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): March 14, 2024

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 March 14, 2024, CytoSorbents Corporation (the "Company") issued a press release announcing its financial results for the quarter and twelve-months ended December 31, 2023. 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 March 14, 2024
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: March 14, 2024

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 Fourth Quarter and Full Year 2023 Results

- *STAR-T trial results selected for a Breakout Presentation at the American Association of Thoracic Surgery Annual Meeting in late-April 2024*
- *CytoSorbents intends to submit DrugSorb-ATR for regulatory approval to U.S. Food & Drug Administration (FDA) and Health Canada this year*
- *CytoSorb core sales increased approximately 10% year-over-year*
- *2023 Product gross margins increased to 72%*
- *Cumulative CytoSorb treatments surpassed 228,000*

PRINCETON, N.J., March 14, 2024 — 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 financial and operating results for the quarter and year ended December 31, 2023 and provides its 2024 outlook.

Full Year 2023 Financial Results

- 2023 Total Revenue, which includes Product Sales and Grant Income, was $36.3 million versus $34.7 million in 2022, an increase of approximately $1.7 million or 5%
- Total product sales were $31.1 million in 2023 versus $29.4 million in 2022, an increase of approximately $1.7 million or 6%. 2022 product sales benefitted from an additional approximately $0.7 million in Other non-CytoSorb product sales and $0.3 million in COVID-19 related sales compared to 2023
- Core (non-COVID-19 related) CytoSorb sales grew 10% to $31.0 million in 2023, versus $28.3 million in 2022
- The increase in the average Euro to U.S. dollar exchange rate positively impacted 2023 product sales by approximately $0.8 million. The average Euro to dollar exchange rate was 1.08 in 2023 versus 1.05 in 2022
- 2023 Product Gross Margin increased to approximately 72%, from approximately 70% in 2022

Fourth Quarter 2023 Financial Results

- Q4 2023 Total Revenue, which includes Product Sales and Grant Income, was $8.7 million versus $9.4 million in Q4 2022, a decrease of approximately $0.7 million or 8%
- Total Product Sales were $7.3 million in 2023 versus $7.6 million in 2022, a decrease of approximately $0.3 million or 4%
- Core CytoSorb sales in Q4 2023 were $7.3 million compared to $7.4 million in Q4 2022, a decrease of approximately $0.1 million or 1%
- The increase in the average Euro to U.S. dollar exchange rate favorably impacted Q4 2023 product sales by approximately $0.4 million. The average Euro to dollar exchange rate was 1.08 in Q4 2023 versus 1.02 in Q4 2022

Recent Operating Highlights

- Cumulative CytoSorb® treatments delivered exceeded 228,000 at the end of 2023, up 17% from the end of 2022
- The 140-patient, double-blinded, multicenter, pivotal STAR-T randomized, controlled trial was selected for a Breakout Presentation at the American Association of Thoracic Surgery (AATS) Annual Meeting being held April 27-30, 2024 in Toronto, Canada. We expect to follow this event with an Analyst and Investor Day and provide a review of the data by an esteemed thought leader panel
- We plan to submit for regulatory approval of DrugSorb®-ATR to the FDA and Health Canada in the second half of 2024 to reduce the severity of bleeding in patients undergoing isolated coronary artery bypass graft (CABG) surgery on the blood thinner, Brilinta®. This follows the prior discussion of topline study results in December 2023, and subsequent additional data analysis from the STAR-T Trial
- Our European Union CE Mark for CytoSorb was extended under the Medical Devices Directive (MDD) to the earlier of either December 2028 or when we achieve E.U. Medical Device Regulation (MDR) certification, which effort is currently ongoing
- Entered into a new strategic partnership and temporary distribution agreement in India for CytoSorb with the publicly-traded Indian pharmaceutical company, Eris Lifesciences, following its definitive agreement with Biocon Biologics to acquire Biocon's Nephrology branded formulations business unit, and with it, Biocon's key leadership and field force of these businesses, including the personnel commercializing CytoSorb in India
- Expecting to launch our new PuriFi stand-alone hemoperfusion pump later this year following the expiration of our previously disclosed distribution agreement with Nikkiso Europe GmbH for its PureAdjust® hemoperfusion pump in September 2023

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, “In 2024, we are intent on providing clarity to investors on the key factors that will determine the near-term and future success of this Company. These include visibility on submission of DrugSorb-ATR for regulatory approval to U.S. FDA and Health Canada this year, returning to significant growth in our core existing CytoSorb business outside the U.S. and Canada, continued improvements in product gross margins coupled with a right-sized operating expense structure, and adequately financing CytoSorbents for success.”

STAR-T Update

The pivotal, U.S. and Canadian STAR-T (**S**afe and **T**imely **A**ntithrombotic **R**emoval – **T**icagrelor) randomized controlled trial was designed to support FDA and Health Canada marketing approval for DrugSorb®-ATR to reduce the risk of perioperative bleeding in patients undergoing cardiothoracic surgery potentially caused by Brilinta® (ticagrelor, AstraZeneca). Our technology has received FDA Breakthrough Device Designation for this application, highlighting the major unmet medical need and lack of approved or cleared therapies for this problem.

Following the completion of the STAR-T trial last year, we announced topline data from the study in December 2023 as follows:

- The independent STAR-T Data and Safety Monitoring Board (DSMB) conducted a review of unblinded data on all 140 patients in the trial and concluded there were no issues with device safety, meeting the primary safety endpoint of the study
- Following initial data analysis from STAR-T, the primary effectiveness endpoint in the overall patient population that underwent different types of cardiac surgeries was not met. However, in the pre-specified subpopulation of patients undergoing isolated coronary artery bypass graft (CABG) surgery that accounted for more than 90% of patients enrolled in the STAR-T trial and also represent the main use case for DrugSorb®-ATR, we observed evidence of reduced bleeding complications, including serious bleeding events.

We have since performed additional analyses of our trial data in the isolated CABG population and believe the results further support the favorable benefit-to-risk profile of DrugSorb-ATR in these patients who represent the overwhelming majority facing this clinical unmet need.

We are pleased at the selection of the STAR-T trial for a breakout presentation at the 104th Annual Meeting of the American Association of Thoracic Surgery, described as the world's most prestigious cardiothoracic surgery event. This year, the meeting will be in collaboration with the Society of Cardiovascular Anesthesiologists (SCA), who are often managing blood product usage due to intraoperative bleeding during surgical procedures. In general, this conference is targeted towards cardiothoracic surgeons and physicians in related specialties; perfusionists; non-physician health care providers involved in the care of cardiothoracic surgical patients; as well as fellows, residents, and medical students in cardiothoracic surgery. These are the stakeholders who directly witness and need to manage the perioperative bleeding complications of their patients on blood thinners and who would use DrugSorb-ATR in clinical practice.

Shortly after AATS, we plan to host an Analyst and Investor Day to share these data with participants, who will then be able to evaluate the benefit-risk proposition of DrugSorb-ATR. Our data give us confidence in our decision to submit for regulatory approval to U.S. FDA and Health Canada, estimated in the second-half of 2024. For an interesting discussion on therapies seeking FDA approval in our situation, see page 3 of this report from Zacks Research.

Although we cannot predict the outcome of a regulatory submission, should DrugSorb-ATR be approved in both the U.S. and Canada only for patients undergoing isolated CABG, we believe the initial total addressable market opportunity remains relatively intact at approximately $325 million initially, and may expand significantly as ticagrelor (aka Brilinta®, AstraZeneca) becomes generic this year and potentially displaces generic clopidogrel (aka Plavix®, BMS/Sanofi) in the market as the preferred P2Y12 inhibitor in patients with acute coronary syndromes based on both the superior efficacy data over clopidogrel and the ability to be removed in cases where urgent CABG is required (due to DrugSorb-ATR).

2023 Sales Highlights

2023 was a reasonable recovery year of progress and growth, where core (non-COVID-19) CytoSorb sales grew roughly 10% over the prior year. This was particularly true coming off of a challenging 2022 that we described last year as a "perfect storm" of geopolitical, economic, post-pandemic, and company-specific factors. That said, the results understate some of the excellent progress we are making to grow and diversify our revenue base, based upon our long-term growth strategy and investment commitments to support our hybrid sales model.

- Strong performance from our **International Direct** sales division (representing 14 countries, excluding Germany) resulted in 27% sales growth year-over-year to approximately $6.0 million, or 19% of 2023 product sales
- **Distributor and Partner** sales (representing more than 60 countries) grew 18% (excluding U.S. dsitributor sales in 2022) in the first three quarters of 2023 over the prior year. Based on our stand-alone pump initiative that is expected to catalyze sales of CytoSorb in countries with less developed dialysis capabilities, we had budgeted higher growth in Q4 for this division. For a number of different reasons, it became clear that Nikkiso's PureAdjust® hemoperfusion machine was not the long-term solution for our stand-alone pump initiative and we mutually agreed to not renew our distributor agreement in September 2023. We pivoted to an alternative strategy, focused on the launch of our own hemoperfusion machine called Purifi that we expect to launch later this year. Anticipation of this machine, however, led to some order slippage from distributors to the new year, resulting in lower than expected Q4 2023 sales overall. For the year, Distributor and Partner sales grew 9% (excluding U.S. distributor sales in 2022) to $12.1 million, or 39% of 2023 product sales
- **Direct Sales Germany** was flat at 3% growth to $13.0 million for the year, or 42% of 2023 product sales. German hospitals are still working through the aftermath of the COVID-19 pandemic with staff shortages, decreased hospital beds, fewer patients, and fewer revenue generating procedures, and economic stressors such as inflation, labor, energy, and other unexpected costs. Notwithstanding this market backdrop, the costs and challenges that physicians and healthcare workers continue to face in the management of critical illness and cardiac surgery are real. Given the numerous applications, both old and new, that our products can help to address, and other initiatives such as our preferred supplier agreement with the largest private hospital networks in Germany, we believe there are many opportunities to return to significant growth in the country.

  That said, we are currently tracking a proposal for healthcare reform of Germany's hospital system. In July 2023, Germany's federal and state governments issued a consensus white paper that could result in new laws that change how hospitals are funded. Government payments to hospitals would de-emphasize the DRG (diagnosis-related group) "lump sum" payment system that incentivizes revenue generation through more patients treated and procedures performed, and instead emphasize base payments focused on quality measures and appropriate patient care. This is expected to favor a shift of routine operations and procedures to outpatient centers, consolidation of smaller hospitals into larger ones, and importantly, an increased focus of remaining hospitals on sicker patients, more complex operations such as cardiothoracic surgery and organ transplant, and on therapies that help reduce the severity of illness and help patients recover faster. Given that the goal of our therapies is to improve clinical outcomes while reducing the costs of critical care and cardiac surgery by controlling deadly inflammation and other life-threatening conditions, while reducing the need for expensive life support measures that keep patients in the hospital, we believe such reform may favor our business in the longer-term. Hospital administrators expect such change will take careful planning and time, potentially years, to implement. We continue to track these developments with interest.

As we discussed in the last earnings release, we believe we can return to and potentially even exceed our historic compound annual growth rate (CAGR) of approximately 25%. We outlined a number of macro trends in healthcare that favor our therapies, such as the aging population that is prone to critical illness, the use of blood thinners by millions of people worldwide to reduce the risk of stroke and heart attack, and the epidemic of chronic liver disease that afflicts one in every five people globally. Meanwhile, we also discussed our numerous growth initiatives, like our stand-alone pump intiative with the pending launch of our own PuriFi machine, the impact that supportive data from STAR-T may have on the blood thinner opportunity worldwide, our global marketing agreement with Fresenius Medical Care where CytoSorb is the featured solution for cytokine, bilirubin, and myoglobin removal on its critical care platforms worldwide, our new E.U. trademark of "Expanding the Dimension of Blood Purification®" that highlights the up to 40-50% of patients in the ICU where our therapies could be beneficial, and relatively "new" applications with exciting recently published clinical data in fields such as artificial liver support, fluid balance in septic shock, infective endocarditis, heart transplant, *ex vivo* organ perfusion – particularly lung transplant, acute respiratory distress syndrome (ARDS), and the effect of CytoSorb on gram negative endotoxin-induced cytokine storm – a major cause of septic shock.

Reduced Cash Burn with Tight Control Over Expenses

Following our equity financing in December, we ended the year with $15.6 million in cash, including $1.5 million in restricted cash, and $5 million in debt. We have implemented significant cost cutting measures to significantly reduce our cash burn, including a 15% reduction-in-force, termination of non-core R&D programs, termination of the STAR-D trial to focus on STAR-T, and a third consecutive year of salary freezes for executive management. The benefit of these cost cuts on operating expenses, particularly our headcount reductions, will become more apparent with time as notice periods and severance payments are completed. Finally, we have worked diligently to optimize our manufacturing efficiencies and expect CytoSorb product gross margins to be in the 75-80% range on a quarterly basis this year, after averaging 72% in 2023.

Dr. Chan concluded, “We believe the successful execution of our strategy will form the basis of a strong turnaround of our business and position us well for strong growth and profitability in the next several years. We thank you for your continued support.”

Conference Call Details:

Date: Thursday, March 14th, 2024
Time: 4:30 PM Eastern Time
Participant Dial-In: (888) 596-4144
Conference ID: 5329219
Live Presentation Webcast: https://edge.media-server.com/mmc/p/tgivev9a
Participants are recommended to dial in approximately 10 minutes prior to the start of the call.

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/.

For additional information, please see the Company’s Form 10-K for the period ended December 31, 2023, filed on March 14, 2024, on http://www.sec.gov.

Results of Operations

Comparison of the year ended December 31, 2023 and 2022

Revenues:

For the year ended December 31, 2023, we generated total revenue, which includes product revenue and grant income, of approximately $36,349,000 as compared to revenues of approximately $34,689,000 for the year ended December 31, 2022, an increase of approximately $1,660,000, or 5%. Revenue from CytoSorb product sales was approximately $31,015,000 for the year ended December 31, 2023, as compared to approximately $28,573,000 in the year ended December 31, 2022, an increase of approximately $2,442,000, or 9%. Other product revenue was approximately $70,000 for the year ended December 31, 2023, as compared to $787,000 for the year ended December 31, 2022, a decrease of approximately $717,000. COVID-19 product sales were $0 in 2023 and approximately $300,000 in 2022. Direct sales increased by approximately $928,000, or 5% and distributor sales increased by approximately $797,000, or 7% during the year ended December 31, 2023, as compared to the year ended December 31, 2022. The increase in the average exchange rate of the Euro to the U.S. dollar also positively impacted 2023 product sales by approximately $780,000. For the year ended December 31, 2023, the average exchange rate of the Euro to the U.S. dollar was $1.08 as compared to an average exchange rate of $1.05 for the year ended December 31, 2022.

Grant income was approximately $5,264,000 for the year ended December 31, 2023, as compared to approximately $5,329,000 for the year ended December 31, 2022, a decrease of approximately $65,000, or 1%.

Cost of Revenue:

For the years ended December 31, 2023 and 2022, cost of revenue was approximately $13,957,000 and $13,956,000, respectively. Grant cost of revenue increased approximately $41,000 during the year ended December 31, 2023, as compared to the year ended December 31, 2022. Product cost of revenues decreased approximately $39,000 during the year ended December 31, 2023, as compared to the year ended December 31, 2022. Product gross margins were approximately 72% for the year ended December 31, 2023, and approximately 70% for the year ended December 31, 2022. This increase was primarily due to inefficiencies related to the relocation of our production activities to our new manufacturing facility in Princeton, New Jersey during the year ended December 31, 2022, that did not recur in 2023.

Gross Profit:

Gross profit was approximately $22,392,000 for the year ended December 31, 2023, an increase of approximately $1,659,000 or 8%, versus gross profit of $20,733,000 in 2022. This increase is attributed to increased sales and the increase in product gross margin percentage as discussed above.

Research and Development Expenses:

Our research and development costs were approximately $15,729,000 and $15,119,000 for the years ended December 31, 2023 and 2022, respectively, an increase of approximately $610,000, or 4%. This increase was related to approximately $850,000 of costs incurred related to pre-production manufacturing activities required to bring the new manufacturing plant to a state of commercial readiness and approximately $720,000 of costs related to pre-commercialization activities related to DrugSorb ATR. These increases were offset by a decrease in clinical trial related costs of approximately $940,000, due primarily to the termination of our STAR-D clinical trial in the U.S., and other non-grant related research and development costs of approximately $20,000.

Legal, Financial and Other Consulting Expenses:

Our legal, financial and other consulting costs were approximately $4,272,000 and $2,848,000 for the years ended December 31, 2023 and 2022, respectively, an increase of approximately $1,424,000, or 50%. This increase was due to an increase in legal fees of approximately $1,010,000 due to the abandonment of certain issued patents and patent applications, fees related to Company's equity transactions and the settlement of a litigation matter; an increase in employment agency fees of approximately $178,000 related to the hiring of certain management personnel, an increase in consulting fees of approximately $179,000 related to regulatory matters on DrugSorb-ATR and an increase in accounting fees of approximately $57,000.

Selling, General and Administrative Expenses:

Our selling, general and administrative expenses were approximately $33,600,000 and $34,288,000 for the years ended December 31, 2023 and 2022, respectively, a decrease of approximately $688,000, or 2%. This decrease was due to a decrease in sales and marketing costs, which include advertising and conference attendance, of approximately $839,000, a decrease in royalty expense of approximately $109,000, a decrease in non-cash stock compensation expense (which includes both stock options and restricted stock units) of approximately $115,000, a decrease in commercial insurance of approximately $165,000 and a decrease in public relations costs of approximately $135,000. These decreases were offset by an increase in salaries, commissions, and related costs of approximately $532,000 and an increase in other general and administrative costs of approximately $143,000.

Gain (Loss) on Foreign Currency Transactions:

For the year ended December 31, 2023, the gain on foreign currency transactions was approximately $1,949,000, as compared to a loss on foreign currency transactions of approximately $2,449,000 for the year ended December 31, 2022. The 2023 gain is directly related to the increase of the exchange rate of the Euro as of December 31, 2023, as compared to December 31, 2022. The exchange rate of the Euro to the U.S. dollar was $1.11 per Euro as of December 31, 2023, as compared to $1.07 per Euro at December 31, 2022. The 2022 loss is directly related to the decrease in the exchange rate of the Euro as of December 31, 2022, as compared to December 31, 2021. The exchange rate of the Euro to the U.S. dollar was $1.07 per Euro as of December 31, 2022, as compared to $1.14 per Euro at December 31, 2021.

Benefit from Income Taxes:

Our benefit from income taxes was approximately $814,000 and $1,093,000 for the years ended December 31, 2023 and 2022, respectively. These benefits were realized by utilizing the New Jersey Technology Business Tax Certificate Transfer Program whereby the State of New Jersey allows us to sell a portion of our state net operating losses to a third party.

Liquidity and Capital Resources

Since inception, our operations have been primarily financed through the issuance of debt and equity securities. As of December 31, 2023, we had current assets of approximately $25.7 million and current liabilities of approximately $14.5 million. As of December 31, 2023, $25 million of our total shelf amount was allocated to our ATM facility, of which approximately $20.3 million remained available. During the year ended December 31, 2023, the Company sold 2,656,464 shares pursuant to the Sale Agreement, at an average selling price of $1.76 per share, generating net proceeds of approximately $4,532,000.

In April of 2023, we received approximately $1,000,000 in cash from the approved sale of our net operating losses and research and development credits from the State of New Jersey. In March of 2024, we received approximately $880,000 in cash from the approved sale of our net operating losses and research and development credits from the State of New Jersey.

On December 13, 2023, the Company closed on a registered direct offering for the sale, directly to investors, of 7,733,090 shares of registered common stock and warrants to purchase up to 2,706,561 shares of common stock (the “Offering”). Each share of common stock and accompanying warrant to purchase up to 0.35 shares of common stock, were sold together for a combined purchase price of $1.33, for an aggregate purchase price of approximately $10,285,000. After deducting transaction fees and expenses payable by the Company in connection with the Offering, the Company received net proceeds of approximately $9,785,000, excluding any proceeds that may be received upon the exercise of the warrants. Each warrant is immediately cash exercisable at an exercise price of $2.00 per share and will expire on the fifth anniversary of the issue date.

We are also managing our resources proactively, continuing to invest in key areas such as our U.S. and Canadian pivotal STAR-T trial, which includes the detailed analysis of trial data and the preparation of our application for marketing approval to the U.S. FDA and Health Canada. We have also instituted and continue to maintain tight control over expenditures.

As of December 31, 2023, we have approximately $15.6 million in cash, including approximately $14.1 million and $1.5 million in unrestricted and restricted cash, respectively. We believe this is sufficient to fund the Company's operations into the fourth quarter of 2024. We will need to raise additional capital to support our ongoing operations in the future, and the Company is actively pursuing financing sources, including less or non-dilutive debt financing, royalty financing, strategic or direct investments, equity financing, and/or combinations thereof. There can be no assurance that management will be successful in these endeavors.

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 antithrombotic drugs and inflammatory mediators that can lead to postoperative complications, including severe bleeding and multiple organ failure. At the end of 2023, more than 228,000 CytoSorb devices had 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 completed the FDA-approved, randomized, controlled STAR-T (Safe and Timely Antithrombotic Removal-Ticagrelor) study of 140 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 $50 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™, 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 X (fka 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, including our future sales goals and targets, expectations regarding the future impacts of COVID-19 or the ongoing conflict between Russia and the Ukraine, statements about our growth opportunities, statements regarding the expected impacts of our cost cutting measures, statements about the results of our STAR-T clinical trial and regulatory submissions relating thereto, 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 14, 2024, 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)

	Year ended December 31,		
	2023	2022	2021
Revenue:			
CytoSorb sales	$ 31,015	$ 28,573	$ 39,997
Other sales	70	787	112
Total product sales	31,085	29,360	40,109
Grant income	5,264	5,329	3,057
Total revenue	36,349	34,689	43,166
Cost of revenue	13,957	13,956	11,048
Gross profit	22,392	20,733	32,118
Other Expenses:			
Research and development	15,729	15,119	16,381
Legal, financial and other consulting	4,272	2,848	2,732
Selling, general and administrative	33,600	34,288	35,750
Total expenses	53,601	52,255	54,863
Loss from operations	(31,209)	(31,522)	(22,745)
Other income (expense):			
Interest income (expense), net	(158)	133	28
Gain (loss) on foreign currency transactions	1,949	(2,449)	(2,578)
Miscellaneous income	97	(67)	---
Total other income (expense), net	1,888	(2,383)	(2,550)
Loss before benefit from income taxes	(29,321)	(33,905)	(25,295)
Benefit from income taxes	814	1,092	736
Net loss	$ (28,507)	$ (32,813)	$ (24,559)
Basic and diluted net loss per common share	$ (0.64)	$ (0.75)	$ (0.57)
Weighted average number of shares of common stock outstanding	44,656,391	43,573,215	43,359,186
Net loss	$ (28,507)	$ (32,813)	$ (24,559)
Other comprehensive income (loss):			
Currency translation adjustment	(1,800)	1,804	2,260
Comprehensive loss	$ (30,307)	$ (31,009)	$ (22,299)

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	December 31, 2023	December 31, 2022
ASSETS:		
Current Assets:		
Cash and cash equivalents	$ 14,131	$ 22,145
Grants and accounts receivable, net	6,057	5,665
Inventories	3,680	3,461
Prepaid expenses and other current assets	1,835	2,489
Total current assets	25,703	33,760
Property and equipment, net	10,056	10,743
Restricted Cash	1,484	1,687
Right of use asset	12,059	12,604
Other assets	3,959	4,438
TOTAL ASSETS	$ 53,261	$ 63,232
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current Liabilities:		
Accounts payable	$ 3,802	$ 1,655
Lease liability - current portion	374	109
Accrued expenses and other current liabilities	7,870	7,951
Current maturities of long-term debt	2,500	---
Total current liabilities	14,546	9,715
Lease liability, net of current portion	12,897	13,142
Long-term debt	2,543	5,000
TOTAL LIABILITIES	29,986	27,857
Total stockholders' equity	23,275	35,375
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 53,261	$ 63,232

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