population. There is a severe shortage of donor organs. Currently, there are more than 100,000 individuals on transplant waiting lists in the United States. Cytokine storm is common in these organ donors, resulting in reduced viability of potential donor organs. The potential use of CytoSorb® hemoperfusion to control cytokine storm in brain dead organ donors could increase the number of viable organs harvested from the donor pool and improve the survival of transplanted organs. A proof-of-concept pilot study using our technology in human brain dead donors has been published. In addition, CytoSorb® treatment in a porcine animal model of brain death demonstrated a reduction in cytokines as well as a preservation of cardiac function compared to untreated controls.

Blood Transfusions

The HemoDefend™ platform is designed to be a practical, low cost, and effective way to safeguard the quality and safety of the blood supply. In the United States alone, 15 million packed red blood cell (pRBC) transfusions and another 15 million transfusions of other blood products (e.g. platelet, plasma, and cryoprecipitate) are administered each year with an average of 10% of all US hospital admissions requiring a blood transfusion. The sheer volume of transfusions, not just in the US, but worldwide, complicates an already difficult task of maintaining a safe and reliable blood supply. Trauma, invasive operative procedures, critical care illnesses, supportive care in cancer, military usage, and inherited blood disorders are just some of the drivers of the use of transfused blood. In war, hemorrhage from trauma is a leading cause of preventable death, accounting for an estimated 30 40% of all fatalities. For example, in Operation Iraqi Freedom, due to a high rate of penetrating wound injuries, up to 8% of admissions required massive transfusions, defined as 10 units of blood or more in the first 24 hours. There is a clear need for a stable and safe source of blood products. However, blood shortages are common and exacerbated by the finite lifespan of blood. According to the Red Cross, packed red blood cell (pRBC) units have a refrigerated life span of 42 days. However, many medical experts believe there is an increased risk of infection and transfusion reactions once stored blood ages beyond two weeks. Transfusion-related acute lung injury (TRALI) is the leading cause of non-hemolytic transfusion-related morbidity and mortality, with an incidence of 1 in 2,000 5,000 transfusions and a mortality rate of up to 10%. Fatal cases of TRALI have been most closely related to anti-HLA or anti-granulocyte antibodies found in a donor s transfused blood. Other early transfusion reactions such as transfusion-associated dyspnea, fever and allergic reactions occur in 3 5% of all transfusions and can vary in severity depending on the patient s condition. These are caused by cytokines, bioactive lipids, free hemoglobin, toxins, foreign antigens, certain drugs, and a number of other inflammatory mediators that accumulate in transfused blood products during storage. Leukoreduction can remove the majority of white cells that can produce new cytokines but cannot eliminate those cytokines already in blood, and cannot otherwise remove other causative agents such as free hemoglobin and antibodies. Automated washing of pRBC is effective but is impractical due to the time, cost, and logistics of washing each unit of blood. The HemoDefend™ platform is a potentially superior alternative to purify blood transfusion products to these methods. The total addressable market for HemoDefend™ is more than $500 million for pRBCs alone.

Radiocontrast Removal

ContrastSorb is a development-stage blood purification technology that is being optimized for the removal of IV contrast from blood in order to prevent contrast-induced nephropathy (CIN). Contrast-induced nephropathy is the acute loss of renal function within the first 48 hours following IV contrast administration. IV contrast is

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

DrugSorb