

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

Filing Date: **2013-01-11** | Period of Report: **2013-01-09**
SEC Accession No. [0001144204-13-001843](#)

([HTML Version](#) on [secdatabase.com](#))

FILER

Cytosorbents Corp

CIK: [1175151](#) | IRS No.: [980373793](#) | Fiscal Year End: [1231](#)
Type: **8-K** | Act: **34** | File No.: [000-51038](#) | Film No.: [13524805](#)
SIC: **3841** Surgical & medical instruments & apparatus

Mailing Address

7 DEER PARK DRIVE, SUITE
K
MONMOUTH JUNCTION NJ
08852

Business Address

7 DEER PARK DRIVE, SUITE
K
MONMOUTH JUNCTION NJ
08852
973-329-8885

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 9, 2013

CYTOSORBENTS CORPORATION

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of incorporation)

000-51038
(Commission
File Number)

98-0373793
(IRS Employer
Identification No.)

7 Deer Park Drive, Suite K
Monmouth Junction, New Jersey
(Address of principal executive offices)

08852
(Zip Code)

Registrant's telephone number, including area code: (732) 329-8885

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

Cytosorbents Corporation (the "Company") issued a letter to its shareholders on January 9, 2013 summarizing the Company's achievements in 2012 and the Company's goals for 2013. A copy of the letter is being furnished as Exhibit 99.1 hereto.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	"Shareholder letter issued on January 9, 2013" The Shareholder letter is furnished and not filed pursuant to Instruction B.2 of Form 8-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CytoSorbents Corporation

/s/ Dr. Phillip P. Chan

Date: January 11, 2013

By: Name: Dr. Phillip P. Chan
Title: President and CEO

CytoSorbents™



CytoSorbents 2012 End of Year Shareholder Letter

Monmouth Junction, NJ – (January 9, 2013) – CytoSorbents Corporation (OTCBB:CTSO), a critical care focused company using blood purification to treat life-threatening illnesses, issued the following letter to shareholders.

Dear Shareholders and Friends,

As we welcome 2013, it marks an opportune time to reflect upon our many important accomplishments in the past year and to further elaborate on our vision for the future.

Our mission is to improve and save lives, reduce spiraling healthcare costs, and increase shareholder value by driving the success of CytoSorbents. To this end, we are building the Company upon three pillars of value.

The first and most important pillar is the commercialization of our CytoSorb® cytokine filter in the European Union (E.U.), in other countries outside of the (E.U.), and eventually in the U.S. Based upon the growing number of potential applications we are seeing, we continue to believe that CytoSorb® has the potential to revolutionize critical care medicine by targeting the prevention or treatment of organ failure - the leading cause of death in the intensive care unit from such life-threatening illnesses as sepsis, burn injury, trauma, lung injury, pancreatitis, liver failure, and many others.

- The second pillar is research and development and the creation and testing of valuable new products. Our highly biocompatible, porous polymer bead technology has demonstrated the unique and elegant ability to remove a broad range of unwanted substances from blood and other bodily fluids. We have expanded our product pipeline beyond CytoSorb® and BetaSorb (dialysis), to other development stage technologies that address large markets such as HemoDefend (blood transfusion), ContrastSorb (imaging and interventional radiology/cardiology), DrugSorb (drug overdose), and several more that have not yet been disclosed. We fund R&D through a combination of direct expenditures and non-dilutive government sources. In 2012, we were awarded approximately \$5 million in R&D contracts from two U.S. Department of Defense agencies: DARPA and the U.S. Army. These contracts are valuable because they can advance our technologies while simultaneously helping to fund overall operating expenses.

The third pillar is business development. We seek to unlock the value of our technology portfolio through strategic partnerships with other companies. As a small, but rapidly expanding company, we would like to focus the majority of our resources on the commercialization of CytoSorb®. Partnering with well-positioned and financially capable partners who are leaders in their respective fields and have the ability to bring our products to market, would provide an ideal way to realize the full potential of our technology.

-

This represents our overarching strategy for the Company. With trailing revenues expected to be approximately in the range of \$1.2-1.4 million in 2012 (unaudited results) - a combination of primarily grant income and early product revenue – we hope that we are just at the beginning of creating a valuable growth company.

Commercialization of CytoSorb®

We officially launched direct sales of CytoSorb® in Germany, Austria and Switzerland in the second half of 2012. CytoSorb® is approved in the E.U. as a first-in-class extracorporeal cytokine filter to be used in any situation where cytokines are elevated. We are positioning the device as a safe and powerful new tool to control cytokine storm, reduce uncontrolled inflammation, and potentially prevent or treat organ failure. The launch was the culmination of a significant effort to position CytoSorbents as a commercialization focused company.

- We recruited our Vice President of Sales and Marketing, Dr. Christian Steiner, and a direct sales force of 3 other sales representatives in Germany. We expect to increase the number of sales representatives this year, as needed, to take advantage of increased business opportunities
- We established a European subsidiary in Berlin, Germany that has become the central point of direct commercialization in Germany, Austria and Switzerland
- We manufacture CytoSorb® at our ISO 13485 certified manufacturing facility in New Jersey. We synthesize the polymer beads from raw chemicals and, today, CytoSorb® is one of the highest, ultra-pure, clinical-grade medical sorbents on the market. We are also vertically integrated - assembling and shipping our CytoSorb® filters from this facility while instituting strict controls on quality and cost, with current gross margins greater than 50%. With economies of scale and increased volume, we have the potential to increase the profitability of CytoSorb®

- Reimbursement has been established in both Germany and Austria at more than \$500 per cartridge, reducing a major barrier to adoption
- More than 60 key opinion leaders (KOLs) in our direct sales territories are now either using CytoSorb®, want to use it, or are planning to use it in clinical studies. These KOLs are frequently the chiefs of the critical care department and/or prominent and influential leaders in clinical and scientific research for both surgical and medical critical care. We are also in the planning stage for more than a half dozen investigator-initiated studies
- In 2012, we exhibited at 10 major scientific meetings with research talks or symposia at three of these. As more studies are performed with CytoSorb®, we hope that our KOLs will begin to share these data with their peers at future conferences
- We sponsored World Sepsis Day and participated in charity events in both New York and Berlin to help support non-profit organizations that are working to increase awareness of this significant unmet medical need
- We recently welcomed a new Chief Financial Officer, Thomas Bocchino, an accomplished executive with relevant experience in European and international distribution.

Since the first commercial availability of the CytoSorb® cytokine filter in Q4 2011, through the end of 2012, we have generated product revenues in the range of \$190-\$200K. CytoSorb® sales in Q4 2012 (unaudited results) are expected to be nearly half this total figure, reflecting primarily the first full quarter that our direct sales team was active.

Going forward, we are implementing a multi-pronged strategy for CytoSorb® sales expansion. The first part focuses on direct sales in Germany, Austria and Switzerland, using our direct sales force. The advantage of direct sales is that we intimately control the sales process, have direct contact with the KOLs and end-users that facilitates feedback and planning, and can sell with higher gross margins. We are currently in the key opinion leader adoption phase, where there is naturally a lag between when a KOL first agrees to use or trial the CytoSorb® filter, to when we achieve first sales, to when we can achieve broader departmental usage with reorders. That said, as we have described before, KOL approval is one of the most important steps to driving adoption and greater usage. CytoSorb® has been generally met with enthusiasm by physicians, as little can be done today to help critically ill patients, and CytoSorb® attacks the well-known underlying causes of organ failure. This seeding of the market will hopefully help generate ongoing data and clinical usage in many different applications.

The second phase of the strategy is to work with distributors or strategic partners to expand the commercial footprint of CytoSorb® to the rest of Europe and to other countries that accept European regulatory approval. This will allow us to leverage their pre-established sales force and distribution capabilities, including important KOL contacts, enabling broader CytoSorb® filter sales.

By layering these two sources of revenue with grant income from government R&D contracts, we hope to accelerate our revenue growth and time to cash flow breakeven. If our European strategy is successful, it would provide an abundance of opportunities for the Company. We estimate that Germany alone represents a total addressable market of at least \$500 million to \$1 billion for critical care applications. However, to further drive success of the Company, we plan to pursue U.S. regulatory approval for CytoSorb®. We intend to leverage our existing FDA approved IDE application (to run a small sepsis trial), to run a larger pivotal trial in the U.S. The timing of a trial in the U.S. is subject to many variables, and we are working through those now with the intent of conducting detailed discussions with the FDA regarding trial design later this year. Should a pivotal trial be successful in the U.S., it could lead to U.S. FDA approval and be yet another major catalyst to CytoSorb® adoption and usage worldwide.

With each new CytoSorb® treatment, we learn more about how best to use it. In our ongoing dosing study, CytoSorb® has been successfully used with continuous treatment (each cartridge used for 24 hours) for 7 days with no serious device related events. The trial is ongoing, with additional patients being enrolled, samples collected and data being analyzed. We are currently expanding the study to include a total of seven hospitals in Germany, all of which are leading university hospitals that expressed an interest to join our trial. We are also using the trial as an opportunity to answer some important questions related to treatment, which will be helpful to further guide clinical usage.

Outside of the trial, in every day clinical practice, physicians have had generally encouraging results with CytoSorb®. For example, there have been a number of cases of septic shock and multiple organ failure where CytoSorb® was used in patients with extremely high cytokine levels (e.g. IL-6 greater than 20,000 pg/ml). These patients were extremely sick with a variety of infections ranging from a Streptococcal limb infection to suspected gram negative sepsis following complications from a gynecologic procedure. In each of these cases, the prognosis was reportedly grim by the treating physicians. With Cytosorb® treatment, IL-6 levels dropped dramatically over the course of several days, with an eventual resolution of organ failure, and patient recovery. Based upon feedback from these physicians, they are interested in documenting these surprising results for potential publication.

There have also been a handful of cases, unfortunately, where CytoSorb® has not been able to rescue the patient. A common theme in these treatment failures appears to be either suboptimal usage of Cytosorb® or treatment that was too late in the disease process. We cannot expect CytoSorb® to save all patients, particularly when patient's illnesses are so advanced that recovery is unlikely. That said, the more clinical experience we gain with the technology, the better the odds of treating these patients optimally and having a better clinical outcome.

Overall, we continue to make significant progress in our commercialization efforts and are pleased with the initial physician response and clinical experience.

Research and Development update

We continue to advance our technologies and grow our product pipeline through investments in research and development. We have recently been awarded approximately \$5M in government contracts that help to fund these efforts.

DARPA \$3.8M Contract

As part of DARPA's "Dialysis-like Therapeutics" program to treat sepsis, we were awarded a \$3.8M five-year contract in August to develop advanced polymers that can remove not only cytokines but also a variety of bacterial and biowarfare toxins. Our technology is ideally suited for this broad spectrum capability. In fact, we have already demonstrated the ability of CytoSorb® to remove a number of these toxins *in vitro* such as Staphylococcus aureus alpha toxin, a potent toxin that is responsible for cell destruction and widespread tissue damage in Staph. aureus and methicillin resistant Staph. aureus, or MRSA, infection. MRSA is one of the leading and most deadly hospital acquired infections. Outside of this DARPA contract, Dr. John Kellum at University of Pittsburgh has demonstrated in an animal model of sepsis, that a reduction of cytokines by CytoSorb® hemoadsorption appears to redirect the immune response to the area of infection, helping to control it even in the absence of antibiotics, while preventing unwanted immune-mediated injury to uninvolved, healthy organs. These new and exciting findings highlight the multi-factorial and synergistic benefit that CytoSorb® may have in these critical illnesses (i.e. reduction of cytokine storm, removal of damaging bacterial toxins, redirection of the immune response, and others) and why we believe our technology is the best-in-class solution.

United States Army \$1M Phase 2 SBIR Award

We are nearing the completion of our negotiations of our \$1 million Phase 2 SBIR award with the U.S. Army. Ahead of this, we have been continuing our work from the Phase I SBIR award, and should be in a good position to make rapid progress with funding. We remain excited by the prospect of continuing to work with the Army and obtaining efficacy data in animal models of both burn injury and trauma which, if positive, will help advance these applications in human treatment. We are also encouraged by interest from other branches of the military in our technologies, which may lead to other opportunities.

Business Development

One of the key goals of the Company is to establish strategic partnerships for various products in our pipeline. We cannot commercialize all of them by ourselves, so leveraging the expertise, financial resources, and infrastructure of dedicated partners remains a logical option. The majority of our products under development have achieved proof-of-concept, at a bare minimum.

One of our most advanced development candidates is our HemoDefend blood purification technology. HemoDefend is designed to remove contaminants in blood transfusion products that can cause transfusion reactions, effectively “washing blood” without the cost, time and trouble of actually doing so. We have made significant advances in our in-line blood transfusion filter, demonstrating the ability to filter standard packed red blood cells (pRBCs) that account for nearly half of the 100+ million worldwide blood transfusions each year, while removing significant amounts of contaminants such as toxic free hemoglobin, and others. We have optimized the design so that a unit of packed red blood cells passes relatively easily through this low resistance, high flow filter by gravity alone in under a half an hour. This meets the requirements of the vast number of pRBC transfusions performed each year. We are also in the process of optimizing our packaging to help drive down the unit costs of each device. We also continue to make good progress on our “Beads in a Bag” configuration, with demonstration of our neutrally buoyant bead technology, and efficient removal of contaminants such as antibodies, cytokines, free hemoglobin, and bioactive lipids over 42 days. This was the subject of our scientific poster presentation at the 2012 American Association of Blood Banks (AABB) conference. We believe that HemoDefend represents a significant new innovation and capability to the blood transfusion industry.

Another product that we announced recently is our ContrastSorb technology. ContrastSorb, still in early development, is designed to try to prevent contrast-induced nephropathy. Patients with existing kidney injury from diseases such as diabetes and hypertension, are at higher risk of kidney injury when undergoing standard CT imaging procedures using IV contrast, interventional radiology procedures, and cardiac catheterizations. Unfortunately, due to vascular disease, these are the patients who are most likely to require these procedures. There are an estimated 200 million CT scans performed each year with many requiring contrast administration. There are an estimated 10 million coronary angiograms performed each year worldwide, as either a diagnostic or therapeutic (stent placement or balloon angioplasty) procedure for coronary artery disease, each requiring high doses of IV contrast. Catheterization procedures for peripheral artery disease and other interventional radiology procedures also continue to grow rapidly. With our blood compatible technology that can remove contrast with high single pass efficiency, it potentially could be used during these procedures in high risk patients to mitigate kidney injury. This type of technology could, for example, be interesting to renal/dialysis companies, catheter companies, interventional cardiology and radiology companies, and potentially others.

Investor Relations

In 2012, we were pleased to attract positive analyst coverage from both Zacks Research and Brean Murray. These reports, and the continuing follow-on research notes, summarized the investment opportunity well and represented the first research coverage on the Company since going public in 2006. We commissioned Investorials.com to produce an easy-to-understand and engaging three and a half minute illustrated video synopsis on CytoSorbents that has also garnered praise from both existing and potential investors. We were also interviewed by MoneyTV in a high quality video, with additional follow-on audio segments that helped to bring our message to a broader television audience. We also worked with ProActive Capital to broaden our social media exposure and to bring new content to investors. Also, an article on our Company appeared on the front page of Medical Device Daily, a daily web and print publication that has excellent distribution into the medical device community. Many of these materials can be found on our investor relations homepage. Furthermore, we presented at numerous investor conferences, such as the OneMedForum, Rodman and Renshaw, and Brean Murray conferences.

The above activities demonstrate our commitment to support our shareholders and to share our story with a wider investor audience. In 2013, we plan to go one step further and have formally engaged Alliance Advisors as our investor relations group. They are a well-respected boutique firm that specializes in representing companies of our size, with many institutional and retail investor contacts. We also plan to devote more resources towards increasing the visibility and profile of our Company in the media. Last but not least, we expect the launch of our newly-designed website in the next several months.

Expanding our investor relations efforts fits with our longer term goal of leaving the OTCBB and up-listing to a national stock exchange. This requires significant preparation, and clearly must be done at the appropriate time when our fundamentals justify it. However, the advantages are many, including a higher profile and greater access to the broader investment community, particularly institutional investors.

Goals for 2013-2014

We have laid out an ambitious, yet potentially achievable, agenda for the next two years. Some of our highest priorities are:

- Greater awareness of our story and technology through increased media exposure and improved investor relations
 - Revenue growth and increased product adoption in our direct sales territories
 - Distributor agreements for CytoSorb in Europe and elsewhere
 - Strategic partnerships for our pipeline products
 - Non-dilutive funding from grants and other programs
 - Commencement of a U.S. based trial
 - Clinical data and new clinical applications with data being presented at key scientific conferences
 - Improving liquidity and institutional sponsorship of our stock with potential up-listing to a national stock exchange
-

We appreciate the continued hard work and dedication of our employees and the support of our shareholders and friends. My best wishes to all for a happy, healthy, and prosperous New Year!

Best,

Phillip

Phillip Chan, MD, PhD
Chief Executive Officer - CytoSorbents Corporation

Forward-Looking Statements

This press release includes forward-looking statements intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release are not promises or guarantees and are subject to risks and uncertainties that could cause our actual results to differ materially from those anticipated. These statements are based on management's current expectations and assumptions and are naturally subject to uncertainty and changes in circumstances. We caution you not to place undue reliance upon any such forward-looking statements. Actual results may differ materially from those expressed or implied by the statements herein. CytoSorbents Corporation and CytoSorbents, Inc believe that its primary risk factors include, but are not limited to: obtaining government approvals including required FDA and additional CE Mark approvals; ability to successfully develop commercial operations; dependence on key personnel; acceptance of the Company's medical devices in the marketplace; the outcome of pending or potential litigation; compliance with governmental regulations; reliance on research and testing facilities of various universities and institutions; the ability to obtain adequate and timely financing in the future when needed; product liability risks; limited manufacturing experience; limited marketing, sales and distribution experience; market acceptance of the Company's products; competition; unexpected changes in technologies and technological advances; and other factors detailed in the Company's Form 10-K filed with the SEC on March 31, 2012, which is available at <http://www.sec.gov>.

SOURCE: CytoSorbents Corporation

Contact:

CytoSorbents Corporation

Phillip Chan
Chief Executive Officer
(732) 329-8885 ext. 823
pchan@cytosorbents.com