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): September 27, 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 September 27, 2022, CytoSorbents Corporation (the "Company") issued a press release announcing that the Company has received ISO 13485 Certification of its new manufacturing facility in Princeton, New Jersey from its European Union (E.U.) notified body. 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 September 27, 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: September 27, 2022

CYTOSORBENTS CORPORATION

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

Exhibit 99.1

CytoSorbents Achieves ISO 13485 Certification of Princeton Manufacturing Facility in New Jersey

CytoSorb®, DrugSorb®-ATR, and ECOS-300CY® now cleared for manufacturing from this site

PRINCETON, N.J., September 27, 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 today that it has received ISO 13485 Certification of its new manufacturing facility in Princeton, New Jersey from its European Union (E.U.) notified body, clearing the way for full manufacturing of CytoSorb®, DrugSorb®-ATR, and ECOS-300CY® from this site, with capacity to add additional product lines as they are developed.

Mr. Vincent Capponi, President and Chief Operating Officer of CytoSorbents stated, "We are very excited to receive this certification, which represents another key milestone in our company development and commercialization story. Our manufacturing, engineering, quality, and regulatory teams deserve the credit for this significant accomplishment. This state-of-the-art facility expands our manufacturing capacity to support up to $350-400 million in sales of our commercialized products, and will be a key component in the regulatory application and expected commercial launch of DrugSorb-ATR in the United States."

CytoSorb is an advanced blood purification cartridge approved in the E.U. and distributed in 75 countries worldwide to remove cytokines (inflammation), bilirubin (liver failure), and myoglobin (trauma), from blood. CytoSorb is also E.U. approved to remove the antithrombotic "blood thinning" drugs, Brilinta® (ticagrelor, Astra Zeneca) and Xarelto® (rivaroxaban, Janssen, Bayer) during cardiothoracic surgery to reduce the risk of perioperative bleeding.

DrugSorb-ATR is an investigational blood purification cartridge that uses an equivalent polymer technology to CytoSorb, and is in two pivotal U.S. randomized, controlled clinical trials under dual FDA Breakthrough Device Designations, to remove Brilinta® (STAR-T; Safe and Timely Antithrombotic Removal – Ticagrelor) and the direct oral anticoagulants (DOACs), Eliquis® (apixaban, Pfizer, BMS) and Xarelto® (STAR-D, - DOAC), intraoperatively during cardiothoracic surgery to reduce the risk of perioperative bleeding with the goal of achieving FDA marketing approval. The STAR-T trial is enrolling well and is expected to reach the first milestone with 40 patients enrolled within the next couple of months that will trigger the first Data and Safety Monitoring Board (DSMB) meeting.

ECOS-300CY® is approved in the E.U. as a cytokine adsorber for *ex vivo* organ perfusion machines used in solid organ transplant to reduce circulating cytokines and other inflammatory mediators. The goal of the therapy is to improve the functioning of substandard organs, potentially increasing the pool of donated organs and reduce the waiting list for transplant.

ISO 13485 was written to support medical device manufacturers in designing a quality management system (QMS) that establishes and maintains the effectiveness of their processes. It ensures the consistent design, development, production, installation, and delivery through to disposal of medical devices that are safe for their intended purpose.

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 more than 70 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 June 30, 2022, more than 179,000 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 has initiated two FDA-approved pivotal studies to support FDA marketing approval of DrugSorb-ATR in the United States. The first is the 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. The second study is the STAR-D (Safe and Timely Antithrombotic Removal-Direct Oral Anticoagulants) randomized, controlled trial of 120 patients at 30 centers 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 body fluids through pore entrapment and surface adsorption. The company's technologies have received more than $41.5 million in non-dilutive grants, contracts and other non-dilutive funding from DARPA, the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), the 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 and in-development products based on this unique blood purification technology protected by numerous issued U.S. and international patents and registered trademarks, as well as several pending patent applications, 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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