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 27, 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 27, 2023, CytoSorbents Corporation (the "Company") issued a press release announcing the upcoming original presentations at the 37th European Association of Cardio-Thoracic Surgery (EACTS) Annual Meeting in Vienna, Austria, from October 4-7, 2023, including the second analysis from the international Safe and Timely Antithrombotic Removal (STAR) Registry. 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 27, 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 27, 2023

CYTOSORBENTS CORPORATION

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

Exhibit 99.1

CytoSorbents Highlights Upcoming Presentations at EACTS 2023: Focus on Antithrombotic Removal including the 2nd Analysis of the International STAR Registry

PRINCETON, N.J., September 27, 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, announced the upcoming original presentations at the 37th European Association of Cardio-Thoracic Surgery (EACTS) Annual Meeting in Vienna, Austria, from October 4-7, 2023, including the second analysis from the international **S**afe and **T**imely **A**ntithrombotic **R**emoval (STAR) Registry.

Second Analysis of the International STAR Registry

The International STAR Registry captures high fidelity data on real-world clinical use and associated clinical outcomes using CytoSorb® for antithrombotic drug removal (ATR) in the acute hospital setting. The registry collects cases using CytoSorb to purify the blood of the major modern antithrombotic agents* such as Brilinta®/Brilique®, Plavix®, Effient®, Pradaxa®, Savaysa®/Lixiana®, Xarelto®, and Eliquis® in a variety of clinical scenarios, but particularly in cardiothoracic surgery, where the blood thinners can potentially cause serious and even fatal bleeding. The STAR Registry, not to be confused with the completed U.S. and Canada STAR-T pivotal trial, is enrolling ahead of internal projections with plans for ongoing presentations at large, international conferences.

The first registry analysis entitled, “Insights from the International Safe and Timely Antithrombotic Removal (STAR) Registry” was presented at the EuroPCR conference in May 2023, the largest interventional cardiology conference in the E.U., attracting 11,500+ participants this year. This analysis included 67 patients from 7 centers in the U.K. and Germany who underwent coronary artery bypass graft (CABG) surgery within 2 days of Brilinta® (ticagrelor) administration with a high risk of perioperative bleeding. The analysis reported no device related adverse events and low rates of BARC-4 bleeding (6%), reoperation for bleeding (4%), and 24-hour chest tube drainage (537 ± 231 mL). BARC-4 bleeding is defined as CABG-related bleeding that includes at least one of the following: perioperative intracranial bleeding, reoperation after closure of the chest for the purpose of controlling bleeding, transfusion of 5 units or more of whole blood or packed red blood cells within a 48-hour period, or chest tube output of 2 liters or more within a 24-hour period.

These results compared favorably to the results, referred to in the presentation, from an often cited analysis of the SWEDEHEART registry, the national Swedish registry of all patients hospitalized for acute coronary syndrome or undergoing percutaneous coronary intervention or heart surgery, published in the European Heart Journal. In this study, Hannson and colleagues reported an average 31.4% incidence of severe BARC-4 bleeding in a cohort of patients who similarly required CABG surgery within 48 hours of ticagrelor (Brilinta®) administration but did not get CytoSorb. In addition, patients in this cohort had 12-hour chest tube drainage (CTD) of 813 ± 478 mL and 641 ± 337 mL following CABG surgery within 24 and 48 hours, respectively, from last ticagrelor administration, which was more CTD than seen in patients treated with CytoSorb in the first STAR Registry analysis, yet in only half the time. In the entire study, which included patients who had a chance to wash out the drug for more than 5 days prior to surgery which accounted for approximately 2/3rds of all patients, reoperations due to bleeding was 6.1%.

The second analysis of the International STAR Registry being presented at the 2023 EACTS conference next week, entitled “Intraoperative hemoadsorption for antithrombotic drug removal during cardiac surgery: the International Safe and Timely Antithrombotic Removal (STAR) Registry,” summarizes the use of CytoSorb in patients on blood thinners undergoing a much broader range of heart surgeries than reported previously, mixing isolated CABG patients with more complex and invasive procedures at higher risk of perioperative bleeding including valve replacement, CABG + valve replacement, aortic surgery, and heart transplant. It also includes, for the first time, data on patients being treated with CytoSorb to reduce seven different antithrombotic medications. The analysis is divided between two groups: 114 patients on antiplatelet drugs including Brilinta® (ticagrelor), Plavix® (clopidogrel), and Effient® (prasugrel); and 51 patients on the direct oral anticoagulants (DOACs) including Eliquis® (apixaban), Xarelto® (rivaroxaban), Sayvasa®/Lixiana® (edoxaban), and Pradaxa® (dabigatran). The overall study population was taken from 8 centers in Germany, the United Kingdom, Austria, and Sweden.

The antiplatelet analysis focuses on the use of intraoperative CytoSorb on 114 patients on antiplatelet agents undergoing isolated CABG (78%), or higher risk cardiothoracic surgeries including valve replacement, aortic surgery, and heart transplant (22%). The rate of BARC-4 bleeding for isolated CABG surgery alone was 4.5%, while overall BARC-4 bleeding was 13.2%, reflecting the higher bleeding risk of the more complex surgeries and the use of Plavix® (17%) and Effient® (3%), historically thought to be irreversible platelet inhibitors, in 20% of the patients. In the future, in addition to generating more data on the clinical impact of removing Brilinta®/Brilique®, the STAR Registry is also expected to help answer the question of whether CytoSorb can mitigate the bleeding risk in patients on Plavix® and Effient® in ways not related to drug binding to the platelet.

The Direct Oral Anticoagulant (DOAC) analysis reports on the use of CytoSorb intraoperatively in patients on Eliquis® (47%), Xarelto (27%), Sayvasa®/Lixiana® (24%), and Pradaxa® (2%) undergoing a more evenly divided set of procedures including isolated CABG (23.5%), CABG + valve replacement (15.7%), isolated valve replacement (17.6%), Aortic surgery (15.7%), and other procedures (27.5%). There was no BARC-4 bleeding in the 12 patients undergoing isolated CABG surgery, with 15.7% BARC-4 bleeding overall, reflecting the higher proportion of higher risk and more invasive surgeries.

The international STAR Registry authors concluded that for this analysis, for "patients undergoing cardiac surgery before the recommended washout period, the use of intraoperative antithrombotic drug removal is associated with lower incidence of serious bleeding compared with historical rates," and "importantly, no serious device-related adverse events were observed."

Dr. Efthymios Deliargyris, Chief Medical Officer of CytoSorbents, stated, "We believe the STAR Registry provides a powerful platform to systematically collect high quality, real-world outcomes data on the ability of CytoSorb to reduce perioperative bleeding risk in patients on a variety of antithrombotic drugs undergoing cardiothoracic surgery on an international scale. Given that DrugSorb-ATR uses an equivalent polymer technology as CytoSorb, we believe the outcomes seen in the STAR registry analysis are encouraging and provide greater insights into the clinical benefits of antithrombotic removal that are also investigated in our U.S. and Canada STAR-T and STAR-D programs."

Other Key Presentations at EACTS

In addition to the STAR Registry analysis, another study was selected for presentation entitled, "Antithrombotic drug removal during off-pump coronary artery bypass grafting using hemoadsorption" highlighting the successful use of CytoSorb, in conjunction with a simple hemoperfusion machine, to prophylactically remove Brilinta® or Xarelto® during off-pump CABG surgery. According to the study investigators, Mair et al., stated, "Decoupling of the hemoadsorber from the cardiopulmonary bypass machine will open new future indications in various medical specialties (e.g. trauma, neurosurgery) and in emergency patients on antithrombotic medication."

CytoSorbents will also host a satellite research symposium on Friday, October 6, 2023 at 12:15-13:30 CET.

Hemoadsorption with CytoSorb after 10 years – Where do we stand?
Chairs: Sandra Lindstedt (Sweden) and Piotr Suwalski (Poland)

- The Paris experience – Which patients benefit most?
  Guillaume Lebreton, France
- The Oslo experience – Removal of antithrombotics to reduce complications and costs
  Gry Dahle, Norway
- The Essen experience – Hemoadsorption in aortic surgery
  Heinz Jakob, Germany

*These trademarks are owned by their respective pharmaceutical manufacturers: Eliquis® (Pfizer, BMS), Xarelto® (Bayer, Janssen), Brilinta®/Brilique® (AstraZeneca), Plavix® (BMS, Sanofi), Effient® (Daiichi Sankyo, Eli Lilly), Savaysa®/Lixiana® (Daiichi Sankyo), and Pradaxa® (Boehringer Ingelheim)

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 lead product, CytoSorb®, is approved in the European Union and distributed in 75 countries worldwide with more than 212,000 devices cumulatively used as of Q2 2023. CytoSorb is an extracorporeal cytokine adsorber that reduces “cytokine storm” or “cytokine release syndrome” in common critical illnesses seen in the ICU and cardiac surgery that can lead to massive inflammation, organ failure, and a high risk of patient death. Additional CE mark extensions were granted for bilirubin and myoglobin removal in clinical conditions such as liver disease and trauma, respectively. CytoSorb is also E.U. approved to remove the blood thinners, ticagrelor and rivaroxaban, during cardiothoracic surgery to reduce the risk of perioperative bleeding. CytoSorb has also received FDA Emergency Use Authorization in the United States for use in adult critically ill COVID-19 patients with impending or confirmed respiratory failure.

Meanwhile, the DrugSorb™-ATR antithrombotic removal system, based on the same polymer technology as CytoSorb, targets U.S. FDA and Health Canada marketing approval with the now completed pivotal STAR-T (Safe and Timely Antithrombotic Removal of Ticagrelor) randomized, controlled trial. With topline data expected later this year, the study was designed to evaluate the potential ability of DrugSorb-ATR to reduce ticagrelor-related perioperative bleeding when used intraoperatively during cardiac surgery. DrugSorb-ATR has received two FDA Breakthrough Device Designations for this application, one to remove ticagrelor and another to remove the direct oral anticoagulants (DOAC) apixaban and rivaroxaban, highlighting these major unmet medical needs.

CytoSorbents' purification technologies are based on biocompatible, highly porous polymer beads that can actively remove toxic substances from blood and other bodily fluids by pore capture and surface adsorption. Its technologies have received non-dilutive grant, contract, and other funding of approximately $48 million from DARPA, the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI), the U.S. Army, the U.S. Air Force, U.S. Special Operations Command (SOCOM), Air Force Material Command (USAF/AFMC), and others. The Company has numerous marketed products and products under development based upon this unique blood purification technology protected by many issued U.S. and international patents and registered trademarks, and multiple patent applications pending, including ECOS-300CY®, VetResQ®, CytoSorb-XL™, HemoDefend-BGA™, HemoDefend-RBC™, K^+ontrol™, DrugSorb™, ContrastSorb, and others. For more information, please visit www.cytosorbents.com and www.cytosorb.com or follow us on Facebook and X (fka 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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