

Cytosorbents Corp  
Form S-1/A  
December 08, 2014

As filed with the Securities and Exchange Commission on December 8, 2014

**Registration No. 333-199762**

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

**AMENDMENT NO. 2 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**

Edgar Filing: Cytosorbents Corp - Form S-1/A

(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:

David C. Schwartz, Esq.  
DLA Piper LLP (US)  
51 John F. Kennedy Parkway, Suite 120  
Short Hills, New Jersey 07078  
Tel No.: (973) 520-2550  
Fax No.: (973) 520-2557

**Robert E. Puopolo, Esq.**  
Goodwin Procter LLP  
53 State Street  
Boston, Massachusetts 02109  
Tel No.: (617) 570-1000  
Fax No.: (617) 523-1231

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.

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

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

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

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

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

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company



TABLE OF CONTENTS**CALCULATION OF REGISTRATION FEE**

Title of Each Class Of Securities to be Registered	Amount to Be Registered	Proposed Maximum Aggregate Offering Price per share	Proposed Maximum Aggregate Offering Price	Amount of Registration fee <sup>(1)(5)</sup>
Common Stock, \$0.001 par value per share <sup>(2)</sup>	2,300,000	\$ 5.50	\$12,650,000	\$ 1,470
Underwriter Warrants to purchase Common Stock <sup>(4)</sup>			\$ (3)	\$ (3)
Common Stock issuable upon exercise of Underwriter Warrants <sup>(2)</sup>	60,000	\$ 6.60	\$396,000	\$46
Total Registration Fee			\$13,046,000	\$ 1,516

- (1) Calculated pursuant to Rule 457(o) on the basis of the maximum aggregate offering price of all of the securities to be registered. The Company reserves the right to issue a lower amount of securities and/or a lower offering price. Pursuant to Rule 416 under the Securities Act of 1933, this registration statement shall be deemed to cover the additional securities (i) to be offered or issued in connection with any provision of any securities purported to be registered hereby to be offered pursuant to terms which provide for a change in the amount of securities being offered or issued to prevent dilution resulting from stock splits, stock dividends, or similar transactions and (ii) of the same class as the securities covered by this registration statement issued or issuable prior to completion of the distribution of the securities covered by this registration statement as a result of a split of, or a stock dividend on, the registered securities.

(3) No registration fee required pursuant to Rule 457(g) under the Securities Act.

- 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 Brean Capital, LLC and H.C. Wainwright & Co., LLC for nominal consideration. Resales of the Underwriter Warrants on a delayed or
- (4) 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. See Underwriting.

(5) Registrant previously paid \$2,324 with the Form S-1 filed on October 31, 2014.

**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.**

TABLE OF CONTENTS

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 December 8, 2014***

**CYTOSORBENTS CORPORATION**

2,000,000 SHARES OF COMMON STOCK

We are offering 2,000,000 shares of our common stock. The offering price per share is \$ .

Our common stock is presently quoted on the OTCQB Marketplace, operated by the OTC Markets Group, Inc., or OTCQB, under the symbol CTSOD (until on or about January 4, 2015) and CTSO (beginning on or about January 5, 2015). On December 5, 2014, the last reported sale price of our common stock on the OTCQB was \$5.50 per share. We have applied to list our common stock on the NASDAQ Capital Market ( NASDAQ ) under the symbol CTSO.

**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 <sup>(1)</sup>	\$	\$
Proceeds to Us (Before Expenses)	\$	\$

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

The delivery of the shares is expected to be made on or about , 2014. We have granted the underwriters an

option for a period of 30 days to purchase up to a total of 300,000 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 \_\_\_\_\_, 2014.

*Joint Book Running Managers*

BREAN CAPITAL

**H.C. WAINWRIGHT & CO.**  
*Co-Managers*

MERRIMAN CAPITAL

MLV & CO.

WBB SECURITIES

---

TABLE OF CONTENTS

**TABLE OF CONTENTS**

	Page
<u>Prospectus Summary</u>	<u>1</u>
<u>Risk Factors</u>	<u>8</u>
<u>Use of Proceeds</u>	<u>18</u>
<u>Dilution</u>	<u>19</u>
<u>Description of Business</u>	<u>20</u>
<u>Description of Property</u>	<u>55</u>
<u>Legal Proceedings</u>	<u>55</u>
<u>Market for Common Equity and Related Stockholder Matters</u>	<u>56</u>
<u>Management's Discussion and Analysis of Financial Conditions and Results of Operations</u>	<u>58</u>
<u>Changes in and Disagreements with Accountants on Accounting And Financial Disclosure</u>	<u>66</u>
<u>Directors, Executive Officers and Corporate Governance</u>	<u>67</u>
<u>Executive Compensation</u>	<u>70</u>
<u>Certain Relationships and Related Transactions</u>	<u>74</u>
<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>75</u>
<u>Description of Securities</u>	<u>79</u>
<u>Underwriting</u>	<u>86</u>
<u>Index to Financial Statements</u>	<u>F-1</u>
<u>Other Expenses of Issuance and Distribution</u>	<u>II-1</u>
<u>Indemnification of Directors and Officers</u>	<u>II-1</u>
<u>Recent Sales of Unregistered Securities</u>	<u>II-1</u>
<u>Exhibits and Financial Statement Schedules</u>	<u>II-2</u>
<u>Undertakings</u>	<u>II-4</u>

TABLE OF CONTENTS

## PROSPECTUS SUMMARY

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

### Overview

#### 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.

1

---

## TABLE OF CONTENTS

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 expand 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.

TABLE OF CONTENTS

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 Materiel 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.



TABLE OF CONTENTS

## **Recent Corporate Actions**

We have applied to list our Common Stock on the NASDAQ Capital Market 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.

## **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

Edgar Filing: Cytosorbents Corp - Form S-1/A

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.

TABLE OF CONTENTS

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 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.



TABLE OF CONTENTS

## 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**

2,000,000 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 300,000 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**

25,284,040 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.

Given that there is no minimum offering size of this Offering, it is possible that we could receive significantly less than the \$11 million targeted in the Offering. 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**

Our common stock is presently quoted on the OTCQB Marketplace, operated by the OTC Markets Group, Inc., (OTCQB), under the symbol CTSOD (until on or about January 4, 2015) and CTSO (beginning on or about January 5, 2015). On December 5, 2014, the last reported sale price of our common stock on the OTCQB was \$5.50 per share. We have applied to list our common stock on the NASDAQ Capital



TABLE OF CONTENTS

Market ( NASDAQ ) under the symbol CTSO. There can be no assurances our common stock will be accepted for listing on the NASDAQ Capital Market.

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.

7

---

TABLE OF CONTENTS

## **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

TABLE OF CONTENTS

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 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 October 20, 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 there can be no assurance that they will continue to provide services to us. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Management and other employees may voluntarily terminate their employment with us at any time. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources.

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

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

We have a history of losses and expect to incur substantial future losses, and the report of our auditor on our consolidated

in a timely manner.

9

---

TABLE OF CONTENTS

**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

TABLE OF CONTENTS

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 involves

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

TABLE OF CONTENTS

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.

TABLE OF CONTENTS

**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

TABLE OF CONTENTS

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 5, 2014 the closing price of our common stock, as reported on the OTCQB was \$5.50. 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 applied for listing on the NASDAQ Capital Market under the symbol CTSO, there is no assurance that we will be approved for listing on the NASDAQ Capital Market and that the price of our stock will not continue to be volatile 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

TABLE OF CONTENTS

stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets and also could prevent or cause a change in control. The interests of these stockholders may differ from the interests of our other stockholders. Third parties may be discouraged from making a tender offer or bid to acquire us because of this concentration of ownership.

**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. As a result, on December 5, 2014 the closing price of our common stock, as reported on the OTCQB was \$5.50. We have applied to list our common stock on the NASDAQ Capital Market, but there can be no assurances that our stock will be accepted for listing. To the extent the price of our common stock trades below \$5.00 per share, our common stock will be subject to Rule 15c-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.**

Edgar Filing: Cytosorbents Corp - Form S-1/A

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 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;

TABLE OF CONTENTS

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

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

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, 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.

**Our Common Stock is thinly traded on the OTCQB, and we may be unable to obtain listing of our Common Stock on a more liquid market.**

Our Common Stock is 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). We have applied to list our Common Stock on the NASDAQ Capital Market, but we cannot be certain that we will be accepted for a listing on the NASDAQ Capital Market.

TABLE OF CONTENTS

## **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.

TABLE OF CONTENTS

## **USE OF PROCEEDS**

We estimate that we will receive up to \$11,000,000 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 \$10,130,000. 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 \$1.88 million.

We intend to use the net proceeds as follows:

approximately \$5,000,000 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 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 \$11,000,000, we would apply the funds as stated above but would also need to raise additional funding to complete our business goals. We do not know the amounts or source of the funds and will be required to attempt additional financing.

TABLE OF CONTENTS**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 \$5.50 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 \$17,785,000, or \$0.70 per share after giving effect to our December 3, 2014 twenty-five-for-one reverse split 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 \$0.37 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	\$ 5.50
Net tangible book value per share as of September 30, 2014	\$ 0.33
Increase per share attributable to sale of shares to investors	\$ 0.37
As adjusted net tangible book value per share after the Offering	\$ 0.70
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.



TABLE OF CONTENTS

## **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.

## TABLE OF CONTENTS

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 expand the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. We are currently organizing a pivotal trial in the U.S. using CytoSorb® during cardiac surgery 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.

ContrastSorb a development-stage extracorporeal hemoperfusion cartridge designed to remove

21

---

## TABLE OF CONTENTS

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 Materiel 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

TABLE OF CONTENTS

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.



TABLE OF CONTENTS

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.

TABLE OF CONTENTS

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

Edgar Filing: Cytosorbents Corp - Form S-1/A

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 ;

25

---

TABLE OF CONTENTS

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.

Edgar Filing: Cytosorbents Corp - Form S-1/A

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.

26

---

## TABLE OF CONTENTS

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**

We have applied to list our Common Stock on the NASDAQ Capital Market 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.

### **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

27

---



## TABLE OF CONTENTS

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 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

## TABLE OF CONTENTS

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.

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

TABLE OF CONTENTS

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 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

30

---

## TABLE OF CONTENTS

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 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



## TABLE OF CONTENTS

hospital stay for burn patients is directly correlated with the percent total body surface area (TBSA) burned. Every 1% increase of TBSA burned equates to approximately 1 additional day in the hospital. A single patient with more than 30% TBSA burned who survives, is hospitalized for an average of 30 days and costs approximately \$200,000 to treat.

Major causes of death following severe burn and smoke inhalation injury are multi-organ failure (hemodynamic shock, respiratory failure, acute renal failure) and sepsis, particularly in patients with greater than 30% TBSA burns. Specifically, burns and inhalation injury lead to severe systemic and localized lung inflammation, loss of fluid, and cytokine overproduction. This cytokine storm causes numerous problems, including: hypovolemic shock and inadequate oxygen and blood flow to critical organs, acute respiratory distress syndrome preventing adequate oxygenation of blood, capillary leakage resulting in tissue edema and intravascular depletion, hypermetabolism leading to massive protein degradation and catabolism and yielding increased risk of infection, impaired healing, severe weakness and delayed recovery, immune dysfunction causing a higher risk of secondary infections (wound infections, pneumonia) and sepsis, and direct apoptosis and cell-mediated killing of cells, leading to organ damage.

Up to a third of severe hospitalized burn patients develop multi-organ failure and sepsis that can often lead to complicated, extended hospital courses, or death. Broad reduction of cytokine storm has not been previously feasible and represents a novel approach to limiting or reversing organ failure, potentially enabling more rapid mechanical ventilation weaning, prevention of shock, reversal of the hypermetabolic state encouraging faster healing and patient recovery, reducing hospital costs, and potentially improving survival. The total addressable market in the E.U. for CytoSorb to address burn and smoke inhalation injury is estimated at \$150 - 350 million and \$300 - 600 million in the U.S and E.U.

### Trauma

According to the National Center for Health Statistics, in the U.S., there are more than 31 million visits to hospital emergency rooms, with 1.9 million hospitalizations, and 167,000 deaths every year due to injury. The leading causes of injury are trauma from motor vehicle accidents, being struck by an object or other person, and falls. Trauma is a well-known trigger of the immune response and a surge of cytokine production or cytokine storm. In trauma, cytokine storm contributes to a systemic inflammatory response syndrome (SIRS) and a cascade of events that cause cell death, organ damage, organ failure and often death. Cytokine storm exacerbates physical trauma in many ways. For instance, trauma can cause hypovolemic shock due to blood loss, while cytokine storm causes capillary leak and intravascular volume loss, and triggers nitric oxide production that causes cardiac depression and peripheral dilation. Shock can lead to a lack of oxygenated blood flow to vital organs, causing organ injury. Severe systemic inflammation and cytokine storm can lead to acute lung injury and acute respiratory distress syndrome as is often seen in ischemia and reperfusion injury following severe bleeding injuries. Penetrating wound injury from bullets, shrapnel and knives, can lead to infection and sepsis, another significant cause of organ failure in trauma. Complicating matters is the breakdown of damaged skeletal muscle, or rhabdomyolysis, from blunt trauma that can lead to a massive release of myoglobin into the blood that can crystallize in the kidneys, leading to acute kidney injury and renal failure. Renal failure in trauma is associated with a significant increase in expected mortality. Cytokine and myoglobin reduction by CytoSorb® and related technologies may have benefit in trauma, potentially improving clinical outcome. In December 2011 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

## TABLE OF CONTENTS

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.

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

## TABLE OF CONTENTS

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

### DrugSorb

DrugSorb is a development-stage blood purification technology that is capable of removing a wide variety of drugs and chemicals from blood, as a potential treatment for drug overdose, drug toxicity, toxic chemical exposure, use in

high-dose regional chemotherapy, and other applications. It has demonstrated extremely high single pass removal efficiency of a number of different drugs that exceeds the extraction capability of hemodialysis or other filtration technologies. It is similar in action to activated charcoal hemoperfusion cartridges that have been available for many years, but has the advantage of having inherent biocompatibility and hemocompatibility without coatings, and can be easily customized for specific agents.

## TABLE OF CONTENTS

### Chronic Kidney Failure

The National Kidney Foundation estimates that more than 20 million Americans have chronic kidney disease. Left untreated, chronic kidney disease can ultimately lead to chronic kidney failure, which requires a kidney transplant or chronic dialysis (generally three times per week) to sustain life. There are more than 340,000 patients in the United States currently receiving chronic dialysis and more than 1.5 million worldwide. Approximately 66% of patients with chronic kidney disease are treated with hemodialysis. One of the problems with standard high-flux dialysis is the limited ability to remove certain mid-molecular weight toxins such as b2-microglobulin. Over time, b2-microglobulin can accumulate and cause amyloidosis in joints and elsewhere in the musculoskeletal system, leading to pain and disability. Our BetaSorb™ device has been designed to remove these mid-molecular weight toxins when used in conjunction with standard dialysis. Standard dialysis care typically involves three sessions per week, averaging approximately 150 sessions per year.

## **Products**

The polymer adsorbent technology used in our products can remove middle molecular weight toxins, such as cytokines, from blood and physiologic fluids. All of the potential applications described below (i.e., the adjunctive treatment and/or prevention of sepsis; the adjunctive treatment and/or prevention of other critical care conditions such as acute respiratory distress syndrome, burn injury, trauma and pancreatitis; the prevention of damage to organs donated by brain-dead donors prior to organ harvest; the prevention of post-operative complications of cardiopulmonary bypass surgery; the prevention of kidney injury from IV contrast; and the treatment of chronic kidney failure) share in common high concentrations of toxins in the circulating blood. However, because of the limited studies we have conducted to date, we are subject to substantial risk that our technology will have little or no effect on the treatment of any of these indications. In 2011 we completed our European Sepsis Trial of our CytoSorb® device. The study was a randomized, open label, controlled clinical study in fourteen (14) sites in Germany of one hundred (100) critically ill patients with predominantly septic shock and respiratory failure. The trial successfully demonstrated CytoSorb®'s ability to reduce circulating levels of key cytokines from whole blood by 30 - 50% in treated patients, and that treatment was safe in these critically-ill patients with multiple organ failure. We completed the CytoSorb® technical file review with our Notified Body and CytoSorb® subsequently received European Union regulatory approval under the CE Mark as an extracorporeal cytokine filter indicated for use in any clinical situation where cytokines are elevated. Given sufficient and timely financial resources, we intend to continue to commercialize in Europe and conduct additional clinical studies of our products. However, there can be no assurance that we will ever obtain regulatory approval for any other device, or that the CytoSorb® device will be able to generate significant sales.

### The CytoSorb® Device (Critical Care)

*APPLICATION: Adjunctive Therapy in the Treatment of Sepsis.*

Sepsis is a potentially life threatening disease defined as a systemic inflammatory response in the presence of a known or suspected infection. Sepsis is mediated by high levels of toxic compounds ( cytokines ), which are released into the blood stream as part of the body's auto-immune response to severe infection or injury. These toxins cause severe inflammation and damage healthy tissues, which can lead to organ dysfunction and failure. Sepsis is very expensive to treat and has a high mortality rate.

Potential Benefits: To the extent our adsorbent blood purification technology is able to prevent or reduce the accumulation of cytokines in the circulating blood, we believe our products may be able to prevent or mitigate severe

inflammation, organ dysfunction and failure in sepsis patients. Therapeutic goals as an adjunctive therapy include reduced ICU and total hospitalization time.

Background and Rationale: We believe that the effective treatment of sepsis is the most valuable potential application for our technology. Severe sepsis (sepsis with organ dysfunction) and septic shock (severe sepsis with persistent hypotension despite fluid resuscitation) carries mortality rates of between 28% and 80%. Death can occur within hours or days, depending on many variables, including cause, severity, patient age and co-morbidities. Researchers estimate that there are approximately one million new cases of sepsis in the



TABLE OF CONTENTS

U.S. each year; and based on the reported incidence in a number of developed countries, the worldwide incidence is estimated to be 18 million cases annually. The incidence of sepsis is also rising due to:

- 1) An aging population
- 2) Increased incidence of antibiotic resistance
- 3) Increase in co-morbid conditions like cancer and diabetes
- 4) Increased use of indwelling medical devices that are susceptible to infection

In the U.S. alone, treatment of sepsis costs nearly \$18 billion annually. According to the Centers for Disease Control, sepsis is a top ten cause of death in the U.S. The incidence of sepsis is believed to be under-reported as the primary infection (i.e., pneumonia, pyelonephritis, etc.) is often cited as the cause of death.

An effective treatment for sepsis has been elusive. Pharmaceutical companies have been trying to develop drug therapies to treat the condition. With the exception of a single biologic, Xigris® from Eli Lilly, to our knowledge, no other products have been approved in either the U.S. or Europe for the treatment of sepsis.

Many medical professionals believe that blood purification for the treatment of sepsis holds tremendous promise. Studies using dialysis and hemofiltration technology have been encouraging, but have only had limited benefit to sepsis patients. The reason for this appears to be rooted in a primary limitation of dialysis technology itself: the inability of standard dialysis to effectively and efficiently remove significant quantities of larger toxins such as cytokines from circulating blood. CytoSorb® has demonstrated the ability to safely reduce key cytokines by 30-50% in septic patients with multiple-organ failure in our European Sepsis Trial.

CytoSorb®'s ability to interact safely with blood (hemocompatibility) has been demonstrated through ISO 10993 testing, which includes testing for hemocompatibility, biocompatibility, cytotoxicity, genotoxicity, acute sensitivity and complement activation. Safety data collected from more than 300 treatments in septic patients, where there have been no serious device related adverse events, provide additional evidence that CytoSorb® treatment is safe in this patient population.

CytoSorb® has been designed to achieve broad-spectrum removal of both pro- and anti-inflammatory cytokines, preventing or reducing the accumulation of high concentrations in the bloodstream. This approach is intended to modulate the immune response without causing damage to the immune system. For this reason, researchers have referred to the approach reflected in our technology as immunomodulatory therapy.

Projected Timeline: In 2011, the CytoSorb® filter received European Union regulatory approval under the CE Mark as an extracorporeal cytokine filter to be used in clinical situations where cytokines are elevated. CytoSorbents manufacturing facility has also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the European Union. We are currently manufacturing our CytoSorb® device for commercial sale in the European Union. CytoSorbents is currently selling CytoSorb® in Germany, Austria, and Switzerland with a direct sales force. Based on its CE Mark approval, CytoSorb® can also be sold throughout all 28 countries of the European Union and countries outside the E.U. that will accept European regulatory approval. With sufficient resources and continued positive clinical data, assuming availability of adequate and timely funding, and continued positive results from our clinical studies, we intend to continue its commercialization plans of its product in Europe as well as pursue U.S. clinical trials to seek FDA regulatory approval for CytoSorb® in the United States.

*APPLICATION: Adjunctive Therapy in Other Critical Care Applications.*

Potential Benefits: Cytokine-mediated organ damage and immune suppression can increase the risk of death and infection in patients with commonly seen critical care illnesses such as acute respiratory distress syndrome, severe burn injury, trauma and pancreatitis. If CytoSorb® is useful as a cytokine filter and as an immunomodulator, cytokine reduction, both pro-inflammatory and anti-inflammatory, has the potential to:

prevent or mitigate Multiple Organ Dysfunction Syndrome (MODS) and/or Multiple Organ Failure (MOF)

36

---

TABLE OF CONTENTS

prevent or reduce secondary infections

reduce the need for expensive life-sparing supportive care therapies such as mechanical ventilation  
reduce the need for ICU care, freeing expensive critical care resources, and reducing hospital costs and costs to the healthcare system

**Background and Rationale:** A shared feature of many life-threatening conditions seen in the ICU is severe inflammation (either sepsis or systemic inflammatory response syndrome) due to an over-reactive immune system and high levels of cytokines that can cause or contribute to organ dysfunction, organ failure and patient death. Examples of such conditions include severe burn injury, trauma, acute respiratory distress syndrome and severe acute pancreatitis. MODS and MOF are common causes of death in these illnesses and mortality is directly correlated with the number of organs involved. There are currently few active therapies to prevent or treat MODS or MOF. If CytoSorb® can reduce direct or indirect cytokine injury of organs, it may mitigate MODS or MOF, improve overall patient outcome and reduce costs of treatment. In addition, secondary infection, such as ventilator-acquired pneumonia, urinary tract infections, or catheter-related line infections, are another major cause of morbidity and mortality in all patients treated in the ICU. Prolonged illness, malnutrition, age, multiple interventional procedures, and exposure to antibiotic resistant pathogens are just some of the many risk factors for functional immune suppression and infection. In sepsis and SIRS, the overexpression of pro-inflammatory cytokines can also cause a depletion of immune effector cells through apoptosis and other means, and anti-inflammatory cytokines can cause profound immune suppression, both major risk factors for infection.

**Projected Timeline:** CytoSorb's E.U. CE Mark approval as an extracorporeal cytokine filter and its broad approved indication to be used in any clinical situation where cytokines are elevated, allows it to be used on label in critical care applications such as acute respiratory distress syndrome, severe burn injury, trauma, liver failure, and pancreatitis, and in other conditions where cytokine storm, sepsis and/or systemic inflammatory response syndrome (SIRS) plays a prominent role in disease pathology. Our goal is to stimulate investigator-initiated clinical studies with our device for these applications. Currently, we have more than 40 investigator initiated studies being planned in Germany, Austria, and the United Kingdom, many of which are currently enrolling patients. We have been moving forward in parallel with a program to further understand the potential benefit of CytoSorb® hemoperfusion in these conditions through additional investigational animal studies and potential human pilot studies in the U.S. funded either directly by us, through grants, or through third-parties. We have previously noted that the U.S. Air Force is funding a 30-patient randomized controlled trial in human trauma patients with rhabdomyolysis that has been approved to start by the FDA under an IDE (investigational device exemption) approval. Commencement of these and other formal studies is contingent upon adequate funding and, in the case of U.S. human studies, FDA investigational device exemption (IDE) approval of the respective human trial protocols.

**APPLICATION:** *Prevention and treatment of post-operative complications of cardiopulmonary bypass surgery.*

**Potential Benefits:** If CytoSorb® is able to prevent or reduce high-levels of cytokines from accumulating in the blood system during and following cardiac surgery, we anticipate that post-operative complications of cardiopulmonary bypass surgery may be able to be prevented or mitigated. The primary goals for this application are to:

- reduce ventilator and oxygen therapy requirements;
- reduce post-operative complications such as ARDS, acute kidney injury, post-perfusion syndrome;
- reduce length of stay in hospital intensive care units; and
- reduce the total cost of patient care.

**Background and Rationale:** Due to the highly invasive nature of cardiopulmonary bypass surgery, high levels of cytokines are produced by the body, triggering severe inflammation. In addition, hemolysis of red blood cells frequently occurs, resulting in the release of free hemoglobin into the bloodstream. These inflammatory mediators can lead to post-operative complications. CytoSorb® is the only cytokine reduction technology



## TABLE OF CONTENTS

approved in the E.U. that can be used intraoperatively in a bypass circuit in a heart-lung machine without the need for another machine. If our products are able to prevent or reduce the accumulation of cytokines or free hemoglobin in a patient's blood stream, we may be able to prevent or mitigate post-operative complications caused by an excessive or protracted inflammatory response to the surgery. Intra-operative use of CytoSorb® on high risk cardiac surgery patients, where the risk of post-operative complications is the highest, is expected to be the main initial target market.

The use of CytoSorb® in the post-operative period to treat post-operative SIRS is another application of the technology.

**Projected Timeline:** We commissioned the University of Pittsburgh to conduct a study to characterize the production of cytokines as a function of the surgical timeline for cardiopulmonary bypass surgery. An observational study of 32 patients was completed, and information was obtained with respect to the onset and duration of cytokine release.

Cardiac surgeons and cardiac perfusionists in Germany and Austria have now used CytoSorb® successfully intra-operatively and post-operatively on cardiac surgery patients. This application is also the subject of more than 8 investigator-initiated studies in Germany and Austria. With sufficient resources, we plan to conduct additional clinical studies in cardiac surgery patients in the near future.

*APPLICATION: Prevention and treatment of organ dysfunction in brain-dead organ donors to increase the number and quality of viable organs harvested from donors.*

**Potential Benefits:** If CytoSorb® is able to prevent or reduce high-levels of cytokines from accumulating in the bloodstream of brain-dead organ donors, we believe CytoSorb® may be able to mitigate organ dysfunction and failure, which results from severe inflammation following brain-death. The primary goals for this application are:

improving the viability of organs which can be harvested from brain-dead organ donors, and increasing the likelihood of organ survival following transplant.

**Background and Rationale:** When brain death occurs, the body responds by generating large quantities of inflammatory cytokines. This process is similar to systemic inflammatory response syndrome and sepsis. A high percentage of donated organs are never transplanted due to this response, which damages healthy organs and prevents transplant. In addition, inflammation in the donor may damage organs that are harvested and reduce the probability of graft survival following transplant. CytoSorb® treatment in a porcine animal model of brain death demonstrated a reduction in cytokines as well as a preservation of cardiac function compared to untreated controls.

There is a shortage of donated organs worldwide, with approximately 100,000 people currently on the waiting list for organ transplants in the United States alone. Because there are an insufficient number of organs donated to satisfy demand, it is vital to maximize the number of viable organs donated, and optimize the probability of organ survival following transplant.

**Projected Timeline:** Studies have been conducted under a \$1 million grant from the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services. Researchers at the University of Pittsburgh Medical Center and the University of Texas, Houston Medical Center have completed the observational and dosing phases of the project. The results were published in Critical Care Medicine, January 2008. The next phase of this study, the treatment phase, would involve viable donors treated with the CytoSorb® device. In this phase of the project, viable donors will be treated and the survival and function of organs in transplant recipients will be tracked and measured. The treatment phase would be contingent upon further discussion with the FDA and HRSA regarding study design, as well as obtaining additional funding.

The HemoDefend Blood Purification Technology Platform (Acute and Critical Care)

*APPLICATION: Reduction of contaminants in the blood supply that can cause transfusion reactions or disease when administering blood and blood products to patients.*

Potential Benefits: The HemoDefend blood purification technology platform is designed to reduce contaminants in the blood supply that can cause transfusion reactions or disease. It is a development stage

## TABLE OF CONTENTS

technology that is not yet approved in any markets, but is comprised of CytoSorbents highly advanced, biocompatible, polymer bead technology. If this technology is successfully developed and then incorporated into a regulatory approved product, it could have a number of important benefits.

reduce the risk of transfusion reactions and improve patient outcome  
improve the quality, or extend the shelf life of stored blood products  
improve the availability of blood and reduce blood shortages by reducing the limitations of donors to donate blood  
allow easier processing of blood

**Background and Rationale:** The HemoDefend technology platform was built upon our successes in designing and manufacturing porous polymer beads that can remove cytokines. We have expanded the technology to be able to remove substances as small as drugs and bioactive lipids, to proteins as large as antibodies from blood that can cause transfusion reactions and disease. Although the frequency of these reactions are relatively low (~3-5%), the sheer number of blood transfusions is so large, that the number of transfusion reactions, ranging from mild to life-threatening, is substantial, ranging from several hundreds of thousands to more than a million reactions each year in the U.S. alone. In critically-ill patients the risk of transfusion reactions is significantly higher than in the general population and can increase the risk of death because their underlying illnesses have depleted protective mechanisms and have primed their bodies to respond more vigorously to transfusion-associated insults.

A number of retrospective studies have also suggested that administration of older blood leads to increased adverse events and even increased mortality, compared with blood recently harvested. Biological studies have demonstrated the accumulation of erythrocyte storage lesions that compromise the function and structural integrity of packed red blood cells and have also demonstrated the accumulation of substances during blood storage that can lead to transfusion reactions. There are currently two complete and one ongoing adult, prospective, randomized, controlled studies, RECESS, ABLE, and TRANSFUSE looking at morbidity and mortality in cardiovascular surgery patients, critically ill patients, and critically ill patients, respectively, treated with either new or fresh or older blood. The outcome of these studies should not alter the current pressing need for better solutions to reduce transfusion-related adverse events and to improve clinical outcome. However, should they demonstrate that older blood has increased risk, it could result in an increased need for new technologies such as the HemoDefend™ platform. The preliminary results of the RECESS trial, giving new blood (10 days) versus older blood (21 days old) to 1,098 evaluable complex cardiac surgery patients, were recently announced and showed no difference in multiple organ dysfunction score (MODS) or mortality between patients getting new versus old blood. The incidence of serious adverse events was approximately 50% in both arms of the trial. We await the final paper and subgroup analyses as well as data from the completed ABLE trial.

**Projected Timeline:** The HemoDefend™ platform is a development stage product based on our advanced polymer technology. The base polymer is ISO 10993 biocompatible, meeting standards for biocompatibility, hemocompatibility, cytotoxicity, genotoxicity, acute sensitivity and complement activation. HemoDefend™ has demonstrated the *in vitro* removal of many different substances from blood such as antibodies, free hemoglobin, cytokines and bioactive lipids. We have also prototyped a number of different implementations of the HemoDefend™ technology, including the Beads in a Bag blood treatment blood storage bag, and standard in-line blood filters. We seek to out-license this technology to a strategic partner in the transfusion medicine space, but may elect to continue our development in parallel with out-licensing efforts.

### **ContrastSorb (Radiology and Interventional Radiology)**

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

Potential Benefits: IV contrast can lead to contrast-induced nephropathy (CIN) in susceptible patients. Risk factors include chronic kidney disease and renal insufficiency caused by age, diabetes, congestive heart failure,



## TABLE OF CONTENTS

long-standing hypertension, and others co-morbid illnesses. CIN can lead to increased risk of patient morbidity and mortality. Removal of IV contrast by ContrastSorb may:

reduce the risk of acute kidney injury

improve the safety of these procedures and reduce the risk of morbidity and mortality

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

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

### The BetaSorb™ Device (Chronic Care)

*APPLICATION: Prevention and treatment of health complications caused by the accumulation of metabolic toxins in patients with chronic renal failure.*

**Potential Benefits:** If BetaSorb™ is able to prevent or reduce high levels of metabolic waste products from accumulating in the blood and tissues of long-term dialysis patients, we anticipate that the health complications characteristic to these patients can be prevented or mitigated. The primary goals for this application are to:

improve and maintain the general health of dialysis patients;  
reduce disability and improve the quality of life of these patients;  
reduce the total cost of patient care; and  
increase life expectancy.

**Background and Rationale:** Our BetaSorb™ device is intended for use on patients suffering from chronic kidney failure who rely on long-term dialysis therapy to sustain life. Due to the widely recognized inability of dialysis to remove larger proteins from blood, metabolic waste products, such as Beta-2 microglobulin, accumulate to toxic levels and are deposited in the joints and tissues of patients. Specific toxins known to accumulate in these patients have been linked to their severe health complications, increased healthcare costs, and reduced quality of life.

Researchers also believe that the accumulation of toxins may play an important role in the significantly reduced life expectancy experienced by dialysis patients. In the U.S., the average life expectancy of a dialysis patient is five years.

Industry research has identified links between many of these toxins and poor patient outcomes. If our BetaSorb™ device is able to routinely remove these toxins during dialysis and prevent or reduce their accumulation, we expect our

BetaSorb™ device to maintain or improve patient health in the long-term. We believe that by reducing the incidence of health complications, the annual cost of patient care will be reduced and life expectancy increased.

## TABLE OF CONTENTS

The poor health experienced by chronic dialysis patients is illustrated by the fact that in the U.S. alone, more than \$20 billion is spent annually caring for this patient population. While the cost of providing dialysis therapy alone is approximately \$23,000 per patient per year, the total cost of caring for a patient ranges from \$60,000 to more than \$120,000 annually due to various health complications associated with dialysis.

**Projected Timeline:** We have collected a significant amount of empirical data for the development of this application. As the developer of this technology, we had to undertake extensive research, as no comparable technology was available for reference purposes. We have completed four human pilot studies, including a clinical pilot of six patients in California for up to 24 weeks in which our BetaSorb™ device removed the targeted toxin, beta2-microglobulin, as expected. In total, we have sponsored clinical studies utilizing our BetaSorb™ device on 20 patients involving approximately 345 total treatments. Each study was conducted by a clinic or hospital personnel with CytoSorbents providing technical assistance as requested.

As discussed above, due to practical and economic considerations, we are focusing our efforts and resources on commercializing our CytoSorb® device for critical care applications. Following commercial introduction of the CytoSorb® device, and with sufficient additional resources, we plan to continue development of the BetaSorb™ resin and may conduct additional clinical studies using the BetaSorb™ device in the treatment of end stage renal disease patients.

## **Commercial and Research Partners**

### University of Pittsburgh Medical Center

Two government research grants by the National Institutes of Health (NIH) and Health and Human Services (HHS) have been awarded to investigators at the University of Pittsburgh to explore the use of adsorbent polymers in the treatment of sepsis and organ transplant preservation. Under Sub Award Agreements with the University of Pittsburgh, we have been developing polymers for use in these studies.

A grant of \$1 million was awarded to the University of Pittsburgh Medical Center in 2003. The project seeks to improve the quantity and viability of organs donated for transplant by using CytoSorb® to detoxify the donor's blood.

The observational and dosing phases of the study, involving 30 viable donors and eight non-viable donors, respectively, have been completed. The next phase of this study, the treatment phase, will involve viable donors. We are not currently focusing our efforts on the commercialization of CytoSorb® for application in organ donors. The treatment phase would be contingent upon further discussion with the FDA and HRSA regarding study design, as well as obtaining additional funding.

In addition, in September 2005, the University of Pittsburgh Medical Center was awarded a grant of approximately \$7 million from NIH entitled Systems Engineering of a Pheresis Intervention for Sepsis (SEPSIS) to study the use of adsorbent polymer technology in the treatment of severe sepsis. The study, which lasted for a total of five years, commenced in September 2005. Under a SubAward Agreement, we worked with researchers at the University of Pittsburgh Critical Care Medicine Department. We believe that the only polymers used in this study were polymers we have developed specifically for use in the study, which are similar to the polymers used in our devices. Under the SubAward Agreement, for our efforts in support of the grant during 2006 through 2010, we received approximately \$402,000.

These grants represent a substantial research cost savings to us and demonstrate the strong interest of the medical and scientific communities in our technology.

Researchers at UPMC have participated in nearly every major clinical study of potential sepsis intervention during the past twenty years. Drs. Derek Angus and John Kellum were investigators for Eli Lilly's sepsis drug, Xigris®. Dr. Kellum, a member of the UPMC faculty since 1994, is the Chairman of our Severe Sepsis and Inflammatory Disease Advisory Board. Dr. Kellum's research interests span various aspects of Critical Care Medicine, but center on critical care nephrology (including acid-base, and renal replacement therapy), sepsis and multi-organ failure, and clinical epidemiology. He is Chairman of the Fellow Research Committee at the University of Pittsburgh Medical Center, has authored more than 300 publications and has received numerous research grants from foundations and industry.

## TABLE OF CONTENTS

### DARPA

In August 2012, the Defense Advanced Research Projects Agency (DARPA) awarded CytoSorbents a five-year technology development contract valued at \$3.8 million as part of its Dialysis-Like Therapeutics (DLT) program to treat sepsis. DARPA has been instrumental in funding many of the major technological and medical advances since its inception in 1958, including development of the Internet, the GPS, and robotic surgery. The DLT program in sepsis seeks to develop a therapeutic blood purification device that is capable of identifying the cause of sepsis (e.g., cytokines, toxins, pathogens, activated cells) and remove these substances in an intelligent, automated, and efficient manner. DARPA is funding CytoSorbents to further develop its technologies to remove both cytokines and a variety of toxins (e.g., pathogen-derived, naturally occurring, or biowarfare generated). In 2013 and 2012, CytoSorbents recognized approximately \$1.1 and \$1.1 million in grant income following the successful completion of milestones under its contract.

### United States Army

In December 2011 and September 2012, The US Army Medical Research and Material Command awarded CytoSorbents a \$100,000 Phase I SBIR (Small Business Innovation Research), and a \$1 million Phase II SBIR contract, respectively, to develop our technologies for the treatment of trauma and burn injury. During 2012, we received the full amount of the Phase I SBIR contract and in 2013 we recognized half of the approximately \$753,000 awarded under the Phase II SBIR contract with the granting agency.

### Fresenius Medical Care AG

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

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

Fresenius Medical Care is also the world's largest provider of dialysis products, such as hemodialysis machines, dialyzers and related disposable products.

### Advisory Boards

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

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

Our Sepsis Advisory Board consists of four medical doctors, one of whom is affiliated with UPMC, with expertise in critical care medicine, sepsis, multi-organ failure and related clinical study design.

Our Cardiac Advisory Board consists of seven medical doctors with deep expertise in cardiothoracic surgery and cardiac surgery clinical trials in the United States. They are guiding the development of the planned cardiac surgery

clinical trial.

Our Trauma Advisory Board consists of four medical doctors with expertise in trauma, burn injury and critical care medicine.

We compensate members of our Advisory Boards at the rate of \$2,000 for each full-day meeting they attend in person; \$1,200 if attendance is by telephone. When we consult with members of our Advisory Board (whether in person or by telephone) for a period of less than one day, we compensate them at the rate of \$200 per hour. We also reimburse members of our Advisory Boards for their travel expenses for attending our meetings.

TABLE OF CONTENTS

## **Royalty Agreements**

### With Principal Stockholder

In August 2003, in order to induce Guillermina Vega Montiel, a principal stockholder of ours at the time, to make a \$4 million investment in us, we granted Ms. Montiel a perpetual royalty equal to three percent of all gross revenues received by us from sales of CytoSorb® in the applications of sepsis, cardiopulmonary bypass surgery, organ donor, chemotherapy and inflammation control. In addition, for her investment, Ms. Montiel received 1,230,770 of our membership units, which at the time was a limited liability company. Those membership units ultimately became 185,477 shares of our common stock following our June 30, 2006 merger. For the year ended December 31, 2013 we recorded royalty costs of approximately \$26,000.

### With Purolite

In 2003, Purolite filed a lawsuit against us asserting, among other things, co-ownership and co-inventorship of certain of our patents. On September 1, 2006, the United States District Court for the Eastern District of Pennsylvania approved a Stipulated Order and Settlement Agreement under which we and Purolite agreed to the settlement of the action. The Settlement Agreement provides us with the exclusive right to use our patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. In particular, the Settlement Agreement relates to several of our issued patents and several of our pending patent applications covering our biocompatible polymeric resins, our methods of producing these polymers, and the methods of using the polymers to remove impurities from physiological fluids, such as blood. For the year ended December 31, 2013 per the terms of the license agreement we recorded royalty costs of approximately \$21,000.

Under the terms of the Settlement Agreement, we have agreed to pay Purolite royalties of 2.5% to 5% on the sale of those of our products, if and when those products are sold commercially, that are used in direct contact with blood. However, if the first product we offer for commercial sale is a biocompatible polymer to be used in direct contact with a physiological fluid other than blood, royalties will be payable with respect to that product as well. The royalty payments provided for under the Settlement Agreement would apply to our currently envisioned CytoSorb® and BetaSorb™ products.

Following the expiration of the eighteen year term of the Settlement Agreement, the patents and patent applications that are the subject of the Settlement Agreement should have expired under current patent laws, and the technology claimed in them will be available to the public. However, following such time, we would continue to exclusively own any confidential and proprietary know how.

## **Product Payment & Reimbursement**

### Critical Care Applications

## **Europe**

Payment for our CytoSorb® device for the removal of cytokines in patients with life-threatening illnesses is country dependent in Europe. We are initially marketing the device in Germany where a path for separate CytoSorb® reimbursement has been established. Reimbursement can also be covered by the standard diagnosis related group (DRG) acute care reimbursement. Under this system, hospitals would purchase CytoSorb® and subtract the cost from

a pre-determined lump-sum payment made by the payor to the hospital based on the patient's diagnosis. If we continue to gain traction of the CytoSorb® device into the German market we intend to apply for reimbursement in France, England, Italy and Spain representing the other four economic leaders in Europe and introduce our products in those countries accordingly. Reimbursement is specific to each country. There can be no assurances that reimbursement will be granted or that additional clinical data may not be required to establish reimbursement.

United States

We have not yet sought reimbursement for the CytoSorb® device in the United States, but expect to in the future. As in Germany, payment for our CytoSorb® device in the US for the treatment and prevention of sepsis and other related acute care applications is initially anticipated to fall under the DRG in-patient reimbursement system, which is currently the predominant basis of hospital medical billing in the



## TABLE OF CONTENTS

United States. Under this system, predetermined payment amounts are assigned to categories of medical patients with respect to their treatments at medical facilities based on the DRG that they fall within (which is a function of such characteristics as medical condition, age, sex, etc.) and the length of time spent by the patient at the facility. Reimbursement is not determined by the actual procedures used in the treatment of these patients, and a separate reimbursement decision would not be required to be made by Medicare, the HMO or other provider of medical benefits in connection with the actual method used to treat the patient.

Critical care applications such as those targeted by our CytoSorb® device involve a high mortality rate and extended hospitalization, coupled with extremely expensive ICU time. In view of these high costs and high mortality rates, we believe acceptance of our proprietary technology by critical care practitioners and hospital administrators will primarily depend on safety and efficacy factors rather than cost.

## **Competition**

### General

We believe that our products represent a unique approach to disease states and health complications associated with the presence of larger toxins (often referred to as middle molecular weight toxins) in the bloodstream, including sepsis, acute respiratory distress syndrome, trauma, severe burn injury, pancreatitis, post-operative complications of cardiac surgery, damage to organs donated for transplant prior to organ harvest, and renal disease. Researchers have explored the potential of using existing membrane-based dialysis technology to treat patients suffering from sepsis. These techniques are unable to effectively remove the middle molecular weight toxins. We have demonstrated the statistically significant reduction of a number of key cytokines by CytoSorb® on the order of 30 – 50% in human patients with predominantly septic shock and acute respiratory distress syndrome. In a post-hoc subgroup analysis of our European Sepsis Trial, we have also demonstrated statistically significant improvements in mortality in patients at high risk of death, including patients with either very high cytokine levels or patients older than age 65, both of which have a high predicted mortality.

The CytoSorb®, DrugSorb, ContrastSorb, and BetaSorb™ devices consist of a cartridge containing adsorbent polymer beads. The cartridge incorporates industry standard connectors at either end of the device which connect directly to an extra-corporeal circuit (bloodlines) on a standalone basis. The extra-corporeal circuit consists of plastic tubing through which the blood flows, our cartridge containing our adsorbent polymer beads, pressure monitoring gauges, and a blood pump to maintain blood flow. The patient's blood is accessed through a catheter inserted into his or her veins. The catheter is connected to the extra-corporeal circuit and the blood pump draws blood from the patient, pumps it through the cartridge and returns it back to the patient in a closed loop system. As blood passes over the polymer beads in the cartridge, toxins are adsorbed from the blood, without removing any fluids from the blood or the need for replacement fluid or dialysate.

There are three common forms of blood purification, including hemodialysis, hemofiltration, and hemoperfusion. All modes are generally supported by standard hemodialysis machines. All take blood out of the body to remove toxins and unwanted substances from blood, and utilize extracorporeal circuits and blood pumps. Dialysis and hemofiltration remove substances from blood by diffusion and ultrafiltration, respectively, through a semi-permeable membrane, allowing the passage of certain sized molecules across the membrane, but preventing the passage of other, larger molecules. Hemoperfusion utilizes solid or porous sorbents to remove things based on pore capture and surface adsorption, not filtration.

CytoSorb® is a hemoperfusion cartridge, using an adsorbent of specified pore size, which controls the size of the

molecules which can pass into the adsorbent and vastly increases the area available for surface adsorption. As blood flows over our polymer adsorbent, middle molecules such as cytokines flow into the polymer adsorbent and are adsorbed. Our devices do not use semipermeable membranes or dialysate. In addition, our devices do not remove fluids from the blood like hemodialysis or hemofiltration. Accordingly, we believe that our technology has significant advantages as compared to traditional dialysis techniques, including ease of use.

CytoSorbents HemoDefend™ platform is a development-stage technology utilizing a mixture of proprietary porous polymer beads that target the removal of contaminants that can cause transfusion reactions or cause disease in patients receiving transfused blood products. The HemoDefend™ beads can be used in multiple

## TABLE OF CONTENTS

configurations, including the common in-line filter between the blood bag and the patient as well as a unique, patent-pending Beads in a Bag treatment configuration, where the beads are placed directly into a blood storage bag.

### Sepsis

Researchers have explored the potential of using existing membrane-based dialysis technologies to treat patients suffering from sepsis. These techniques are unable to effectively remove middle molecular weight toxins, which leading researchers have shown to cause and complicate sepsis. The same experts believe that a blood purification technique that efficiently removes, or significantly reduces, the circulating concentrations of such toxins might represent a successful therapeutic option. CytoSorb® has demonstrated the ability to remove middle molecular weight toxins, such as cytokines, from circulating blood in a statistically significant manner.

Medical research during the past two decades has focused on drug interventions aimed at chemically blocking or suppressing the function of one or two inflammatory agents. In hindsight, some researchers now believe this approach has little chance of significantly improving patient outcomes because of the complex pathways and multiple chemical factors at play. Clinical studies of these drug therapies have been largely unsuccessful. An Eli Lilly drug, Xigris®, cleared by the FDA in November 2001, is the first and only drug to be approved for the treatment of severe sepsis. Clinical studies demonstrated that use of Xigris® resulted in an average absolute 6% reduction in 28-day mortality, and an absolute 13% reduction in 28-day mortality in the most severe sepsis patients. The drug remains controversial and is considered expensive when compared to the percentage of patients who benefit. In 2011 after completing a follow up study required by the FDA, it was subsequently determined that Xigris® does not have a statistically significant mortality benefit, and in October 2011, Eli Lilly withdrew Xigris® from all markets worldwide.

Pharmaceutical research for the treatment of sepsis continues with a number of clinical stage drug trials being presently conducted including, but not limited to, drug and biologic candidates from Eisai Co., Ltd, AM-Pharma B.V., Agennix AG and AstraZeneca/BTG plc. In February 2012, Agennix announced a halt to its Phase 2/3 OASIS sepsis trial due to increased mortality in treatment arm. The study is being un-blinded to further analyze the cause of this increased mortality. In January 2011, Eisai announced that its 2,000 patient pivotal Phase III ACCESS trial using Eritoran to treat patients with severe sepsis did not meet its primary endpoint of 28-day all-cause mortality, but will continue analyzing its clinical data and determine next steps. Eritoran is a toll-like receptor 4 (TLR-4) antagonist designed to prevent or reduce activation of the immune system by endotoxin. In August 2012, AstraZeneca and partner BTG discontinued development of CytoFab after a failed Phase IIb study.

Using a medical device to treat sepsis remains a relatively novel treatment approach. Toray Industries currently markets an endotoxin removal cartridge called Toraymyxin™ for the treatment of sepsis in Europe, Japan, and 16 other countries, but is not yet approved in the United States. To date, it has been used to treat more than 80,000 patients since 1994. Toraymyxin does not directly reduce cytokines. Spectral Diagnostics, Inc has obtained exclusive development and commercial rights in the U.S. for Toraymyxin, with plans to combine the use of its endotoxin activity assay to create a theranostic product. In June 2010, Spectral began enrollment of its targeted 360 patient, 30-site randomized, controlled U.S. Phase III trial (EUPHRATES) to diagnose endotoxemia and then treat sepsis with Toraymyxin. Approximately 200 patients have enrolled to date. The endpoint of the trial is 28-day all-cause mortality.

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. To date, all anti-endotoxin strategies have failed in large scale randomized controlled sepsis trials. Toray also markets its Hemofeel CH1.0 polymethylmethacrylate membrane (PMMA) in Japan and it has been used in several non-controlled, or historically controlled, clinical or case studies treating patients with sepsis, acute respiratory distress syndrome and pancreatitis. We are not aware of any prospective, randomized controlled studies using this PMMA hemofilter in patients with sepsis. Without such studies,

it is difficult to assess the true impact of this technology in these conditions. Gambro AB launched its Prismaflex eXeed system in August 2009 and introduced the SepteX high molecular weight cutoff hemodialyzer in Europe, intended to treat patients with acute renal failure and the removal of inflammatory mediators from blood. It is not specifically approved for the treatment of sepsis. Fresenius has launched a similar high

## TABLE OF CONTENTS

molecular weight cut off filter called the Ultraflux EMiC2. To our knowledge, there has been a lack of published data on the treatment of sepsis with these devices. Bellco S.R.L. also sells the CPFA (coupled plasma filtration and adsorption) system in Europe. This uses a sorbent cartridge to remove cytokines from plasma. However, because the sorbent cannot treat blood directly, it requires the cost and complexity of an additional plasma separator to treat blood.

Kaneka Corporation currently markets Lixelle™, a modified porous cellulosic bead, for the removal of beta2-microglobulin during hemodialysis in Japan. Lixelle has been used in several small human pilot studies including a 5 patient pilot study in 2002 and a 4 patient pilot study in 2009. Though these studies correlate Lixelle use with cytokine reduction, they are not randomized, controlled studies and so do not control for natural cytokine clearance. To our knowledge, no large, randomized, controlled trials have been conducted with Lixelle as a treatment for sepsis. Kaneka has since developed a modified cellulosic resin called CTR that can also remove cytokines from experimental pre-clinical systems. In 2009, CTR was used in an 18-patient randomized, controlled trial in patients with septic shock with undisclosed improvements in APACHE II scores and IL-6 and IL-8. To our knowledge, Kaneka has not conducted or published any other study using CTR to treat human sepsis patients since then. Ube Industries, LTD is currently developing an adsorbent resin called CF-X for the removal of cytokines. To our knowledge, Ube has not published any study using CF-X to treat human sepsis patients. CytoPherx Inc., has developed an extracorporeal system based on selective cytoapheresis, or the inactivation or removal of activated leukocytes. It was enrolling a 344 patient pivotal trial that began in August 2011 and was expected to be completed by December 2014 in patients with acute kidney injury with or without severe sepsis, on continuous renal replacement therapy with the goal of reducing mortality. This system does not remove cytokines directly, but attempts to reduce the numbers of activated white blood cells that can produce cytokines or cause cell-mediated injury. The status of the trial is unknown. ExThera Medical Corporation has developed its Seraph™ (Selective Removal by Apheresis) platform that consists of heparin coated, solid polyethylene beads. Heparin has the ability to bind some, but not all viruses, bacteria, toxins and cytokines. In *in vitro* studies using 1 mL of human septic blood, there was no statistically different change in IL-6 or Interferon-gamma compared to control, but effected a ~50% reduction in TNF-alpha. This inability to remove a broad range of cytokines will likely limit its efficacy as a treatment in sepsis. It has repositioned Seraph™ as a pathogen removal technology, and plans to conduct a human trial in Germany in the future. In addition, it has partnered with BioBridge Global to apply its technology to pathogen reduction in transfused blood products. Other potential competitors include the now defunct Arbios Systems, Inc. Hemolife Medical, Inc. and Hemocleanse Technologies, LLC. We believe our CytoSorb® cartridge has significant competitive, technological, and economic advantages over systems by these other companies.

### Acute Respiratory Distress Syndrome (ARDS)

Treatment of ARDS is predominantly supportive care using supplemental oxygen, careful fluid management and multiple modes of ventilation incorporating the concepts of low tidal volume, high frequency oscillation, and prone ventilation. Corticosteroids, nitric oxide, and surfactant therapy have been tried, but are not indicated for the treatment of ARDS. We are not aware of any specific products approved to treat ARDS.

### Severe Burn Injury

Modern management of severe burn injury patients involves a combination of therapies. From a burn standpoint, patients undergo active escharotomy and debridement of burns, the use of skin grafts and substitutes, anti-microbial dressings and negative pressure dressings. Tight fluid control, nutrition, prevention of hypothermia and infection are also priorities. Smoke and chemical inhalation injury in burn victims is also common and increasing as a cause of death in severe burn injury. Carbon monoxide and cyanide poisoning is also an issue. Supplemental oxygen and mechanical ventilation are often required and are the mainstay of supportive care treatment. Recently continuous renal replacement therapy has been used to treat patients with acute kidney injury with an improvement in survival compared to a historical control cohort. We believe CytoSorb® therapy may yield improved results. We are not aware

of any specific products approved to directly address inhalational lung injury or multiple organ failure in severe burn injury.

Trauma

Trauma management initially involves respiratory, hemodynamic and physical stabilization of the patient. However, in the days to weeks that ensue, the focus shifts to preventing or treating organ failure and

46

---

## TABLE OF CONTENTS

preventing or treating infection. We are not aware of any specific therapies to prevent or treat multiple organ dysfunction or multiple organ failure in trauma. Rhabdomyolysis, or the breakdown of muscle fibers due to crush injury or other means, occurs in trauma and can lead to acute kidney injury or renal failure. Aggressive hydration, urine alkalinization, and forced diuresis are the main therapies to prevent renal injury. Continuous hemodiafiltration with super-high-flux membranes has demonstrated modest myoglobin clearance but was associated with albumin loss. In general, however, most extracorporeal therapies are not well-suited to remove myoglobin. We have developed a polymer resin that removes myoglobin efficiently without major losses of albumin. The US Army Medical Research and Materiel Command has funded the development of our polymer resins to treat trauma and rhabdomyolysis under a Phase I and Phase II SBIR grant awarded to CytoSorbents in December 2011 and September 2012, respectively.

### Severe Acute Pancreatitis

Treatment of severe acute pancreatitis is predominantly supportive care focused on aggressive hydration, intravenous nutrition and pain control. Mechanical ventilation, hemodialysis and vasopressor use is common in cases of multiple organ failure. In cases where cholelithiasis or other obstruction is the underlying cause of the pancreatitis, endoscopic retrograde cholangiopancreatography and/or stent placement can be used to relieve the obstruction. Antibiotics are often instituted to prevent or treat infection. Surgery is sometimes indicated to remove or drain necrotic or infected portions of the pancreas. To our knowledge, there are no other specific treatments approved to treat severe acute pancreatitis or multiple organ failure that is caused by systemic inflammation in this disease.

### Cardiopulmonary Bypass Surgery

There is currently a pre-existing market for the use of leukocyte reduction filters sold by Pall Corporation, Terumo Medical Corporation and others in the cardiopulmonary bypass circuit. The purpose of these devices is to reduce cytokine-producing white blood cells from blood. They do not remove cytokines directly and are not considered by many to be an effective solution for cytokine reduction. We are not aware of any practical competitive approaches for removing cytokines in CPB patients. To our knowledge, CytoSorb® is the only cytokine reduction therapy capable of being placed directly into a bypass circuit in the heart-lung machine without the need for another pump. Alternative therapies such as off-pump surgeries are available but post-bypass syndrome and cytokine production still remain a problem in this less invasive, but more technically challenging procedure. If successful, CytoSorb® is expected to be useful in both on-pump and off-pump procedures.

### Radiocontrast Removal

ContrastSorb has demonstrated the rapid, high efficiency single pass removal of IV contrast. The use of low osmolar IV contrast, oral 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. Hydration of high risk patients pre-procedure is standard of care but has limited efficacy. PLC Medical Systems, Inc, received CE Mark approval for its RenalGuard system in 2007. RenalGuard encourages excretion of IV contrast and a reduction of CIN, by administering IV hydration that matches urine output in patients receiving a loop diuretic. Hemodialysis can remove IV contrast, but is relatively slow (46% at 1 hour, 65% at 2 hours, 75% at 3 hours) in chronic renal failure patients who lack normal renal clearance. In high risk patients, the rapid and direct removal of IV contrast from the blood with ContrastSorb to prevent CIN represents a potentially more effective alternative.

### Chronic Dialysis

Although standard dialysis treatment effectively removes urea and creatinine from the blood stream (which are normally filtered by functioning kidneys), standard dialysis has not been effective in removing beta2-microglobulin

toxins from the blood of patients suffering from chronic kidney failure. High flux dialyzers by Gambro, Fresenius, Nephros and others are capable of removing some beta2-microglobulin. However, we believe our technology would significantly improve clearance of this and other toxins. Kaneka markets Lixelle™ outside the US to remove beta2-microglobulin in dialysis patients. We know of no other device, medication or therapy considered directly competitive with our technology.



## TABLE OF CONTENTS

Efforts to improve removal of middle molecular weight toxins with enhanced dialyzer designs have achieved modest success. Many experts believe that dialyzer technology has reached its limit in this respect. A variation of high-flux hemodialysis, known as hemodiafiltration, has existed for many years. However, due to the complexity, cost and increased risks, this dialysis technique is less widely used. In addition, many larger toxins are not effectively filtered by hemodiafiltration, despite its more open pore structure. As a result, hemodiafiltration is expected to be less efficient in large toxin removal compared with the BetaSorb™ device. In terms of resin technology, Kaneka Corporation is the only company currently marketing a resin cartridge (Lixelle) in Japan designed to address this need.

### Treatment of Organ Dysfunction in Brain-Dead Organ Donors

We are not aware of any directly competitive products to address the application of our technology for the mitigation of organ dysfunction and failure resulting from severe inflammation following brain-death.

### HemoDefend Purification Technology Platform for Transfused Blood Products

There are only a few directly competitive approved products to address the removal of substances from blood and blood products that can cause transfusion reactions, Leukoreduction (Pall Corporation, Terumo-BCT, Hemerus Corporation, others) is widely used in transfusion medicine and can remove the majority of white cells that can produce new cytokines but cannot eliminate those cytokines already in blood, and cannot otherwise remove other causative agents. Automated washing of pRBC is very effective at cleansing contaminants from blood, but is impractical due to the time, cost, and logistics of washing each unit of blood and is not widely used. Blood filters that utilize affinity technologies are in development to remove certain substances such as antibodies from blood, but have other issues, such as cost and concern about the stability or leachability of the affinity technology. The HemoDefend™ platform represents a potentially superior alternative to these methods, as it can provide comprehensive removal of a wide variety of contaminants that can trigger transfusion reactions without washing blood, requires no additional equipment, energy source, or manipulation, and can be incorporated directly into the blood storage bag or used as an in-line blood filter.

## **Clinical Studies**

Our first clinical studies were conducted in patients with chronic renal failure. The health of these patients is challenged by high levels of toxins circulating in their blood but, unlike sepsis patients, they are not at imminent risk of death. The toxins involved in chronic renal failure are generally different from those involved in sepsis, eroding health gradually over time. The treatment of patients with chronic renal failure is a significant target market for us, although not the current focus of our efforts and resources. Our clinical studies and product development work in this application functioned as a low risk method of evaluating the safety of the technology in a clinical setting, with direct benefit to the development of the critical care applications on which we are now focusing our efforts.

We are focusing our research efforts on critical care applications of its technology.

### Sepsis

In 2011, the CytoSorb® filter received European Union regulatory approval under the CE Mark as an extracorporeal cytokine filter to be used in clinical situations where cytokines are elevated. As part of the CE Mark approval process, we completed our randomized, controlled, European Sepsis Trial amongst fourteen trial sites in Germany, with enrollment of one hundred (100) patients with sepsis and respiratory failure. The purpose of the trial was to demonstrate safety and the broad reduction of key cytokines such as IL-6 in critically-ill patients. Taking into account

all 100 patients, the treatment was well-tolerated with no serious device related adverse events reported in more than 300 human treatments in the trial. Although the trial was not powered to demonstrate significant reduction in other clinical endpoints such as mortality, these were also included as secondary and exploratory endpoints in the trial.

The first 22 patients in the study represented a sepsis pilot study. In the next 31 patients, a compromise of the manual randomization schedule at two trial sites led to an imbalance in the severity of illness between the control and treatment patient groups of the study. After a thorough review, the Scientific Advisory Board (SAB) and the independent Data Safety Monitoring Board (DSMB) both recommended that due to this

## TABLE OF CONTENTS

enrollment bias, these 31 patients should only be used for safety evaluation purposes and that new patients should be enrolled into the trial using electronic web-based randomization to randomly assign patients into either the control or treatment arms.

Excluding four patients that withdrew, the remaining forty three (43) patients enrolled under electronic randomization were relatively balanced in terms of the severity of illness in treatment and control patients, confirming the findings of the SAB and DSMB. In these forty three (43) patients the European Sepsis Trial successfully demonstrated, on a statistically significant basis ( $p < 0.05$ ), CytoSorb®'s ability to reduce circulating levels of key cytokines from whole blood in treated patients on the average of 30–50% over the 7 day treatment period. Additionally, post-hoc subgroup analyses of the clinical outcome data from patients enrolled under electronic randomization demonstrated statistically significant reduction in mortality in patients at high risk of death in sepsis, specifically in patients with:

Very high cytokine levels (IL-6 1,000 pg/mL and/or IL-1ra 16,000 pg/mL) where 28-day mortality was 0% treated vs 63% control,  $p = 0.03$ ,  $n = 14$ , and

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

In patients aged 65 years old, however, seven days of treatment with CytoSorb® was not adequate to extend the observed 14-day mortality benefit out to 28-days (40% vs 45% control,  $p = 0.6$ ,  $n = 21$ ). These critically ill patients carried two major mortality risk factors: multiple organ failure and age 65 years old, which itself confers a 2.3-fold relative risk of death. Treatment of life-threatening infections with antibiotics often requires 7–14 days of treatment.

We hypothesize that treatment of the run-away immune response should mirror treatment with antibiotics. We are currently conducting a dose ranging study ( Dosing Study ) in Germany amongst eight clinical trial sites to evaluate the safety and efficacy of CytoSorb® when used continuously for 7 days, or for 6 hours per day for more than 7 days. Patients are being stratified for age, cytokine levels, and co-morbid illnesses in this matched pairs analysis. Data from this Dosing study are intended to help clinicians with additional treatment options for CytoSorb®, help support the positive clinical data from our first European Sepsis Trial, and help shape the trial protocol for a U.S. based pivotal study.

At the end of 2013, we reported a clinical update on the first 28 treated patients that were enrolled in the first arm of the Dosing study (24 hours of treatment for 7 days, each day with a new device). Treatment was safe and well-tolerated at flow rates up to 300 mL/min, with no serious device related adverse events. 24-hour treatment increased platelet reduction compared to 6-hour treatment in the EST, but with no reported complications. Broad spectrum antibiotics, such as the carbapenem class, were compatible with CytoSorb®, requiring only modest dose adjustments. IL-6 reduction continued throughout the entire 24-hour period, higher at the beginning of treatment when IL-6 levels are highest, and with an overall average instantaneous IL-6 reduction of 8% per pass. In this preliminary analysis, the overall 28-day all-cause mortality and 28-day all-cause mortality in patients 65 years and older was not statistically different from the treatment data reported in the EST (electronic randomized cohort). Severity of illness in the overall treatment groups were comparably high, with 50% or more of the treated patients (dosing > EST) having an APACHE II severity of illness score > 25 at the time of enrollment, predicting very high mortality of 55% or more. In comparison, the overall control patients reported in the EST (electronic randomization cohort) had a lower severity of illness with only 20% having an APACHE 2 score > 25.

In 2007, Cytosorbents received FDA approval of its investigational device exemption (IDE) application to run a single center sepsis study in the United States. We have since generated safety data in approximately 500 human treatments in patients with septic shock and multiple organ failure in its European Sepsis Trial and Dosing study. Assuming availability of adequate and timely funding, and continued positive results from our clinical studies, we intend to continue commercializing our product in Europe while pursuing pivotal sepsis studies in the E.U. and U.S.

### Cardiac Surgery

With adequate funding and continued positive data, we intend to conduct clinical studies using CytoSorb® in cardiac surgery patients in the U.S. We seek to demonstrate the ability of CytoSorb®, when used intra-operatively in a bypass circuit in a heart-lung machine, to improve clinical outcome and reduce cytokines and free hemoglobin that are generated during cardiac surgery procedures in high risk patients. We also look

## TABLE OF CONTENTS

to foster data on the ability of CytoSorb® to resolve post-operative SIRS in cardiac surgery patients, when administered post-operatively with standard hemodialysis machines.

### Trauma

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 primary endpoint is myoglobin removal. The FDA has approved our Investigational Device Exemption (IDE) application for this study. We have recently received ethics committee approval to proceed, and the study is anticipated to commence enrollment shortly.

### Other Critical Care Applications

There are currently more than 40 ongoing investigator initiated studies being planned or enrolling in Germany, Austria and the United Kingdom. These trials, which are funded and supported by renowned university hospitals and key opinion leaders, will provide invaluable information regarding the success of the device in the treatment of sepsis, cardiac surgery, trauma, burn injury, pancreatitis, liver failure, acute kidney injury, acute respiratory distress syndrome, and many other indications, and will be integral to helping us determine the ultimate course of our U.S. clinical trial pathway.

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

## **Government Research Grants**

A grant of \$1 million was awarded to the University of Pittsburgh Medical Center in 2003. The project seeks to improve the quantity and viability of organs donated for transplant by using CytoSorb™ to detoxify the donor's blood.

The observational and dosing phases of the study, involving 30 viable donors and eight non-viable donors, respectively, have been completed. The next phase of this study, the treatment phase, will involve viable donors. We are not currently focusing our efforts on the commercialization of CytoSorb™ for application in organ donors. The treatment phase would be contingent upon further discussion with the FDA and HRSA regarding study design, as well as obtaining additional funding.

In addition, in September 2005, the University of Pittsburgh Medical Center was awarded a grant of approximately \$7 million from NIH entitled Systems Engineering of a Pheresis Intervention for Sepsis (SEPSIS) to study the use of adsorbent polymer technology in the treatment of severe sepsis. The study, which lasted for a total of five years, commenced in September 2005. Under a SubAward Agreement, we worked with researchers at the University of Pittsburgh Critical Care Medicine Department. We believe that the only polymers used in this study were polymers we have developed specifically for use in the study, which are similar to the polymers used in our devices. Under the SubAward Agreement, for our efforts in support of the grant during 2006 through 2010, we received approximately \$402,000.

In October 2010 CytoSorbents was awarded a grant of approximately \$489,000 from the federal Qualifying

## Edgar Filing: Cytosorbents Corp - Form S-1/A

Therapeutic Discovery Project (QTDP) program for two products in its pipeline including the development of CytoSorb® for the treatment of sepsis and other critical care illnesses. We received half of the grant in November 2010 and the second half in February 2011.

In December 2011 CytoSorbents was awarded a \$100,000 Phase I SBIR (Small Business Innovation Research) contract, and subsequently a \$50,000 Phase I extension, by the US Army Medical Research and Materiel Command to evaluate our technology for cytokine and myoglobin removal in the treatment of burn injury and trauma. This work is supported by the U.S. Army Medical Research and Material Command under an amendment to Contract W81XWH-12-C-0038.

In August 2012, the Defense Advanced Research Projects Agency (DARPA) awarded CytoSorbents a five-year technology development contract valued at \$3.8 million as part of its Dialysis-Like Therapeutics (DLT) program to treat sepsis. DARPA is funding CytoSorbents to further develop its technologies to remove both

## TABLE OF CONTENTS

cytokines and a variety of toxins (e.g. pathogen-derived, naturally occurring, or biowarfare generated). CytoSorbents work is supported by DARPA and SSC Pacific under Contract No. N66001-12-C-4199.

In September 2012 CytoSorbents was awarded a \$1 million Phase II SBIR (Small Business Innovation Research) contract by the US Army Medical Research and Materiel Command to evaluate our technology for the treatment of trauma and burn injury in large animal models. In 2013, we finalized a Phase II SBIR contract for approximately \$753,000 with the granting agency. This work is supported by the U.S. Army Medical Research and Material Command under an amendment to Contract W81XWH-12-C-0038.

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. Though CytoSorbents does not expect to receive material direct funding from this \$3 million budgeted program, the study may generate valuable data that can be used commercially or in future trauma studies.

In September 2013, the National Heart, Lung, and Blood Institute ( NHLBI ), a division of the National Institutes of Health ( NIH ), awarded us a Phase I SBIR (Small Business Innovation Research) contract to further advance our 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 program is to reduce the risk of potential side effects of blood transfusions, and help to extend the useful life of pRBCs.

Our business could be adversely impacted by automatic cuts in Federal spending. The American Taxpayer Relief Act (ATRA) of 2012, referred to generally as the fiscal cliff deal, that went into effect on March 1, 2013, enacted automatic spending cuts of nearly \$1 trillion over the next 10 years (commonly known as sequestration ) that were included under the Budget Control Act of 2011. Sequestration may delay payments under the DARPA and SBIR grant agreements, although no material delays have occurred to date. The economic impact of the sequester in the US in 2014 is expected to be less than seen in 2013. The short term and long term economic impact of the sequestration will not be known until the actual spending cuts are implemented and the economic impact of the changes in the budget and taxes are known. It will take an extended number of years to understand the impact of any changes brought about from the sequester.

These grants represent a substantial research cost savings to us and demonstrate the strong interest of the medical and scientific communities in our technology.

## **Regulation**

The medical devices that we manufacture are subject to regulation by numerous regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation program be conducted before a device receives approval for commercial distribution.

In the European Union, medical devices are required to comply with the Medical Devices Directive and obtain CE Mark certification in order to market medical devices. The CE Mark certification, granted following approval from an independent Notified Body, is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. Distributors of medical devices may also be required to comply

with other foreign regulations such as Ministry of Health Labor and Welfare approval in Japan. The time required to obtain these foreign approvals to market our products may be longer or shorter than that required in the U.S., and requirements for those approvals may differ from those required by the FDA.

In March 2011 we successfully completed our technical file review with the Notified Body, and received approval to apply the CE Mark to the CytoSorb® device as an extracorporeal 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 E.U.



## TABLE OF CONTENTS

In the U.S., permission to distribute a new device generally can be met in one of two ways. The first process requires that a pre-market notification (510(k) Submission) be made to the FDA to demonstrate that the device is as safe and effective as, or substantially equivalent to, a legally marketed device that is not subject to pre-market approval (PMA).

A legally marketed device is a device that (i) was legally marketed prior to May 28, 1976, (ii) has been reclassified from Class III to Class II or I, or (iii) has been found to be substantially equivalent to another legally marketed device following a 510(k) Submission. The legally marketed device to which equivalence is drawn is known as the predicate device. Applicants must submit descriptive data and, when necessary, performance data to establish that the device is substantially equivalent to a predicate device. In some instances, data from human clinical studies must also be submitted in support of a 510(k) Submission. If so, these data must be collected in a manner that conforms with specific requirements in accordance with federal regulations. The FDA must issue an order finding substantial equivalence before commercial distribution can occur. Changes to existing devices covered by a 510(k) Submission which do not significantly affect safety or effectiveness can generally be made by us without additional 510(k) Submissions.

The second process requires that an application for premarket approval (PMA) be made to the FDA to demonstrate that the device is safe and effective for its intended use as manufactured. This approval process applies to most Class III devices. In this case, two steps of FDA approval are generally required before marketing in the U.S. can begin.

First, investigational device exemption (IDE) regulations must be complied with in connection with any human clinical investigation of the device in the U.S. Second, the FDA must review the PMA application that contains, among other things, clinical information acquired under the IDE. The FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose.

In the United States, our CytoSorb® and BetaSorb™ devices are classified as Class III (CFR 876.5870 Sorbent Hemoperfusion System) 510(k) devices, but may require pre-market approval (PMA) by the FDA. In Europe, our devices are classified as Class IIb, and will need to conform to the Medical Devices Directive.

The process of obtaining clearance to market products is costly and time-consuming in virtually all of the major markets in which we expect to sell products and may delay the marketing and sale of our products. Countries around the world have recently adopted more stringent regulatory requirements, which are expected to add to the delays and uncertainties associated with new product releases, as well as the clinical and regulatory costs of supporting those releases. No assurance can be given that any of our other medical devices will be approved on a timely basis, if at all, or that our CytoSorb® device will be approved for CE Mark labeling in other potential medical applications or that it will be approved for cytokine filtration in markets not covered by the CE Mark on a timely basis, or at all. In addition, regulations regarding the development, manufacture and sale of medical devices are subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. to take advantage of differing regulatory requirements.

## **Sales and Marketing**

In 2012, we established our European subsidiary, CytoSorbents Europe GmbH, a wholly-owned subsidiary of CytoSorbents Corporation. Located in Berlin, Germany, it serves as the center of our sales activities in Europe. Following the completion of a controlled market release in late June 2012, CytoSorb® was formally launched in

Germany with reimbursement established at more than \$500 per cartridge. We recruited Dr. Christian Steiner, MD as our Vice President of Sales and Marketing and hired three additional sales representatives who completed training in Q3 2012. Q4 2012 was the first full quarter of direct CytoSorb® sales with our sales force in place. We began expansion into Austria, where reimbursement for CytoSorb® is now available, and Switzerland. From the beginning of the controlled market release in Q4 2011 through the end of December 31, 2013, we achieved cumulative sales of approximately \$1,009,000 in sales of CytoSorb®.

## TABLE OF CONTENTS

At the end of 2013, we had more than 100 key opinion leaders (KOL) who were either using CytoSorb® or interested in using it in clinical practice and/or in clinical studies. These KOL relationships were an essential step in our initial goal of driving usage, adoption and reorders of CytoSorb® as they facilitate ordering and reimbursement within the hospital, have a strong influential role within their department and amongst their peers and colleagues outside the hospital, and have the ability to conduct studies and generate data, papers and conference presentations that could drive awareness and demand.

We are approved to sell CytoSorb® in all 28 countries in the European Union, including Germany, United Kingdom, Italy, France and Spain. We plan to expand to other countries in the E.U., and with registration, other countries outside the E.U. that will accept CE Mark approval with a mixed direct and independent distributor strategy, that can be augmented through strategic partnerships. We currently have distributorships in the U.K., Ireland, the Netherlands, Turkey, Russia, and India. In India, we have established a strategic partnership with Biocon Ltd., India's largest biotechnology company, with an initial focus on exclusive distribution of CytoSorb® in India, and select emerging countries. In April, 2014, the Company 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. Registration and reimbursement in other countries may or may not require additional clinical data. We plan to continue our commercialization plans in Europe provided we receive adequate and timely funding to support our planned activities and that our products continue to perform as expected in clinical studies.

## **Intellectual Property and Patent Litigation**

The medical device market in which we primarily participate is in large part technology driven. As a result, intellectual property rights, particularly patents and trade secrets, play a significant role in product development and differentiation. However, intellectual property litigation to defend or create market advantage is inherently complex, unpredictable and is expensive to pursue. Litigation often is not ultimately resolved until an appeal process is completed and appellate courts frequently overturn lower court patent decisions.

Moreover, competing parties frequently file multiple suits to leverage patent portfolios across product lines, technologies and geographies and to balance risk and exposure between the parties. In some cases, several competitors are parties in the same proceeding, or in a series of related proceedings, or litigate multiple features of a single class of devices. These forces frequently drive settlement not only of individual cases, but also of a series of pending and potentially related and unrelated cases. In addition, although monetary and injunctive relief is typically sought, remedies are generally not determined until the conclusion of the proceedings, and are frequently modified on appeal. Accordingly, the outcomes of individual cases are difficult to time, predict or quantify and are often dependent upon the outcomes of other cases in other forums, both domestic and international.

We rely on a combination of patents, trademarks, trade secrets and non-disclosure agreements to protect our intellectual property. We hold 32 issued U.S. patents, some of which have foreign counterparts, and additional patent applications pending worldwide that cover various aspects of our technology. There can be no assurance that pending patent applications will result in issued patents, that patents issued to us will not be challenged or circumvented by competitors, or that such patents will be found to be valid or sufficiently broad to protect our technology or to provide us with a competitive advantage.

We also rely on non-disclosure and non-competition agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. There can be no assurance that these agreements will

not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

Several years ago we engaged in discussions with the Dow Chemical Company, which had indicated a strong interest in being our polymer manufacturer. After a Dow representative on our Advisory Board resigned, Dow filed and received five patents naming our former Advisory Board member as an inventor. These patents, two of which subsequently lapsed for failure to pay maintenance fees, concern the area of coating high divinylbenzene-content polymers to render them hemocompatible, and using such coated polymers to treat

TABLE OF CONTENTS

blood or plasma. In management's view the Dow patents improperly incorporate our technology, are based on our proprietary technology, and should not have been granted to Dow. While we believe that our own patents would prevent Dow from producing our products as they are currently envisioned, Dow could attempt to assert its patents against us. To date, to our knowledge, Dow has not utilized their patents for the commercial manufacture of products that would be competitive with us, and we currently have no plans to challenge Dow's patents. However, the existence of these Dow patents could result in a potential dispute with Dow in the future and additional expenses for us.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how and to determine the scope and validity of the proprietary rights of others. Patent litigation can be costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that the outcome of litigation will be favorable to us. Accordingly, we may seek to settle some or all of our pending litigation described below. Settlement may include cross-licensing of the patents which are the subject of the litigation as well as our other intellectual property and may involve monetary payments to or from third parties.

**Employees**

As of October 20, 2014, we had thirty-four full-time employees. We also utilize consultants and temporary service providers who are not employees of the Company, as necessary. None of our employees are represented by a labor union or are subject to collective-bargaining agreements. We believe that we maintain good relationships with our employees.

TABLE OF CONTENTS

## **DESCRIPTION OF PROPERTY**

We currently operate a facility near Princeton, New Jersey with approximately 10,750 sq. ft., housing research laboratories, clinical manufacturing operations and administrative offices, under a lease agreement, of which 950 sq. ft. expire in February 2015 and 9,800 sq. ft. expire in May 2015. In the opinion of management, the leased properties are adequately insured, are in good condition and suitable for the conduct of our business. We also collaborate with numerous institutions, universities and commercial entities who conduct research and testing of our products at their facilities. We rent this space for approximately \$27,000 per month.

We also operate a small office facility in Berlin, Germany housing sales and administrative offices. We entered into a lease for this office on March 1, 2012. The lease expires on February 28, 2016. We rent this space for €1,200 per month or approximately US\$1,500 per month.

## **LEGAL PROCEEDINGS**

The Company is currently not involved, but may at times be involved in various claims and legal actions. Management is currently of the opinion that these claims and legal actions would have no merit, and any ultimate outcome will not have a material adverse impact on the consolidated financial position of the Company and/or the results of its operations.

TABLE OF CONTENTS

# MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our Common Stock presently trades in the over-the-counter-market ( OTC ) on the OTCQB Marketplace, operated by the OTC Markets Group, Inc., ( OTCQB ), under the symbol CTSOD (until on or about January 4, 2015) and CTSO (beginning on or about January 5, 2015). The OTCQB is a quotation service that displays real-time quotes, last-sale prices, and volume information in the OTC equity securities. An OTCQB equity security generally is any equity security that is not listed or traded on a national securities exchange. Prior to May 2010, our common stock traded under the symbol MSBT , but was changed to CTSO as part of our name change to CytoSorbents Corporation.

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 5, 2014 the closing price of our common stock, as reported on the OTCQB was \$5.50.

## Price Range of Common Stock

The following table shows, for the periods indicated, the high and low bid prices per share of our Common Stock as reported by the OTCQB quotation service and does not give effect to the twenty-five-for-one (25:1) reverse split of our common stock or our merger with and into our recently formed, wholly-owned Delaware subsidiary, each effected on December 3, 2014. These bid prices represent prices quoted by broker-dealers on the OTCQB quotation service. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

	High	Low
2012		
First quarter	\$ 0.17	\$ 0.14
Second quarter	\$ 0.15	\$ 0.09
Third quarter	\$ 0.16	\$ 0.12
Fourth quarter	\$ 0.15	\$ 0.11
2013		
First quarter	\$ 0.15	\$ 0.09
Second quarter	\$ 0.15	\$ 0.11
Third quarter	\$ 0.13	\$ 0.08
Fourth quarter	\$ 0.14	\$ 0.09
2014		
First quarter	\$ 0.35	\$ 0.12
Second quarter	\$ 0.26	\$ 0.20
Third quarter	\$ 0.31	\$ 0.20
Fourth quarter (through December 2, 2014)	\$ 0.28	\$ 0.20

## **Approximate Number of Equity Security Holders**

As of November 10, 2014, there were approximately 5,200 stockholders. Because shares of our Common Stock are held by depositaries, brokers and other nominees, the number of beneficial holders of our shares is larger than the number of stockholders.

As of December 3, 2014, after giving effect to the twenty-five-for-one (25:1) reverse split of our common stock and our merger with and into our recently formed, wholly-owned Delaware subsidiary, each effected on December 3, 2014, there were approximately 5,814 stockholders. Because shares of our Common Stock are held by depositaries, brokers and other nominees, the number of beneficial holders of our shares is larger than the number of stockholders.



TABLE OF CONTENTS

**Dividends**

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

57

---

TABLE OF CONTENTS

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

*You should read the following discussion of our operating and financial condition and prospects in conjunction with the financial statements and the notes thereto included elsewhere in this prospectus. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus.*

## 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

## TABLE OF CONTENTS

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.

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 expand the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. We are currently organizing a pivotal trial in the U.S. using CytoSorb® during cardiac surgery 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.



TABLE OF CONTENTS

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.

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 Materiel 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.



TABLE OF CONTENTS

## **Results of Operations**

### **Comparison for the nine months ended September 30, 2014 and 2013:**

#### **Revenues:**

For the nine months ended September 30, 2014, we generated revenue of approximately \$3,249,000 as compared to revenues of approximately \$1,544,000, for the nine months ended September 30, 2013, an increase of approximately \$1,424,000 or 110%. Revenue from product sales was approximately \$2,264,000 in the nine months ended September 30, 2014, as compared to approximately \$508,000 in the nine months ended September 30, 2013, an increase approximately \$1,756,000 or 346%. This increase in sales is a result of the efforts of our four person sales team which was established in August 2012 and was expanded in 2014 to seven people, as well as sales to distributors in other parts of Europe and elsewhere in the world.

#### **Cost of Revenues:**

For the nine months ended September 30, 2014 and 2013, cost of revenue was approximately \$1,805,000 and \$1,074,000, respectively. The increase is due to increased sales and expenditures related to progress on grant objectives.

Overall blended gross margins were approximately 44%, with product gross margins of approximately 66% for the nine months ended September 30, 2014.

#### ***Research and Development Expenses:***

For the nine months ended September 30, 2014, research and development expenses were approximately \$1,464,000, as compared to research and development expenses of approximately \$1,706,000 for the nine months ended September 30, 2013. The decrease of approximately \$242,000 in research and development expenses was primarily due to an increase of \$257,000 in grant costs included in costs of revenue, decreases in consulting costs of approximately \$68,000, a change in the classification of approximately \$170,000 of salaries from research and development expenses in 2013 to selling, general and administrative expenses in 2014 as a result of a change in the duties of an executive of the Company, and decreases in patent expenses of approximately \$62,000, all of which were offset by increased costs for clinical studies and license fees of approximately \$309,000.

#### **Legal, Financial and Other Consulting Expense:**

Legal, financial and other consulting expenses were approximately \$733,000 for the nine months ended September 30, 2014, as compared to approximately \$570,000 for the nine months ended September 30, 2013. The increase of approximately \$203,000 was due to an increase in fees to consultants, fees to secure certain key employees, and fees to consultants for investor relations and other advisory services.

#### **Selling, General and Administrative Expense:**

Selling, general and administrative expenses were approximately \$3,471,000 for the nine months ended September 30, 2014 as compared to approximately \$1,902,000 for the nine months ending September 30, 2013. The increase of approximately \$1,568,000 in selling, general, and administrative expenses was primarily due to a change in



classification of approximately \$170,000 of payroll costs from research and development expenses to selling, general and administrative expenses, other increases in payroll, commissions and employee-related expenses of approximately \$674,000, increased royalties of approximately \$93,000, increases in advertising and marketing costs of approximately \$173,000, increased costs of medical conference and congresses of approximately \$187,000, increased loss on foreign exchange of approximately \$141,000 and increases in stock option costs of approximately \$129,000.

### **Interest Expense:**

For the nine months ended September 30, 2014, interest expense was approximately \$311,000, as compared to interest expense of approximately \$300,000 for the nine months ended September 30, 2013. The increase was principally due to the interest payable and amortization of financing costs related to the convertible notes.

### **Change in Warrant Liability:**

We recognize warrants as liabilities at their fair value on the date of the grant because of price adjustment provisions in the warrants, then measure the fair value of the warrants on each reporting date, and records a

## TABLE OF CONTENTS

change to the warrant liability as appropriate. The change in warrant liability was approximately \$208,000 and \$-0- for the nine months ended September 30, 2014 and 2013, respectively. The change in warrant liability was as a result of the change in the fair value of the warrant liability from March 11, 2014 (the date of our \$10,200,000 2014 offering) to September 30, 2014. There was no warrant liability in 2013, and therefore there was no change in warrant expense in 2013.

### **History of Operating Losses:**

We have experienced substantial operating losses since inception. As of September 30, 2014, we had an accumulated deficit of approximately \$113,903,000, which included losses of approximately \$4,327,000 and \$4,009,000 for the nine month periods ended September 30, 2014 and 2013, respectively. Historically, losses have resulted principally from costs incurred in the research and development of our polymer technology, clinical studies, and general and administrative expenses.

### **Comparison for the three months ended September 30, 2014 and 2013:**

#### **Revenues:**

For the three months ended September 30, 2014, we generated revenues of approximately \$1,162,000 as compared to revenues of approximately \$881,000 for the three months ended September 30, 2013. Product revenues were approximately \$1,032,000 for the quarter ended September 30, 2014, as compared to product revenues of \$204,000 for the quarter ended September 30, 2013. This \$828,000 or approximately 406% increase in product revenues was a result of our direct sales effort to hospitals in Germany, Austria and Switzerland which began in 2012, as well as sales to distributors in Europe and elsewhere in the world. Additionally, grant revenue and other income was approximately \$131,000 and \$677,000 for the three month periods ended September 30, 2014 and 2013, respectively.

#### **Cost of Revenues:**

For the three months ended September 30, 2014, cost of revenue was approximately \$476,000 as compared to cost of revenue of approximately \$621,000 for the three months ended September 30, 2013. The decrease in cost of revenues is due to decreases in grant expenditures, which were partially offset by a increases in the cost of sales related to product sales. For the quarter ended September 30, 2014, overall blended gross margins were approximately 59%, with product gross margins of approximately 65%.

#### ***Research and Development Expenses:***

For the three months ending September 30, 2014, research and development costs were approximately \$880,000, as compared to research and development costs of approximately \$294,000 for the three months ended September 30, 2013. The increase of approximately \$586,000 was primarily due to increases in research and development costs not offset by grant income of approximately \$422,000 and increased costs for clinical studies of approximately \$164,000.

#### **Legal, Financial and Other Consulting Expense:**

Legal, financial and other consulting costs were approximately \$183,000 for the three months ending September 30, 2014, as compared to legal financial and other consulting costs of approximately \$158,000 for the three months ended September 30, 2013. This increase of approximately \$25,000 was primarily due to increased recruitment and other

consulting fees.

### **Selling, General and Administrative Expense:**

Selling, general and administrative expenses were approximately \$1,310,000 for the three months ended September 30, 2014, compared to approximately \$688,000 for the three months ended September 30, 2013, an increase of approximately \$622,000. This was primarily due to increases in payroll related costs of approximately \$262,000, advertising and marketing costs of approximately \$115,000, increased royalties due to increased sales of approximately \$50,000, increased loss on foreign exchange of approximately \$139,000 and increases in medical conference and congresses expenses of approximately \$42,000.

62

---

TABLE OF CONTENTS

**Interest (Income)/Expense Net:**

For the three months ended September 30, 2014, our net interest expense was approximately \$47,000, as compared to net interest expense of approximately \$85,000 for the three months ended September 30, 2013. The decrease in net interest expense is primarily due to interest and amortization of financing costs related to convertible notes.

**Change in Warrant Liability:**

The change in warrant liability was approximately \$235,000 and \$-0- for the three months ended September 30, 2014 and 2013, respectively. The change in warrant liability was as a result of the change in the fair value of the warrant liability from June 30, 2014 to September 30, 2014. There was no warrant liability in 2013, and therefore there was no change in warrant expense in 2013.

**Comparison of the year ended December 31, 2013 and 2012**

**Revenues**

For the year ended December 31, 2013, we generated revenue of approximately \$2,423,000 as compared to revenues of approximately \$1,343,000 for the year ended December 31, 2012, an increase of 80%. Revenue from product sales was approximately \$822,000 for the year ended December 31, 2013, as compared to approximately \$152,000 in the year ended December 31, 2012, an increase of 441%. Fourth quarter 2013 product sales of CytoSorb® were approximately \$314,000, an increase of 54% over third quarter 2013 product sales. This increase in sales is the result of the efforts of our direct sales force covering Germany, Austria, and Switzerland, as well as sales to distributors in other parts of Europe and the Middle East.

Another approximately \$37,000 in revenues related to orders completed during the fourth quarter of 2013 was recognized in 2014. Due to common carrier delays, the products were not picked up until January 2, 2014. Our revenue recognition policies require that we recognize revenue on products at the time when title and risk of loss passes to the customer, which occurs when the products are picked up by common carrier.

Product gross margins were approximately 61% for the year ended December 31, 2013.

Revenue from grants was approximately \$1,601,000, as compared to approximately \$1,191,000 in the year ended December 31, 2012.

**Research and Development Expenses**

Our research and development costs were, approximately \$1,739,000 and \$2,532,000, for the years ended December 31, 2013 and 2012 respectively. The decrease of approximately \$793,000 in research and development expenditures is directly related to an increase in 2013 of direct labor and other costs being deployed toward grant-funded activities, which has the effect of reducing the amount of our non-reimbursable research and development costs.

**Legal, Financial and Other Consulting Expenses**

Our legal, financial and other consulting costs were, approximately \$908,000 and \$627,000, for the years ended December 31, 2013 and 2012 respectively. In 2013, legal, financial, and other consulting costs increased by

approximately \$281,000, or approximately 44.8%. This is primarily comprised of an increase in legal fees of approximately \$45,000 associated with international contracts with product distributors and certain improvements in our compliance documents, approximately \$52,000 in accounting fees which were associated with our audit services, S-1 registration related fees, and other reports, approximately \$70,000 associated with accounting consultants and temporary services, approximately \$88,000 in consulting fees related to new systems and employment related fees of approximately \$27,000 incurred to secure specialized executive talent.

## **General and Administrative Expenses**

Our general and administrative costs were approximately \$2,577,000 for the year ended December 31, 2013, an increase of approximately \$1,222,000 over general and administrative costs of approximately \$1,355,000 for the year ended December 31, 2012. The increase in selling, general, and administrative expenses was

## TABLE OF CONTENTS

primarily due to the addition of our German-based sales and support team resulting in direct costs increases of \$430,000, increases in advertising and marketing costs of approximately \$290,000, increases in option expenses of \$294,000, increase in royalty expenses of approximately \$38,000, and increases in consulting costs of \$70,000.

### **Interest Expenses**

For the year ended December 31, 2013, our net interest expense was approximately \$423,000, as compared to interest expenses of approximately \$564,000 for the year ended December 31, 2012. This decrease was principally due to lower amortization of debt discount charged to interest expense in 2013.

### **Benefit from Income Taxes**

Our benefit from income taxes was approximately \$458,000 and \$392,000 for the years ended December 31, 2013 and 2012, respectively. These benefits were realized by utilizing the New Jersey Technology Business Tax Certificate Transfer Program whereby we sold our net operating losses to the State of New Jersey.

We have experienced substantial operating losses since inception. As of December 31, 2013, we had a deficit accumulated during the development stage of approximately \$105,806,000, which included losses of approximately \$4,678,000 and \$3,664,000 for years ended December 31, 2013 and 2012 respectively. Historically, our losses have resulted principally from costs incurred in the research and development of our polymer technology, and general and administrative expenses, which together were \$4,316,000 and \$3,887,000 for the years ended December 31, 2013 and 2012 respectively.

### **Liquidity and Capital Resources**

Since inception, our operations have been primarily financed through the private placement of its 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 U.S. and/or Germany. We will be better able to assess this need once the specific protocols are finalized with appropriate regulatory bodies. In addition, we may require additional capital to support our sales and marketing efforts, to fund clinical studies, for expansion of our production capacity, to further develop our products, and for general working capital purposes.

### **Effects of Recent Accounting Pronouncements**

Accounting Standards Update ( ASU ) 2014-10, which for public business entities will be effective for annual reporting periods beginning after December 15, 2014 and interim periods therein, removes the definition of a development stage entity from the Accounting Standards Codification, thereby eliminating the financial reporting distinction between development stage entities from U.S. GAAP. Specifically eliminated are the requirements to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development state entity that in prior years it had been in the development stage. The Company has adopted ASU 2014-10 within its September 30, 2014 financial statements.

In May 2014, the Financial Account Standards Board ( FASB ) issued ASU 2014-09, Revenue with Contracts from Customers. ASU 2014-09 supercedes the current revenue recognition guidance, including industry-specific guidance.

The ASU introduces a five-step model to achieve its core principal of the entity recognizing revenue to depict the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. The updated guidance is effective for interim and annual periods beginning after December 15, 2016 and early adoption is not permitted. The Company is currently evaluating the impact of the updated guidance, but the Company does not believe that the adoption of ASU 2014-09 will have a significant impact on its consolidated financial statements.

TABLE OF CONTENTS

## **Critical Accounting Policies**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. We believe the following critical accounting policies have significant effect in the preparation of our consolidated financial statements.

### **Patents**

Legal costs incurred to establish patents are capitalized. When patents are issued, capitalized costs are amortized on the straight-line method over the related patent term. In the event a patent is abandoned, the net book value of the patent is written off.

### **Revenue Recognition**

*Product Sales:* Revenues from sales of products are recognized at the time of delivery when title and risk of loss passes to the customer. Recognition of revenue also requires reasonable assurance of collection of sales proceeds and completion of all performance obligations.

*Grant Revenue:* Revenue from grant income is based on contractual agreements. Certain agreements provide for reimbursement of costs, while other agreements provide for reimbursement of costs and an overhead margin. Revenues are recognized when milestones have been achieved and revenues have been earned. Costs are recorded as incurred. Costs subject to reimbursement by these grants have been reflected as costs of revenue.

*Deferred Revenue:* We defer revenue that have been received but not yet earned on government contracts. This revenue will be recognized as income in the period in which the revenue is earned. All deferred revenue is expected to be earned within a one year of the balance sheet date.

### **Research and Development**

All research and development costs, payments to laboratories and research consultants are expensed when incurred.

### **Stock Based-Compensation**

We account for stock-based compensation under the recognition requirements of accounting standards for accounting for stock-based compensation, for employees and directors whereby each option granted is valued at fair market value on the date of grant. Under these accounting standards, the fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model.

We also follow the guidance of accounting standards for accounting for equity instruments that are issued to other than employees for acquiring, or in conjunction with selling, goods or services for equity instruments issued to consultants.



## **Determination of Fair Value for Stock Dividend and Stock Based Compensation**

Effective January 1, 2010, we have changed our basis for estimating the fair value of the preferred stock dividends from the underlying conversion prices of the Series A and Series B Preferred Stock, to a five day volume weighted average price of actual closing market prices for our common stock. We believe that there has been relative improvement in stock trading volumes of our common stock and that this new market based methodology is a better proxy for fair valuation of its preferred stock dividends.

## **Conversion of Redeemable Series B Convertible Preferred Stock**

Upon conversions of our Redeemable Series B Convertible Preferred Stock into shares of common stock, we reduce the Series B Preferred Stock carrying value based on the original issuance price of approximately \$103 per share on a first-in first-out basis and reclassifies the amount into additional paid-in capital.

## **Off-balance Sheet Arrangements**

We have no off-balance sheet arrangements.

TABLE OF CONTENTS

## **Going Concern**

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has experienced negative cash flows from operations since inception and has an accumulated deficit at September 30, 2014 of approximately \$113,902,000. While the Company's revenues are increasing, it remains dependent on the proceeds of present and future offerings to fund its research, development and commercialization program. The Company currently has adequate funding for more than the next twelve months of operations; however, it may have to raise additional capital to fund future operations and/or clinical trials. Although the Company has historically been successful in raising additional capital through equity and debt offerings, there can be no assurance that the Company will be successful in raising additional capital in the future or that it will be on favorable terms. Furthermore, if the Company is successful in raising the additional offering, there can be no assurance that the amount will be sufficient to complete the Company's plans. These matters raise substantial doubt about the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

## **CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

There have been no changes in or disagreements with our accountants on accounting or financial disclosure matters.

TABLE OF CONTENTS**DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

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

Name	Age	Position
Phillip Chan, MD, PhD	44	President and Chief Executive Officer, Director
Al W. Kraus	69	Chairman of the Board
Edward R. Jones, MD, MBA	65	Director
James Gunton	47	Director
Alan D. Sobel	53	Director
Vincent Capponi	56	Chief Operating Officer
Kathleen Bloch	59	Chief Financial Officer
Robert Bartlett, MD	74	Chief Medical Officer

**Phillip Chan, MD, PhD.** Dr. Chan became a director of the Company in 2008 and since January 2009 is also Chief Executive Officer. Prior to CytoSorbents, Dr. Chan led healthcare and life science investments as Partner for the NJTC Investment Fund. Dr. Chan co-founded Andrew Technologies, a medical device company commercializing its HydraSolve™ lipoplasty system for plastic surgery. He is a Board-certified Internal Medicine physician with a strong background in clinical medicine and research. Dr. Chan received his MD and PhD from the Yale University School of Medicine and completed his Internal Medicine residency at Beth Israel Deaconess Medical Center at Harvard. He also holds a BS in cell and molecular biology from Cornell University.

**Al Kraus.** Mr. Kraus has been a director of the Company since 2003 and up until the end of 2008 was the Company's President and CEO. Mr. Kraus currently serves as Chairman of the Board of Directors. Mr. Kraus has more than twenty-five years' experience managing companies in the dialysis, medical device products, personal computer and custom software industries. Prior to joining us, from 2001 to 2003, Mr. Kraus was President and CEO of NovoVascular Inc., an early stage company developing coated stent technology. From 1996 to 1998, Mr. Kraus was President and CEO of Althin Healthcare and from 1998 to 2000, of Althin Medical Inc., a manufacturer of products for the treatment of end stage renal disease. While CEO of Althin, he provided strategic direction and management for operations throughout the Americas. From 1979 to 1985, Mr. Kraus was U.S. Subsidiary Manager and Chief Operating Officer of Gambro Inc., a leading medical technology and healthcare company. Mr. Kraus was the Chief Operating Officer of Gambro when it went public in the United States in an offering led by Morgan Stanley.

**Edward R. Jones, MD, MBA.** Dr. Jones has been a director of the Company since April 2007. Dr. Jones is an attending physician at the Albert Einstein Medical Center and Chestnut Hill Hospital as well as Clinical Professor of Medicine at Temple University Hospital. Dr. Jones has published or contributed to the publishing of 30 chapters, articles, and abstracts on the subject of treating kidney-related illnesses. He is a sixteen-year member of the Renal Physicians Association, the Philadelphia County Medical Society and a past board member of the National Kidney Foundation of the Delaware Valley. Dr. Jones is a past President of the Renal Physicians Association.

**James Gunton, MBA.** Mr. Gunton became a director of the Company in 2008. He is a cofounder of the NJTC Investment Fund. Mr. Gunton has been investing in privately-held growth technology companies for fifteen years. Before co-founding in 2001 the \$80 million NJTC Investment Fund, Jim was a manager at Oracle Corporation in the Silicon Valley. He represents NJTC Investment Fund at nine portfolio companies and is a former Governor of the National Association of Small Business Investment Companies. Jim earned a BS from Stanford University and an

MBA with distinction from Duke University.

***Alan D. Sobel, CPA.*** Mr. Sobel has been a director of the Company since November 2014. Since 1994, Mr. Sobel has served as the Managing Member of Sobel & Co., LLC, a full-service accounting, auditing, taxation, and business consulting firm. He has provided corporate advisory and consulting services, including mergers and acquisitions, for clients in the real estate, manufacturing, pharmaceutical, and distribution businesses, among others. Mr. Sobel is a Certified Public Accountant, and has served in various leadership

## TABLE OF CONTENTS

roles including Chairman of the Audit Committee of the New Jersey Society of Certified Public Accountants. He earned a BS in Accountancy from Bentley College and a MS in Taxation from Fairleigh Dickinson University.

**Vincent Capponi, MS.** Mr. Capponi joined the Company as Vice President of Operations in 2002 and became its Chief Operating Officer in July 2005. He has more than 20 years of management experience in medical device, pharmaceutical and imaging equipment at companies including Upjohn, Sims Deltec and Sabratek. Prior to joining CytoSorbents in 2002, Mr. Capponi held several senior management positions at Sabratek and its diagnostics division GDS, and was interim president of GDS diagnostics in 2001. From 1998 to 2000, Mr. Capponi was Senior Vice President and Chief Operating Officer for Sabratek and Vice President Operations from 1996 to 1998. He received his MS in Chemistry and his BS in Chemistry and Microbiology from Bowling Green State University.

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

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

**Robert Bartlett, MD.** Dr. Bartlett became our Chief Medical Officer in January 2009. He is Professor Emeritus of Surgery at the University of Michigan Health System. Prior to becoming Professor Emeritus in 2005, Dr. Bartlett was Director of the Surgical Intensive Care Unit, Chief of the Trauma/Clinical Care Division and Director of the Extracorporeal Life Support Program at the University of Michigan Medical Center. Dr. Bartlett was the pioneer in the development of the extracorporeal membrane oxygenation machine (ECMO), used to oxygenate blood in critically ill patients worldwide. He received his MD from the University of Michigan Medical School, cum laude. He completed his general surgery residency at Peter Bent Brigham Hospital in Boston, and was Chief resident in thoracic surgery. Dr. Bartlett was also a NIH Trainee in Academic Surgery at Harvard Medical School, and was previously faculty at the University of California, Irvine. Dr. Bartlett is the recipient of 26 separate research grants, 14 from the National Institute of Health, including an RO1 grant for the development of a totally artificial lung. He has also received numerous national and international awards for his contributions to critical care medicine.

## **Audit Committee Financial Expert**

On November 11, 2014, our Board of Directors, upon the recommendation of a majority of the independent directors of the Board of Directors, unanimously appointed Alan D. Sobel to serve as a member of the Board of Directors, effective November 13, 2014. The Board also appointed Mr. Sobel to serve as Chairperson of the newly formed Nominating and Corporate Governance Committee of the Board and to serve as Chairperson of the newly formed

Audit Committee of the Board. The Audit Committee of the Board is comprised of three directors, all of which meet independence standards set forth in NASDAQ Marketplace Rule 4200(a)(15). The Board of Directors have determined that Mr. Sobel qualifies as an audit committee financial expert, as such term is defined by Item 4.07(d)(5) of Regulation S-K as promulgated by the Securities and Exchange Commission.

TABLE OF CONTENTS

## **Code of Business Conduct and Ethics**

In October, 2013, the Company adopted a Code of Business Conduct and Ethics. All CytoSorbents employees, including our Chief Executive Officer and other senior executives, are required to comply with the Code of Business Conduct and Ethics to help ensure that our business is conducted in accordance with the highest standards of ethical behavior. Our Code of Conduct covers all areas of professional conduct, including customer relationships, conflicts of interest, insider trading, intellectual property and confidential information, as well as requiring strict adherence to all

laws and regulations applicable to our business. Employees are required to bring any violations and suspected violations of the Code of Conduct to the attention of the Company, through management, the Board of Directors, or our legal counsel. At the current time, the Code of Business Conduct has been signed by all employees in the United States and is being translated into German. Upon completion of the translation, we will secure the signatures of our Germany-based employees.

TABLE OF CONTENTS**EXECUTIVE COMPENSATION**

The following summary compensation table sets forth all compensation awarded to, earned by, or paid to the named executive officers paid by us during the periods ended December 31, 2013 and 2012. All disclosures have been updated to give effect to the reverse stock split which occurred on December 3, 2014.

**Summary Compensation Table**

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

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards <sup>(1)</sup> (\$)	All Other Compensation	Total (\$)
Phillip Chan	2013	245,368 <sup>(2)</sup>	-0-	-0-	-0-	245,368
<i>Chief Executive Officer</i>	2012	231,496	-0-	-0-	8,000	239,496
Vincent Capponi,	2013	222,445 <sup>(3)</sup>	200	-0-	-0-	239,645
<i>Chief Operating Officer</i>	2012	219,674	30,200	-0-	-0-	249,874
Kathleen P. Bloch,	2013	118,974	-0-	5,375 <sup>(4)</sup>	-0-	124,549
<i>Chief Financial Officer<sup>(5)</sup></i>	2012	-0-	-0-	-0-	-0-	-0-
David Lamadrid	2013	-0-	-0-	-0-	-0-	-0-
<i>Chief Financial Officer<sup>(5)</sup></i>	2012	108,706	-0-	-0-	-0-	108,706
Ronald Berger	2013	-0-	200	9,800 <sup>(6)</sup>	100,526	110,526
<i>Interim Chief Financial Officer<sup>(5)</sup></i>	2012	-0-	200	1,030 <sup>(7)</sup>	102,472	103,702
Dr. Robert Bartlett	2013	-0-	-0-	-0-	52,000	52,000
<i>Chief Medical Officer</i>	2012	-0-	-0-	-0-	52,000	52,000

The value of option awards granted to the Named Executive Officers has been estimated pursuant to recognition requirements of accounting standards for accounting for stock-based compensation for the options described in the footnotes below, except that for purposes of this table, we have assumed that none of the options will be forfeited.

(1) The Named Executive Officers will not realize the estimated value of these awards in cash until these awards are vested and exercised or sold. For information regarding our valuation of option awards, see Stock-Based Compensation in Note 2 of our financial statements for the period ended December 31, 2013.

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

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

In connection with her employment, Ms. Bloch received options to purchase 40,000 shares on May 29, 2013 at an (4) exercise price of \$2.90. These options vest as follows: (1) 20,000 on May 9, 2014; and (2) 20,000 on May 9, 2015 and expire on May 29, 2023.

Mr. Lamadrid resigned as our Chief Financial Officer effective July 11, 2012. Mr. Berger assumed the position of (5) Interim CFO on July 12, 2012. On May 29, 2013, Ms. Bloch became Chief Financial Officer. Her annual salary is \$200,000.

(6) On February 6, 2013, Mr. Berger received options to purchase 14,000 shares of stock at an exercise price of \$2.65. These options vested on February 6, 2013, and expire five years from the date of issuance.

(7) On January 18, 2012, Mr. Berger received options to purchase 1,200 shares of stock at an exercise price of \$4.20. Twenty (20) percent of the options vested immediately upon issuance and the remainder vest evenly over five



years and expire in five years.  
70

---

TABLE OF CONTENTS**Outstanding Equity Awards at Fiscal Year End**

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

**Outstanding Equity Awards At December 31, 2013**

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Option Awards		Option Exercise Price (\$)	Option Expiration Date
		Number of Securities Underlying Unexercised Options (#) Unexercisable			
Phillip Chan	600		2,000	(1)	12/31/18
	100,155		2,100	(1)	1/8/19
	16,000	4,000	4,325	(2)	1/4/20
	89,100		3,450	(1)	5/5/20
Vincent Capponi		66,000	2,875	(3)	4/4/23
	2,000		41.25	(1)	12/31/16
	44,000		6.25	(1)	01/16/18
	88,000		0.875	(1)	06/25/18
	16,000		4.200	(1)	01/28/19
	16,000	4,000	4,325	(2)	1/4/20
	81,300		3,450	(1)	5/5/20
Kathleen P. Bloch		62,000	2,875	(4)	4/4/23
	0	40,000	2,900	(5)	5/7/23
		20,000	2,875	(6)	4/4/23
Robert Bartlett	2,000		2,100	(1)	01/08/14
	5,600	140	4,325	(7)	1/4/20
	20,600		3,450	(1)	5/5/20
		16,000	2,875	(8)	4/4/23

(1) Fully vested.

(2) Vests and becomes exercisable as to (i) 4,000 shares on January 4, 2010; (ii) 4,000 shares on January 4, 2011; (iii) 4,000 shares on January 4, 2012; (iv) 4,000 shares on January 4, 2013; and (v) 4,000 shares on January 4, 2014.

These options will become exercisable based on the achievement of certain milestones connected to the Company's operations, subject to approval by the Board of Directors. In March 2014 the Board of Directors reviewed the milestones achieved, and determined that Dr. Chan earned 30,500 of the milestone options which vest and become exercisable as to (i) 15,250 on December 31, 2014; and (ii) 15,250 on December 31, 2015. The remaining 35,500 options were cancelled.

(4) These options will become exercisable based on the achievement of certain milestones connected to the Company's operations, subject to approval by the Board of Directors. In March 2014 the Board of Directors reviewed the milestones achieved, and determined that Mr. Capponi earned 30,000 of the milestone options which vest and become exercisable as to (i) 15,000 on December 31, 2014; and (ii) 15,000 on December 31, 2015. The remaining

32,000 options were cancelled.

- (5) Vests and becomes exercisable as to (1) 20,000 shares on May 9, 2014; and (ii) 20,000 shares on May 9, 2015. These options will become exercisable based on the achievement of certain milestones connected to the Company's operations, subject to approval by the Board of Directors. In March 2014 the Board of Directors reviewed the milestones achieved, and determined that Ms. Bloch earned 20,000 of the milestone options which vests and becomes exercisable as to (i) 10,000 on December 31, 2014; and (ii) 10,000 on December 31, 2015.

71

---

TABLE OF CONTENTS

- (7) Vests and becomes exercisable as to (i) 1,400 shares on January 4, 2010; (ii) 1,400 shares on January 4, 2011; (iii) 1,400 shares on January 4, 2012; (iv) 1,400 shares on January 4, 2013; and (v) 1,400 shares on January 4, 2014. These options will become exercisable based on the achievement of certain milestones connected to the Company's operations, subject to approval by the Board of Directors. In March, 2014, based upon milestones achieved, the Board awarded Dr. Bartlett 8,000 of the milestone options which vests and becomes exercisable as to (i) 4,000 on December 31, 2014; and (ii) 4,000 on December 31, 2015.

**Director Compensation**

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

**Director Compensation for Fiscal 2013**

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

- The value of option awards granted to directors has been estimated pursuant to the recognition requirements of accounting standards for accounting for stock-based compensation for the options described in the footnotes below, except that for purposes of this table, we have assumed that none of the options will be forfeited. The directors will not realize the estimated value of these awards in cash until these awards are vested and exercised or sold. For information regarding our valuation of option awards, see **Stock-Based Compensation** in Note 2 of our financial statements for the period ended December 31, 2013.

- (1) In connection with his service as a director in 2013 we issued Mr. Rubin options to purchase 6,000 shares of our common stock at an exercise price of \$2.875 per share, which were granted on April 4, 2013 and expire on April 4, 2023. All 6,000 shares vest and become exercisable on April 4, 2014. Mr. Rubin passed away in September 2014.

- (2) In connection with his service as a director in 2013 we issued Dr. Jones options to purchase 6,000 shares of our common stock at an exercise price of \$2.875 per share, which were granted on April 4, 2013 and expire on April 4, 2023. All 6,000 shares vest and become exercisable on April 4, 2014.

- (3) In connection with Mr. Gunton's service as a director in 2013, the NJTC Investment Fund, LP was issued options to purchase 6,000 shares of our common stock at an exercise price of \$2.875 per share, which were granted on April 4, 2013 and expire on April 4, 2023. All 6,000 shares vest and become exercisable on April 4, 2014.

- (4) Pursuant to an agreement and in connection with Mr. Kraus's service as a director in 2013 we issued options to purchase 12,000 shares of our common stock at an exercise price of \$2.875 per share, which were granted on April 4, 2013 and expire on April 4, 2023. All 12,000 shares vest and become exercisable on April 4, 2014.

- (5) Effective July 24, 2008, Dr. Chan was appointed to the Company's Board of Directors and Compensation Committee. Effective January 1, 2009, Dr. Chan entered into an employment agreement becoming interim Chief Executive Officer of the Company. In January 2009, Dr. Chan resigned his position as a member on the

Compensation Committee. Dr. Chan officially became CEO and President in 2010. During 2013, Dr. Chan was an employee Director and was not eligible to receive compensation for Director services.

In 2007, we approved arrangements under which each non-employee director receives a fee of \$2,000 for each quarterly Board meeting attended in person and a fee of \$1,000 for each quarterly Board meeting participated in by telephone. In 2013, these fees were increased to \$2,500 for in person participation and \$1,000 for conference call participation in each quarterly meeting. In addition, each non-employee director will be eligible to be issued options to purchase up to 400 shares of our common stock. Such options will be

TABLE OF CONTENTS

exercisable in accordance with the Company's option pricing policy on the date of grant. Our directors are also reimbursed for actual out-of-pocket expenses incurred by them in connection with their attendance at meetings of the Board of Directors.

In connection with his appointment as Chairman of the Board in January 2009, we agreed to compensate Mr. Kraus at the rate of \$20,000 per annum, and on January 8, 2009 we issued Mr. Kraus a ten year option to purchase 8,000 shares of our common stock at a price of \$2.10 per share. In December 2009, we issued Mr. Kraus an additional option to purchase 4,000 shares of common stock at an exercise price of \$4.15 per share. Additionally for services performed as Chief Executive Officer of the company through December 31, 2008, the Board approved a 10 year option to purchase 18,000 shares of our common stock at a price of \$4.20 per share on January 28, 2009. In January 2011, we renewed the agreement with Al Kraus, as Chairman of the Board of Directors for an additional two year term period. In February 2013, Mr. Kraus entered into another agreement with the Company to remain Chairman of the Board for the fiscal 2013 year, compensated at \$25,000 per annum, with the issuance of a ten year option to purchase 12,000 shares of our common stock at a price of \$2.875 per share.

## **Employment Agreements with Named Executive Officers**

### Phillip Chan

Effective December 31, 2013, we renewed the employment agreement by and between Dr. Phillip Chan and the Company as Chief Executive Officer retroactive to January 1, 2013. Per the terms of the agreement, we agreed to pay Phillip Chan an annual base compensation of \$245,386 payable in equal semimonthly installments in accordance with our usual practice. This base compensation shall be subject to review by our Compensation Committee, but his compensation may not be reduced from then current level. He is eligible for employee stock options, which will be adjusted on the same basis as all other stockholders to account for any stock split, stock dividends, combination or recapitalization.

### Vincent Capponi

Effective December 31, 2013, we renewed the employment agreement by and between Vincent Capponi and the Company as Chief Operating Officer retroactive to January 1, 2013. Per the terms of the agreement, we agree to pay Vincent Capponi an annual base compensation of \$239,445 payable in equal semimonthly installments in accordance with our usual practice. This base compensation shall be subject to review by our Compensation Committee, but his compensation may not be reduced from then current level. He is eligible for employee stock options, which will be adjusted on the same basis as all other stockholders to account for any stock split, stock dividends, combination or recapitalization.

### Robert Bartlett

Effective December 31, 2013, we renewed the consulting agreement with Dr. Bartlett. Pursuant to this consulting agreement, in 2013 we agreed to pay Dr. Robert Bartlett consulting fees at an annualized rate of \$52,000 payable in equal monthly installments of \$4,333.33 per month. In addition, effective December 31, 2013, we entered into a consulting agreement for 2014 in which we agreed to pay Dr. Robert Bartlett consulting fees at an annualized rate of \$53,000 payable in equal monthly installments of \$4,416.67 per month. He is eligible for stock options, which will be adjusted on the same basis as all other stockholders to account for any stock split, stock dividends, combination or recapitalization.

Kathleen P. Bloch

Effective May 29, 2013, we entered into the employment agreement with Ms. Kathleen P. Bloch. Pursuant to this employment agreement, Ms. Bloch will perform the services and duties that are normally and customarily associated with these positions as well as other associated duties as our Board reasonably determines. The agreement commences on May 29, 2013 and expires on May 31, 2014 and calls for an initial base salary of \$200,000 payable in equal semi-monthly installments in accordance with the Company's usual practice. As a signing bonus, Ms. Bloch was also given a ten-year option to purchase 40,000 shares of the Company's common stock. This option vests in equal installments over the next two years: 20,000 options at the 12 month anniversary, and 20,000 options at 24 month anniversary of the signing of this employment agreement, provided that Ms. Bloch remains a full-time employee of the Company.

TABLE OF CONTENTS

**CERTAIN RELATIONSHIPS AND RELATED  
TRANSACTIONS**

**Director Independence**

All members of our Board of Directors, other than Phillip Chan, our President and Chief Executive Officer, are independent under the standards set forth in Nasdaq Marketplace Rule 4200(a)(15).

74

---



TABLE OF CONTENTS

# SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT PRINCIPAL STOCKHOLDERS

The following table sets forth information known to us with respect to the beneficial ownership of common stock held of record as of December 3, 2014, as adjusted for the reverse split by (1) all persons who are owners of 5% or more of our common stock, (2) each of our named executive officers (see Summary Compensation Table ), (3) each director, and (4) all of our executive officers and directors as a group. Each of the stockholders can be reached at our principal executive offices located at 7 Deer Park Drive, Suite K, Monmouth Junction, New Jersey 08852.

	SHARES BENEFICIALLY OWNED <sup>(1)</sup>	
	Number	Percent (%)
Directors and Executive Officers		
Al Kraus <sup>(2)</sup> , <i>Chairman of the Board of Directors</i>	398,281	1.5 %
Phillip Chan <sup>(3)</sup> , <i>President and Chief Executive Officer, Director</i>	393,798	1.4 %
Vince Capponi <sup>(4)</sup> <i>Chief Operating Officer</i>	360,024	1.3 %
Joseph Rubin <sup>(5)</sup> <i>Director</i>	76,683	*
Robert Bartlett <sup>(6)</sup> <i>Chief Medical Officer</i>	55,600	*
James Gunton <sup>(7)</sup> <i>Director</i>	4,895,779	18.0 %
Edward R. Jones <sup>(8)</sup> <i>Director</i>	27,300	*
Thomas Bocchino**		*
Ronald Berger <sup>(9)</sup> <i>Former Interim Chief Financial Officer***</i>	53,420	*
Kathleen Bloch <sup>(10)</sup> <i>Chief Financial Officer***</i>	123,000	*
All directors and executive officers as a group (ten persons)	6,383,885	23.5 %
Beneficial Owners of more than 5% of common stock (other than directors and executive officers)		
Robert Shipley <sup>(11)</sup>	2,973,219	10.9 %
NJTC Venture Fund SBIC, LP <sup>(12)</sup>	4,895,779	18.0 %

\*

Less than 1%.

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

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

Based upon 27,166,024 fully-diluted shares of Common Stock and common stock equivalents as of December 3, 2014. Shares of Common Stock subject to options or warrants currently exercisable or expected to be exercisable with the passage of time, are deemed outstanding for purposes of computing the percentage of the person holding such options or warrants.

(2)

Edgar Filing: Cytosorbents Corp - Form S-1/A

Includes 65,746 shares of common stock and 332,535 shares of common stock issuable upon exercise of stock options.

(3) Includes 71,976 shares of common stock and 321,822 shares of common stock issuable upon exercise of warrants and stock options.

(4) Includes 16,724 shares of common stock and 343,300 shares of common stock issuable upon exercise of stock options.

(5) Includes 32,986 shares of common stock, 40,299 shares of common stock issuable upon exercise of warrants and stock options, and 3,398 shares of common stock beneficially owned by Mr. Rubin's spouse, as to which he disclaims beneficial ownership. Mr. Rubin passed away in September 2014.

(6) These shares are issuable upon exercise of stock options.

75

---

TABLE OF CONTENTS

Includes 4,870,219 shares of common stock and 25,560 shares of common stock issuable upon exercise of stock (7) options. These securities are held directly by NJTC Investment Fund SBIC, LP, of which Mr. Gunton is a partner. Mr. Gunton disclaims beneficial ownership.

(8) These shares are issuable upon exercise of stock options.

(9) Includes 13,486 shares of common stock, 39,934 shares of common stock issuable upon exercise of warrants and stock options.

(10) Includes 116,000 shares of common stock issuable upon exercise of stock options, and 7,000 shares of common stock beneficially owned by Ms. Bloch's spouse, as to which she disclaims beneficial ownership.

(11) Includes 2,972,819 shares of common stock, and 400 shares of common stock issuable upon exercise of stock options.

(12) Includes 4,870,219 shares of common stock and 25,560 shares of common stock issuable upon exercise of stock options. These securities are held directly by NJTC Investment Fund SBIC, LP and indirectly through James Gunton, a partner at NJTC.

## **Auditors; Code of Ethics; Audit Committee**

On November 11, 2014, our Board of Directors, upon the recommendation of a majority of the independent directors of the Board of Directors, unanimously appointed Alan D. Sobel to serve as a member of the Board of Directors, effective November 13, 2014. The Board also appointed Mr. Sobel to serve as Chairperson of the newly formed Nominating and Corporate Governance Committee of the Board and to serve as Chairperson of the newly formed Audit Committee of the Board. The Audit Committee of the Board is comprised of three directors, all of which meet independence standards set forth in NASDAQ Marketplace Rule 4200(a)(15). The Board of Directors have determined that Mr. Sobel qualifies as an audit committee financial expert, as such term is defined by Item 4.07(d)(5) of Regulation S-K as promulgated by the Securities and Exchange Commission.

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

TABLE OF CONTENTS**EQUITY COMPENSATION PLAN INFORMATION**

The following table summarizes outstanding options as of December 31, 2013, after giving effect to the reverse stocksplit and the merger and subsequent grants.\* The Registrant had no options outstanding prior to the 2006 Merger, and all of the options below were issued either in connection with the 2006 Merger to former option holders of CytoSorbents or subsequently as new grants to employees, directors, and consultants.

	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column)	
Equity compensation plans approved by stockholders	0	n/a	16,000	(1)
Equity compensation plans not approved by stockholders	1,916,962	\$ 5.00	12,156	(2)
Total	1,916,962 <sup>(3)</sup>	\$ 0.20 <sup>(3)</sup>	12,156	

Effective December 2, 2014, the Company's stockholders, approved the forms, terms and provisions of the \*CytoSorbents Corporation 2014 Long-Term Incentive Plan, under which 2,400,000 shares of common stock are authorized for issuance.

(1) Represents options that may be issued under our 2003 Stock Option Plan.

Represents the number of options that may be issued under our 2006 Long-Term Incentive Plan, after giving effect (2) to options cancelled. The options available under the pool may be increased to maintain 15% of the fully diluted share count as needed.

(3) Represents options to purchase (i) 76 shares of common stock at a price of \$539.25 per share, (ii) 16,995 shares of common stock at a price of \$166.00 per share, (iii) 6,800 shares of common stock at a price of \$47.50 per share, (iv) 12,240 shares of common stock at a price of \$41.25 per share, (v) 16,000 shares of common stock at a price of \$31.50 per share, (vi) 6,673 shares of common stock at a price of \$31.25 per share, (vii) 120,200 shares of common stock at a price of \$6.25 per share, (viii) 5,505 shares of common stock at a price of \$5.50, (ix) 94,800 shares of common stock at a price of \$4.325 per share, (x) 89,000 shares of common stock at a price of \$4.20, (xi) 1,000 shares of common stock at a price of \$4.173, (xii) 16,320 shares of common stock at a price of \$4.15, (xiii) 16,320 shares of common stock at a price of \$4.125, (xiv) 1,000 shares of common stock at a price of \$4.095, (xv) 200 shares of common stock at a price of \$3.975, (xvi) 1,000 shares of common stock at a price of \$3.910, (xvii) 80 shares of common stock at a price of \$3.85, (xviii) 2,000 shares of common stock at a price of \$3.845, (xix) 20,000 shares of common stock at a price of \$3.705, (xx) 1,400 shares of common stock at a price of \$3.575, (xxi) 4,000 shares of common stock at a price of \$3.50, (xxii) 324,800 shares of common stock at a price of \$3.45, (xxiii) 3,600 shares of common stock at a price of \$3.40 per share, (xxiv) 12,080 shares of common stock at a price of \$3.35 per share, (xxv) 2,000 shares of common stock at a price of \$3.323 per share, (xxvi) 21,000 shares of common stock at a price of \$3.25 per share, (xxvii) 30,000 shares of common stock at a price of \$3.225 per share,

Edgar Filing: Cytosorbents Corp - Form S-1/A

(xxviii) 8,000 shares of common stock at a price of \$3.215 per share, (xxix) 3,240 shares of common stock at a price of \$3.075 per share, (xxx) 40,000 shares of common stock at a price of \$2.90 per share, (xxxi) 412,200 shares of common stock at a price of \$2.875 per share, (xxxii) 400 shares of common stock at a price of \$2.675 per share, (xxxiii) 31,800 shares of common stock at a price of \$2.65 per share, (xxxiv) 1,200 shares of common stock at a price of \$2.425 per share, (xxxv) 80 shares of common stock at a price of \$2.25 per share, (xxxvi) 280 shares of common stock at a price of \$2.225 per share, (xxxvii) 110,155 shares at a price of \$2.10 per share, (xxxviii) 4,000 shares of common stock at a price of \$2.00 per share, and (xxxix) 480,518 shares of common stock at a price of \$0.875 per share.

77

---

TABLE OF CONTENTS

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

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

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

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

TABLE OF CONTENTS

## DESCRIPTION OF SECURITIES

### General

As of September 30, 2014, our total authorized capital stock consists of 800,000,000 shares of Common Stock, par value \$0.001 per share and 100,000,000 shares of preferred stock, par value \$0.001 per share. As of September 30, 2014, we had designated 12,000,000 shares of our preferred stock as Series A 10% Cumulative Convertible Preferred Stock (the Series A Preferred Stock ), and 200,000 shares of our preferred stock as Series B 10% Cumulative Convertible Preferred Stock (the Series B Preferred Stock ). As of September 30, 2014, there were 322,775,473 shares of our Common Stock outstanding, 84,283.99 shares of our Series B Preferred Stock outstanding, and 1,894,969 shares of Series A Preferred outstanding.

#### Conversion of Series A Shares into Shares of Common Stock

On October 9, 2014, the Company filed with the Nevada Secretary of State an Amendment (the Series A Amendment ) to the Certificate of Designation, as amended (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.

#### Conversion of Series B Shares into Shares of Common Stock

On October 9, 2014, the Company also filed with the Nevada Secretary of State an Amendment (the Series B Amendment ) to the Certificate of Designation (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 (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 conversion price 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 were issued a dividend of 10%, and then the 92,712.27 shares of Series B Preferred Stock were converted into 256,111,243 shares of Common Stock.

## Description of Capital Stock Following Certain Corporate Actions

On December 1, 2014, the Company received stockholder approval authorizing the Company's Board of Directors to (i) amend the Company's Articles of Incorporation, as amended, to effect a reverse split of the Company's Common Stock, with a reverse split ratio of twenty-five-to-one (25:1); (ii) amend the Company's 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 the Company's 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 the



## TABLE OF CONTENTS

Company's 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-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 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 wholly-owned Delaware subsidiary. The reincorporation merger was accomplished by the filing of (i) articles of merger with the Secretary of State of the State of Nevada, and (ii) a certificate of merger with the Secretary of State of the State of Delaware. 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 approximately 64.37% of our outstanding common stock. As of December 3, 2014, our total authorized capital stock consists of 50,000,000 shares of common stock, \$0.001 par value per share and 5,000,000 shares of preferred stock, \$0.001 par value per share. As of December 3, 2014, there were 23,284,040 shares of our Common Stock issued and outstanding and no shares of preferred stock issued and outstanding.

## **Common Stock**

After giving effect to the merger, the holders of common stock will be entitled to one vote per share on all matters to be voted upon by the stockholders. The holders of common stock will be entitled to receive ratably those dividends, if any, that may be declared from time to time by our board of directors out of funds legally available, subject to preferences that may be applicable to preferred stock, if any, then outstanding. In the event of a liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding. The common stock has no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and non-assessable, and will be fully-paid and non-assessable following the merger.

## **Preferred Stock**

After giving effect to the merger, our Board of Directors will be authorized to issue preferred stock in one or more series, to establish the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of these shares and any qualifications, limitations or restrictions thereof. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of the Company without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others. At present, we have no plans to issue any of the preferred stock.



TABLE OF CONTENTSWarrants

As of September 30, 2014, the Company has the following warrants to purchase common stock outstanding:

Number of Shares To be Purchased	Warrant Exercise Price per Share	Warrant Expiration Date
70,000	\$ 2.500	August 16, 2015
64,000	\$ 3.125	August 16, 2015
53,335	\$ 3.750	August 16, 2015
19,600	\$ 2.500	October 22, 2015
7,840	\$ 3.125	October 22, 2015
6,535	\$ 3.750	October 22, 2015
20,000	\$ 2.500	November 19, 2015
8,000	\$ 3.125	November 19, 2015
6,667	\$ 3.750	November 19, 2015
28,000	\$ 2.500	February 15, 2016
61,600	\$ 3.125	February 15, 2016
56,670	\$ 3.750	February 15, 2016
9,605	\$ 31.250	October 24, 2016
46,668	\$ 4.375	February 10, 2017
175,680	\$ 3.750	June 21, 2018
149,000	\$ 3.125	September 30, 2018
816,000	\$ 7.815	March 11, 2019
48,960	\$ 7.500	March 11, 2019
1,648,160		

**Underwriter Warrants**

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 to the Underwriters 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.

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



TABLE OF CONTENTSOptions

As of September 30, 2014, the Company had the following options outstanding:

# of Options Outstanding	Exercise Price	Expiration Date
437	\$ 166.00	December 29, 2014
600	\$ 4.33	January 4, 2015
1,400	\$ 3.58	April 12, 2015
3,600	\$ 3.40	January 6, 2016
2,400	\$ 31.25	January 30, 2016
3,273	\$ 31.25	June 12, 2016
1,000	\$ 31.25	July 29, 2016
13,284	\$ 166.00	September 29, 2016
120	\$ 41.25	October 2, 2016
4,000	\$ 41.25	December 31, 2016
3,274	\$ 166.00	December 31, 2016
8,120	\$ 41.25	January 1, 2017
6,800	\$ 47.50	January 16, 2017
2,400	\$ 4.20	January 18, 2017
16,000	\$ 31.50	February 8, 2017
20,000	\$ 3.25	March 6, 2017
8,000	\$ 3.22	June 1, 2017
4,000	\$ 3.50	August 30, 2017
12,000	\$ 3.71	October 1, 2017
5,505	\$ 5.50	December 31, 2017
120,200	\$ 6.25	January 16, 2018
3,240	\$ 3.08	January 16, 2018
17,200	\$ 2.65	February 6, 2018
12,000	\$ 2.60	March 25, 2018
15,000	\$ 2.88	April 4, 2018
385,466	\$ 0.88	June 25, 2018
4,000	\$ 2.45	August 30, 2018
4,000	\$ 2.00	December 31, 2018
108,155	\$ 2.10	January 8, 2019
70,000	\$ 4.20	January 28, 2019
8,000	\$ 6.85	January 28, 2019
8,000	\$ 6.63	February 17, 2019
4,000	\$ 4.88	March 28, 2019
12,000	\$ 4.15	December 31, 2019
4,320	\$ 4.15	January 1, 2020
76,440	\$ 4.33	January 4, 2020
80	\$ 3.85	March 31, 2020
316,800	\$ 3.45	May 5, 2020
80	\$ 2.23	June 30, 2020
80	\$ 2.25	September 30, 2020
12,080	\$ 3.35	December 31, 2020

Edgar Filing: Cytosorbents Corp - Form S-1/A

8,000	\$ 3.45	January 6, 2021
2,000	\$ 3.32	November 17, 2021
1,000	\$ 4.17	January 2, 2022
16,320	\$ 4.13	January 18, 2022

82

---

TABLE OF CONTENTS

# of Options Outstanding	Exercise Price	Expiration Date
1,000	\$ 3.31	January 23, 2022
2,000	\$ 3.85	February 22, 2022
1,000	\$ 3.25	May 14, 2022
12,650	\$ 2.65	February 6, 2023
2,000	\$ 2.50	March 5, 2023
217,100	\$ 2.88	April 4, 2023
30,000	\$ 3.23	April 15, 2023
40,000	\$ 2.90	May 7, 2023
3,000	\$ 6.00	March 10, 2024
578,000	\$ 4.88	March 28, 2024
8,000	\$ 2.88	April 4, 2024
2,000	\$ 6.08	July 1, 2024
3,000	\$ 6.20	August 8, 2024
2,000	\$ 5.83	September 19, 2024
1,400	\$ 5.45	September 26, 2024
6,000	\$ 5.55	September 29, 2024
2,233,824		

Of the 2,233,824 options outstanding, 1,343,831 are vested and 889,993 are not vested at September 30, 2014.

## Anti-Takeover Provisions

On December 1, 2014, the Company received stockholder approval authorizing the Company's Board of Directors to (i) amend the Company's Articles of Incorporation, as amended, to effect a reverse split of the Company's Common Stock, with a reverse split ratio of twenty-five-to-one (25:1); (ii) amend the Company's 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 the Company's 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 the Company's 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

Edgar Filing: Cytosorbents Corp - Form S-1/A

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.

Some provisions of Delaware law and the certificate of incorporation and bylaws after giving effect to the merger could make the acquisition of the Company by means of a tender offer, a proxy contest or otherwise

83

---



TABLE OF CONTENTS

more difficult. These provisions, summarized below, are expected to discourage and prevent coercive takeover practices and inadequate takeover bids. These provisions are designed to encourage persons seeking to acquire control to negotiate first with the board of directors. They are also intended to provide management with the flexibility to enhance the likelihood of continuity and stability if the board of directors determines that a takeover is not in the best interests of its stockholders. These provisions, however, could have the effect of discouraging attempts to acquire the Company, which could deprive its stockholders of opportunities to sell their shares of common stock at prices higher than prevailing market prices. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

*Special Stockholder Meetings.* Under the certificate of incorporation and bylaws after giving the effect to the merger, only the board of directors, the chairman of the board, and the chief executive officer may call special meetings of stockholders.

*Requirements for Advance Notification of Stockholder Nominations and Proposals.* After giving effect to the merger, the bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of its board of directors or a committee of its board of directors.

*Delaware Anti-takeover Law.* Following the merger the Company will be subject to Section 203 of the Delaware General Corporation Law, which is an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date that the person became an interested stockholder, unless the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or another transaction resulting in a financial benefit to the interested stockholder. Generally, an interested stockholder is a person who, together with affiliates and associates, owns 15.0% or more of the corporation's voting stock. The existence of this provision may have an anti-takeover effect with respect to transactions that are not approved in advance by the board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

*Elimination of Stockholder Action by Written Consent.* The certificate of incorporation and bylaws, after giving effect to the merger, eliminate the right of stockholders to act by written consent without a meeting.

*No Cumulative Voting.* Under Delaware law, cumulative voting for the election of directors is not permitted unless a corporation's certificate of incorporation authorizes cumulative voting. The certificate of incorporation, after giving effect to the merger, does not provide for cumulative voting in the election of directors. Cumulative voting allows a minority stockholder to vote a portion or all of its shares for one or more candidates for seats on our board of directors. Without cumulative voting, a minority stockholder will not be able to gain as many seats on our board of directors based on the number of shares of stock the stockholder holds as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence its decision regarding a takeover.

*Undesignated Preferred Stock.* The authorization of undesignated preferred stock makes it possible for the board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of the company.

These and other provisions could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of the common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

TABLE OF CONTENTS

**Transfer Agent**

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

**Interests of Named Experts and Counsel**

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

DLA Piper LLP (US) located at 51 John F. Kennedy Parkway, Suite 120, Short Hills, NJ 07078 will pass on the validity of the securities being offered pursuant to this prospectus. Certain legal matters relating to the Offering will be passed upon for the Underwriters by Goodwin Procter LLP, Boston, Massachusetts.

The financial statements as of December 31, 2013 and December 31, 2012, and for the years ended December 31, 2013 and 2012, included in this prospectus and the registration statement have been audited by WithumSmith+Brown, PC, an independent registered public accounting firm, to the extent and for the periods set forth in their report appearing elsewhere herein and in the registration statement, and are included in reliance upon such report given upon the authority of said firm as experts in auditing and accounting.

TABLE OF CONTENTS**UNDERWRITING**

Brean Capital, LLC, H.C. Wainwright and Co., LLC. or the Representatives, are acting as the joint book-running managers of this offering and as the representatives of the underwriters in this offering. We have entered into an underwriting agreement dated the date of this prospectus with the Representatives. Subject to the terms and conditions set forth in an underwriting agreement dated the date of this prospectus among us and the underwriters named below, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase from us, the number of units listed next to its name in the following table. Unless otherwise indicated, all share and per share amounts have been adjusted for all periods presented to reflect the 25:1 reverse stock split of our common stock effected on December 3, 2014.

Underwriters	Number of Shares
Brean Capital, LLC	
H.C. Wainwright & Co., LLC	
Merriman Capital, Inc.	
MLV & Co.	
WBB Securities, LLC	
Total	

The underwriters are committed to purchase all the shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of nondefaulting underwriters may be increased or the offering may be terminated. The underwriters are not obligated to purchase the shares covered by the underwriters' over-allotment option described below. The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

**Discounts and Commissions**

The underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ per share. After the initial offering of the shares, the public offering price and other selling terms may be changed by the Representatives.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Without Option	With Option
Public offering price			
Underwriting discounts and commissions paid by us (6.0%)			
Proceeds, before other expenses, to us <sup>(1)</sup>			

(1) In addition to the underwriting discounts and commissions, we agreed to pay or reimburse the underwriters to cover certain out of pocket expenses of the underwriters in connection with this offering.

The total estimated expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, are approximately \$and are payable by us.

## **Representatives Warrants**

We have also agreed to issue to the Representatives or their designees, at the closing of this offering, warrants, or the Representatives Warrants, to purchase that number of our shares of common stock equal to 3% of the aggregate number of shares sold in the offering, not including the underwriters overallotment option. The Representatives Warrants will be exercisable at any time and from time to time, in whole or in part, during

## TABLE OF CONTENTS

the five-year period commencing on the date of effectiveness of the registration statement of which this prospectus forms a part, at a price per share equal to 120% of the public offering price per share of common stock in the offering. The Representatives' Warrants and the shares of common stock underlying the Representatives' Warrants have been deemed compensation by the Financial Industry Regulatory Authority, or FINRA, and are, therefore, subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The Representatives (or permitted assignees under the Rule) will not sell, transfer, assign, pledge or hypothecate the Representatives' Warrants or the shares of common stock underlying the Representatives' Warrants, nor will they engage in any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the Representatives' Warrants or the common stock underlying the Representatives' Warrants for a period of 180 days after the effective date of the registration statement of which this prospectus is a part. The Representatives' Warrants will provide for piggyback registration rights and customary anti-dilution provisions (for stock dividends and splits and recapitalizations) consistent with FINRA Rule 5110, and further, the number of shares underlying the Representatives' Warrants shall be reduced if necessary to comply with FINRA rules or regulations. Such piggyback registration rights will terminate on the fifth anniversary of the effective date of the registration statement of which this prospectus is a part.

## **Right of First Refusal**

We also granted Brean Capital, LLC a right of first refusal to act as lead or co-lead managing underwriter or lead or co-lead placement agent in any subsequent equity offering or placement of our securities that takes place within nine months following the closing of the offering contemplated in this prospectus. This right of first refusal is subject to a minimum of \$10 million of gross proceeds being raised by the Company in this Offering.

## **Expenses**

In addition to the underwriters' discount, we agreed to pay or reimburse the underwriters (i) accountable expenses of the underwriters in connection with this offering other than as set forth in (ii), (iii) and (iv) below, up to a maximum of \$25,000, (ii) accountable marketing and other road show expenses of the underwriters up to a maximum of \$10,000, (iii) accountable expenses of underwriters for underwriters' counsel relating to this offering up to a maximum of \$100,000, and (iv) accountable expenses of underwriters for underwriters' counsel relating to filings with the Financial Industry Regulatory Authority, or FINRA, up to a maximum of \$15,000.

## **Over-Allotment Option**

We have granted the underwriters an option to purchase up to additional shares at the public offering price, less underwriting discounts and commissions. The underwriters may exercise this option for 30 days from the date of this prospectus solely to cover sales of shares of common stock by the underwriters in excess of the total number of shares set forth in the table above. The underwriters may exercise the over-allotment option in whole or in part and as to shares. If any shares are purchased pursuant to this over-allotment option, the underwriters will purchase the additional shares in approximately the same proportion as shown in the table above. If any of these additional shares are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered. We will pay the expenses associated with the exercise of the over-allotment option.

## **Determination of Offering Price**

The public offering price was negotiated between us and the Representatives. Among the factors considered in these negotiations were:

Edgar Filing: Cytosorbents Corp - Form S-1/A

the market price of our common stock;  
the historical trading range of our common stock;  
the prospects for our company and the industry in which we operate;  
our past and present financial and operating performance;  
financial and operating information and market valuations of publicly traded companies engaged in activities similar  
to ours;

87

---

TABLE OF CONTENTS

the prevailing conditions of U.S. securities markets at the time of this offering; and  
other factors deemed relevant.

## **Lock-Up Agreements**

We, our officers and directors and have entered into lock-up agreements with the underwriters. Under these agreements, we and these other individuals have agreed, subject to specified exceptions, not to sell or transfer any common stock, options, warrants, or other of our securities, during a period ending days after the effectiveness of the registration statement of which this prospectus is a part, without first obtaining the written consent of Representatives.

Specifically, we and these other individuals have agreed not to during a period ending days after the date of the registration statement of which this prospectus forms a part, without first obtaining the written consent of Representatives:

offer, sell, contract to sell, pledge, grant any option to purchase (except for options granted by the Company to our directors and officers), make any short sale or otherwise dispose of, engage in any hedging or other transactions, including, without limitation, any short sale or any purchase, sale or grant of any right (including without limitation any put or call option) with respect to, or with respect to any security that includes, relates to, or derives any significant part of its value from, any of our securities, or any securities convertible into or exercisable or exchangeable for, or any rights to purchase or otherwise acquire, any shares of our securities; or exercise or seek to exercise or effectuate in any manner any rights of any nature to register the sale, transfer or other disposition of any of our securities, or to otherwise participate as a selling security holder in any manner in any registration effected by us.

The restrictions described above do not apply to transfers below, provided that prior to such transfer, the donee, trustee, distributee or transferee shall have executed and delivered a lock-up agreement to the representatives of the underwriters, and with respect to the first six bullets below, the transfer does not involve a disposition for value:

as a bona fide gift or gifts;

to any trust for the direct or indirect benefit of a security holder or the immediate family of a security holder; to any beneficiary of a security holder pursuant to a will or other testamentary document or applicable laws of descent;

to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which are held by a security holder or the immediate family of a security holder;

if the security holder is a corporation, partnership, limited liability company or other business entity, any transfers to any shareholder, partner or member of, or owner of a similar equity interest in, the security holder;

the exercise by a security holder of any stock options or warrants issued pursuant to our existing stock plans, including any exercise effected by the delivery of our securities; provided, that any securities received upon exercise of such options shall be subject to the terms of the lock-up agreement; or of any of the following events: (1) an acquisition by an individual or legal entity or of effective control (whether through legal or beneficial ownership of our capital stock) of 100% of our voting securities; (2) we merge into or consolidate with any other entity, or any entity merges into or consolidates with us; or (3) we sell or transfer all or substantially all of our assets to another person; provided, that, in the case of each of the events set forth in clauses (1) through (3), our securities remain subject to the restrictions on transfer.

88



TABLE OF CONTENTS

## Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

## Listing

Our common stock is currently quoted on the OTCQB Marketplace, operated by the OTC Markets Group, Inc. ( OTCQB ) under the symbol CTSOD (until on or about January 4, 2015) and CTSO (beginning on or about January 5, 2015). In November 2014, we applied to list our common stock on the NASDAQ Capital Market under the symbol CTSO.

## Price Stabilization, Short Positions and Penalty Bids

In order to facilitate the offering of our common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in the offering.

Covered short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of common stock in the offering. The underwriters may close out any covered short position by either exercising their over-allotment option or purchasing shares of common stock in the open market. In determining the source of shares of common stock to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As result, the price of our common stock may be higher than the price that might otherwise exist in the open market.

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of our common stock, including the imposition of penalty bids. This means that if the Representatives purchases common stock in the open market in stabilizing transactions or to cover short sales, the Representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

The underwriters make no representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

## **Electronic Offer, Sale and Distribution of Shares**

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares of common stock to underwriters and selling group members for sale to their online brokerage account holders.

Internet distributions will be allocated by the Representatives and selling group members that may make Internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites and any information contained in any other website maintained by the underwriters is not part of this prospectus or the registration statement of which this prospectus forms a part.

TABLE OF CONTENTS

## **Other Relationships**

From time to time, certain of the underwriters and their affiliates have provided, and may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions.

## **Offer Restrictions Outside the United States**

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

### **Australia**

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer for the offeree under this prospectus.

### **China**

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to qualified domestic institutional investors.

## **European Economic Area Belgium, Germany, Luxembourg and Netherlands**

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC, Prospectus Directive, as implemented in Member States of the

European Economic Area, each, a Relevant Member State, from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- (a) to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);
- (c) to fewer than 100 natural or legal persons (other than qualified investors within the meaning of

90

---

## TABLE OF CONTENTS

Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or

in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of (d) securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

### **France**

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers, or AMF. The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

### **Ireland**

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005, or the Prospectus Regulations. The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(1) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

### **Israel**

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority, or the ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject

to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

## Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società e la Borsa, or CONSOB, pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998, or Decree No. 58, other than:

to Italian qualified investors, as defined in Article 100 of Decree no. 58 by reference to

91

---

## TABLE OF CONTENTS

Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999, or Regulation no. 11971, as amended, or Qualified Investors; and

in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and

in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

## **Japan**

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended, or the FIEL, pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder).

Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors.

Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

## **Portugal**

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are qualified investors (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

## **Sweden**

Edgar Filing: Cytosorbents Corp - Form S-1/A

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are qualified investors (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.



TABLE OF CONTENTS

## **Switzerland**

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority.

This document is personal to the recipient only and not for general circulation in Switzerland.

## **United Arab Emirates**

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates, or the UAE, or any other governmental authority in the UAE, nor has the Company received authorization or licensing from the Central Bank of the UAE or any other governmental authority in the UAE to market or sell the securities within the UAE. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the UAE by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

## **United Kingdom**

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended, or FSMA) has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to qualified investors (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA.

This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005, or FPO, (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated, together Relevant Persons. The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, Relevant Persons. Any person who is not a Relevant Person should not act or rely on this document or any of its contents.

TABLE OF CONTENTS

**FINANCIAL STATEMENTS**

Financial Statements (September 30, 2014 and 2013 are unaudited)

<u>CONSOLIDATED BALANCE SHEETS</u>	<u>F-2</u>
<u>CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS</u>	<u>F-3</u>
<u>CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIENCY)</u>	<u>F-4</u>
<u>CONSOLIDATED STATEMENTS OF CASH FLOWS</u>	<u>F-5</u>
<u>NOTES TO CONSOLIDATED FINANCIAL STATEMENTS</u>	<u>F-7</u>

Financial Statements (December 31, 2013 and 2012 are audited)

<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u>	<u>F-19</u>
<u>REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS</u>	<u>F-20</u>
<u>CONSOLIDATED BALANCE SHEETS</u>	<u>F-21</u>
<u>CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS</u>	<u>F-22</u>
<u>CONSOLIDATED STATEMENTS OF CHANGES REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIENCY)</u>	<u>F-23</u>
<u>CONSOLIDATED STATEMENTS OF CASH FLOWS</u>	<u>F-32</u>
<u>NOTES TO CONSOLIDATED FINANCIAL STATEMENTS</u>	<u>F-35</u>

F-1

---

TABLE OF CONTENTS

# CYTOSORBENTS CORPORATION

## CONSOLIDATED BALANCE SHEETS

	September 30, 2014 (Unaudited)	December 31, 2013
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$433,423	\$2,183,030
Grants and accounts receivable, net of allowance for doubtful accounts of \$3,236 at September 30, 2014 and \$-0- at December 31, 2013	561,964	453,017
Short-term investments	7,346,994	
Inventories	387,075	245,608
Prepaid expenses and other current assets	225,004	605,312
Total current assets	8,954,460	3,486,967
Property and equipment net	191,127	144,393
Other assets	481,017	414,375
Total long-term assets	672,144	558,768
Total Assets	\$9,626,604	\$4,045,735
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$446,167	\$786,517
Accrued expenses and other current liabilities	445,110	361,700
Deferred revenue	3,333	272,359
Warrant liability	654,840	
Convertible notes payable, net of debt discount in the amount of \$0 at September 30, 2014 and \$198,644 at December 31, 2013		1,644,356
Total current liabilities	1,549,450	3,064,932
Series B 10% Cumulative Convertible Preferred Stock, par value \$0.001, 200,000 Shares authorized; 84,283.99 and 79,336.54 issued and outstanding at September 30, 2014 and December 31, 2013, respectively	18,874,241	15,246,350
Stockholders Equity/(Deficiency):		
Series A 10% Cumulative Convertible Preferred Stock, 12,000,000 shares authorized; 1,894,969 and 1,759,666 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	1,895	1,760
Common Stock, 800,000,000 shares authorized; 322,775,473 and 251,319,547 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	322,775	251,320
Additional paid-in capital	102,713,676	91,343,135
Accumulated other comprehensive income (loss)	67,196	(55,987 )
Accumulated deficit	(113,902,629)	(105,805,775)

Edgar Filing: Cytosorbents Corp - Form S-1/A

Total stockholders' equity (deficiency)	(10,797,087 )	(14,265,547 )
Total Liabilities and Stockholders' Equity (Deficiency)	\$9,626,604	\$4,045,735

See accompanying notes to consolidated financial statements.

F-2

---

TABLE OF CONTENTS**CYTOSORBENTS CORPORATION****CONSOLIDATED STATEMENTS OF OPERATIONS AND  
COMPREHENSIVE LOSS**

	Nine months ended September 30,		Three months ended September 30,	
	2014	2013	2014	2013
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue:				
Sales	\$2,264,237	\$507,628	\$1,031,761	\$203,561
Grant income	978,271	1,035,877	128,087	677,131
Other revenue	6,666		2,499	
Total revenue	3,249,174	1,543,505	1,162,347	880,692
Cost of revenue	1,804,578	1,073,689	475,890	620,623
Gross profit	1,444,596	469,816	686,457	260,069
Other Expenses:				
Research and development	1,464,059	1,706,498	880,292	294,198
Legal, financial and other consulting	733,056	570,465	182,996	157,926
Selling, general and administrative	3,471,138	1,901,768	1,309,519	687,788
Total expenses	5,668,253	4,178,731	2,372,807	1,139,912
Loss from operations	(4,223,657 )	(3,708,915 )	(1,686,350 )	(879,843 )
Other (income)/expense:				
Interest expense/(income), net	311,458	299,805	46,600	84,946
Change in warrant liability	(208,080 )		(234,600 )	
Total other (income) expense, net	103,378	299,805	(188,000 )	84,946
Loss before benefit from income taxes	(4,327,035 )	(4,008,720 )	(1,498,350 )	(964,789 )
Benefit from income taxes				
Net loss	(4,327,035 )	(4,008,720 )	(1,498,350 )	(964,789 )
Preferred Stock Dividend	3,769,819	1,728,053	1,281,058	525,148
Net Loss available to common shareholders	\$(8,096,854 )	\$(5,736,773 )	\$(2,779,408 )	\$(1,489,937 )
Basic and diluted net loss per common share	\$(0.03 )	\$(0.02 )	\$(0.01 )	\$(0.01 )
Weighted average number of shares of common stock outstanding	293,189,313	232,426,316	312,400,345	242,512,486
Net loss	\$(4,327,035 )	\$(4,008,720 )	\$(1,498,350 )	\$(964,789 )
Other comprehensive loss:				
Currency translation adjustment	123,183	36,915	118,032	40,184
Comprehensive loss	\$(4,203,852 )	\$(3,971,805 )	\$(1,380,318 )	\$(924,605 )

See accompanying notes to consolidated financial statements.

TABLE OF CONTENTS

**CYTOSORBENTS CORPORATION**

**CONSOLIDATED STATEMENT OF CHANGES IN  
REDEEMABLE CONVERTIBLE  
PREFERRED STOCK AND STOCKHOLDERS EQUITY  
(DEFICIENCY)**

**Period from December 31, 2013 to September 30, 2014  
(Unaudited):**

See accompanying notes to consolidated financial statements.

F-4

---



TABLE OF CONTENTS**CYTOSORBENTS CORPORATION****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Nine months ended September 30, 2014 (Unaudited)	Nine months ended September 30, 2013 (Unaudited)
Cash flows from operating activities:		
Net loss	\$(4,327,035)	\$(4,008,720 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Issuance of common stock to consultant for services	180,100	65,468
Depreciation and amortization	70,449	47,573
Amortization of debt discount	198,644	228,468
Bad debt expense	3,236	
Expense for issuance of options	150,273	300,105
Change in warrant liability	(208,080 )	
Changes in operating assets and liabilities:		
Grants and accounts receivable	(112,183 )	(142,094 )
Inventories	(141,467 )	319,830
Prepaid expenses and other current assets	380,308	318,438
Other assets	(4,568 )	9,442
Accounts payable and accrued expenses	(109,500 )	38,989
Deferred revenue	(269,026 )	435,686
Net cash used by operating activities	(4,188,849)	(2,386,815 )
Cash flows from investing activities:		
Purchases of property and equipment	(89,495 )	(33,276 )
Patent costs	(89,762 )	(18,861 )
Purchases of short-term investments	(7,346,994)	
Net cash used by investing activities	(7,526,251)	(52,137 )
Cash flows from financing activities:		
Equity contributions net of fees incurred	9,751,455	1,599,967
Proceeds from borrowings		1,263,000
Proceeds from exercise of stock options	90,855	20,194
Proceeds from exercise of warrants		139,526
Net cash provided by financing activities	9,842,310	3,022,687
Effect of exchange rates on cash	123,183	36,915
Net change in cash and cash equivalents	(1,749,607)	620,650
Cash and cash equivalents beginning of period	2,183,030	1,729,344
Cash and cash equivalents end of period	\$433,423	\$2,349,994
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$	\$
Supplemental schedule of noncash investing and financing activities:		

Edgar Filing: Cytosorbents Corp - Form S-1/A

Increase in other current assets through the issuance of convertible debt	\$	\$ 580,000
Fair value of warrant liability upon issuance	\$862,920	\$
Debt discount in connection with issuance of convertible debt	\$	\$ 331,117
Fair value of shares issued as costs of raising capital	\$7,137	\$ 34,034

See accompanying notes to consolidated financial statements.

F-5

---

TABLE OF CONTENTS**CYTOSORBENTS CORPORATION****CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)**

	Nine months ended September 30, 2014 (Unaudited)	Nine months ended September 30, 2013 (Unaudited)
Note payable principal and interest conversion to equity	\$ 1,990,440	\$ 1,226,042
Costs paid from proceeds in conjunction with issuance of common stock and preferred stock	\$ 748,545	\$
Preferred stock dividends	\$ 3,769,819	\$ 1,728,053

During the nine months ended September 30, 2014 and 2013, 1,124.73 and 198.27 shares of Series B 10% Cumulative Convertible Preferred Stock, \$0.001 par value per share (the "Series B Preferred Stock") were converted into 3,106,988 and 547,707 shares of Common Stock, \$0.001 par value per share (the "Common Stock"), respectively. During the nine months ended September 30, 2014 and 2013, no shares of Series A 10% Cumulative Convertible Preferred Stock, \$0.001 par value per share (the "Series A Preferred Stock") were converted into shares of Common Stock.

See accompanying notes to consolidated financial statements.

TABLE OF CONTENTS

# CytoSorbents Corporation

## Notes to Consolidated Financial Statements (UNAUDITED) September 30, 2014

### 1. BASIS OF PRESENTATION

The accompanying unaudited interim consolidated financial statements have been prepared in accordance with the requirements of Form 10-Q of the Securities and Exchange Commission (the Commission) and include the results of CytoSorbents Corporation (the Parent), CytoSorbents, Inc. (as of October 28, 2014, known as CytoSorbents Medical, Inc.), its wholly-owned operating subsidiary (the Subsidiary), and CytoSorbents Europe GmbH, its wholly-owned European subsidiary (the European Subsidiary), collectively referred to as the Company.

Accordingly, certain information and footnote disclosures required in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. Interim statements are subject to possible adjustments in connection with the annual audit of the Company's accounts for the year ended December 31, 2014. In the opinion of the Company's management, the accompanying unaudited consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) which the Company considers necessary for the fair presentation of the Company's consolidated financial position as of September 30, 2014 and the results of its operations and cash flows for the nine and three month periods ended September 30, 2014 and 2013. Results for the nine months ended September 30, 2014 and 2013 are not necessarily indicative of results that may be expected for the entire year. The unaudited interim consolidated financial statements should be read in conjunction with the audited financial statements of the Company and the notes thereto as of and for the year ended December 31, 2013 as included in the Company's Form 10-K filed with the Commission on March 31, 2014.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has experienced negative cash flows from operations since inception. The Company is not currently generating significant revenue and is dependent on the proceeds of present and future offerings to fund its research, development and commercialization program. The Company currently has adequate funding for more than the next twelve months of operations; however, it may have to raise additional capital to fund future operations. Although the Company has historically been successful in raising additional capital through equity and debt offerings, there can be no assurance that the Company will be successful in raising additional capital in the future or that it will be on favorable terms. Furthermore, if the Company is successful in raising the additional offering, there can be no assurance that the amount will be sufficient to complete the Company's plans. These matters raise substantial doubt about the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

Since inception, the Company's expenses relate primarily to research and development, organizational activities, clinical manufacturing, regulatory compliance and operational strategic planning. Although the Company has made advances on these matters, there can be no assurance that the Company will continue to be successful regarding these

issues, nor can there be any assurance that the Company will successfully implement its long-term strategic plans.

## **2. PRINCIPAL BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

### **Nature of Business**

The Company, through its subsidiary CytoSorbents, Inc. (as of October 28, 2014, known as CytoSorbents Medical, Inc.), is engaged in the research, development and commercialization of medical devices with its platform blood purification technology incorporating a proprietary adsorbent polymer technology. The Company, through CytoSorbents Europe, GmbH, its European subsidiary, has commenced initial sales and marketing related operations for the CytoSorb® device in the European Union. The Company is focused on developing this technology for multiple applications in the medical field, specifically to provide improved

F-7

---

TABLE OF CONTENTS

## **CytoSorbents Corporation**

### **Notes to Consolidated Financial Statements (UNAUDITED) September 30, 2014**

#### **2. PRINCIPAL BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES: (continued)**

blood purification for the treatment of acute and chronic health complications associated with blood toxicity. In March 2011, the Company received CE Mark approval for its CytoSorb® device.

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 U.S. 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.

#### **Principles of Consolidation**

The consolidated financial statements include the accounts of CytoSorbents Corporation, the Parent, and its wholly-owned subsidiaries, CytoSorbents, Inc. (as of October 28, 2014, known as CytoSorbents Medical, Inc.) and CytoSorbents Europe GmbH. All significant intercompany transactions and balances have been eliminated in consolidation.

#### **Cash and Cash Equivalents**

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

#### **Grants and Accounts Receivable**

Grants receivable represent amounts due from U.S. government agencies. Accounts receivable are unsecured, non-interest bearing customer obligations due under normal trade terms. The Company sells its devices to various hospitals and distributors. The Company performs ongoing credit evaluations of customers' financial condition. Management reviews accounts receivable periodically to determine collectability. Balances that are determined to be uncollectible are written off to the allowance for doubtful accounts. The allowance for doubtful accounts contains a general accrual for estimated bad debts and had a balance of \$3,236 at September 30, 2014 and \$-0- at December 31, 2013.

## Short-Term Investments

Short-term investments include certificates of deposit with original maturities of greater than three months. The cost of the certificates of deposit approximates fair value.

## Inventories

Inventories are valued at the lower of cost or market. At September 30, 2014 and December 31, 2013, the Company's inventory was comprised of finished goods, which amounted to approximately \$101,000 and \$107,000, respectively; work in process which amounted to approximately \$250,000 and \$101,000, respectively; and raw materials, which amounted to approximately \$36,000 and \$38,000, respectively. Devices used in clinical trials or for research and development purposes are removed from inventory and charged to research and development expenses at the time of their use.

## Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation of property and equipment is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the lesser of their economic useful lives or the term of the related leases. Gains and losses on depreciable assets retired or sold are recognized in the statements of operations in the year of disposal. Repairs and maintenance expenditures are expensed as incurred.

F-8

---

TABLE OF CONTENTS

## **CytoSorbents Corporation**

### **Notes to Consolidated Financial Statements (UNAUDITED) September 30, 2014**

#### **2. PRINCIPAL BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES: (continued)**

##### **Patents**

Legal costs incurred to establish and successfully defend patents are capitalized. When patents are issued, capitalized costs are amortized on the straight-line method over the related patent term. In the event a patent is abandoned, the net book value of the patent is written off.

##### **Impairment or Disposal of Long-Lived Assets**

The Company assesses the impairment of patents and other long-lived assets under accounting standards for the impairment or disposal of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. For long-lived assets to be held and used, the Company recognizes an impairment loss only if its carrying amount is not recoverable through its undiscounted cash flows and measures the impairment loss based on the difference between the carrying amount and fair value.

##### **Warrant Liability**

The Company recognizes the fair value of the warrants as of the date of the warrant grant using the binomial lattice valuation model. At each subsequent reporting date, the Company again measures the fair value of the warrants, and records a change to the warrant liability as appropriate, and the change is reported in the statement of operations.

##### **Revenue Recognition**

*Product Sales:* Revenues from sales of products are recognized at the time of delivery when title and risk of loss passes to the customer. Recognition of revenue also requires reasonable assurance of collection of sales proceeds and completion of all performance obligations.

*Grant Revenue:* Revenue from grant income is based on contractual agreements. Certain agreements provide for reimbursement of costs, while other agreements provide for reimbursement of costs and an overhead margin. Revenues are recognized when milestones have been achieved and revenues have been earned. Costs are recorded as incurred. Costs subject to reimbursement by these grants have been reflected as costs of revenue.



*Deferred Revenue:* The Company defers revenue that has been received but not yet earned on government contracts and product sales. This revenue will be recognized as income in the period in which the revenue is earned. All deferred revenue is expected to be earned within one year of the balance sheet date.

## **Research and Development**

All research and development costs, payments to laboratories and research consultants are expensed when incurred.

## **Advertising Expenses**

Advertising costs are charged to activities when incurred. Advertising expenses amounted to approximately \$94,000 and \$30,000 for the nine months ended September 30, 2014 and 2013, respectively, and is included in selling, general, and administrative expenses on the consolidated statement of operations.

## **Income Taxes**

Income taxes are accounted for under the asset and liability method prescribed by accounting standards for accounting for income taxes. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation

TABLE OF CONTENTS

## **CytoSorbents Corporation**

### **Notes to Consolidated Financial Statements (UNAUDITED) September 30, 2014**

#### **2. PRINCIPAL BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES: (continued)**

allowance is provided if it is more likely than not that some or all of the deferred tax asset will not be realized. Under Section 382 of the Internal Revenue Code, the net operating losses generated prior to the reverse merger may be limited due to the change in ownership. Additionally, net operating losses generated subsequent to the reverse merger may be limited in the event of changes in ownership.

The Company follows accounting standards associated with uncertain tax positions. The Company had no unrecognized tax benefits at September 30, 2014 or December 31, 2013. The Company files tax returns in the U.S. federal and state jurisdictions. The Company currently has no open years prior to December 31, 2010 and has no income tax related penalties or interest for the periods presented in these financial statements.

The Company's European subsidiary, CytoSorbents Europe GmbH annually files a corporate tax return, VAT return and a trade tax return in Germany.

#### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities. Actual results could differ from these estimates. Significant estimates in these financials are the valuation of options granted, the valuation of preferred shares issued as stock dividends, valuation methods used to determine the fair value of the warrant liability, and valuation methods used in determining any debt discount associated with convertible securities.

#### **Concentration of Credit Risk**

The Company maintains cash balances, at times, with financial institutions in excess of amounts insured by the Federal Deposit Insurance Corporation. Management monitors the soundness of these institutions in an effort to minimize its collection risk of these balances.

As of September 30, 2014, four distributors and one hospital accounted for approximately 64% of outstanding grant and accounts receivable. At December 31, 2013, one U.S. government agency accounted for approximately 66% of outstanding accounts receivable. For the nine months ended September 30, 2014, approximately 19% of revenues were from one U.S. government agency, and no other agency, distributor, or direct customer represented more than

10% of the Company's revenue. For the nine months ended September 30, 2013, approximately 67% of revenues were from two U.S. government grant agencies, and no other agency, distributor, or direct customer represented more than 10% of the Company's revenue.

## **Financial Instruments**

The carrying values of cash and cash equivalents, short-term investments, accounts payable, notes payable, and other debt obligations approximate their fair values due to their short-term nature.

## **Net Loss Per Common Share**

Basic EPS is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period. The computation of Diluted EPS does not assume conversion, exercise or contingent exercise of securities that would have an anti-dilutive effect on earnings (See Note 7).

## **Stock-Based Compensation**

The Company accounts for its stock-based compensation under the recognition requirements of accounting standards for accounting for stock-based compensation, for employees and directors whereby each option granted is valued at fair market value on the date of grant. Under these accounting standards, the fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model.

TABLE OF CONTENTS

## **CytoSorbents Corporation**

### **Notes to Consolidated Financial Statements (UNAUDITED) September 30, 2014**

#### **2. PRINCIPAL BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES: (continued)**

The Company also follows the guidance of accounting standards for accounting for equity instruments that are issued to other than employees for acquiring, or in conjunction with selling, goods or services for equity instruments issued to consultants.

#### **Effects of Recent Accounting Pronouncements**

Accounting Standards Update ( ASU ) 2014-10, which for public business entities will be effective for annual reporting periods beginning after December 15, 2014 and interim periods therein, removes the definition of a development stage entity from the Accounting Standards Codification, thereby eliminating the financial reporting distinction between development stage entities from U.S. GAAP. Specifically eliminated are the requirements to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development state entity that in prior years it had been in the development stage. The Company has adopted ASU 2014-10 within its September 30, 2014 financial statements.

In May 2014, the Financial Account Standards Board ( FASB ) issued ASU 2014-09, Revenue with Contracts from Customers. ASU 2014-09 supercedes the current revenue recognition guidance, including industry-specific guidance.

The ASU introduces a five-step model to achieve its core principal of the entity recognizing revenue to depict the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. The updated guidance is effective for public entities for interim and annual periods beginning after December 15, 2016 and early adoption is not permitted. The Company is currently evaluating the impact of the updated guidance, but the Company does not believe that the adoption of ASU 2014-09 will have a significant impact on its consolidated financial statements.

#### **Shipping and Handling Costs**

The costs of shipping product to customers and distributors is typically borne by the customer or distributor. The Company records other shipping and handling costs in Research and Development. Total freight costs amounted to approximately \$77,000 and \$17,000 for the nine months ended September 30, 2014 and September 30, 2013, respectively.

### 3. CONVERTIBLE NOTES

On June 21, 2013 (the June Closing Date), the Company issued convertible notes to certain accredited investors (the June Purchasers), whereby the Company agreed to sell and the June Purchasers agreed to purchase the convertible notes in the aggregate principal amount of \$1,098,000 (the June Notes). The June Notes were to mature one (1) year from the June Closing Date (the June Maturity Date), bear interest at an annual rate of 8%, and automatically convert into shares of the Company's Common Stock at a conversion price of \$0.125 at maturity or earlier at the option of the June Purchaser. In connection with the issuance of the June Notes, the Company issued warrants to purchase shares of Common Stock, providing 50% coverage, exercisable at \$0.15 per share (the June Warrants). On June 21, 2014, all outstanding June Notes were converted into 9,486,720 shares of Common Stock, consisting of 8,784,000 shares related to the principal value of the June Notes and 702,720 shares of Common Stock for payment of interest earned on the June Notes.

On September 30, 2013 (the September Closing Date), the Company issued convertible notes to certain accredited investors (the September Purchasers), whereby the Company agreed to sell and the September Purchasers agreed to purchase the convertible notes in the aggregate principal amount of \$745,000 (the September Notes). The September Notes were to mature one (1) year from the September Closing Date

F-11

---

TABLE OF CONTENTS

## **CytoSorbents Corporation**

# **Notes to Consolidated Financial Statements (UNAUDITED) September 30, 2014**

### **3. CONVERTIBLE NOTES (continued)**

(the September Maturity Date ), bear interest at an annual rate of 8%, and automatically convert into shares of Common Stock at a conversion price of \$0.10 at maturity, or earlier at the option of the September Purchaser. In connection with the issuance of the September Notes, the Company issued warrants to purchase shares of Common Stock, providing 50% coverage, exercisable at \$0.125 per share (the September Warrants ). On September 30, 2014, all outstanding September Notes were converted into 7,450,000 shares of Common Stock related to the principal value of the September Notes and 596,000 shares of Common Stock for payment of interest earned on the September Notes.

The Company allocates the proceeds associated with the issuance of convertible notes based on the relative fair value of the convertible notes and warrants. Additionally, the Company evaluates if the embedded conversion option results in a beneficial conversion feature by comparing the relative fair value allocated to the convertible notes to the market value of the underlying Common Stock subject to conversion. In connection with the convertible note issuances during the years ended December 31, 2013, the Company received proceeds of \$1,843,000. The Company allocated the proceeds in accordance with FASB Codification Topic 470 based on the related fair value as follows: \$1,511,883 was allocated to the convertible notes and \$171,012 to the warrants. Additionally, the embedded conversion feature resulted in a beneficial conversion feature in the amount of \$160,105. The value assigned to the warrants resulting from the relative fair value calculation as well as the value of the beneficial conversion feature is recorded as a debt discount and is presented in the consolidated balance sheets. The debt discount has been amortized to interest expense over the term of the convertible notes. During the nine months ended September 30, 2014 and 2013, debt discount of approximately \$199,000 and \$228,000, respectively, was charged to interest expense.

### **4. STOCKHOLDERS EQUITY (DEFICIT)**

On March 7, 2014, the Company entered into subscription agreements with certain investors providing for the issuance and sale by the Company (the 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 Common Stock, priced at \$0.25 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 the Units, is only exercisable for cash, and is only exercisable if there is an effective registration statement registering the warrants and shares underlying the warrants. The Common Stock underlying these warrants were registered in the registration statement on Form S-1 (File No. 333-193053), which was declared effective by the Commission on February 14, 2014 and an additional registration statement on Form S-1 (File No. 333-194394).

The Company received net proceeds from the Offering of approximately \$9,451,000 million. The net proceeds received by the Company from the Offering is being used for building additional sales and marketing infrastructure,

clinical studies, working capital and general corporate purposes.

The Company conducted the Offering pursuant to a registration statement on Form S-1 (File No. 333-193053), which was declared effective by the 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. The Company filed a final prospectus on March 7, 2014, disclosing the final terms of the Offering.

In connection with the Offering, on March 7, 2014, the Company entered into a placement agency agreement with Brean Capital, LLC, pursuant to which Brean Capital, LLC agreed to act as the Company's exclusive placement agent (the Placement Agent) for the Offering and sale of the Units.

F-12

---

TABLE OF CONTENTS**CytoSorbents Corporation****Notes to Consolidated Financial Statements  
(UNAUDITED)  
September 30, 2014****4. STOCKHOLDERS EQUITY (DEFICIT) (continued)**

In connection with the successful completion of the 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 Offering, or \$612,000, 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). The Placement Agent Warrant contains piggy-back registration rights which expire on the fifth anniversary of the effective date of the registration statement. The Company has 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. The Company also granted the Placement Agent a right of first refusal to participate in any subsequent offering or placement of its securities that takes place within twelve months following the effective date of the registration statement.

During the nine months ended September 30, 2014, the Company recorded non-cash stock dividends totaling \$3,769,819 in connection with the issuance of 6,072.18 shares of Series B Preferred Stock and 135,303 shares of Series A Preferred Stock as stock dividends to its preferred shareholders.

During the nine months ended September 30, 2014, the Company incurred stock-based compensation expense due to the issuance of stock options, and amortization of unvested stock options. The aggregate expense for the nine months ended September 30, 2014 is approximately \$150,000, of which approximately \$130,000 was recorded in general and administrative expenses and approximately \$20,000 was recorded as research and development expenses.

The summary of the stock option activity for the nine months ended September 30, 2014 is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding, January 1, 2014	47,923,642	\$ 0.20	5.1
Granted	16,135,000	\$ 0.20	9.1
Cancelled	(5,695,250 )	\$ 0.13	7.6
Exercised	(2,466,300 )	\$ 0.04	3.6
Expired	(51,809 )	\$ 0.83	
Outstanding September 30, 2014	55,845,283	\$ 0.21	6.3

The fair value of each stock option was estimated using the Black-Scholes pricing model which takes into account as of the grant date the exercise price (ranging from \$0.195 to \$0.274 per share) and expected life of the stock option



(ranging from 5 to 10 years), the current price of the underlying stock and its expected volatility (approximately 28%), expected dividends on the stock (0%) and the risk free interest rate (0.8 to 2.1%) for the term of the stock option.

At September 30, 2014, the aggregate intrinsic value of options outstanding and currently exercisable amounted to approximately \$3,552,000.

F-13

---

TABLE OF CONTENTS**CytoSorbents Corporation**

**Notes to Consolidated Financial Statements**  
**(UNAUDITED)**  
**September 30, 2014**

**4. STOCKHOLDERS EQUITY (DEFICIT) (continued)**

The summary of the status of the Company's non-vested options for the six months ended September 30, 2014 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2014	13,418,000	\$ 0.034
Granted	16,135,000	\$ 0.058
Cancelled	(4,861,250 )	\$ 0.033
Vested	(2,412,250 )	\$ 0.044
Non-vested, September 30, 2014	22,279,500	\$ 0.051

As of September 30, 2014, the Company had approximately \$159,000 of total unrecognized compensation cost related to stock options. In March 2014, the Board of Directors set aside a pool of 14,010,000 options to be awarded to the Company's employees if the Company achieves certain specific, predetermined milestones. The grant date fair value of these unvested options amounted to approximately \$791,000. Due to the uncertainty over whether these options will vest, which only occurs if the Company meets the predetermined milestones, no charge for these options has been recorded in the consolidated statements of operations for the nine months ended September 30, 2014. The Company will evaluate on an ongoing basis the probability and likelihood of any of these performance milestones being achieved and will accrue charges as it becomes likely that they will be achieved.

As of September 30, 2014, the Company has the following warrants to purchase Common Stock outstanding:

Number of Shares To be Purchased	Warrant Exercise Price per Share	Warrant Expiration Date
1,750,000	\$ 0.1000	August 16, 2015
1,600,000	\$ 0.1250	August 16, 2015
1,333,333	\$ 0.1500	August 16, 2015
490,000	\$ 0.1000	October 22, 2015
196,000	\$ 0.1250	October 22, 2015
163,333	\$ 0.1500	October 22, 2015
500,000	\$ 0.1000	November 19, 2015
200,000	\$ 0.1250	November 19, 2015

Edgar Filing: Cytosorbents Corp - Form S-1/A

166,667	\$ 0.1500	November 19, 2015
700,000	\$ 0.1000	February 15, 2016
1,540,000	\$ 0.1250	February 15, 2016
1,416,666	\$ 0.1500	February 15, 2016
240,125	\$ 1.2500	October 24, 2016
1,166,667	\$ 0.1750	February 10, 2017
4,392,000	\$ 0.1500	June 21, 2018
3,725,000	\$ 0.1250	September 30, 2018
20,400,000	\$ 0.3125	March 11, 2019
1,224,000	\$ 0.3000	March 11, 2019
41,203,791		

In addition, during the nine months ended September 30, 2014, the Company issued 1,123,033 shares of Common Stock valued at \$180,100 to a vendor for consulting services, 2,466,300 options were exercised for

F-14

---

TABLE OF CONTENTS

## **CytoSorbents Corporation**

### **Notes to Consolidated Financial Statements (UNAUDITED) September 30, 2014**

#### **4. STOCKHOLDERS EQUITY (DEFICIT) (continued)**

2,451,070 shares of Common Stock, and warrants to purchase 6,460,000 shares of Common Stock were exercised for 3,958,716 shares of Common Stock. On June 21, 2014, \$1,098,000 in convertible notes matured. In accordance with the terms of the notes, the note holders were issued 9,486,720 shares of Common Stock which included 8,784,000 shares of Common Stock for payment of the convertible notes and 702,720 shares representing payment of interest accrued on the convertible notes. On September 30, 2014, \$745,000 in convertible notes matured.

In accordance with the terms of the notes, the note holders were issued 8,046,000 shares of Common Stock, which included 7,450,000 share of Common Stock for payment of the convertible notes and 596,000 shares representing payment of interest accrued on the convertible notes.

In December 2011, the Company terminated a purchase agreement with Lincoln Park Capital Fund, LLC ( LPC ) and executed a new purchase agreement (the New Purchase Agreement ), and a registration rights agreement with LPC. Under the New Purchase Agreement, LPC is obligated, under certain conditions, to purchase from the Company up to \$8.5 million of its Common Stock, from time to time, over a thirty-two (32) month period.

Under the New Purchase Agreement, the Company had the right, but not the obligation, to direct LPC to purchase up to \$8,500,000 of its Common Stock in amounts up to \$50,000 as often as every two business days under certain conditions. The Company could also accelerate the amount of its Common Stock to be purchased under certain circumstances. No sales of Common Stock could occur at a purchase price below \$0.10 per share or without a registration statement having been declared effective. The purchase price of the Common Stock was based on the market prices of the Company's Common Stock at the time of sale as computed under the New Purchase Agreement without any fixed discount. The Company had the right at any time at its sole discretion to terminate the New Purchase Agreement without fee, penalty or cost upon one business days notice.

There was no up-front commitment fee paid to LPC for entering into the New Purchase Agreement. In the event the Company directs LPC to purchase up to \$8,500,000 of its Common Stock, the Company would have been obligated to issue up to an additional 1,634,615 commitment fee shares of Common Stock on a pro rata basis. LPC could not assign any of its rights or obligations under the New Purchase Agreement.

During the nine months ended September 30, 2014, the Company received approximately \$300,000 as proceeds from the sale of 2,425,709 shares of Common Stock per the terms of the New Purchase Agreement with LPC at an average price of approximately \$0.124 per share of Common Stock. Per the terms of the New Purchase Agreement, the Company also issued an additional 57,690 shares of Common Stock as additional commitment fee shares.

The Company has not sold any shares of its Common Stock under the New Purchase Agreement since January 17, 2014. The New Purchase Agreement expired pursuant to its terms in August 2014. At the time of expiration, \$2,400,000 remained unused under the new Purchase Agreement with LPC.

## **5. WARRANT LIABILITY**

In connection with its March 11, 2014 offering, the Company issued warrants to purchase 20,400,000 shares of Common Stock. The Company recognizes these warrants as liabilities at their fair value on the date of grant, then measures the fair value of the warrants on each reporting date, and records a change to the warrant liability as appropriate. The warrants have certain pricing provisions which apply if the Company sells or issues Common Stock or Common Stock equivalents at a price that is less than the exercise price of the warrants, over the life of the warrants, excluding certain exempt issuances.

F-15

---

TABLE OF CONTENTS**CytoSorbents Corporation****Notes to Consolidated Financial Statements  
(UNAUDITED)  
September 30, 2014****5. WARRANT LIABILITY (continued)**

The Company recognized an initial warrant liability for the warrants issued in connection with the Offering completed in March 2014. The initial warrant liability recognized on the related warrants totaled \$862,920, which was based on the March 11, 2014 five-day weighted average closing price per share of the Company's Common Stock of \$0.24. On September 30, 2014, the five day weighted average closing price per share of Common Stock was \$0.224. Due to the fluctuations in the market value of the Company's Common Stock from March 11, 2014 through September 30, 2014, the Company recorded a change in the fair value of the warrant liability of \$208,080 during the nine months ended September 30, 2014.

The assumptions used in connection with the valuation of warrants issued utilizing the binomial lattice valuation model were as follows:

	September 30, 2014		Initial Measurement March 11, 2014	
Number of shares underlying the warrants	20,400,000		20,400,000	
Exercise price	\$0.3125		\$0.3125	
Volatility	28.3	%	28.3	%
Risk-free interest rate	1.60	%	1.62	%
Expected dividend yield	0		0	
Expected warrant life (years)	4.44		5	
Stock Price	\$0.224		\$0.240	

**6. COMMITMENTS AND CONTINGENCIES****Employment Agreements**

The Company is currently in the process of renewing employment agreements with certain key executives.

**Litigation**

We are from time to time subject to claims and litigation arising out of the ordinary course of business. We intend to defend vigorously against any future claims and litigation. We are not currently a party to any legal proceedings.

## **Royalty Agreements**

Pursuant to an agreement dated August 11, 2003, an existing investor agreed to make a \$4 million equity investment in the Company. These amounts were received by the Company in 2003. In connection with this agreement, the Company granted the investor a future royalty of 3% on all gross revenues received by the Company from the sale of its CytoSorb® device. For the nine months ended September 30, 2014 the Company has recorded royalty costs of approximately \$68,000.

## **License Agreements**

In September 2006, the Company entered into a license agreement which provides the Company the exclusive right to use its patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the agreement, the Company has agreed to pay royalties of 2.5% to 5% on the sale of certain of its products if and when those products are sold commercially for a term not greater than 18 years commencing with the first sale of such product. For the nine months ended September 30, 2014 per the terms of the license agreement the Company has recorded royalty costs of approximately \$57,000.

TABLE OF CONTENTS

## **CytoSorbents Corporation**

### **Notes to Consolidated Financial Statements (UNAUDITED) September 30, 2014**

#### **6. COMMITMENTS AND CONTINGENCIES (continued)**

##### **Warrant Agreement**

As inducement to invest additional funds in the private placement of Series B Preferred Stock, additional consideration was granted to the participants of the Series B Preferred Stock offering in the event that litigation is commenced against the Company prior to June 30, 2018, claiming patent infringement on certain of the Company's issued patents. In the event this litigation arose, the Company may have been required to issue warrants to purchase in the aggregate up to a maximum of ten million shares of Common Stock subject to certain adjustments. Through September 30, 2014 no such litigation has arisen and the Company has not booked a contingent liability for this agreement. On October 9, 2014, all the shares of Series B Preferred Stock were converted into Common Stock (see Note 8, Subsequent Events), and therefore this additional consideration is no longer applicable.

#### **7. NET LOSS PER SHARE**

Basic loss per share and diluted loss per share for the three months ended September 30, 2014 and 2013 have been computed by dividing the net loss for each respective period by the weighted average number of shares outstanding during that period.

All outstanding warrants and options representing approximately 97,049,000 and 74,289,000 incremental shares at September 30, 2014 and 2013, respectively, as well as shares issuable upon conversion of Series A and Series B Preferred Stock representing approximately 234,478,000 and 215,310,000 incremental shares at September 30, 2014 and 2013, respectively, as well as potential shares issuable upon Note conversion into Common Stock representing approximately -0- and 16,234,000 incremental shares at September 30, 2014 and 2013, respectively, have been excluded from the computation of diluted loss per share as they are anti-dilutive.

#### **8. SUBSEQUENT EVENTS**

##### **Conversion of Series A and Series B Preferred Stock into Common Stock.**

On October 9, 2014, the Company filed with the Nevada Secretary of State an Amendment (the "Series A Amendment") to the Certificate of Designation, as amended (the "Series A Certificate of Designation") of the Series A Preferred Stock. The Series A Amendment, which became effective on October 9, 2014, (i) amended 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 of the Company, \$0.001 par value per share (the Common Stock ), at the then-effective Conversion Price, as defined in the Series A Certificate of Designation, and (ii) as consideration for approving such amendment, amended 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 this election by the holders of Series A Preferred Stock, 1,894,969 shares of Series A Preferred Stock were converted into 2,583,289 shares of Common Stock.

In addition, on October 9, 2014, the Company also filed with the Nevada Secretary of State an Amendment (the Series B Amendment ) to the Certificate of Designation (the Series B Certificate of Designation ) of the Series B Preferred Stock. The Series B Amendment, which became effective on October 9, 2014, amended 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

F-17

---

TABLE OF CONTENTS

## **CytoSorbents Corporation**

# **Notes to Consolidated Financial Statements (UNAUDITED) September 30, 2014**

### **8. SUBSEQUENT EVENTS (continued)**

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 had a stated value of \$100.00 (the Series B Stated Value), and was convertible into that number of shares of Common Stock equal to the Series B Stated Value at a conversion price of \$0.036. As consideration for approving 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 this election by the holders of Series B Preferred Stock, 84,283.99 shares of Series B Preferred Stock were issued a dividend of 10% and then the 92,712.27 were converted into 256,111,243 shares of Common Stock. As a result of the conversion, the carrying value of the Series B stock was reclassified to permanent equity.

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.

### **Proposed Corporate Actions Subject to Stockholder Consent.**

The Company previously announced its intention to up-list its Common Stock to a national exchange by the end of calendar year 2014. In order to facilitate that process, on November 6, 2014, the Company sought stockholder consent authorizing its Board of Directors to (i) amend the Company's Articles of Incorporation, as amended, to effect a reverse split of its Common Stock, with a reverse split ratio of twenty five-to-one; (ii) amend its 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 its 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 the domicile of the Company from the State of Nevada to the State of Delaware through a merger with and into a newly-organized, wholly-owned subsidiary of the Company which was organized under the laws of the State of Delaware. Assuming such proposals are approved by stockholders, the Company intends to implement such corporate actions in December 2014. There can be no assurances that the stockholders will approve any of the above corporate actions, including the merger, or that the Company will receive approval to list its Common Stock on a national exchange.

### **Subsidiaries.**

Edgar Filing: Cytosorbents Corp - Form S-1/A

On October 28, 2014, the Company formed CytoSorbents Corporation, a wholly-owned subsidiary of the Company, with the Secretary of State of Delaware in order to facilitate the merger discussed above. On the same day, the Company changed the name of its U.S. subsidiary, CytoSorbents, Inc., to CytoSorbents Medical, Inc. with the Secretary of State of Delaware.

F-18

---

TABLE OF CONTENTS

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders,

CytoSorbents Corporation:

We have audited the accompanying consolidated balance sheets of CytoSorbents Corporation (a development stage company), as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive loss, changes in redeemable convertible preferred stock and stockholders' equity (deficiency) and cash flows for the years then ended and the cumulative period from January 22, 1997 (date of inception) to December 31, 2013. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We did not audit the consolidated financial statements of CytoSorbents Corporation for the period from January 22, 1997 (date of inception) to December 31, 2000. Such statements are included in the cumulative total from inception to December 31, 2013 on the consolidated statements of operations and cash flows and reflect a net loss of 19.8% of the related cumulative total. Those statements were audited by other auditors whose report has been furnished to us and our opinion, insofar as it relates to the amounts for the period from January 22, 1997 (date of inception) to December 31, 2000 included in the cumulative totals, is based solely upon the report of the other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation.

We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of CytoSorbents Corporation as of December 31, 2013 and 2012 and the consolidated results of their operations and their cash flows for the years then ended and the cumulative period from January 22, 1997 (date of inception) to December 31, 2013 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, although management has indicated that the Company currently has adequate funding for more than the next twelve months of operations, the Company has experienced recurring net losses and negative cash flows from operations. As a result, the Company may have to raise additional capital to continue to operate and these matters raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**/s/ WithumSmith+Brown, PC**

New Brunswick, New Jersey

March 25, 2014

F-19

---

TABLE OF CONTENTS

**\*\*\*\*\* This report is a copy of a previously issued report and has not been reissued by Arthur Andersen pursuant to rule 2-02(e) of Regulation SX \*\*\*\*\***

**REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To the Board of Directors and Stockholders,

CytoSorbents Corporation:

We have audited the accompanying balance sheets of CytoSorbents Corporation (a development stage company), as of December 31, 2000 and 1999, and the related statements of operations, changes in members' equity and cash flows for the period from inception (January 22, 1997) through December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of CytoSorbents Corporation as of December 31, 2000 and 1999, and the results of its operations and its cash flows for the period from inception (January 22, 1997) to December 31, 2000, in conformity with accounting principles generally accepted in the United States.

Arthur Andersen, LLP  
New York, New York  
December 27, 2001

F-20

---

TABLE OF CONTENTS

# CYTOSORBENTS CORPORATION

## (a development stage company)

### CONSOLIDATED BALANCE SHEETS

December 31,	2013	2012
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$2,183,030	\$1,729,344
Grants and accounts receivable, net of allowance for doubtful accounts of \$-0-	453,017	51,779
Inventories	245,608	682,372
Prepaid expenses and other current assets	605,312	476,093
Total current assets	3,486,967	2,939,588
Property and equipment net	144,393	145,600
Other assets	414,375	254,220
Total long-term assets	558,768	399,820
Total Assets	\$4,045,735	\$3,339,408
<b>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIENCY)</b>		
Current Liabilities:		
Accounts payable	\$786,517	\$800,670
Accrued expenses and other current liabilities	361,700	349,841
Deferred revenue	272,359	
Current portion of convertible notes payable, net of debt discount in the amount of \$198,644 at December 31, 2013 and \$178,775 at December 31, 2012	1,644,356	926,225
Total current liabilities	3,064,932	2,076,736
Total liabilities	3,064,932	2,076,736
Redeemable Series B Convertible Preferred Stock, 200,000 shares authorized at December 31, 2013 and December 31, 2012, respectively, 79,336.54 and 72,073.26 issued and outstanding, respectively	15,246,350	12,887,817
Stockholders Equity/(Deficiency):		
10% Series A Convertible Preferred Stock, 12,000,000 shares authorized at December 31, 2013 and 2012, respectively; 1,759,666 and 1,594,164 shares issued and outstanding, respectively	1,760	1,594
Common Stock, Par Value \$0.001, 800,000,000 shares authorized at December 31, 2013 and 2012, respectively; 251,319,547 and 214,967,503 shares issued and outstanding, respectively	251,320	214,968
Additional paid-in capital	91,343,135	86,903,415
Accumulated other comprehensive income	(55,987 )	(12,662 )
Deficit accumulated during the development stage	(105,805,775)	(98,732,460)
Total stockholders equity/(deficiency)	(14,265,547 )	(11,625,145)
Total Liabilities and Stockholders Equity (Deficiency)	\$4,045,735	\$3,339,408

The Notes to Consolidated Financial Statements are an integral part of these statements.

F-21

---



TABLE OF CONTENTS

**CYTOSORBENTS CORPORATION**  
**(a development stage company)**

**CONSOLIDATED STATEMENTS OF OPERATIONS AND  
COMPREHENSIVE LOSS**

	Period from January 22, 1997 (date of inception) to December 31, 2013	Year ended December 31, 2013	Year ended December 31, 2012
Revenue:			
Sales	\$ 1,009,439	\$ 821,787	\$ 151,574
Grant income	3,792,687	1,600,880	1,191,362
Total revenue	4,802,126	2,422,667	1,342,936