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 19, 2021

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.)

7 Deer Park Drive, Suite K, **Monmouth Junction, New Jersey**	**08852**
(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 April 19, 2021, CytoSorbents Corporation (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has granted conditional approval of its investigational device exemption (IDE) application for the U.S. Safe and Timely Antithrombotic Removal - Ticagrelor (STAR-T) randomized, controlled trial. A copy of the full press release is attached as Exhibit 99.1 hereto and is incorporated by reference herein.

Item 9.01 Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release of the Company, dated April 19, 2021

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 20, 2021

CYTOSORBENTS CORPORATION

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

Exhibit 99.1

U.S. FDA Approves CytoSorbents to Initiate U.S. STAR-T Trial For Ticagrelor Removal During Cardiothoracic Surgery

MONMOUTH JUNCTION, N.J., April 19, 2021 — CytoSorbents Corporation (NASDAQ: CTSO), a critical care leader whose flagship E.U. approved CytoSorb® blood purification technology is intended to treat deadly conditions in critically-ill and cardiac surgery patients, announces that the U.S. Food and Drug Administration (FDA) has granted conditional approval of its investigational device exemption (IDE) application for the U.S. **S**afe and **T**imely **A**ntithrombotic **R**emoval - **T**icagrelor (**STAR-T**) randomized, controlled trial. Based on this conditional approval, study initiation activities, including clinical trial agreement negotiations and institutional review board (IRB) submissions, can now commence, putting the study ahead of the Company's internal schedule. The Company has already identified and pre-screened many high-quality U.S. clinical centers that have indicated strong interest to participate in the STAR-T trial. The Company believes conditions for full IDE approval can be appropriately addressed within the 45-day timeframe outlined by the FDA, and once accepted, the Company expects to provide additional detail on the trial.

Dr. David Cox, Vice President of Global Regulatory of CytoSorbents stated, "We are pleased that the FDA has approved our randomized, controlled clinical trial for the removal of ticagrelor (Brilinta®,AstraZeneca) during cardiothoracic surgery to reduce perioperative bleeding complications. We will promptly address FDA's conditions of approval and finalize the IDE protocol to best support a U.S. marketing submission of our FDA Breakthrough Device technology for this application."

Mr. Vincent Capponi, President and Chief Operating Officer of CytoSorbents added, "We are very excited to have received the go ahead from the FDA to begin the STAR-T trial, that if successful, is expected to support our first U.S. FDA marketing submission. In the future, we plan to leverage the alignment with FDA and the STAR-T study infrastructure, including the academic leadership, operational framework, and participating clinical trial sites to seek label expansions in antithrombotic removal beyond ticagrelor. This IDE approval marks a key first step forward in our long-term U.S. commercialization strategy to become the *de facto* standard of care therapy to remove antithrombotic drugs, generically called blood thinners, during cardiothoracic surgery, with an estimated total addressable U.S. market of $1 billion."

In April 2020, the FDA granted CytoSorbents Breakthrough Device Designation to remove ticagrelor during cardiothoracic surgery, recognizing this major unmet medical need. Each year, ticagrelor is prescribed to millions of cardiovascular patients worldwide to reduce the risk of recurrent hearts attack, stroke or cardiovascular death. Ticagrelor is frequently preferred as first line therapy in patients presenting to hospitals with an acute coronary syndrome in preparation of percutaneous coronary intervention (PCI) and stent placement. However, up to 10% of these patients will require coronary artery bypass graft (CABG) open heart surgery and as several clinical studies, such as the PLATO trial, have shown, they face a very high risk of severe or life-threatening bleeding during surgery.

Mr. Capponi continued, “CytoSorbents’ blood purification technology offers a simple solution to mitigate bleeding risk by being placed in the cardiopulmonary bypass machine blood circuit to directly remove ticagrelor during cardiothoracic surgery. We are working collaboratively with FDA under Breakthrough Device Designation to aggressively pursue this opportunity and address this major unmet clinical need. This approval accelerates our internal timeline, and with the identification of clinical sites already completed, we are now in a position to move agressively forward with the execution of the STAR-T trial.”

About CytoSorbents Corporation (NASDAQ: CTSO)

CytoSorbents Corporation is a leader in critical care immunotherapy, specializing in blood purification. Its flagship product, CytoSorb® is approved in the European Union with distribution in 67 countries outside of the US, as an extracorporeal cytokine adsorber designed to reduce the “cytokine storm” or “cytokine release syndrome” that may result in massive inflammation, organ failure and death in common critical illnesses. These are conditions where the risk of death may be extremely high, yet no effective treatments exist. CytoSorb® is also being used during and after cardiac surgery to remove inflammatory mediators that can lead to post-operative complications, including multiple organ failure. CytoSorb® has been used in more than 121,000 human treatments to date. CytoSorb has received CE-Mark label expansions for the removal of bilirubin (liver disease), myoglobin (trauma), and both ticagrelor and rivaroxaban during cardiothoracic surgery. CytoSorb has also received FDA Emergency Use Authorization in the United States for use in critically ill COVID-19 patients with imminent or confirmed respiratory failure, in defined circumstances. CytoSorb has also been granted FDA Breakthrough Designation for the removal of ticagrelor in a cardiopulmonary bypass circuit during emergent and urgent cardiothoracic surgery.

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 more than $38 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 products under development based upon this unique blood purification technology protected by many issued U.S. and international patents and multiple 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 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, 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, 2021, 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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Investor Relations Contact:
Amy Vogel
Investor Relations
(732) 398-5394
avogel@cytosorbents.com

Public Relations Contact:
Eric Kim
Rubenstein Public Relations
212-805-3052
ekim@rubensteinpr.com