

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): April 20, 2023

CYTOSORBENTS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-36792

(Commission File Number)

98-0373793

(I.R.S. Employer Identification No.)

305 College Road East

Princeton, New Jersey

(Address of principal executive offices)

08540

(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 April 20, 2023, CytoSorbents Corporation (the “Company”) issued a press release announcing that the Company’s Safe and Timely Antithrombotic Removal – Ticagrelor randomized, controlled trial enrolled 80 patients, achieving the second of three key enrollment milestones, and triggering a pre-specified Data and Safety Monitoring Board safety review. A copy of the press release is included as Exhibit 99.1 and incorporated by reference herein.

**Item 9.01      Exhibits**

(d) Exhibits

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press Release of the Company, dated April 20, 2023</u></a>
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

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**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: April 26, 2023

CYTOSORBENTS CORPORATION

By: /s/ Dr. Phillip P. Chan

Name: Dr. Phillip P. Chan

Title: Chief Executive Officer

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WORKING TO SAVE LIVES

## CytoSorbents' Pivotal STAR-T Trial Reaches Second Key Milestone With 80 Patients Enrolled

PRINCETON, N.J., April 20, 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, announces that its pivotal STAR-T (Safe and Timely Antithrombotic Removal – Ticagrelor) randomized, controlled trial has enrolled 80 patients, achieving the second of three key enrollment milestones, and triggering a pre-specified Data and Safety Monitoring Board (DSMB) safety review.

Dr. Efthymios N. Deliargyris, Chief Medical Officer of CytoSorbents stated, “We are pleased with the solid enrollment pace of the STAR-T trial, now two-thirds enrolled, and believe it reflects a) the positive enthusiasm and commitment of participating U.S. and Canadian study centers, b) the large unmet medical need and numbers of patients on ticagrelor undergoing cardiothoracic surgery, and c) the laser focus of our clinical team. We expect completion of the second DSMB safety review over the next several months.”

Dr. Deliargyris continued, “Because of the brisk enrollment of the trial, we continue to project that STAR-T will be fully enrolled this summer. Because of this, as we discussed in our last earnings call in March, we have elected to forego an interim analysis at this stage which would have otherwise taken several months to conclude, and instead race to complete trial enrollment on schedule and initiate the final study analysis, while preserving the full statistical power of the study. This would put us in the position of having top-line data later this year, with the goal of filing for U.S. FDA and Health Canada regulatory approval thereafter.”

The STAR-T trial intends to enroll approximately 120 patients at 30 centers in the U.S. and Canada to evaluate whether intraoperative use of DrugSorb<sup>®</sup>-ATR can reduce the high perioperative risk of bleeding in patients undergoing cardiothoracic surgery who have recently received the blood thinning agent, ticagrelor. This pivotal study is intended to support U.S. FDA and Health Canada marketing approval for DrugSorb-ATR in this application, for which CytoSorbents received FDA Breakthrough Device Designation in April 2020, recognizing it as a major unmet medical need for which there are no FDA-approved or cleared therapies.

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## 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<sup>®</sup>, 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 2022, more than 195,000 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<sup>™</sup>-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 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 \$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<sup>®</sup>, CytoSorb-XL<sup>™</sup>, HemoDefend-RBC<sup>™</sup>, HemoDefend-BGA<sup>™</sup>, VetResQ<sup>®</sup>, K<sup>+</sup>ontrol<sup>™</sup>, DrugSorb<sup>™</sup>, DrugSorb<sup>™</sup>-ATR, ContrastSorb, and others. For more information, please visit the Company's websites at [www.cytosorbents.com](http://www.cytosorbents.com) and [www.cytosorb.com](http://www.cytosorb.com) or follow us on [Facebook](#) and [Twitter](#).

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## **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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### **U.S. Company Contact:**

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