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): December 28, 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 December 28, 2023, CytoSorbents Corporation (the "Company") issued a press release announcing an update on the initial data analysis of primary safety and effectiveness endpoints and the final independent Data and Safety Monitoring Board analysis for the pivotal U.S. and Canadian STAR-T (Safe and Timely Antithrombotic Removal of Ticagrelor) randomized controlled trial. 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 December 28, 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: December 28, 2023

CYTOSORBENTS CORPORATION

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

Exhibit 99.1

WORKING TO SAVE LIVES

CytoSorbents Provides Update on the STAR-T Trial and Reports Final Independent Data and Safety Monitoring Board Recommendation

PRINCETON, N.J., December 28, 2023 —CytoSorbents Corporation (NASDAQ: CTSO), a leader in the treatment of life-threatening conditions in the intensive care unit and cardiac surgery using blood purification via its proprietary polymer adsorption technology, today announces an update on the initial data analysis of primary safety and effectiveness endpoints and the final independent Data and Safety Monitoring Board ("DSMB") analysis for the pivotal U.S. and Canadian STAR-T (**S**afe and **T**imely **A**ntithrombotic **R**emoval of **T**icagrelor) randomized controlled trial.

STAR-T is a double-blind, randomized, controlled, multi-center pivotal trial that investigated the ability of DrugSorb®-ATR to reduce perioperative bleeding in 140 enrolled patients on ticagrelor (Brilinta®, Brilique® - AstraZeneca) undergoing cardiothoracic surgery before completing the recommended washout period. Patients were randomized in a 1:1 ratio to receive either DrugSorb-ATR or a sham device during cardiopulmonary bypass, with a primary composite effectiveness endpoint measuring perioperative bleeding.

The independent DSMB met recently to perform the final review of the full unblinded data on all 140 patients in the STAR-T trial and concluded there were no issues with device safety, meeting the primary safety endpoint of the study. The Company has also performed the initial data analysis on the primary effectiveness endpoint of STAR-T. Based on this analysis, the study did not meet the primary effectiveness endpoint in the overall patient population that underwent different types of cardiac surgeries. However, the study did demonstrate evidence of reduced bleeding complications in patients in the pre-specified isolated coronary artery bypass graft ("CABG") surgery population, representing more than 90% of the overall study population.

The Company expects to complete the analysis of the full trial results in the next several weeks. Pending this final analysis, the Company believes the safety and effectiveness data from STAR-T may support the regulatory submission of DrugSorb-ATR to the U.S. FDA and Health Canada. Meanwhile, the Company had previously submitted a promissory abstract to the American College of Cardiology 2024 conference, triggering a "silent" period for publicly discussing detailed study results. If accepted, the full results of the STAR-T trial are expected to be presented next April 2024 in Atlanta.

Dr. Efthymios N. Deliargyris, Chief Medical Officer of CytoSorbents stated, "We are encouraged that the use of the DrugSorb-ATR device in this high-risk population was deemed safe by the independent DSMB. Although the primary effectiveness endpoint of the study was not met in the overall population, we identified evidence of benefit of reduced bleeding complications in patients undergoing isolated CABG surgery, including serious bleeding events. This suggests a favorable benefit-to-risk profile in this population that represents the vast majority of ticagrelor-treated patients requiring cardiac surgery. Additional analyses are ongoing and we look forward to sharing the detailed results at a major medical conference in the near future."

Dr. Irina Kulinets, Senior Vice President of Global Regulatory of CytoSorbents stated, "In the next several weeks, we aim to complete the full data analysis of the study that is intended to form the basis of anticipated regulatory submissions. From a regulatory perspective, it is important that DrugSorb-ATR successfully met the primary safety endpoint of the study and has demonstrated clinical evidence of effectiveness in the pre-specified isolated CABG subpopulation. These data are supported by the successful real-world usage of CytoSorb® for this same indication, as captured by our International STAR Registry and as seen in multiple world markets including Europe, Latin America, Middle East, and others. Although we cannot predict how FDA will view our results, we are encouraged that FDA has already granted Breakthrough Device Designation to DrugSorb-ATR for this application, recognizing the problem as a major unmet medical need that causes significant patient morbidity and mortality and has no approved therapy in the U.S."

Ticagrelor is one of the leading anti-thrombotic drugs used as part of dual-antiplatelet therapy in patients with acute coronary syndrome. However, up to 10% of these patients will need to undergo CABG surgery and risk serious bleeding complications if the surgery is performed within the first few days from the last ticagrelor dose. Waiting in the hospital to washout the drug over the span of 3-5 days is the only acceptable alternative, but comes with potential clinical risk for complications while waiting, and high additional hospital costs. The goal of DrugSorb-ATR is to allow patients to safely get the critical CABG surgery they need without requiring extensive drug washout.

DrugSorb-ATR has been previously granted U.S. FDA Breakthrough Device Designation, acknowledging that perioperative bleeding in cardiac surgery due to ticagrelor is a major unmet medical need. There are currently no approved or cleared therapies for this unmet need in the U.S. or Canada. Outside of the U.S. and Canada, only CytoSorb® is specifically approved for this indication. The Breakthrough Devices Program provides for more effective treatment of life-threatening or irreversibly debilitating diseases or conditions - in this case the need to reduce serious or life-threatening perioperative bleeding due to ticagrelor in emergent or urgent cardiac surgery. With Breakthrough Designation, CytoSorbents intends to work with FDA to facilitate the regulatory review of DrugSorb-ATR, while maintaining statutory standards of regulatory approval (e.g., 510(k), *de novo* 510(k), or premarket approval (PMA)) consistent with the Agency's mission to protect and promote public health.

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. It is an extracorporeal cytokine adsorber that reduces "cytokine storm" or "cytokine release syndrome" in common critical illnesses that can lead to massive inflammation, organ failure and patient death. In these diseases, the risk of death can be extremely high, and there are few, if any, effective treatments. CytoSorb is also used during and after cardiothoracic surgery to remove antithrombotic drugs and inflammatory mediators that can lead to postoperative complications, including severe bleeding and multiple organ failure. At the end of Q3 2023, more than 221,000 CytoSorb devices had been used cumulatively. CytoSorb was originally launched in the European Union under CE mark as the first cytokine adsorber. Additional CE mark extensions were granted for bilirubin and myoglobin removal in clinical conditions such as liver disease and trauma, respectively, and for ticagrelor and rivaroxaban removal in cardiothoracic surgery procedures. 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. The DrugSorb™-ATR antithrombotic removal system, based on the same polymer technology as CytoSorb, also received two FDA Breakthrough Device Designations, one for the removal of ticagrelor and another for the removal of the direct oral anticoagulants (DOAC) apixaban and rivaroxaban in a cardiopulmonary bypass circuit during urgent cardiothoracic procedures. The Company has completed the FDA-approved, randomized, controlled STAR-T (Safe and Timely Antithrombotic Removal-Ticagrelor) study of 140 patients at approximately 30 centers in U.S. and Canada to evaluate whether intraoperative use of DrugSorb-ATR can reduce the perioperative risk of bleeding in patients receiving ticagrelor and undergoing cardiothoracic surgery. This pivotal study is intended to support U.S. FDA and Health Canada marketing approval for DrugSorb-ATR in this application.

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 $50 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®, CytoSorb-XL™, HemoDefend-RBC™, HemoDefend-BGA™, VetResQ®, K^{+}ontrol™, DrugSorb™, ContrastSorb, and others. For more information, please visit the Company's websites at 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 our preliminary analysis and expectations with respect to the STAR-T clinical trial results and our expectations regarding the content and timing of sharing further detailed results in the future 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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