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 3, 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 2.02 Results of Operation and Financial Condition

On November 3, 2022, CytoSorbents Corporation (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release of the Company, dated November 3, 2022
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

* The information in Item 2.02 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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 3, 2022

CYTOSORBENTS CORPORATION

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

Exhibit 99.1

CytoSorbents™

Working to Save Lives Through Blood Purification

CytoSorbents Reports Third Quarter 2022 Financial and Operational Results

CytoSorbents expects to achieve first milestone of the U.S. pivotal STAR-T Trial this month

PRINCETON, N.J., November 3, 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, today reported unaudited financial and operating results for the quarter ended September 30, 2022.

Third Quarter 2022 Financial Results

- Total revenue, including product sales and grant income, for Q3 2022 was $8.1 million, a decrease of 17% compared to $9.8 million in Q3 2021
- Q3 2022 product sales were $6.5 million (negligible COVID-related sales) versus $8.9 million (includes $1.1 million in COVID-related sales) in Q3 2021. The decrease in the average Euro to U.S. dollar exchange rate lowered Q3 2022 product sales by approximately $771,000. On a constant currency basis, Q3 2022 core non-COVID sales would have been approximately $7.2 million, which represents a 7% decrease from approximately $7.8 million in core non-COVID sales a year ago
- As expected, COVID-19 related sales during the quarter were negligible, reflecting the low severity of current COVID-19 illness resulting from high rates of vaccination and natural immunity
- Product gross margins were approximately 55% in Q3 2022, versus 82% in Q3 2021. The decrease in the gross margin percentage was due primarily to an inventory write-off related to an equipment failure and to inefficiencies associated with lower production due to a decrease in sales and the process of relocating our production activities to the new facility. Excluding the inventory write-off, product gross margin in Q3 2022 would have been 64%

- The Company maintains a healthy balance sheet with cash and cash equivalents of $24.2 million (which includes $1.7 million in restricted cash) as of September 30, 2022, and no debt

Recent Operating Highlights:

- More than 186,000 cumulative CytoSorb devices have been utilized worldwide as of September 30, 2022, compared to more than 152,000 devices utilized cumulatively a year ago
- The U.S. STAR-T Trial is enrolling well with the expectation of achieving the first milestone with 40 patients enrolled this month
- Presented final data from the U.S. CytoSorb Therapy in COVID-19 (CTC) Registry at the European Society of Intensive Care Medicine conference last week, highlighting the early use of CytoSorb with ECMO (extracorporeal membrane oxygenation) to achieve "enhanced lung rest" and high survival in 100 critically ill COVID-19 patients with refractory lung failure treated at 5 U.S. academic centers
- Achieved ISO 13485 certification of our new Princeton, New Jersey manufacturing facility
- The Israeli Ministry of Health assigned national reimbursement coverage to CytoSorb for key intraoperative cardiac surgery indications such as antithrombotic drug removal, infective endocarditis, and aortic dissection
- The Turkish Ministry of Health granted national reimbursement to CytoSorb, which is now a reimbursed catalog product in the State Supply of Turkey (DMO) portal and can be purchased directly by hospitals and physicians without restrictions
- CytoSorbents received funding for HemoDefend-BGA™, a development stage product designed to enable life-saving universal plasma, under two separate Department of Defense contracts. This includes a two year contract valued at $1,977,024 to develop a fully-finished, commercial device that will be evaluated in a pre-clinical porcine study and a three-year Phase III contract valued at $4,292,641 to customize the design of the HemoDefend-BGA™ filter to enable freeze-dried universal plasma
- Released new cardiac surgery data at the European Association for Cardio-Thoracic Surgery (EACTS) highlighting the benefits of CytoSorb when used intraoperatively during cardiothoracic surgery in Staphylococcus aureus infective endocarditis, heart transplantation, and to remove antithrombotic agents
- The National Institute of General Medical Sciences (NIGMS), a division of the U.S. National Institutes of Health, granted a Phase I SBIR award, valued at $281,835, to CytoSorbents to test novel polymers for cytokine and endotoxin removal from septic porcine plasma, with the goal of advancing new blood purification technologies to treat Gram negative sepsis, a deadly global killer

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, “Based upon the increased pace of enrollment, we are excited to be very close to achieving the first of three milestones of the U.S. STAR-T pivotal randomized, controlled study, where we expect to have 40 patients enrolled this month. Should the pace of the study continue, we expect to achieve the second milestone of 80 patients enrolled this Spring 2023, which would trigger a formal interim analysis, and if needed, expected potential completion of enrollment of all 120 patients by Summer 2023. We expect that if the STAR-T study is successful, we would be in a position to submit for U.S. FDA marketing approval for DrugSorb-ATR® in the second half of 2023.

Based upon these projections, and based upon the current macroenvironment, market conditions, and cash conservation imperative, we are taking a number of proactive steps as we work towards the expected achievement of this key objective.

1. Prioritize completion of the U.S. STAR-T Trial

The STAR-T randomized, controlled trial is a 120-patient, 30 center pivotal study designed to evaluate the ability of DrugSorb-ATR to reduce perioperative bleeding by removing the antithrombotic agent, Brilinta® (ticagrelor, Astra Zeneca) in patients undergoing cardiothoracic surgery. Today, Brilinta usage is being fueled by the fact that, according to the U.S. Centers of Disease Control and Prevention (CDC), heart disease is the leading cause of mortality in the U.S., accounting for 1 in every 5 deaths. Coronary artery disease is the most common form of heart disease, killing nearly 400,000 people from heart attacks each year. The CDC states that someone in the U.S. has a heart attack every 40 seconds, or more than 800,000 people annually. This is relevant for Brilinta because when patients have signs and symptoms of having a heart attack and cannot get a stent placed or coronary artery bypass graft (CABG) surgery right away, they are often placed on dual antiplatelet therapy (DAPT) in the hospital consisting of aspirin and a “super-asprin” like Brilinta, to thin the blood and reduce the risk of a worsening heart attack and death. If they are not candidates for a stent, they may require surgery but now face the risk of severe or uncontrolled bleeding because of DAPT intervention. The risk of bleeding depends on when the surgery takes place, but the risk of major fatal or life-threatening CABG-related bleeding can be higher than 50% if the surgery happens that day.

The goal of DrugSorb-ATR® is to allow patients to get the critical surgery that they need without delay, while reducing or preventing this bleeding risk by actively removing the drug during the surgery.

This indication has received FDA Breakthrough Device Designation, and is already approved in the European Union, with very positive published data on a reduction in bleeding risk, which is the primary endpoint of the STAR-T trial. In addition to this, there are a number of other reasons why we are excited about this study and believe it is the right time to primarily focus our resources on this trial.

a. STAR-T has overcome the typical inertia of new studies and is enrolling well with many centers participating
b. FDA has given approval to expand the study to Canadian hospitals, who are high users of ticagrelor and have been historically top enrollers in cardiac surgery trials. Expansion to Canada has the potential to accelerate enrollment and completion of the trial. We also believe inclusion of Canadian centers in the STAR-T study may support Health Canada marketing approval for DrugSorb-ATR, potentially helping to expand our commercial sales opportunities in North America
c. Ticagrelor will become generic globally in 2024, likely eliminating cost as the current barrier to usage, and should we stay on schedule, may be ideal timing for the expected commercial availability of DrugSorb-ATR in the U.S. and Canada
d. Ticagrelor monotherapy is now increasingly considered by the cardiology community as a more effective approach than aspirin to reduce cardio-thrombotic events, strokes, and ischemia in patients at high risk. As this treatment paradigm shift evolves, it may potentially change the recommendations on ticagrelor usage from 1 year, to lifelong therapy
e. Based on recent events and certain competitive dynamics, we believe we have the potential to have first-mover advantage in the U.S. market
f. And finally, we have received strong cardiothoracic surgeon feedback for this application internationally, highlighted by the rapidly enrolling STAR registry, which is ahead of schedule and has now enrolled 125 patients

2. Pause the U.S. STAR-D Trial

The U.S. STAR-D randomized, controlled trial is a 120-patient, 30 center pivotal study designed to evaluate the ability of DrugSorb-ATR to reduce perioperative bleeding by removing the direct oral anticoagulants (DOACs), Xarelto® (rivaroxaban, Janssen/Bayer) and Eliquis® (apixaban, Bristol-Myers Squibb/Pfizer), in patients undergoing cardiothoracic surgery. DOACs are used as chronic therapy to thin the blood to reduce the risk of stroke and heart attack in patients with atrial fibrillation, or a history of stroke, heart attack, or vascular disease, but uses a different mechanism of action than ticagrelor and are <u>not</u> directly interchangeable. However, like ticagrelor, patients on DOACs who require urgent cardiothoracic surgery have a particularly high risk of perioperative bleeding. The goal of DrugSorb-ATR in this population is identical to that for ticagrelor – remove the drug and reduce or prevent perioperative bleeding. In fact, we believe DrugSorb-ATR will eventually become the “one-stop-shop” for the removal of all classes of antithrombotic agents during cardiothoracic surgery, and potentially other surgeries such as orthopedic and neurosurgery, in the future.

We view STAR-D as the sister trial to STAR-T, that leverages many of the same study centers, trial design and user training, but trails STAR-T by at least 6 months. Rather than run this study in parallel, we have decided to pause STAR-D to focus our internal resources on our lead program, STAR-T, including opening new Canadian trial sites to potentially accelerate enrollment and drive STAR-T to completion. This will save an estimated $4 million in expenses in 2023. We fully intend to return to STAR-D when either STAR-T nears, or is at, completion or when we have the financial resources to do so.

3. Restore sales growth and product gross margins

We strongly believe that our commercial markets will recover, but it will take some time. To this point, 2022 continues to be a work-in-progress as hospitals in our core markets continue to struggle to recover from the worst of the COVID pandemic, while grappling with macroeconomic issues such as inflation and high energy costs. Internationally, many hospitals are operating in the red, with rising costs and decreased revenue from issues such as healthcare workforce shortages that negatively impact bed capacity, scheduled operations and procedures, and patient volume. Given our focus on critical care, cardiac surgery, and the hospital market, we are witnessing these issues firsthand. That said, we recorded approximately $6.5 million in core non-COVID product sales in a historically weak seasonal quarter, which on a constant currency basis, was approximately $7.2 million. Adjusting for currency effects, core sales were down 7% year over year, which we view as a modest decline.

As we wait for these global headwinds to clear, we are actively pursuing new exciting growth initiatives and sales optimization strategies to drive sales, despite the challenging environment. We have previously detailed a number of important programs that we are executing upon, such as our standalone blood pump initiative with Nikkiso, our global marketing agreement with Fresenius Medical Care, our therapy area focus in critical care, cardiac surgery, and liver & kidney, and our preferred supplier agreements with the top two largest private hospital networks in Germany, Asklepios and Helios. We believe each of these initiatives has the potential for a tangible return on investment and the ability to add significantly to our growth prospects. We also believe there are some exciting areas of growth in the treatment of acute respiratory distress syndrome (ECMO and CytoSorb), liver dysfunction and failure (CytoSorb), blood thinner removal (DrugSorb-ATR and CytoSorb), and *ex vivo* organ perfusion for transplant (e.g., ECOS-300CY® and PerSorb®), some of which we will discuss in more detail in the earnings call. In the meantime, we currently expect to return our product gross margins to historic levels (≥ 80%) in 2023, once we consolidate manufacturing completely to the new Princeton, New Jersey facility and close the old facility, and upon an expected resumption in CytoSorb sales growth, pending an improvement in market conditions.

4. **Strengthen our cash balance with debt**

   We currently expect to bolster our balance sheet and current cash position by drawing down a portion of the $15 million in debt under our existing term loan facility before year-end. We believe this amount of debt is very manageable and will provide a suitable financial cushion for us as we drive our clinical and commercial initiatives.

5. **Control expenses**

   Cash conservation is a priority and we continue to focus on controlling expenses. During 2022, we have already reduced our headcount by approximately 10% across our company, including full and part-time employees, and consultants, and shifted our R&D headcount to funded grant programs, where we have an extensive $13.2 million backlog as of the end of Q3 2022. Some of the cost savings of our headcount reduction are not yet visible in our results due to notice periods and labor laws in Europe, but will be reflected in our 2023 operating budget. Meanwhile, we are working diligently to prioritize activities that we believe have a near-term return on investment and advance our strategic priorities, while cutting non-core or non-essential activities and spend. Our goal is, through a combination of driving an increase in sales and gross margin, and cutting costs, to significantly reduce our cash burn and to extend our operating runway with the resources we have.

Dr. Chan concluded, “We are excited to rally around the progress of our U.S. STAR-T program and if successful, strongly believe this has the potential to unlock significant value in our Company and open up a very important commercial growth opportunity for years to come.”

Results of Operations

Comparison for the three months ended September 30, 2022 and 2021:

Revenues:

Total revenues were approximately $8.1 million for the three months ended September 30, 2022, as compared to total revenues of approximately $9.8 million for the three months ended September 30, 2021, a decrease of approximately $1.6 million, or 17%. Revenue from product sales was approximately $6.5 million in the three months ended September 30, 2022, as compared to approximately $8.9 million in the three months ended September 30, 2021, a decrease of approximately $2.4 million or 27%. The decrease in the average exchange rate of the Euro to the U.S. dollar negatively impacted 2022 product sales by approximately $.7 million. For the three months ended September 30, 2022, the average exchange rate of the Euro to the U.S. dollar was $1.01 as compared to an average exchange rate of $1.18 for the three months ended September 30, 2021. We estimate that demand for CytoSorb to treat COVID-19 patients was de minimis in the third quarter of 2022 as compared to approximately $1.1 million in the third quarter of 2021. Overall direct sales declined by approximately $1,407,000 resulting primarily from lower sales in Germany due to COVID-19 pandemic-driven market conditions, and unfavorable currency conversions. Although improved, continued staffing shortages, reduction in ICU bed capacity, decreased elective surgical procedures, hospital budgets, and hospital restrictions which at some hospitals continue to limit our access to hospital personnel, continue to impact the hospital market.

Grant income was approximately $1.6 million for the three months ended September 30, 2022, as compared to approximately $859,000 for the three months ended September 30, 2021, an increase of approximately $790,000, or 92%. During the three months ended September 30, 2021, our research and development employees were either deployed to work-from-home status or reassigned to assist in activities related to increasing the production of CytoSorb. In 2022, research and development employees were assigned exclusively to grant and other research and development activities.

Cost of Revenues:

For the three months ended September 30, 2022 and 2021, cost of revenue was approximately $4.5 million and $2.5 million, respectively. Product gross margins were approximately 55% for the three months ended September 30, 2022 as compared to approximately 82% for the three months ended September 30, 2021. The decrease in the gross margin percentage was due to an equipment failure of a refrigeration unit at our new manufacturing facility that caused a write-off of approximately $0.6 million of work-in-process inventory and to inefficiencies associated with lower production due to a decrease in sales and the process of relocating our production activities to the new facility. Excluding the write-off of inventory related to the equipment failure, product gross margin would have been 64% in Q3 2022.

Operating Expenses*:*

For the three months ended September 30, 2022, operating expenses were approximately $12.6 million, as compared to approximately $12.7 million for the three months ended September 30, 2021, a decrease of approximately $0.1 million. Selling, general and administrative (SG&A) expenses increased approximately $0.9 million to $8.7 million in the quarter from $7.8 million in the prior year. This increase was due to an increase in sales and marketing costs, which include advertising and conference attendance of approximately $0.4 million, an increase in occupancy costs of approximately $0.4 million related to the rent expense on our new manufacturing facility, increases in salaries, severance, commissions, and related costs of approximately $0.1 million and an increase in other general and administrative expenses of approximately $0.2 million. This was offset by a decrease in royalty expenses of approximately $0.2 million due to the decrease in product sales. Research and development expenses decreased approximately $1.0 million due to a decrease of approximately $0.7 million in clinical trial expenditures and a decrease in non-grant R&D activities of approximately $0.3 million.

Loss on Foreign Currency Transactions:

For the three months ended September 30, 2022, the loss on foreign currency transactions was approximately $3.2 million as compared to a loss of approximately $1.0 million for the three months ended September 30, 2021. The 2022 loss was directly related to the decrease in the spot exchange rate of the Euro to the U.S. dollar, which was $0.98 as of September 30, 2022 as compared to $1.05 at June 30, 2022.

Comparison for the nine months ended September 30, 2022 and 2021:

Revenues:

Total revenues were approximately $25.3 million for the nine months ended September 30, 2022, as compared to total revenues of approximately $32.4 million for the nine months ended September 30, 2021, a decrease of approximately $7.1 million, or 22%. Revenue from product sales was approximately $21.1 million in the nine months ended September 30, 2022, as compared to approximately $30.4 million in the nine months ended September 30, 2021, a decrease of approximately $8.7 million, or 29%. The decrease in the average exchange rate of the Euro to the U.S. dollar negatively impacted 2022 product sales by approximately $2.3 million. For the nine months ended September 30, 2022, the average exchange rate of the Euro to the U.S. dollar was $1.06 as compared to an average exchange rate of $1.20 for the nine months ended September 30, 2021. Though difficult to quantify, we estimate that approximately $0.3 million of total product sales in the nine months ended September 30, 2022 was due to the demand for CytoSorb to treat COVID-19 patients as compared to $4.6 million in the nine months ended September 30, 2021. Overall direct sales declined by of approximately $6.8 million resulting primarily from lower sales in Germany due to COVID-19 pandemic-driven market conditions and unfavorable currency exchange conversions. Although improved, continued staffing shortages, reduction in ICU bed capacity, decreased elective surgical procedures, hospital budgets, and hospital restrictions which at some hospitals continue to limit our access to hospital personnel, continue to impact the hospital market.

Grant income was approximately $3.6 million for the nine months ended September 30, 2022 as compared to approximately $2.0 million for the nine months ended September 30, 2021, an increase of approximately $1.6 million or 81%. During the nine months ended September 30, 2021, our research and development employees were either deployed to work-from-home status or reassigned to assist in activities related to increasing the production of CytoSorb. In 2022, research and development employees were assigned exclusively to grant and other research and development activities.

Cost of Revenues:

For the nine months ended September 30, 2022 and 2021, cost of revenue was approximately $10.3 million and $7.9 million, respectively, an increase of approximately $2.4 million. Product gross margins were approximately 68% for the nine months ended September 30, 2022 and approximately 80% for the nine months ended September 30, 2021. The decrease in the gross margin percentage in 2022 was primarily due to an equipment failure of a refrigeration unit at our new manufacturing facility that caused a write-off of approximately $0.6 million of work-in-process inventory and to inefficiencies associated with lower production due to a decrease in sales and the process of relocating our production activities to the new facility, including a scheduled four-week production hiatus in Q2 2022.

Operating Expenses*:*

For the nine months ended September 30, 2022, operating expenses were approximately $40.1 million as compared to approximately $37.6 million for the nine months ended September 30, 2021, an increase of approximately $2.5 million, or 7%, for the nine months ended September 30, 2022. Research and development expenses were approximately $11.7 million as compared to approximately $10.2 million for nine months ended September 30, 2021, an increase of approximately $1.5 million or 14%. This increase was primarily due to an increase in costs associated with our STAR-T and STAR-D trials in the United States. Selling, general and administrative expenses were approximately $26.3 million for the nine months ended September 30, 2022, as compared to $25.3 million for the nine months ended September 30, 2021, an increase of $1.0 million. This increase is related to an increase in sales and marketing costs, which include advertising and conference attendance of approximately $1.1 million, an increase in salaries, severance, commissions, and related costs of approximately $1.3 million, an increase in travel and entertainment costs of approximately $0.5 million and an increase in occupancy costs of approximately $1.1 million related to the rent expense on our new manufacturing facility. These increases were offset by a decrease in royalty expenses of approximately $0.7 million, a decrease in non-cash restricted stock expense of approximately $1.7 million related to restricted stock units granted to the Company's executive officers, a decrease in non-cash stock compensation expense of approximately $0.7 million.

Loss on Foreign Currency Transactions:

For the nine months ended September 30, 2022, the loss on foreign currency transactions was approximately $7.0 million as compared to a loss of approximately $2.1 million for the nine months ended September 30, 2021. The 2022 loss was directly related to the decrease in the spot exchange rate of the Euro to the U.S. dollar which was $0.98 as of September 30, 2022 as compared to $1.14 as of December 31, 2021.

Liquidity and Capital Resources

Since inception, our operations have been primarily financed through the issuance of debt and equity securities. As of September 30, 2022, we had current assets of approximately $32.4 million including unrestricted cash on hand of approximately $22.6 million and current liabilities of approximately $10.1 million. As of September 30, 2022, $25 million of our total shelf amount was allocated to our ATM facility, all of which remains available. In addition, we have $15 million of debt availability, providing financial flexibility, if needed. In April of 2022, we received approximately $0.7 million in cash from the approved sale of our net operating losses and research and development credits from the State of New Jersey.

We are also managing our resources proactively, continuing to invest in key areas such as our U.S. clinical program. while driving cost-cutting throughout our Company. At the beginning of Q2 2022, we began instituting tighter cost controls and have reduced our headcount internationally by 10%, with the goal of reducing our cash burn. A reduction in product sales and product gross margins, as well as a delay in realizing headcount reduction cost savings in Europe, have offset these cost cutting efforts. We are currently actively engaged in making further reductions to our operating costs to reduce our future cash burn.

Including cash related to the use of a portion of our available debt facility, we believe that we have sufficient cash to fund the Company's operations beyond twelve months from the issuance of these consolidated financial statements.

Outlook Guidance

The macro environment in which we operate remains difficult to predict given the complex drivers of our business, the global nature of our operations, and external factors such as the COVID-19 pandemic, the Russia-Ukraine war, inflation, foreign currency exchange rate volatility, and other factors that are not under our direct control.

We expect that our business, and in particular product sales, will continue to be challenging for the remainder of 2022 and into 2023. However, we expect a gradual recovery of normalized hospital activity and sales access in Germany and other key countries in the coming quarters. With improved access, we expect a resumption of growth in our core non-COVID-19 product sales.

Meanwhile, we remain focused on completing enrollment of our U.S. STAR-T randomized, controlled trial for ticagrelor removal during cardiothoracic surgery, estimated for Summer 2023, and if successful, being in a position to apply for U.S. FDA marketing approval in the second half of 2023.

For additional information, please see the Company's Form 10-Q for the period ended September 30, 2022, filed on November 3, 2022, on http://www.sec.gov.

Conference Call

The Company will conduct its third quarter 2022 results call today at 4:30 p.m. Eastern time.

Conference Call Details:

Date: Thursday, November 3rd, 2022
Time: 4:30 PM Eastern Time
Toll free: 1-800-458-4121
International: 1-929-477-0402
Conference ID: 1375266
Live Presentation Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1576192&tp_key=7e23c8c13c

It is recommended that participants dial in approximately 10 minutes prior to the start of the call. There will also be a simultaneous live webcast of the conference call that can be accessed through the following audio feed link: : **https://viavid.webcasts.com/starthere.jsp?ei=1576192&tp_key=7e23c8c13c**

An archived recording of the conference call will be available under the Investor Relations section of the Company's website at http://cytosorbents.com/investor-relations/financial-results/.

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 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 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.

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue:				
CytoSorb sales	$ 6,271	$ 8,901	$ 21,176	$ 30,405
Other sales	191	1	542	6
Total product sales	6,462	8,902	21,718	30,411
Grant income	1,649	858	3,580	1,972
Total revenue	8,111	9,760	25,298	32,383
Cost of revenue	4,494	2,463	10,322	7,924
Gross profit	3,617	7,297	14,976	24,459
Other Expenses:				
Research and development	3,290	4,262	11,717	10,244
Legal, financial and other consulting	609	665	2,089	2,090
Selling, general and administrative	8,735	7,776	26,335	25,308
Total expenses	12,634	12,703	40,141	37,642
Loss from operations	(9,017)	(5,406)	(25,165)	(13,183)
Other income/(expense):				
Interest income (expense), net	47	13	79	16
Loss on foreign currency transactions	(3,231)	(1,013)	(6,967)	(2,085)
Miscellaneous Income	-----	-----	7	-----
Total other expense), net	(3,184)	(1,000)	(6,881)	(2,069)
Loss before benefit from income taxes	(12,201)	(6,406)	(32,046)	(15,252)
Benefit from income taxes	-----	-----	-----	-----
Net loss	$ (12,201)	$ (6,406)	$ (32,046)	$ (15,252)
Basic and diluted net loss per common share	$ (0.28)	$ (0.15)	$ (0.74)	$ (0.35)
Weighted average number of shares of common stock outstanding	43,606,980	43,396,464	43,552,238	43,319,507
Net loss	$ (12,201)	$ (6,406)	$ (32,046)	$ (15,252)
Other comprehensive income (loss):				
Currency translation adjustment	2,659	808	5,675	1,701
Total Comprehensive loss	$ (9,542)	$ (5,598)	$ (26,371)	$ (13,551)

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	September 30, 2022	December 31, 2021
ASSETS:		
Current Assets:		
Cash and cash equivalents	$ 22,552	$ 52,138
Grants and accounts receivable, net	4,961	4,523
Inventories	3,542	4,766
Prepaid expenses and other current assets	1,326	2,872
Total current assets	32,381	64,299
Property and equipment, net	10,712	5,151
Restricted Cash	1,687	1,687
Right of use asset	12,794	13,423
Other assets	4,696	4,959
TOTAL ASSETS	$ 62,270	$ 89,519
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current Liabilities:		
Accounts payable	$ 2,348	$ 2,805
Lease liability - current portion	377	571
Accrued expenses and other current liabilities	7,394	10,314
Total current liabilities	10,119	13,690
Lease liability, net of current portion	13,009	13,251
TOTAL LIABILITIES	23,128	26,941
Total stockholders' equity	39,142	62,578
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 62,270	$ 89,519

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