Cytosorbents Corp
Form S-1/A
February 14, 2014

As filed with the Securities and Exchange Commission on February 13, 2014

Registration No. 333-193053

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Amendment Number 4 to

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CYTOSORBENTS CORPORATION

(Exact name of registrant as specified in its charter)

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

7 Deer Park Drive, Suite K

Monmouth Junction, New Jersey 08852

(732) 329-8885

(Address, including zip code, and telephone number,

including area code, of registrant's principal executive offices)

(Name, address, including zip code, and telephone number,

including area code, of agent for service)

Copies to:

Gregg Jaclin, Esq.

Szaferman Lakind Blumstein & Blader, PC

101 Grovers Mill Road, Second Floor

Lawrenceville, NJ 08648

Tel No.: (609) 275-0400

Robert E. Puopolo, Esq.

Greenberg Traurig LLP

One International Place

Boston, Massachusetts 02110

Tel No.: (617) 310-6000

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective. If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

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

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	¨	Accelerated filer	¨
Non-accelerated filer	¨	Smaller reporting company	x

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 (1)
Units of Common Stock and Warrants (immediately separable) (2)	34,000,000		$ 8,500,000	$ 1,094.80
(i) 34,000,000 Common Stock, $0.001 par value per share (3)			$ — (6)	$ — (6)
(ii) 17,000,000 Warrants to purchase Common Stock (5)			$ — (6)	$ — (6)
Common Stock issuable upon exercise of Warrants (3)(4)	17,000,000		$ 5,312,500	$ 684.25
Total Registration Fee	51,000,000		$ 13,812,500	$ 1,779.05

(1) Calculated pursuant to Rule 457(o) on the basis of the maximum aggregate offering price of all of the securities to be registered.

(2) These units consist of (i) the Common Stock and (ii) Warrants listed in the above fee table. Such Common Stock and Warrants are immediately separable upon the closing of the offering. The Units will consist of 1 share of common stock and a warrant to purchase a half share of common stock.

(3) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable upon exercise of warrants registered hereunder as a result of stock splits, stock dividends, or similar transactions.

(4) We have calculated the securities included in this registration statement by assuming that each Warrant is exercisable into 1 share of Common Stock at an assumed exercise price per share of $0.3125, which is 125% of the assumed price per share of Common Stock being sold in this offering.

(5) No additional consideration is payable upon issuance of the Warrants.

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

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 SECTION 8(a), MAY DETERMINE.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and 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 _____, 2014

CYTOSORBENTS CORPORATION

UP TO 34,000,000 UNITS, EACH CONSISTING OF

ONE (1) SHARE OF COMMON STOCK AND

A WARRANT TO PURCHASE .5 SHARES OF COMMON STOCK

We are offering up to 34,000,000 units, each unit consisting of one (1) share of our common stock and one (1) warrant to purchase 0.50 shares of common stock at an exercise price of $[__] per share issued as part of this Unit. The warrants will be exercisable on or after the closing date of this offering through and including close of business on [ ], 2019. The units will not be certificated and the common stock and warrants will be immediately separable and will be separately transferable immediately upon issuance.

Our common stock is presently quoted on the OTC Bulletin Board, under the symbol “CTSO.” We do not intend to apply for listing of the warrants on any securities exchange. On February 7, 2014, the last reported sale price of our common stock on the OTC Bulletin Board was $0.2460 per share. There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange or other nationally recognized trading system.

Investing in the offered securities involves risks, including those set forth in the “Risk Factors” section of this prospectus beginning on page 5 as well as those set forth in any prospectus supplement.

Brean Capital, LLC has agreed to act as our placement agent in connection with this offering. The placement agent is not required to sell any specific number or dollar amount of securities but will use their best efforts to sell the

securities offered. This is a best efforts, no minimum offering and we may not sell the entire amount of securities being offered pursuant to this prospectus. We expect the offering to end on March 6, 2014, there are no minimum purchase requirements and there are no arrangements to place funds in an escrow, trust or similar account. The closing of the offering of the units willclose no later than 15 business days following the effectiveness of the registration statement. The units being offered may be priced at a discount to the market price of our common stock, although as of the date hereof, there has been no definitive pricing of the units. We have agreed to pay the placement agent a cash fee equal to 6% of the gross proceeds of the offering. Subject to compliance with FINRA Rule 5110(f)(2)(D), we have also agreed to pay the placement agent for out-of-pocket expenses related to the Offering. We have also agreed to issue the placement agent common stock purchase warrants equal to 3% of the aggregate number of shares of common stock sold in the Offering.

We may complete the offering even if we do not raise the entire maximum offering amount. The amount raised may be substantially less than the total maximum offering amount and any investor funds not placed in escrow may be used by the Company prior to the maximum offering being sold. If we are voluntarily or involuntarily placed into bankruptcy or receivership, any investor funds may be property of the estate and used for the benefit of creditors and not recoverable by the investors.

	Per Unit
Public Offering Price	$
Placement Agent Commissions	$
Proceeds to Us (Before Expenses)	$

The delivery of the shares and warrants is expected to be made on or about [_____], 2014.

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

The date of this prospectus is _____, 2014.

BREAN CAPITAL, LLC

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PROSPECTUS SUMMARY

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

Overview

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 prospectus to "MedaSorb,", "CytoSorbents", "us" or "we" with respect to events prior to June 30, 2006 are references to CytoSorbents, Inc. and its predecessors.

We have experienced substantial operating losses since inception. As of September 30, 2013, we had a deficit accumulated during the development stage of approximately $104,469,233, which included losses of approximately $4,009,000 and $3,126,000 for the nine month periods ended September 30, 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 approximately $3,608,000 and $2,770,000 for the nine month periods ended September 30, 2013 and 2012. We may continue to incur losses in the future. In part due to these losses, our 2012 audited consolidated financial statements have been prepared assuming we will continue as a going concern, and the auditors' report on those financial statements express substantial doubt about our ability to continue as a going concern.

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

Summary of Our Business

CytoSorbents is a development stage critical care focused company using blood purification to treat disease. 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.

There are three major components of our business. The first is the manufacturing and sale of our flagship product, CytoSorb®, now approved and available for commercial sale throughout the entire European Union (E.U.). The second is the generation of clinical data on CytoSorb® as well as research and development of new products and technologies, partially funded through government contracts. The third is business development and out-licensing of our product pipeline and technology portfolio.

Commercialization of CytoSorb®

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 life threatening conditions 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, 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 control cytokine storm, and broadly reduce key cytokines. In a post-hoc subgroup analysis, CytoSorb® was associated with a 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).

The Company plans 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 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. The Company also established a reimbursement path for CytoSorb® in Germany and Austria.

From September 2011 through June 2012, the Company 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® for the treatment of critical care illnesses such as sepsis, burn injury, trauma, acute respiratory distress syndrome, pancreatitis and other conditions where inflammation plays a detrimental role, such as cardiac surgery. We hired Dr. Christian Steiner as Vice President of Sales and Marketing and three additional sales representatives who joined the Company and completed their sales training in Q3 2012. Q4 2012 represented the first quarter of direct sales with the full sales team in place. During this period, we expanded our direct sales efforts to include both Austria and Switzerland and have established reimbursement in Germany and Austria. At the end of the third quarter of 2013, we had more than 100 key opinion leaders (KOLs) in critical care and blood purification who were either using CytoSorb® or committed to using CytoSorb® in the near future, with 26 investigator initiated studies either underway or in the planning phase.

We have also begun to complement our direct sales efforts with sales to distributors and corporate partners. In 2013, we reached agreement with distributors in the United Kingdom, Ireland, Turkey, Russia, and the Netherlands, and we are currently in negotiations with and/or evaluating other potential distributor networks in other major countries where we are approved to market the device. In September 2013, we entered into a strategic partnership with Biocon Ltd., India'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®.

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 are intended to help clinicians with additional treatment options for CytoSorb®, help support the positive clinical data from the Company's first European Sepsis Trial, and help shape the trial protocol for a U.S. based pivotal study.

In the event we are able to successfully commercialize our products in the European market, we will review our plans for the United States to determine whether to conduct clinical trials in support of 510(k) or PMA registration. No assurance can be given that our CytoSorb® product will work as intended or that we will be able to obtain FDA approval to sell CytoSorb® in the United States.

Research and Development of New Products and Technologies

The Company's 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.)

- 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

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.

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

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

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

In August 2012, the Company was awarded a $3.8 million contract by the Defense Advanced Research Projects Agency (DARPA) for its "Dialysis-Like Therapeutics" program to treat sepsis. This five-year 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. CytoSorbents has begun work on Year 2 milestones 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 evaluation 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.

In September 2013, the National Heart, Lung, and Blood Institute (NHLBI), a division of the National Institutes of Health ("NIH"), awarded the Company 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, with funding to start immediately. 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.

Business Development

We seek strategic partnerships or distributorships to help further develop or commercialize our technology portfolio. Because of the breadth of clinical applications that we attempt to address, the types of corporate partners are many. Examples of potential partners include companies focused on: medical devices, renal/dialysis, pharmaceuticals and biotechnology, critical-care, blood purification, advanced biomaterials, and others. No assurance can be given that we will be successful in our business development activities.

Recent Developments

Preliminary Results for the Year Ended December 31, 2013

Although our financial statements as of and for the year ended December 31, 2013 are not yet available, the following information reflects our estimates of our results based on currently available information.

For the year ended December 31, 2013, we expect to report the following results:

(in thousands of $)

	Estimated 12/31/2013	Actual 12/31/2012
Balance Sheet Data		
Cash	$ 2,153	$ 1,729
Stockholders' deficit	$ (14,422)	$ (11,625)
Statement of Operations Data		
Research and development	$ 2,131	$ 2,532
Legal, financial and other consulting	777	627
General and administrative	2,621	1,354
Total operating expenses	5,529	4,514
Net loss	$ (6,931)	$ (6,175)
Net loss per share, basic and diluted	$ (0.03)	$ (0.03)
Weighted average number of common shares outstanding, basic and diluted	236,019,972	198,228,289

Research and development expenses in 2013 are expected to decrease by approximately $401,000 because certain research and development costs were offset by grants awarded to the company. The research and development costs associated with grants is included in cost of goods sold. General and administrative expenses in 2014 are expected to increase by approximately $1.3 million over 2013, with the increase being primarily attributable to an increase in costs associated with the sales force and related personnel expenses for our product commercialization efforts in Germany, Austria, and Switzerland.

We have recently issued a letter to shareholders detailing some of our recent developments and future expectations. Some of our 2013 financial highlights include:

· 2013 represents the first full year of CytoSorb® commercialization

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We expect to report total 2013 revenue of approximately $2.4 million, including both product sales and grant income

- Full year 2013 CytoSorb® sales are expected to be in the range of $840,000 to $870,000

- Expected Q4 2013 product sales in the range of $330,000 to $360,000 were a record for the Company and represent a greater than 60% sequential increase from the previous Q3 2013, and a greater than 275% increase from the year ago fourth quarter

- Gross product margins in Q4 2013 are expected to exceed 60%

- Ramping manufacturing of CytoSorb® to meet increased demand from direct sales and distributors

The foregoing constitute forward-looking statements and should be read in light of the section of this prospectus supplement entitled “Special Note Regarding Forward-Looking Information.” These preliminary results are unaudited and represent our estimates only, and our actual results could differ materially and adversely from those set forth above as a result of various factors, some of which are listed in the section of the accompanying prospectus entitled “Risk Factors.” In addition, these factors include, without limitation, the risk that additional information may arise during our close process or as a result of subsequent events that would require us to make adjustments to the financial information, as well as the risk that adjustments to our financial statements may be identified through the course of our independent registered public accounting firm completing its audit of our financial statements.

Where You Can Find Us

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

The Offering

Common stock offered	Up to 34,000,000 units. Each unit consists of 1 (one) share of our common stock and 1 (one) warrant to purchase 0.50 shares of our common stock issued as part of the unit. The units will not be certificated and the common stock and warrants will be immediately separable and will be separately transferable immediately upon issuance.
Common stock outstanding before the offering	As of November 30, 2013 there were 246,972,191 shares of the issuer’s common stock, par value $0.001, outstanding.

Common stock outstanding after the offering	297,972,191 shares, assuming all of the Units are sold, which includes 17,000,000 shares of common stock issuable upon exercise of the warrants included in the offered units or the shares of common stock issuable upon the exercise of the placement agent warrants.
Use of proceeds	We expect to use the proceeds received from the offering to further develop our products, to support our sales and marketing efforts, to help fund clinical studies, and for general working capital purposes. Given that there is no minimum offering size of this offering, it is possible that we could receive significantly less than the $8,500,000 targeted 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 7.

RISK FACTORS

The shares of our common stock being offered are highly speculative in nature, involve a high degree of risk and should be purchased only by persons who can afford to lose the entire amount invested in the common stock. Before purchasing any of the shares of common stock, you should carefully consider the following factors relating to our business and prospects. If any of the following risks actually occurs, our business, financial condition or operating results could be materially adversely affected. In such case, you may lose all or part of your investment. You should carefully consider the risks described below and the other information in this process before investing in our common stock.

Risks Related to our Industry and our Business

We require additional capital to continue operations.

As of September 30, 2013 we had cash on hand of approximately $2,350,000 and current liabilities of approximately $3,066,000 (which includes approximately $1,562,000 of notes payable which are convertible into common shares). We will need 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.

We may direct Lincoln Park Capital ("LPC") to purchase up to $8,500,000 worth of shares of our common stock under our agreement over a 32 month period expiring in August 2014 generally in amounts of up to $50,000 every two business days, which amounts may be increased under certain circumstances. At November 30, 2013, we had $3,200,000 of proceeds remaining under this Agreement.

The extent to which we rely on LPC as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from LPC were to prove unavailable or prohibitively dilutive and if we are unable to sell enough of our products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all $3,200,000 remaining under the Purchase Agreement to LPC, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, we may have to relinquish economic and/or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourselves.

We currently are in the process of commercializing our products, but there can be no assurance that we will be successful in developing commercial operations.

We are a development stage company and have been engaged primarily in research and development activities and have 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 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, 2013, we had an accumulated deficit of approximately $104,469,000, which included net losses of approximately $4,009,000 for the nine months ended September 30, 2013, approximately $3,664,000 for the year ended December 31, 2012 and approximately $5,482,000 for the year ended December 31, 2011. In part due to these losses, our audited consolidated financial statements have been prepared assuming we will continue as a going concern, and the auditors' report on those financial statements express substantial doubt about our ability to continue as a going concern. Our losses have resulted principally from costs incurred in the research and development of our polymer technology and general and administrative expenses. Because our predecessor was a limited liability company until December 2005, substantially all of these losses were allocated to that company's members and will not be available for tax purposes to us in future periods. We intend to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for the establishment of manufacturing arrangements and a marketing and distribution presence and other general and administrative expenses, are expected to result in continuing operating losses for the foreseeable future. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our technology and commercial products, obtaining additional requisite regulatory approvals in markets not covered by the CE Mark and for potential label extensions of our current CE Mark, establishing manufacturing and sales and marketing arrangements with third parties, and raising sufficient funds to finance our activities. No assurance can be given that our product development efforts will be successful, that our current CE Mark will enable us to achieve profitability, that additional regulatory approvals in other countries will be obtained, that any of our products will be manufactured at a competitive cost and will be of acceptable quality, or that the we will be able to achieve profitability or that profitability, if achieved, can be sustained.

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

As of November 30, 2013 we currently have twenty-five full-time employees and we also utilize consultants and temporary help who are not employees of the Company, as necessary. 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 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 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 FDA) will be required before we can market our device in countries not covered by the CE Mark. There is no guarantee that the Company will be able to achieve additional regulatory approvals, and even if we do, our products may not achieve market acceptance in the countries covered by such approvals. The degree of market acceptance will depend upon a number of factors, including:

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

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

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

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" settlement discussed below, we may be exposed to additional future litigation by third parties seeking to challenge the validity of our rights based on claims that our technologies, products or activities infringe the intellectual property rights of others or are invalid, or that we have misappropriated the trade secrets of others.

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

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

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.

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