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): July 7, 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 July 7, 2023, CytoSorbents Corporation (the "Company") issued a press release announcing that it has completed enrollment of the pivotal Safe and Timely Antithrombotic Removal – Ticagrelor (STAR-T) randomized, controlled trial, evaluating the ability of DrugSorb®-ATR to reduce perioperative bleeding in patients undergoing cardiothoracic surgery on ticagrelor. A copy of the press release is included as Exhibit 99.1 and incorporated by reference herein.

Item 9.01 Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release of the Company, dated July 7, 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: July 7, 2023

CYTOSORBENTS CORPORATION

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

Exhibit 99.1

CytoSorbents Completes Enrollment of the STAR-T Pivotal Trial

PRINCETON, N.J., July 7, 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 that it has completed enrollment of the pivotal **S**afe and **T**imely **A**ntithrombotic **R**emoval – **T**icagrelor (**STAR-T**) randomized, controlled trial, evaluating the ability of DrugSorb®-ATR to reduce perioperative bleeding in patients undergoing cardiothoracic surgery on ticagrelor.

The STAR-T trial Principal Investigators, Drs. Michael Mack, C. Michael Gibson, and Richard Whitlock, commented in a joint statement, "We want to thank all participating investigators and their research teams for their commitment and dedication that helped STAR-T complete enrollment ahead of projections. Ticagrelor (Brilinta®, AstraZeneca) is used widely in the U.S. and Canada and we routinely encounter patients on ticagrelor who require cardiothoracic surgery. Currently, because of the high risk of bleeding complications in these patients, we delay surgery for multiple days until the ticagrelor effect is worn off which carries the risk that these patients suffer a complication while waiting, but also significantly increases the length and cost of their hospitalization. The surgical community is in urgent need of a solution that allows the safe and timely treatment of these high-risk patients. We look forward to the results of STAR-T which we plan to present at a major international cardiovascular conference in early 2024 and remain committed to lead further trials investigating drug removal by DrugSorb-ATR of additional antithrombotic agents, such as the direct oral anticoagulants apixaban (Eliquis®, Bristol-Myers Squibb/Pfizer) and rivaroxaban (Xarelto®, Janssen/Bayer) that are among the most widely prescribed medications in the world."

Dr. Efthymios N. Deliargyris, Chief Medical Officer of CytoSorbents stated, "We are very pleased to deliver STAR-T across the finish line ahead of schedule. The fast enrollment pace was the direct result of the high frequency that eligible patients presented at our participating sites validating the large size of the unmet need. With this major milestone achieved, our attention now turns to completion of data collection and study closeout activities ahead of the final results. With our clinical operations capabilities now fully in place we look forward to executing the next round of trials, including STAR-D, investigating the expansion of antithrombotic drug removal to additional agents and hospital wide applications beyond cardiac surgery."

The STAR-T randomized, controlled trial is a pivotal study being conducted in both the U.S. and Canada that is designed to evaluate the ability of DrugSorb-ATR® to reduce perioperative bleeding by removing the antithrombotic agent, ticagrelor (Brilinta®, AstraZeneca) in patients undergoing cardiothoracic surgery. Brilinta is one of the leading “blood thinners” used as part of dual-antiplatelet therapy in patients suspected of having a heart attack. But if the patient is one of the up to 10% that need to undergo coronary artery bypass graft (CABG) or other open heart surgery, the risk of major fatal or life-threatening CABG-related bleeding can be as high as 50-65%, particularly if the surgery is performed within several days of the last Brilinta dose. Waiting in the hospital to wash out the drug is the only acceptable alternative, but this comes at high cost and potential clinical risk. The goal of DrugSorb-ATR is to allow patients to get the critical surgery they need without delay, while reducing or preventing this bleeding risk by actively removing the drug during the surgery. DrugSorb-ATR has received FDA Breakthrough Device Designation for this indication. The STAR-T pivotal study is being conducted by many of the leading cardiothoracic surgery centers in North America and is intended to support U.S. FDA and Health Canada marketing approval for DrugSorb-ATR in this application.

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 Q1 2023, more than 203,000 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 is currently conducting the FDA and Health Canada-approved, randomized, controlled STAR-T (Safe and Timely Antithrombotic Removal-Ticagrelor) study 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 $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®, CytoSorb-XL™, HemoDefend-RBC™, HemoDefend-BGA™, VetResQ®, K^+ontrol™, DrugSorb™, DrugSorb™-ATR, 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 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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