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): September 11, 2023

CYTOSORBENTS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**001-36792**	**98-0373793**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

305 College Road East **Princeton, New Jersey**	**08540**
(Address of principal executive offices)	(Zip Code)

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

Not Applicable
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
common stock, $0.001 par value	CTSO	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

☐

Item 8.01 Other Events

On September 11, 2023, CytoSorbents Corporation (the "Company") issued a press release highlighting the growing momentum of *ex vivo* organ perfusion in organ transplantation and the vital role CytoSorb® and ECOS-300CY® are playing in this burgeoning field. A copy of the press release is filed herewith as Exhibit 99.1 and incorporated by reference into this Item 8.01.

Item 9.01 Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release of the Company, dated September 11, 2023.
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

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.

Dated: September 12, 2023

CYTOSORBENTS CORPORATION

By: /s/ Dr. Phillip P. Chan
Name: Dr. Phillip P. Chan
Title: Chief Executive Officer

Exhibit 99.1

CytoSorb with Ex Vivo Organ Perfusion: Transforming the Future of Solid Organ Transplantation

In the first human retrospective study, CytoSorb and ex vivo lung perfusion prior to lung transplant increased in-hospital and one-year survival

PRINCETON, N.J., September 11, 2023 — CytoSorbents Corporation (NASDAQ: CTSO), a leader in the treatment of life-threatening conditions in intensive care and cardiac surgery using blood purification via its proprietary polymer adsorption technology, highlights the growing momentum of *ex vivo* organ perfusion in organ transplantation and the vital role CytoSorb® and ECOS-300CY® are playing in this burgeoning field. In particular, these technologies may help to improve the quality and number of usable organs while improving transplant success rates. Importantly, data from recent peer-reviewed publications highlight how these innovative therapies may improve outcomes in the specific field of lung transplantation.

Background – Organ Transplantation, *Ex Vivo* Organ Perfusion, and CytoSorb/ECOS-300CY

Organ transplantation is the gold standard treatment for end-stage organ failure. However, suitable donor organs are scarce and many patients often die waiting for an organ to become available. According to the Global Observatory on Donation and Transplantation, there were approximately 158,000 solid organ transplants in 2022 globally. According to the United Network of Organ Sharing (UNOS) and the European Directorate for the Quality of Medicine and Healthcare (EDQM), in 2022 in the U.S. and E.U. alone, there were approximately an equal number of patients, roughly 153,000, on the transplantation waitlist, primarily due to the lack of suitable organs. Every 10 minutes, someone is added to the waitlist, and roughly every half hour, someone dies on the waiting list, waiting for an organ that never comes.

The vast majority of donated organs are from deceased donors, often due to irreversible cardiac or brain death. However, due to a variety of factors, including ischemia and reperfusion injury, cold storage, and the manner by which the donor died, these organs are often damaged with significant inflammation, jeopardizing organ health and importantly the success of the transplantation. In the U.S., according to a 2020 Millman research report, a single lung transplant costs approximately $930,000, a two lung transplant: $1.3 million, a kidney transplant: $443,000, a liver transplant: $878,000, and a heart transplant: $1.7 million. Due to the expense of failure, many organs are discarded, despite the significant need. In addition, many organs, despite being deemed transplantable, develop problems of delayed graft function or primary graft dysfunction after surgery. This is different from organ rejection and can happen with any organ. For example, in lung transplantation, the rates of potentially life-threatening lung failure within the first several days after transplant, called severe primary graft dysfunction (PGD), can be as high as 30%, resulting in high 90-day (20-25%) and 1-year (30-35%) mortality, which is 3-5 times higher than if PGD did not occur. Strategies that can improve the health of organs or improve postoperative outcomes are key to the future of solid organ transplant.

Ex vivo organ perfusion is an increasingly used strategy to preserve and potentially improve the functioning of lungs, hearts, livers and kidneys following organ harvest and during transport by reducing ischemic, reperfusion, and cold storage injuries caused by conventional static cold storage. It also has the potential to increase the available donor pool of organs by salvaging substandard ones that would otherwise be discarded. *Ex vivo* perfusion circulates temperature controlled, oxygenated, nutrient rich fluid or blood products through the organ to improve its viability. However, *ex vivo* perfusion does not adequately address the ongoing release of cytokines and other inflammatory mediators generated by the damaged organ that cause ongoing injury and compromised function. Based on recent data, we believe the integration of our cytokine adsorptive technologies (i.e. CytoSorb, ECOS-300CY) with *ex vivo* organ perfusion has the potential to transform the field of organ transplantation by not only elevating organ preservation and rehabilitation to a new level, but by improving clinical outcomes after the surgery. The combination has been used successfully in heart, liver, and kidney transplants to date, but the largest body of data comes from lung transplantation.

CytoSorb and ECOS-300CY in Lung Transplantation

The final analysis of the U.S. CytoSorb Therapy in COVID-19 (CTC) Registry was published recently in the journal Critical Care and demonstrated that the combination of CytoSorb and extracorporeal membrane oxygenation (ECMO) therapy resulted in 74% 90-day survival in 100 critically ill patients from 5 major U.S. ECMO centers who had COVID-19 with severe acute respiratory distress syndrome (ARDS) and who failed mechanical ventilation. This compared favorably to the 52% 90-day survival rate reported by the Extracorporeal Life Support Organization (ELSO) in over 15,000 comparably ill COVID-19 patients using ECMO alone. The paper highlighted the concept of “enhanced lung rest,” where CytoSorb is used to remove circulating inflammatory cytokines and toxins that can cause or worsen lung injury via capillary leak syndrome, pulmonary edema (i.e. fluid in the lungs), and severe inflammation. The ultimate goal of CytoSorb therapy is to help stop severe inflammation and promote lung healing and recovery.

This same “enhanced lung rest” concept has carried over to lung transplant, where inflammation in donated lungs causes the same capillary leak syndrome, pulmonary edema, and compromised lung function, and is a major contributor to primary graft dysfunction (PGD), as mentioned earlier.

In 2017, Iskender and Inci, et al., from University Hospital Zurich in Switzerland, published the first study in the Journal of Heart and Lung Transplantation using CytoSorb with *ex vivo* lung perfusion (EVLP) in a controlled pig lung model, demonstrating decreased circulating cytokines, decreased microscopic lung injury, improved electrolyte balance, and improved lung mechanics with easier ventilation of the lung. In 2021, the team published a follow-up study in the Journal of Heart and Lung Transplantation where they took the model to the next step by transplanting the EVLP-treated lungs (with or without CytoSorb) into pig recipients. They found that EVLP with CytoSorb significantly improved the functioning of the transplanted lung from both a mechanics and gas exchange standpoint.

In the 2022 landmark paper published in the prestigious journal Nature Communications, Ghaidan and Lindstedt, et. al., studied the impact of CytoSorb and EVLP in a pig lung transplantation model. Lung injury and ARDS were induced in pig donors by endotoxin injection. Once harvested, these compromised lungs all underwent EVLP and single lung transplantation into a new pig recipient. The study was divided into three groups. The “**untreated**” group did not have CytoSorb at any time. The “treated” group was subdivided into a) the “**One-step**” group that did not receive CytoSorb during EVLP but received CytoSorb postoperatively following lung transplant, and b) the “**Two-step**” group had CytoSorb both during EVLP, and then again postoperatively following lung transplant. In a detailed and well-controlled study, the researchers followed many parameters, including cytokines and inflammatory cells in the blood and lung, level of lung inflammation, changes in histopathology and gross pathology in the lungs, and many clinical parameters including recovery of lung function, oxygenation, hemodynamic stability, and development of severe (Grade 3) primary graft dysfunction (PGD). Importantly, the rates of PGD in the first 72 hours after transplantation, which directly correlates with risk of death, were much lower when CytoSorb was used. Researchers noted that 83% (5/6) in the Two-Step group, and 50% (2/4) in the One-Step group had no PGD at all, compared to the 83% (5/6) in the non-treated group that developed Grade 3 severe PGD. Overall, researchers concluded that the use of CytoSorb both during EVLP and in the recipient after transplantation was superior in virtually all respects compared to not using it at all, or using it only after transplantation. They concluded that the use of CytoSorb in this model has been shown to:

> ***“(i) reduce inflammation and restore pulmonary function during EVLP, (ii) restore function and decrease inflammation following transplantation, and (iii) reduce the incidence of PGD (primary graft dysfunction) in transplanted recipients. The work outlined here represents the utilization of the cytokine adsorber in the context of lung transplantation using severely damaged donor lungs. It is thus envisioned that adsorption may be an intervention that could lead to the acceptance of more lungs for transplantation. It may also further increase the tolerability of such lungs in a recipient, a needed outcome given the role that PGD continues to play as the leading cause of early mortality and as a contributor to the development of chronic graft dysfunction.”***

Based upon this work, Prof. Sandra Lindstedt and her team at Lund University Hospital, Sweden are now conducting a ten patient randomized controlled pilot study in human lung transplantation using CytoSorb. They recently published a brief communication based on the first 4 human lung transplant subjects, where 2 received CytoSorb intraoperatively, and 2 did not. Those treated with CytoSorb had lower circulating nucleosome levels (inversely correlated with PGD) and did not develop PGD, while the two patients not treated with CytoSorb had higher nucleosome levels and developed Grade 1 and Grade 3 (severe) PGD postoperatively, respectively.

Recently, Prof. Massimo Boffini and his group from the University of Turin, Italy published the largest retrospective human clinical study to date investigating the feasibility and safety of CytoSorb® adsorption during EVLP in the peer-reviewed journal, Transplant International. From July 2011 to March 2020, physicians performed a total of 54 EVLP procedures on lungs that had originally failed to qualify for transplantation. Of these, 33 were performed without CytoSorb and 21 were performed with CytoSorb integrated with EVLP. Among the 38 patients who ultimately underwent lung transplant, the CytoSorb treated group had significantly decreased cytokines in the perfusate compared to the control group, with 76% (16/21) of lungs from the CytoSorb group qualifying for transplantation after the EVLP procedure versus 67% (22/33) from the non-treated control. Importantly, patients receiving lung transplants treated with CytoSorb during EVLP had significantly lower in-hospital mortality (0% vs. 13%; p=0.03) and a lower 1-year mortality rate (0% vs. 36%; p=0.01) compared to those who received lungs treated with EVLP alone. In addition, the use of CytoSorb was associated with a trend of fewer cases of Grade 3 severe PGD, and less need for ECMO support, which likely was associated with significant cost savings. These results were observed despite none of these patients receiving additional intraoperative or postoperative CytoSorb treatment.

Dr. Phillip Chan, MD, PhD, Chief Executive Officer of CytoSorbents, stated, “Collectively, these data are very exciting for a number of reasons. First, the data support the potentially pivotal role that our cytokine adsorption technologies, including CytoSorb and ECOS-300CY - which is specifically approved in the E.U. for *ex vivo* organ perfusion, has in lung transplantation. We see multiple opportunities in improving the functioning of the lung graft, expanding the donor pool of transplant-eligible lungs by reconditioning substandard ones, and most importantly reducing the rates of severe primary graft dysfunction and mortality. Secondly, although lung transplantation is not as common as kidney or liver transplantation, we believe the fundamental principles of cytokine reduction and treating inflammation in both the organ and the host will translate into similar benefits in other solid organ transplants. For example, Hosgood, et al., published that *ex vivo* kidney perfusion with CytoSorb reduced inflammation, inflammatory mediators, and improved renal blood flow in pig kidneys. One of our key partners, Aferetica, is currently working with transplant surgeons to investigate the benefit of our technology, private-labeled as PerSorb® in their *ex vivo* organ perfusion system PerLife®, in human kidney and liver transplants, and PerLungs® platform for lung transplant. We plan to increase awareness of these publications and concepts in the organ transplant community to foster increasing innovation and opportunities in this space.”

Dr. Chan continued, “Finally, these important data corroborate the ability of CytoSorb to help improve lung function in multiple different settings and importantly provide mechanistic data on how CytoSorb can help to treat acute respiratory distress syndrome (ARDS) by promoting lung rest and healing. Even prior to the COVID pandemic, ARDS was highly prevalent, diagnosed in approximately 10% of all ICU admissions. ARDS and associated complications such a respiratory failure and hospital acquired infections, were the primary cause of morbidity and mortality in both the 2009 H1N1 influenza and 2020-2022 COVID-19 pandemics. We believe CytoSorb represents a new innovation to treat ARDS, which has the potential to drive significant revenue growth.”

Commenting on the Boffini study specifically, Mr. Mauro Atti, Chief Executive Officer of Aferetica SRL, stated, “This published study comes from a project started in 2015 with the City of Health and Science University Hospital of Turin in the field of organ transplantation, where researchers were among the first pioneers to use CytoSorb for this purpose. In fact, their early findings with CytoSorb were a major driving force leading us to develop our PerLife® and PerLungs® platforms to enable perfusion and purification of liver and kidneys, and lungs, respectively. Both integrate perfectly with the PerSorb® sorbent that CytoSorbents provides us thanks to an international strategic agreement. These data demonstrate how the perfusion and purification of organs can recover marginal organs, reduce post-transplant side effects, and even improve the survival of transplanted patients – further confirming our correct decision to invest in this field and partner with CytoSorbents.”

About CytoSorbents Corporation (NASDAQ: CTSO)

CytoSorbents Corporation is a leader in the treatment of life-threatening conditions in the intensive care unit and in cardiac surgery through blood purification. Its flagship product, CytoSorb®, is approved in the European Union, distributed in 75 countries worldwide, and has accumulated more than 212,000 human treatments to date, to reduce "cytokine storm" and other toxins that can cause organ failure. The DrugSorb™-ATR antithrombotic removal system, based on the same polymer technology as CytoSorb, has received two U.S. FDA Breakthrough Device Designations to remove two separate blood thinners during cardiothoracic surgery, including ticagrelor and the direct oral anticoagulants (DOAC) apixaban and rivaroxaban, and is undergoing pivotal clinical studies. For more information, please visit the Company's websites at www.cytosorbents.com and www.cytosorb.com or follow us on Facebook and Twitter.

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. These forward-looking statements include, but are not limited to, statements about our plans, objectives, future targets and outlooks for our business, statements about potential exposures resulting from our cash positions, representations and contentions, and are not historical facts and typically are identified by use of terms such as "may," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements in this press release represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. Factors which could cause or contribute to such differences include, but are not limited to, the risks discussed in our Annual Report on Form 10-K, filed with the SEC on March 9, 2023, as updated by the risks reported in our Quarterly Reports on Form 10-Q, and in the press releases and other communications to shareholders issued by us from time to time which attempt to advise interested parties of the risks and factors which may affect our business. We caution you not to place undue reliance upon any such forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, other than as required under the Federal securities laws.

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