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): November 14, 2022

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 November 14, 2022, CytoSorbents Corporation (the "Company") issued a press release announcing that 40 of the targeted 120 patients have been enrolled in the Safe and Timely Antithrombotic Removal – Ticagrelor (STAR-T) trial, achieving the first enrollment milestone and triggering a pre-specified Data and Safety Monitoring Board review. 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 November 14, 2022
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: November 16, 2022

CYTOSORBENTS CORPORATION

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

Exhibit 99.1

CytoSorbents Announces Pivotal STAR-T Trial Reaches First Milestone With 40 Patients Enrolled

PRINCETON, N.J., November 14, 2022 — 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, announced that 40 of the targeted 120 patients have been enrolled in the **S**afe and **T**imely **A**ntithrombotic **R**emoval – **T**icagrelor (**STAR-T**) trial, achieving the first enrollment milestone and triggering a pre-specified Data and Safety Monitoring Board (DSMB) review. This pivotal study intends to support both U.S. FDA and Health Canada marketing approval of DrugSorb-ATR in the United States and Canada, respectively, to remove the anti-thrombotic agent, ticagrelor (Brilinta®, AstraZeneca), during cardiothoracic surgery.

Dr. Michael J. Mack, Director of the Cardiovascular Service line at Baylor Scott & White Health System, Chairman of the Baylor Plano Research Center in Texas and co-Principal Investigator of the STAR-T trial commented: “Reaching our first trial enrollment milestone of 40 patients is a critical first step in the execution of the landmark STAR-T trial. Currently, cardiac surgeons are either forced to delay life-saving heart surgery in patients who are on antithrombotic drugs or proceed to operation when they are at very high risk for bleeding. The DrugSorb-ATR device is a novel approach that could potentially allow these high-risk surgeries to proceed in a safe and timely manner. We have designed two rigorous, pivotal trials to test the efficacy and safety of this novel device that if successful could make it available to all U.S. cardiac surgeons, so they can join their international colleagues who have it available and use it routinely in their everyday practice. We are currently focused on bringing the STAR-T trial across the finish line, so we can then turn our attention to STAR-D. I’d like to thank all of the participating centers and investigators for helping us reach this first crucial enrollment milestone and we remain very excited to welcome our Canadian colleagues who should begin contributing to enrollment very soon.”

Dr. Efthymios N. Deliargyris, Chief Medical Officer of CytoSorbents stated, “We are pleased to have enrolled a third of our STAR-T pivotal study, which now triggers the first safety review by the independent DSMB of the study. We are now working diligently to complete the necessary operational steps including data collection and validation to support the upcoming DSMB safety review which is estimated in approximately 2 months. With our full attention and resources now dedicated to STAR-T and the upcoming addition of Canadian sites, we anticipate the momentum to continue and project that we can achieve the next study milestone of 80 patients enrolled in Spring 2023 that will trigger the next DSMB safety review and the pre-specified interim analysis.

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 inflammatory mediators that can lead to postoperative complications, including multiple organ failure. As of September 30, 2022, more than 186,000 CytoSorb devices have 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-approved, randomized, controlled STAR-T (Safe and Timely Antithrombotic Removal-Ticagrelor) study of 120 patients at 30 centers 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 intends to support both U.S. FDA and Health Canada marketing approval of DrugSorb-ATR in the United States and Canada, respectively, for this application. The STAR-T trial will be followed by the STAR-D (Safe and Timely Antithrombotic Removal-Direct Oral Anticoagulants) pivotal trial evaluating the intraoperative use of DrugSorb-ATR to reduce perioperative bleeding risk in patients undergoing cardiothoracic surgery and taking direct oral anticoagulants, including apixaban and rivaroxaban.

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, expectations regarding the future impacts of COVID-19 or the ongoing conflict between Russia and the Ukraine, 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 10, 2022, 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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