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 9, 2023

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 9, 2023, CytoSorbents Corporation (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 9, 2023.
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 9, 2023

CYTOSORBENTS CORPORATION

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

Exhibit 99.1

WORKING TO SAVE LIVES

CytoSorbents Reports Third Quarter 2023 Financial and Operational Results

Q3 2023 Product sales grew 20% to $7.8M versus $6.5M in Q3 2022. Q3 2023 Total revenue was approximately $8.8M. The pivotal STAR-T trial remains blinded with database lock nearing and initial data analysis completion expected before year-end.

PRINCETON, N.J., November 9, 2023 — CytoSorbents Corporation (NASDAQ: CTSO), a leader in the treatment of life-threatening conditions in the intensive care unit and cardiac surgery using blood purification via its proprietary polymer adsorption technology, today reported unaudited financial and operating results for the quarter ended September 30, 2023.

Third Quarter 2023 Financial Results

- Total revenue for Q3 2023, including product sales and grant income, was $8.8 million, an increase of 9% compared to $8.1 million in Q3 2022
- Q3 2023 product sales were $7.8 million versus $6.5 million in Q3 2022, an increase of $1.3 million or 20%
- Product gross margins were approximately 72% in Q3 2023, compared to 55% in Q3 2022
- Total cash, including cash and cash equivalents and restricted cash was $10.0 million as of September 30, 2023

Recent Operating Highlights:

- Completed the U.S. and Canadian pivotal STAR-T trial in August 2023, following the last scheduled patient follow-up. The trial remains blinded with database lock nearing, with initial data analysis expected before year-end
- Highlighted the low rates of perioperative bleeding observed in everyday practice and reported by the International STAR Registry when CytoSorb® is used in patients undergoing isolated coronary artery bypass graft (CABG) surgery within 2 days of Brilinta®/Brilique® (ticagrelor, AstraZeneca) discontinuation at the 2023 European Association for Cardio-Thoracic Surgery (EACTS) meeting in Vienna, Austria
- As of the end of Q3 2023, more than 221,000 CytoSorb devices have been cumulatively delivered across more than 75 countries worldwide since launch

- Expanded ANVISA registration of CytoSorb to treat shock in Brazil, Latin America's largest medical device market, and the 7th most populous country in the world. CytoSorb is commercialized in Brazil through Fresenius Medical Care in critical care and by Contatti Medical in the field of cardiac surgery
- Discussed how the use of CytoSorb and ECOS-300CY with *ex vivo* organ perfusion are helping to transform the future of solid organ transplantation, highlighting newly published studies in lung transplantation that correlate the use of our technology and *ex vivo* lung perfusion with improved organ function, as well as improved hospital and 1-year survival
- Announced that Kathleen Bloch resumed duties as full-time Chief Financial Officer

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, "Our core business is built upon our E.U. approved flagship CytoSorb® blood purification therapy, used in more than 221,000 human treatments with more than $205 million in sales to date, including $31.4 million in the last 12 months alone. CytoSorb addresses multi-billion dollar markets in critical care and cardiac surgery in 75 countries worldwide by treating deadly inflammation and other life-threatening conditions. These are common everyday ICU conditions like sepsis, trauma, burn injury, respiratory failure, liver failure, and complications of surgery where mortality is high despite standard therapies. With the world struggling in the aftermath of the pandemic with war, natural disasters, and illness, we believe our life-saving therapy has never been more relevant.

The DrugSorb®-ATR anti-thrombotic removal system is our other focus, having completed the U.S. and Canadian pivotal STAR-T (**S**afe and **T**imely **A**ntithrombotic **R**emoval of **T**icagrelor) randomized controlled trial that was designed to demonstrate a reduction in perioperative bleeding in patients undergoing cardiothoracic surgery on Brilinta® (ticagrelor, AstraZeneca). Brilinta is increasingly the "super-aspirin" blood thinner of choice for patients suffering from a heart attack, or receiving a cardiac stent. Should the data, which currently remain blinded, support U.S. FDA and Health Canada regulatory approval, it would open up an estimated $650 million dollar total addressable market in these two countries alone, where we expect rapid adoption and strong user demand, reflecting our FDA Breakthrough Device designation.

We believe we have made excellent progress on both of these programs so far this year and are specifically pleased to report 20% product sales growth in Q3 2023 versus a year ago, and nearing database lock of the STAR-T trial and final data analysis before year-end.

1. The STAR-T Pivotal Trial Update – What do we know?

Coronary artery bypass graft (CABG) surgery to bypass blocked heart arteries is the most common type of open heart surgery performed in the United States and worldwide. Approximately 300,000 CABG surgeries are performed each year in the U.S., often triggered by a heart attack, with the vast majority operated on an urgent basis during the index hospitalization. An estimated 100,000 of these patients are at risk of excessive bleeding due to blood thinners with approximately half of them on Brilinta®. CytoSorb, which uses an equivalent polymer technology to DrugSorb®-ATR, is already approved and is increasingly used in the E.U. to remove Brilinta®/Brilique® and reduce bleeding risk in this indication. The initial results from the International STAR Registry reporting on this real-world experience have shown favorably low rates of serious perioperative bleeding.

As we noted in August, we completed the STAR-T trial ahead of our own internal expectations with follow-up on 100% of the subjects, highlighting the excellent execution of the trial by our 30 U.S. and Canadian trial centers, contract research organization (CRO), and our clinical team.

We reported earlier this year in June, that following the second scheduled Data and Safety Monitoring Board (DSMB) data review of the first 80 patients enrolled in the pivotal STAR-T study, no device-related safety issues were raised and that the DSMB recommended to complete the study without modification. The final DSMB review on the full STAR-T trial will occur after database lock in the near future.

It is important to note the STAR-T study data remains blinded to all parties and will not be unblinded until after database lock, when the final statistical analysis will occur. Because of this, the results of the study are currently unknown.

We are working diligently to complete our initial STAR-T data analysis before year-end. We intend to announce whether we believe the results from STAR-T can support an FDA marketing approval application thereafter. With supportive results, our goal is to submit for U.S. FDA and Health Canada marketing approval in early-2024. This process is currently being led in parallel to our clinical activities by our SVP of Global Regulatory, Dr. Irina Kulinets, who has an extensive track record of U.S. and international regulatory success with the approval/clearance of medical products in numerous therapeutic areas, including many Class II 510(k) and Class III Premarket Approval (PMA) medical devices. We believe our FDA Breakthrough Device Designation for DrugSorb-ATR in this indication, which highlights the major unmet clinical need for which no approved or cleared alternatives exist in the U.S., will help to expedite the regulatory review of our application. Although there can be no certainty, based on published FDA review timelines, and dependent on the timing of regulatory filing and a favorable review of our data by FDA, we would anticipate potential U.S. marketing approval of DrugSorb-ATR by late-2024 or early-2025.

Through many discussions with cardiothoracic surgeons in the U.S., Canada, and abroad, we continue to confirm the vexing and serious clinical and economic problem that blood thinners cause patients, surgeons, and hospitals.

- For patients, delaying surgery to wash out the drug puts those with active ischemic heart disease at risk, while going to CABG surgery without waiting risks serious perioperative bleeding associated with longer hospital stays and increased risk of worsened clinical outcomes and even death
- For surgeons, excessive intraoperative bleeding due to blood thinners is difficult and unpredictable to manage, often complicating the surgery and requiring significant additional operative time to achieve hemostasis. Postoperatively, bleeding complicates and delays recovery and disposition, and if rapid or persistent, may require expensive and time-consuming re-exploratory surgery
- For hospitals, patients on blood thinners consume scarce resources and complicate patient logistics. Preoperatively, patients in the U.S. occupy hospital beds for 3 to 5 days to washout the drug, costing $6,000 to $30,000 to wait depending on the severity of their condition, based upon an approximate daily cost of $6,000 in the ICU, $4,000 in the ICU step-down, and $2,000-$3,000 for a cardiac monitored ward bed

  Intraoperatively, the inability to stop bleeding delays completion of the case and is very expensive. Shorter overall operative times have been cited in a previous study when CytoSorb was used intraoperatively in patients undergoing cardiac surgery on Brilinta. Based on average published operating room charges from the Cleveland Clinic hospital system, each additional 30 minute increment adds more than $4,000 in cost to the operation.

  Perioperatively, bleeding complications are very expensive as well, due to the need for blood transfusions, reoperations, and longer ICU and hospitals stays. Recently, in a study published in the American Journal of Cardiovascular Drugs, Cohen et al. modeled the projected cost savings of less perioperative bleeding that DrugSorb-ATR could provide in the U.S. in patients undergoing surgery before completing washout of Brilinta® – a similar cohort being evaluated in the STAR-T trial. Using assumptions based on published studies, they found the use of DrugSorb-ATR in these cases had a cost-dominant value proposition based on delivering improved clinical outcomes for patients and substantial cost savings (inclusive of the cost of the device) to the hospital. Finally, outcomes in CABG surgery, the most common cardiothoracic surgical procedure in the United States, such as death rates, readmissions, and postoperative hemorrhage (classified as a Serious Complication) reflect heavily in the Hospital's Quality Star Rating patient safety rating, as defined by the U.S. Centers of Medicare & Medicaid Services (CMS). The hospital's overall Star rating is critical as it helps to differentiate the hospital on objective quality measures from others in the area, important in driving patient traffic and procedure revenue to the hospital, and with direct implications on overall profitability.

Because of this, we believe DrugSorb-ATR could represent a “win-win-win” for patients, surgeons and hospital administrators by potentially allowing safe and timely surgery by actively removing the drug from the bloodstream, while reducing the serious bleeding risk and unnecessary costs in such patients. With the appropriate approvals, we intend to commercialize CytoSorb in the U.S. and Canada primarily with a direct sales force focused regionally at high volume cardiac surgery centers, including our clinical trial centers, and supplemented with cardiac surgery-focused distributors or strategic partners.

We have extensive experience in manufacturing and commercialization of our products abroad. Under the leadership of our President and Chief Operating Officer, Vincent Capponi, our Chief Medical Officer, Dr. Efthymios Deliargyris, and Vice President of U.S. Sales and Marketing, James Komsa, who led the Northeast Cardiac and Vascular Group (CVG) at Medtronic that generated $310 million in annual sales at Medtronic, our goal is to drive rapid awareness, adoption, reimbursement, and sales of DrugSorb-ATR in the U.S. and Canada. We believe product gross margins of DrugSorb-ATR will exceed 90% and based on revenue and operating expense projections, we expect the U.S. operations to achieve breakeven in the first year of commercialization.

Based on the above, we eagerly await the results of the STAR-T trial, and the potential future initiation of the STAR-D trial for the removal of the leading blood thinners, Xarelto® (Bayer, Janssen) and Eliquis® (Pfizer, BMS), with the ultimate goal of establishing DrugSorb®-ATR as the one-stop shop for blood thinner removal, not just in cardiac surgery, but hospital-wide.

2. CytoSorb – The Future of Critical Care and Cardiac Surgery

In the third quarter of 2023, we achieved 20% growth in product sales year-over-year in what is typically a highly seasonal quarter where most European businesses slow due to the summer holidays. Quarterly core (non-COVID-19 related) sales grew for the third straight period year-over-year, with trailing 12-month product sales of approximately $31.4 million. Trailing 12-month total revenue was $37.1 million, which includes product sales and grant income. Product gross margins were 72%, a significant improvement from the 55% reported a year ago, despite some continued manufacturing inefficiencies including overtime shifts to increase CytoSorb inventory levels. In the near term, we expect product gross margins to be more consistently in the range of 75-80%.

From 2017-2021, our compounded annual growth rate (CAGR) for core (non-COVID-19) sales was 26%. Following the post-COVID-19 hangover in 2022 and a year of recovery in 2023, we believe our core CytoSorb business has stabilized and project returning to, and potentially even exceeding, these historic growth rates in the future.

- We are riding major macro trends in healthcare, such as the aging baby boomer population that are prone to life-threatening conditions such as infection and sepsis, trauma, structural and coronary heart disease, lung injury, and organ failure, or the use of blood thinners to reduce stroke and heart attack risk. Unfortunately, these conditions are so common that most of us know someone who falls into one or more of these categories
- Second, we have multiple Company-specific initiatives underway that are helping to expand our business opportunities. Examples include our standalone hemoperfusion pump initiative that can enable earlier and more frequent usage of our blood purification therapies - particularly in countries that do not have a robust dialysis infrastructure; additional new leadership in our therapy area verticals in critical care, cardiac surgery, and liver/kidney applications that is intended to foster more focused market development; preferred supplier agreements with the largest private hospital networks in Germany; and new direct and distributor territories that are gaining market momentum
- Third, we are “Expanding the Dimension of Blood Purification®.” Every person has two main blood purification organs – the kidneys and the liver. Dialysis and related techniques are the most common blood purification technologies and are used to replace kidney function in the approximately 10-15% of ICU patients who develop kidney failure. CytoSorb, on the other hand, is compatible with dialysis and CRRT machines, but functions like the liver and is capable of not just removing liver toxins, but a broad range of cytokines and other inflammatory mediators that drive severe or massive inflammation in up to 40-50% of patients in the ICU. Left unchecked, this uncontrolled inflammation destabilizes patients, worsens the severity of critical illness, and can directly contribute to organ failure and death. In addition to our core markets mentioned above, with new data, we are now adding major new applications including the treatment of liver disease, rhabdomyolysis, and acute respiratory distress syndrome (ARDS)

Fresenius Medical Care, the largest dialysis company in the world and our strategic partner, has publicly-disclosed that its critical care business, focused primarily on kidney replacement therapy, is approximately €500 million to €1 billion worldwide and has both high strategic value and growth potential for the company. Consistent with this strategy, last year Fresenius and CytoSorbents entered into a global marketing agreement where CytoSorb is helping to "Expand the Dimension of Blood Purification" for both companies as the "featured blood purification therapy for the removal of cytokines (e.g. sepsis and inflammation), bilirubin (e.g. liver disease), and myoglobin (e.g. trauma) on Fresenius' critical care blood pump machines worldwide (excluding the U.S.). The goal is to drive growth of both companies by promoting concurrent utilization of Fresenius' machines and disposables with CytoSorb on a much larger percentage of patients in the ICU. This partnership is expected to launch formally next year.

Similarly, Baxter, the second largest dialysis company globally, has publicly-disclosed that it will spin out its critical care Acute Therapies division and Renal Therapies division into a new U.S. publicly-traded entity, Vantive, next year. In public filings, Baxter has disclosed that its Acute Therapies division generates roughly $700 million in annual revenue worldwide mainly from dialysis, with roughly two-thirds of revenue, or approximately $475 million, coming from outside the U.S., with heavy overlap where we sell CytoSorb®.

The information above puts into perspective the relevance of our high margin sales of CytoSorb, where $31.4 million in trailing twelve-month sales already represents roughly 5-6% of the non-U.S. critical care sales of these market leaders, with the potential for even more growth ahead. It also highlights how uniquely positioned we believe our Company is to open major new avenues of growth in critical care and cardiac surgery, and how this is directly synergistic with our partners in these fields.

3. Managing Cash and Cash Burn

The last formal equity financing that we did was in July 2020, where we raised $57.5 million, before fees. We utilized that capital, together with other cash on hand, to:

- Meet international COVID-19 demand for CytoSorb
- Retire our $15 million term loan facility
- Build out our new state-of-the-art manufacturing facility that has increased our sales capacity five-fold while maintaining high product gross margins
- Fund to completion our U.S. and Canadian pivotal STAR-T randomized controlled trial with strong clinical and regulatory resources to lead it
- Buffer the impact of the post-pandemic effects of COVID
- Invest in key positions throughout the Company to support our future success

This spend has positioned us well, giving us a stronger foundation for the future.

That said, the financing environment for healthcare and life science companies has been challenging to say the least for the past two years, exacerbated by the bear market in small and microcap biotech and medical device stocks, the regional bank financial crisis earlier this year, weak M&A activity, rising interest rates, and many other factors. Even companies with revenue and near-term catalysts like ours have struggled. We have been working to strengthen our balance sheet to give us the financial resources to pursue all of our growth opportunities aggressively, while actively cutting costs across the organization, eliminating non-core programs to focus on core activities. Like many companies, we initiated an equity offering but terminated the process after determining that current market conditions and terms of an offering would not be in the best interests of our shareholders. We are currently focused on a number of alternative sources of capital, including less or non-dilutive debt financing, royalty financing, strategic or direct investments, equity financing, and/or combinations thereof. We believe we benefit from having a valuable and strategic core business that generates high margin sales, and the potential prospect of opening the important U.S. and Canadian markets for DrugSorb-ATR with supportive data. We hope to have an update on this front for shareholders soon.

Back to the Future

As we look forward to 2024 and beyond, we remain excited and confident about the growth prospects for CytoSorb and the potential of opening the U.S. and Canadian markets with DrugSorb-ATR. Either business would be good alone, but together, we expect significant synergies on both sales growth and profitability. Importantly, it represents a path to potentially becoming a truly global leader in acute care blood purification. We thank you for your continued support."

Results of Operations

Comparison for the three months ended September 30, 2023 and 2022:

Revenues:

Revenue from product sales was approximately $7,754,000 in the three months ended September 30, 2023, as compared to approximately $6,463,000 in the three months ended September 30, 2022, an increase of approximately $1,291,000, or 20%. Direct sales increased approximately $586,000, or 16%. Distributor sales increased approximately $705,000, or 25%. The increase in the average exchange rate of the Euro to the U.S. dollar positively impacted third quarter 2023 product sales by approximately $508,000. For the three months ended September 30, 2023, the average exchange rate of the Euro to the U.S. dollar was $1.09 as compared to an average exchange rate of $1.01 for the three months ended September 30, 2022.

Grant income was approximately $1,057,000 for the three months ended September 30, 2023 as compared to approximately $1,649,000 for the three months ended September 30, 2022, a decrease of approximately $592,000, or 36%. This decrease was a result of the conclusion of several grants during the three months ended September 30, 2023.

Total revenues were approximately $8,811,000 for the three months ended September 30, 2023, as compared to total revenues of approximately $8,111,000 for the three months ended September 30, 2022, an increase of approximately $700,000, or 9%.

Cost of Revenues:

For the three months ended September 30, 2023 and 2022, cost of revenue was approximately $3,204,000 and $4,494,000, respectively, a decrease of approximately $1,290,000. Product cost of revenue was approximately $2,161,000 and $2,916,000, respectively, for the three months ended September 30, 2023 and 2022, a decrease of approximately $755,000. The decrease is due primarily to inefficiencies associated with the relocation of our production activities to our new manufacturing facility in Princeton, New Jersey during the three months ended September 30, 2022 that did not recur in 2023. Product gross margins were approximately 72% for the three months ended September 30, 2023 as compared to approximately 55% for the three months ended September 30, 2022.

Research and Development Expenses*:*

For the three months ended September 30, 2023, research and development expenses were approximately $3,749,000, as compared to research and development expenses of approximately $3,290,000 for the three months ended September 30, 2022, an increase of approximately $459,000. This increase was due to an increase in our clinical trial activities of approximately $164,000 resulting from the costs related to our Star-T trial, approximately $147,000 in commercial readiness activities related to DrugSorb ATR and an increase in other non-grant research and development activities of approximately $148,000.

Legal, Financial and Other Consulting Expenses:

Legal, financial, and other consulting expenses were approximately $1,103,000 for the three months ended September 30, 2023, as compared to approximately $610,000 for the three months ended September 30, 2022, an increase of approximately $494,000. This increase was due to costs related to the abandonment of certain patent applications of approximately $183,000, other increases in legal expenses of approximately $42,000, an increase in consulting costs of approximately $152,000 related to regulatory matters on DrugSorb-ATR, an increase in employment agency fees of approximately $93,000 and an increase in accounting fees of approximately $24,000.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were approximately $8,104,000 for the three months ended September 30, 2023, as compared to approximately $8,735,000 for the three months ending September 30, 2022, a decrease of $631,000. This decrease was due to a decrease in advertising costs of approximately $683,000, a decrease in salaries, commissions, and related costs of approximately $28,000, and a decrease in non-cash restricted stock expense of approximately $105,000. These decreases were offset by an increase in non-cash stock compensation expense of approximately $81,000, an increase in travel and entertainment costs of approximately $73,000 and an increase in other general and administrative costs of approximately $31,000.

Loss on Foreign Currency Transactions:

For the three months ended September 30, 2023, the loss on foreign currency transactions was approximately $1,810,000 as compared to a loss of approximately $3,230,000 for the three months ended September 30, 2022. The 2023 loss was directly related to the decrease in the spot exchange rate of the Euro to the U.S. dollar at September 30, 2023 as compared to June 30, 2023. The spot exchange rate of the Euro to the U.S. dollar was $1.06 per Euro at September 30, 2023, as compared to $1.09 per Euro at June 30, 2023. The 2022 loss was directly related to the decrease in the spot exchange rate of the Euro to the U.S. dollar at September 30, 2022 as compared to June 30, 2022. The spot exchange rate of the Euro to the U.S. dollar was $0.98 per Euro at September 30, 2022, as compared to $1.05 per Euro at June 30, 2022.

Comparison for the nine months ended September 30, 2023 and 2022:

Revenues:

Revenue from product sales was approximately $23,736,000 for the nine months ended September 30, 2023, as compared to approximately $21,718,000 for the nine months ended September 30, 2022, an increase of approximately $2,019,000, or 9%. Direct sales increased by approximately $716,000, or 6%. Distributor sales increased by approximately $1,303,000, or 15%. The increase in the average exchange rate of the Euro to the U.S. dollar positively impacted product sales for the nine months ended September 30, 2023 by approximately $404,000. For the nine months ended September 30, 2023, the average exchange rate of the Euro to the U.S. dollar was $1.08 as compared to an average exchange rate of $1.06 for the nine months ended September 30, 2022.

Grant income was approximately $3,945,000 for the nine months ended September 30, 2023 as compared to approximately $3,580,000 for the nine months ended September 30, 2022, an increase of approximately $364,000 or 10%. This increase is the result of the impact of new grants awarded during the nine months ended September 30, 2023.

Total revenues were approximately $27,681,000 for the nine months ended September 30, 2023, as compared to total revenues of approximately $25,298,000 for the nine months ended September 30, 2022, an increase of approximately $2,383,000, or 9%.

Cost of Revenues:

For the nine months ended September 30, 2023 and 2022, cost of revenue was approximately $10,600,000 and $10,322,000, respectively, an increase of approximately $278,000. Product cost of revenue was approximately $6,785,000 and $6,924,000, respectively, for the nine months ended September 30, 2023 and 2022, a decrease of approximately $139,000. The decrease in product cost of revenue was due to a reduction in the cost per device manufactured as we begin to realize production efficiencies at our new manufacturing facility in Princeton, New Jersey. Grant cost of revenue for the nine months ended September 30, 2023 was approximately $3,815,000 as compared to $3,398,000 for the nine months ended September 30, 2022, an increase of approximately $417,000. This increase in cost of grant revenue was due primarily to an increase in grant revenue. Product gross margins were approximately 71% for the nine months ended September 30, 2023 and approximately 68% for the nine months ended September 30, 2022. The increase in product gross margin is due primarily to inefficiencies associated with the relocation of our production activities to our new manufacturing facility in Princeton, New Jersey during the nine months ended September 30, 2022 that did not recur in 2023.

Research and Development Expenses:

For the nine months ended September 30, 2023, research and development expenses were approximately $11,632,000 as compared to approximately $11,717,000 for the nine months ended September 30, 2022, a decrease of approximately $85,000 . This decrease was due to a decrease in costs associated with our clinical trial activities of approximately $1,270,000 related to the pause of our STAR-D trial in November 2022. This decrease was offset by 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, approximately $268,000 of costs related to commercial readiness activities related to DrugSorb ATR and an increase of other non-grant related research and development activities of approximately $67,000.

Legal, Financial and Other Consulting Expenses:

Legal, financial, and other consulting expenses were approximately $2,958,000 for the nine months ended September 30, 2023, as compared to approximately $2,089,000 for the nine months ending September 30, 2022. The increase of approximately $869,000 was due to settlement costs of certain pending litigation matters of approximately $280,000, and increase in legal fees of approximately $205,000, an increase in employment agency fees of approximately $174,000, an increase in consulting costs of approximately $153,000 related to regulatory matters on DrugSorb-ATR, an increase in costs related to the abandonment of certain patent applications of approximately $45,000 and an increase in accounting fees of approximately $12,000.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were approximately $24,358,000 for the nine months ended September 30, 2023, as compared to $26,335,000 for the nine months ended September 30, 2022, a decrease of $1,977,000. This decrease was due to a decrease in salaries, commissions and related costs of approximately $712,000, a decrease in advertising costs of approximately $643,000, a decrease in travel and entertainment expenses of approximately $54,000, a decrease in non-cash stock compensation expense of approximately $67,000, a decrease in commercial insurance expenses of approximately $173,000, a decrease in public relations costs of approximately $156,000, a decrease in royalty expense of approximately $78,000, a decrease in occupancy costs of approximately $83,000 and a decrease in other general and administrative expenses of approximately $11,000.

Loss on Foreign Currency Transactions:

For the nine months ended September 30, 2023, the loss on foreign currency transactions was approximately $734,000 as compared to a loss of approximately $6,967,000 for the nine months ended September 30, 2022. The 2023 loss was directly related to the decrease in the spot exchange rate of the Euro to the U.S. dollar as of September 30, 2023 as compared to December 31, 2022. The spot exchange rate of the Euro to the U.S. dollar was $1.06 per Euro as of September 30, 2023, as compared to $1.07 per Euro at December 31, 2022. The 2022 loss was directly related to the decrease in the spot exchange rate of the Euro to U.S. dollar which was at September 30, 2022 as compared to June 30, 2022. The spot exchange rate of the Euro to the U.S. dollar 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, 2023, we had current assets of approximately $19,261,000 and current liabilities of approximately $11,972,000. As of September 30, 2023, $25 million of our total shelf amount was allocated to our ATM facility, of which approximately $22.8 million is still available. 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.

We are also managing our resources proactively, continuing to invest in key areas such as our U.S. pivotal STAR-T trial and we have instituted tight cost controls.

At September 30, 2023, we have approximately $10.0 million in cash, including approximately $8.4 million and $1.7 million in unrestricted and restricted cash, respectively. We believe this is sufficient to fund the Company's operations through the first quarter of 2024. The Company had commenced a confidential marketing process for an underwritten public offering of its common stock and decided to terminate such process. The termination resulted from an assessment by the Company's Board of Directors and management team that current market conditions were not conducive for the offering on terms that would be in the best interests of the Company's stockholders. The Company continues to pursue alternative sources of capital, which may include debt financing, royalty financing, strategic or direct investments, equity financing and/or combinations thereof.

Q3 2023 Earnings Conference Call

The Company will conduct its third quarter 2023 results call today at 4:30 p.m. Eastern time.

Conference Call Details:
Date: Thursday, November 9, 2023
Time: 4:30 PM Eastern Time
Live Presentation Webcast: https://edge.media-server.com/mmc/p/9egdsb9a

Participant Dial in:
United States - New York +1.646.968.2525
USA & Canada - Toll-Free +1.888.596.4144
Conference ID: 5576338

For either the webcast or conference call, it is recommended that participants log or 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 https://ir.cytosorbents.com/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 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 Q3 2023, more than 221,000 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 enrollment in 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, statements about potential exposures resulting from our cash positions, representations and contentions, and are not historical facts and typically are identified by use of terms such as "may," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements in this press release represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. Factors which could cause or contribute to such differences include, but are not limited to, the risks discussed in our Annual Report on Form 10-K, filed with the SEC on March 9, 2023, as updated by the risks reported in our Quarterly Reports on Form 10-Q, and in the press releases and other communications to shareholders issued by us from time to time which attempt to advise interested parties of the risks and factors which may affect our business. We caution you not to place undue reliance upon any such forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, other than as required under the Federal securities laws.

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue:				
CytoSorb sales	$ 7,709	$ 6,271	$ 23,681	$ 21,176
Other sales	45	191	55	542
Total product sales	7,754	6,462	23,736	21,718
Grant income	1,057	1,649	3,945	3,580
Total revenue	8,811	8,111	27,681	25,298
Cost of revenue	3,204	4,494	10,600	10,322
Gross profit	5,607	3,617	17,081	14,976
Other Expenses:				
Research and development	3,749	3,290	11,632	11,717
Legal, financial and other consulting	1,104	609	2,958	2,089
Selling, general and administrative	8,104	8,735	24,359	26,335
Total expenses	12,957	12,634	38,949	40,141
Loss from operations	(7,350)	(9,017)	(21,868)	(25,165)
Other income/(expense):				
Interest income (expense), net	(34)	47	(106)	79
Gain (loss) on foreign currency transactions	(1,809)	(3,231)	(734)	(6,967)
Miscellaneous Income (Expense)	-----	-----	35	7
Total other income (expense), net	(1,843)	(3,184)	(805)	(6,881)
Loss before benefit from income taxes	(9,193)	(12,201)	(22,673)	(32,046)
Benefit from income taxes	----	----	----	----
Net loss	$ (9,193)	$ (12,201)	$ (22,673)	$ (32,046)
Basic and diluted net loss per common share	$ (0.21)	$ (0.28)	$ (0.52)	$ (0.74)
Weighted average number of shares of common stock outstanding	44,373,969	43,606,980	44,024,483	43,552,238
Net loss	$ (9,193)	$ (12,201)	$ (22,673)	$ (32,046)
Other comprehensive income (loss):				
Currency translation adjustment	1,656	2,659	655	5,675
Comprehensive loss	$ (7,537)	$ (9,542)	$ (22,018)	$ (26,371)

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	September 30, 2023	December 31, 2022
ASSETS:		
Current Assets:		
Cash and cash equivalents	$ 8,359	$ 22,145
Grants and accounts receivable, net	6,179	5,665
Inventories	2,977	3,461
Prepaid expenses and other current assets	1,746	2,489
Total current assets	19,261	33,760
Property and equipment, net	10,282	10,743
Restricted Cash	1,687	1,687
Right of use asset	12,196	12,604
Other assets	4,149	4,438
TOTAL ASSETS	$ 47,575	$ 63,232
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current Liabilities:		
Accounts payable	$ 3,442	$ 1,655
Current maturities of long-term debt	833	----
Lease liability - current portion	117	109
Accrued expenses and other current liabilities	7,580	7,951
Total current liabilities	11,972	9,715
Lease liability, net of current portion	12,892	13,142
Long-term debt, net of current maturities	4,199	5,000
TOTAL LIABILITIES	29,063	27,857
Total stockholders' equity	18,512	35,375
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 47,575	$ 63,232

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