

Cytosorbents Corp  
Form 424B1  
July 02, 2010

DATED: JUNE 22, 2010

Filed Pursuant to Rule 424(b)(1)  
Registration No. 333-167351

PROSPECTUS

24,653,846 SHARES OF COMMON STOCK

CYTOSORBENTS CORPORATION  
(f/k/a Medasorb Technologies Corporation)

This prospectus is registering an aggregate of 24,653,846 shares of common stock, par value \$0.001, of CytoSorbents Corp. (f/k/a Medasorb Technologies Corporation), a Nevada corporation, and relates to the sale of such shares by Lincoln Park Capital Fund, LLC. Lincoln Park Capital Fund, LLC is sometimes referred to in this prospectus as the selling stockholder or LPC. The prices at which LPC may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. See "Plan of Distribution" on page 18 for a description of how the selling stockholder may dispose of the shares covered by this prospectus. We do not know when or in what amount the selling stockholder may offer the shares for sale. We will not receive proceeds from the sale of our shares by LPC. We have agreed to pay certain expenses related to the registration of the shares of common stock pursuant to the registration statement of which this prospectus forms a part.

Our common stock currently trades on the over-the-counter market and is quoted on the OTC Bulletin Board under the symbol "CTSO." On May 28, 2010, the last reported sale price of our Common Stock was \$0.07 per share.

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

---

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

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

The date of this prospectus is June 22, 2010.

---

TABLE OF CONTENTS

PROSPECTUS SUMMARY	1
SUMMARY OF OUR BUSINESS	1
THE OFFERING	5
RISK FACTORS	6
USE OF PROCEEDS	18
DETERMINATION OF OFFER PRICE	
PLAN OF DISTRIBUTION	18
DESCRIPTION OF SECURITIES	20
THE TRANSACTION	23
THE SELLING STOCKHOLDER	26
INTERESTS OF NAMED EXPERTS AND COUNSEL	26
DESCRIPTION OF BUSINESS	27
DESCRIPTION OF EMPLOYEES AND PROPERTY	48
DESCRIPTION OF LEGAL PROCEEDINGS	48
MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS	48
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS	
MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION	49
CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	52
DIRECTORS AND EXECUTIVE OFFICERS	52
EXECUTIVE COMPENSATION	54
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS	61
WHERE YOU CAN FIND MORE INFORMATION	64

## PROSPECTUS SUMMARY

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

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

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

### The Company

CytoSorbents Corporation was incorporated in Nevada on April 25, 2002 as Gilder Enterprises, Inc. and was originally engaged in the business of installing and operating computer networks that provided high-speed access to the Internet. On June 30, 2006, we disposed of our original business, and pursuant to an Agreement and Plan of Merger, acquired all of the stock of MedaSorb Technologies, Inc., a Delaware corporation in a merger, and its business became our business. Following the merger, in July 2006 we changed our name to MedaSorb Technologies Corporation. In November 2008 we changed the name of our operating subsidiary from MedaSorb Technologies, Inc. to CytoSorbents, Inc. In May 2010 we finalized the name change of MedaSorb Technologies Corporation to CytoSorbents Corporation. Unless otherwise indicated, all references in this Annual Report to “MedaSorb,” “CytoSorbents,” “us” or “we” with respect to events prior to June 30, 2006 are references to CytoSorbents, Inc. and its predecessors.

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

### Summary of Our Business

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

proceeding with the FDA.

1

---

We estimate that the market potential in Europe for our products is substantially equivalent to that in the U.S. Given the opportunity to conduct a much larger clinical study in Europe, and management's belief that the path to a CE Mark should be faster than FDA approval, we have targeted Europe as the introductory market for our CytoSorb™ product. In July 2007 we prepared and filed a request for a clinical trial with a German Central Ethics Committee. We received approval of the final study design in October of 2007.

We are currently approved by the German Ethics Committee to conduct a clinical study of up to 100 patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis. The primary endpoint of our clinical trial is cytokine reduction and is the basis of a planned CE Mark application to approve our device for clinical use in Europe.

After reviewing the initial cytokine data from the first 22 patients enrolled in our original protocol, our medical advisors recommended revisions to our protocol to minimize non-device related artifacts that may potentially arise if the samples are not processed or handled appropriately. The revisions to the protocol also include a provision for testing of our targeted endpoints in plasma instead of serum, changes in cytokine processing and analysis, additional options for anti-coagulation that the clinical sites may use, and an increase in the number of patients we may enroll into the study from 80 to 100.

These changes are intended to optimize the accuracy of our cytokine data for CE Mark submission. The proposed protocol changes and rationale for change were submitted to the German Ethics Committee and approved. Given these changes, cytokine data will not be statistically comparable between these first 22 patients and those enrolled subsequently in the study. While the company will continue to review all patient data in the aggregate, including secondary and exploratory endpoints, the primary use of the data from the first 22 patients will be used to support the planned CE Mark application from a safety perspective. Cytokine data from all patients enrolled subsequent to these first 22 patients, as well as safety data on all patients enrolled in the study, will be used for submission to the CE Mark authority.

While we are currently observing an improvement in our enrollment rate, to date patient enrollment has been slower than originally anticipated. The Company has taken a number of steps to improve recruitment, the most significant of which is the increase in the number of our clinical trial sites. With more sites actively seeking to enroll patients, we expect the patient enrollment rate to continue to increase going forward. Concurrent with the clinical study, we have commenced preparation for the CE Mark submission process. Assuming availability of adequate and timely funding, a successful outcome of the study, and CE Mark regulatory approval, the Company intends to commercialize its product in Europe.

By December 31, 2009 we had initiated and opened for enrollment a total of fourteen (14) hospital units to participate in our clinical study. To date the Company has enrolled sixty six (66) patients in the clinical study. We may enroll up to an additional thirty four (34) patients. In conducting the German Clinical study we have utilized our CytoSorb™ device in approximately 200 treatments to date with no Serious Adverse Events attributable to the device.

The clinical protocol for our European clinical study has been designed to allow us to gather information to support future U.S. studies. In the event we receive the CE Mark and are able to successfully commercialize our products in the European market, we will review our plans for the United States to determine whether to conduct clinical trials in support of 510K or PMA registration. No assurance can be given that our proposed CytoSorb™ product will work as intended or that we will be able to obtain CE Mark (or FDA) approval to sell CytoSorb™. Even if we ultimately obtain CE Mark approval, because we cannot control the timing of responses from regulators to our submissions, there can be no assurance as to when such approval will be obtained.

We have developed two products, CytoSorb™ and BetaSorb™ utilizing our adsorbent polymer technology. These products are known medically as hemoperfusion devices. During hemoperfusion, blood is removed from the body via a catheter

or other blood access device, perfused through a filter medium where toxic compounds are removed, and returned to the body.

2

---

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

To date, we have manufactured the CytoSorb™ device on a limited basis for testing purposes, including for use in clinical studies. We believe that other current state of the art blood purification technologies (such as dialysis) are incapable of effectively clearing the various toxic compounds intended to be adsorbed by our devices. We have demonstrated the ability of CytoSorb to remove cytokines in vitro with whole blood. CytoSorb's™ ability to interact safely with blood (hemocompatibility) and general biocompatibility has been demonstrated through ISO 10993 testing.

Prior to the current European Sepsis Trial, the CytoSorb™ device design was tested on a single patient with bacterial sepsis, producing results that our management found encouraging and consistent with our belief that our device design was appropriate for more extensive sepsis study.

In November 2009, we announced positive clinical data on key secondary endpoints from 7 CytoSorb™ treated patients, compared to 6 control patients, with severe sepsis in the setting of respiratory failure. These data included all fully monitored, completed data sets at that time from a 22 patient sepsis pilot.

We are currently enrolling patients in our European Sepsis Trial using our CytoSorb™ device. The study is a randomized, controlled clinical study in fourteen hospital sites in Germany of up to 100 patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis. Patients are being treated with one new device per day for up to seven (7) consecutive days. The study protocol was designed to support an application for the European CE Mark (regulatory approval to sell medical devices in Europe). This study is designed to be supportive of, but not specifically for, FDA approval for the use of our CytoSorb™ device in the U.S.

Following the sepsis indication, we intend to continue our research in other acute conditions where CytoSorb™ has indicated potential in preliminary studies to prevent or reduce the accumulation of cytokines and other toxic compounds in the bloodstream. These conditions include, but are not limited to, the prevention of post-operative complications of cardiac surgery (cardiopulmonary bypass surgery), damage to organs donated for transplant prior to organ harvest, and removing drugs from blood.

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

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

with a dialyzer. To date, we have manufactured the BetaSorb™ device on a limited basis for testing purposes, including for use in clinical studies.

3

---



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

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

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

## THE OFFERING

On May 5, 2010, we executed a purchase agreement (the “Purchase Agreement”) and a registration rights agreement (the “Registration Rights Agreement”), with Lincoln Park Capital Fund, LLC. (“LPC”) Under the Purchase Agreement, LPC is obligated to purchase from us up to \$6 million of our common stock, from time to time over a 750 day (twenty-five (25) months) period.

Pursuant to the Registration Rights Agreement, we were required to file a registration statement that includes this prospectus with the U.S. Securities and Exchange Commission (“SEC”) covering the shares that have been issued or may be issued to LPC under the Purchase Agreement. We do not have the right to commence any sales of our shares to LPC until the SEC has declared effective the registration statement of which this prospectus is a part. Thereafter, over approximately 750 days, or, 25 months, generally we have the right to direct LPC to purchase up to \$6,000,000 of our common stock in amounts up to \$50,000 as often as every two business days under certain conditions. We can also accelerate the amount of our common stock to be purchased under certain circumstances. No sales of shares may occur at a purchase price below \$0.10 per share. The price of our stock as of May 28, 2010 was \$0.07 and accordingly no sales of shares may occur until such time as the price is again at or above \$0.10. The purchase price of the shares will be based on the market prices of our shares at the time of sale as computed under the Purchase Agreement without any fixed discount. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business days notice. We issued 1,153,846 shares of our common stock to LPC as an initial commitment fee for entering into the agreement (which shares are not a part of this offering), and we are obligated to issue up to an additional 1,153,846 shares pro rata as LPC purchases up to \$6,000,000 of our common stock as directed by us.

As of May 28, 2010, there were 101,175,222 shares of our common stock outstanding of which 99,277,507 shares are held by non-affiliates. 24,653,846 shares are offered hereby consisting of 23,500,000 shares that we may sell to LPC pursuant to the purchase agreement, and a total of 1,153,846 shares that we are obligated to issue to LPC as additional commitment fee shares pro rata as up to \$6,000,000 of our common stock is purchased. If all of the 24,653,846 shares offered by LPC hereby were issued and outstanding as of May 28, 2010, such shares would represent approximately 19.6% of the total common stock outstanding or approximately 19.9% of the non-affiliates shares outstanding, as of the date hereof.

### Securities Offered

Common stock offered by selling stockholder:	24,653,846 shares
Offering Price:	Market Price
Common Stock Currently Outstanding:	101,175,222 shares as of May 28, 2010
Use of proceeds:	We will not receive any proceeds from the sale by the selling stockholder of our common stock covered by this prospectus. However, we will receive proceeds from sales of our common stock under the Purchase Agreement. The proceeds from the Purchase Agreement will be used for working capital and general corporate purposes. See “Use of Proceeds” on page 18.
Risk Factors:	See “Risk Factors” beginning on page 6 and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in the shares.
OTCBB Ticker Symbol:	CTSO.OB



## RISK FACTORS

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

### RISKS RELATED TO OUR INDUSTRY AND OUR BUSINESS

We require additional capital to continue operations.

As of March 31, 2010 we had cash on hand of \$1,346,301 and current liabilities of \$1,320,771. We will need additional financing in the future in order to complete our clinical studies and the commercialization of our proposed products. There can be no assurance that we will be successful in our capital raising efforts.

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

- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical studies;
- the time and costs involved in obtaining regulatory clearance;
- 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.

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.

At such time as the SEC has declared effective a registration statement related to shares underlying the transaction, we may direct LPC to purchase up to \$6,000,000 of shares of our common stock under our Purchase Agreement with LPC over a 750 day (25 month) period, generally in amounts of up to \$50,000 every 2 business days. However, we cannot sell and LPC does not have the right nor the obligation to purchase any shares of our common stock on any business day that the purchase price of our common stock is less than \$0.10 per share. The last closing date price of a share of our common stock on May 28, 2010 was \$0.07 Accordingly, as of May 28, 2010, we cannot sell any shares of our common stock to LPC under the Purchase Agreement unless and until the price of our common stock is again at or above \$0.10. We may therefore realize no proceeds under the Purchase Agreement. We have registered hereby 24,653,846 shares for sale by LPC pursuant to this prospectus (not including the initial commitment shares that have been issued to LPC); however, the selling price of our common stock to LPC will have to average at least \$0.25 per share for us to receive the maximum proceeds of \$6 million under the LPC Purchase Agreement. Assuming a purchase price of \$0.10 per share (the minimum price at which stock may be sold to LPC) and the purchase by LPC of the full 23,500,000 shares under the Purchase Agreement, proceeds to us would be approximately \$2.35 million.

The extent that we rely on LPC as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources such as through the sale of our products. If obtaining sufficient funding from LPC were to prove unavailable or prohibitively dilutive and if we are unable to sell enough of our products, we may need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all \$6,000,000 worth of common stock under the

Purchase Agreement to LPC, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

We currently have no commercial operations and there can be no assurance that we will be successful in developing commercial operations.

We are a development stage company and have been engaged primarily in research and development activities and have not generated any 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, 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. We will also need to raise significant additional funds to complete clinical studies and obtain regulatory approvals before we can begin selling our products. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any products, generate any 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 March 31, 2010, we had an accumulated deficit of \$80,652,936 which included losses from operations of \$969,051 for the three month period ended March 31, 2010. In part due to these losses, our audited consolidated financial statements for the period ended December 31, 2009 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 the requisite regulatory approvals, 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 required regulatory approvals 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.

We currently have only seven employees. Our success will depend to a significant degree upon the continued services of our key management and advisors, including, Dr. Phillip Chan, our Chief Executive Officer; David Lamadrid, our Chief Financial Officer; Vincent Capponi, our Chief Operating Officer and Dr. Robert Bartlett our Chief Medical Officer, who works with us on a consulting basis. These individuals do not have long-term employment agreements, and there can be no assurance that they will continue to provide services to us. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Management and other employees may voluntarily terminate their employment with us at any time. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources.



Effective January 1, 2010, Dr. Phillip Chan, David Lamadrid and Vincent Capponi entered into new Employment Agreements with us pursuant to which their employment will terminate on December 31, 2010 without automatic renewal. There can be no assurance that they will continue to provide services to us. Effective as of December 31, 2008, Al Kraus stepped down from his position as president and Chief Executive Officer. Effective January 1, 2009, Dr. Phillip Chan replaced him as the Interim CEO and effective January 1, 2010, Dr. Chan was appointed CEO. Mr. Kraus remains with us as a Director, serving as Chairman of the Board.

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

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

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

Our future financial performance will depend, at least in part, upon the introduction and customer acceptance of our polymer products. Even if approved for marketing by the necessary regulatory authorities, our products may not achieve market acceptance. 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. 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 if we receive the CE Mark, there can be no assurance that the data from our clinical studies will be viewed as sufficient by the medical community to support the purchase of our products in substantial quantities or at all.

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

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



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

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

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

#### "Alkermes" Litigation

In February 2008, Alkermes, Inc. commenced an action against us in the U.S. District Court for the District of Massachusetts, alleging that our use of the name MedaSorb infringes on Alkermes' registered trademark "MEDISORB." In the action, Alkermes sought an injunction against our further use of the name Medasorb. Pursuant to a Settlement Agreement dated June 18, 2008, we have changed the name of MedaSorb Technologies Corporation to CytoSorbents Corporation and have changed the name of our wholly-owned subsidiary, through which we conduct all of our operational activities, from MedaSorb Technologies Inc. to CytoSorbents, Inc. to avoid any potential confusion with Alkermes' similarly named product.

We have temporarily ceased the application process with the FDA and commenced the process to obtain CE Mark approval of our products in the Europe market.

In 2007, the FDA approved our Investigational Device Exemption (IDE) application to conduct a limited study of five (5) patients in the adjunctive treatment of sepsis. Because we believed this would delay our application process in the United States for at least one year, we decided to temporarily cease proceedings with the FDA and instead commenced the application process of seeking CE Mark approval of our products in the European market. The CE Mark approval process in Europe involves clinical studies and is still lengthy and costly, even though we believe it is faster than the FDA approval process. The failure to obtain the CE Mark approvals 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.

After we obtain the CE Mark approval for our products in Europe, we will consider resuming the application process with the FDA. Even if the clinical protocol for our European clinical study has been designed to allow us to gather information to support future studies, there is no assurance that we will eventually obtain the FDA approval. In addition, there can be no assurance that government regulations applicable to our products or the interpretation of those regulations will not change.

To commercialize our products in the U.S. Market, we also will be subject to other Federal, state, and local laws, regulations and recommendations relating to laboratory and manufacturing practices as well as Medicare, Medicaid and anti-kickback laws. Non-compliance with applicable requirements can result in civil penalties, the recall, injunction or seizure of products, an inability to import products into the United States, the refusal by the government to approve or clear product approval applications, the withdrawal of previously approved product applications and criminal prosecution. The extent of potentially adverse government regulation that might arise from future legislation or administrative action cannot be predicted.

We have commenced the process of seeking regulatory approval of our products, but the approval process will involve clinical studies and is lengthy and costly. The failure to obtain government approvals, internationally or domestically, for our polymer products, or to comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of our products and result in the failure to achieve revenues or maintain our operations.

The manufacturing and marketing of our products will be subject to extensive and rigorous government regulation in the European market, the United States, in various states and in other foreign countries. In the United States and other countries, the process of obtaining and maintaining required regulatory approvals is lengthy, expensive, and uncertain. There can be no assurance that we will ever obtain the necessary approvals to sell our products. Even if we do ultimately receive CE Mark and/or FDA approval for any of our products, we will be subject to extensive ongoing regulation.

Our products will be subject to international regulation as medical devices under the Medical Device Directive. In Europe, which we expect to provide the initial market for our products, the Notified Body and Competent Authority govern, where applicable, development, clinical studies, labeling, manufacturing, registration, notification, clearance or approval, marketing, distribution, record keeping, and reporting requirements for medical devices. Different regulatory requirements may apply to our products depending on how they are categorized by the Notified Body under these laws. Current international regulations classify our CytoSorb™ device (the first product we intend to seek international approval for) as a Class IIb device. Concurrent with the clinical trial in Germany, we plan to pursue CE Mark certification of the CytoSorb™ device. There can be no assurance that the clinical studies we conduct will demonstrate sufficient safety and efficacy to obtain the required regulatory approvals for marketing, or that we will be able to comply with international regulatory requirements. 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 BetaSorb™ device and have commenced our first clinical study of our CytoSorb™ device. Clinical and pre-clinical data is susceptible to varying interpretations, which could delay, limit or prevent regulatory clearances.

To date, we have conducted limited clinical studies on our products. Patient enrollment in our current study has been slower than originally anticipated. The Company has initiated additional hospital units, but there can be no assurance that these sites will be able to enroll patients and meet the projected enrollment. There can be no assurance that we will successfully complete the clinical studies necessary to receive regulatory approvals. 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 regulatory approval. A number of companies in the medical device and pharmaceutical industries have suffered significant setbacks in advanced clinical studies, even after promising results in earlier studies. The failure to adequately demonstrate the safety and effectiveness of an intended product under development could delay or prevent regulatory clearance of the device, resulting in delays to commercialization, and could materially harm our business.

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 and/or FDA approval and commercializing our products.

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

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

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

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

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

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

We remain in the research and development and clinical study phase of product commercialization. Accordingly, once our products are approved for commercial sale, we will need to establish the capability to commercially manufacture our products in accordance with international regulatory requirements. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we or the third-party manufacturers of our products fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products.

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

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

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

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

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

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

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

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

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

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

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

insurance programs, may all result in lower prices for our products. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

## INVESTMENT RISKS

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