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): August 1, 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 August 1, 2023, the CytoSorbents Corporation (the "Company") issued a press release announcing its financial results for the quarter ended June 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 August 1, 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: August 1, 2023

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

CytoSorbents Reports Second Quarter 2023 Financial and Operational Results

Q2 2023 Total Revenue was $9.4 million, an 11% increase from $8.5 million in Q2 2022. Product sales rose 10% to $8.1 million vs $7.3 million in Q2 2022. Product gross margins grew 700 basis points to 74%

PRINCETON, N.J., August 1, 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 June 30, 2023.

Second Quarter 2023 Financial Results

- Total revenue for Q2 2023, including product sales and grant income, was $9.4 million, an increase of 11% compared to $8.5 million in Q2 2022
- Q2 2023 product sales were $8.1 million versus $7.3 million in Q2 2022, an increase of 10%. The increase in the average exchange rate of the Euro to the U.S. dollar positively impacted Q2 2023 product sales by approximately $187,000
- As expected, there were no COVID-19 related sales during the quarter, reflecting the low severity of current COVID-19 illness resulting from high rates of vaccination, anti-viral therapy, and natural immunity
- Product gross margins were approximately 74% in Q2 2023, compared to 68% in Q1 2023 and 67% in Q2 2022
- Total cash, including cash and cash equivalents, and restricted cash was $14.8 million as of June 30, 2023

Recent Operating Highlights:

- The pivotal STAR-T trial completed enrollment ahead of internal projections among 30 participating trial centers in the U.S. and Canada. This follows the recommendation by the independent Data and Safety Monitoring Board (DSMB) in June 2023 to complete the trial without modifications, after it finished the second scheduled safety review at 80 patients enrolled

- More than 212,000 CytoSorb devices have been cumulatively delivered across more than 75 countries worldwide as of the end of Q2 2023
- Appointed Alexander D'Amico as Chief Financial Officer, who brings over 20 years of broad finance, SEC reporting, merger and acquisition, fundraising, and accounting experience to CytoSorbents, to start August 7, 2023. Interim CFO Kathy Bloch will continue to serve in a consulting capacity
- Introduced Michael Bator as the new Chairman of the Board of Directors at the Annual Meeting in June, following the retirement of Al Kraus as former Chairman. A director of CytoSorbents since July 2015, Michael is founder and Partner of Quartz Advisory Group, a capital markets investment bank, and was formerly Managing Director of Healthcare Research at Jennison Associates, a multi-strategy buy-side family of investment funds with more than $175 billion of assets under management
- Announced a theranostic collaboration with Humedics in the field of liver disease, focused on a joint promotion of CytoSorb, a superior extracorporeal liver support blood purification therapy, and Humedics' LiMAx® test, a rapid and precise E.U. approved diagnostic using its innovative breath analysis technology to quantitatively assess liver function

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, "We are pleased to report another successful quarter of executing on our three key business objectives for 2023. Most importantly, we expect to complete the pivotal STAR-T randomized, controlled trial imminently, following the 30-day follow-up of the last patient, which we believe puts us on target for topline data before the end of the year.

1. Opening the U.S. and Canadian markets with DrugSorb®-ATR

We continue to march towards our goal of opening the U.S. and Canadian markets with DrugSorb-ATR through the STAR-T (**S**afe and **T**imely **A**ntithromobotic **R**emoval of **T**icagrelor) and pending STAR-D programs. We thank our U.S. and Canadian STAR-T clinical trial investigators and centers, study Principal Investigators, contract research organizations, and the clinical team at CytoSorbents, for an outstanding performance in the study and for completing enrollment well ahead of schedule. We are also pleased the independent DSMB, following two scheduled reviews of unblinded safety data on the first 80 patients, recommended completion of the study without modifications in June.

We have been working with centers in parallel during the STAR-T study to ensure timely entry and monitoring of data, and despite enrolling the final 60 patients in the last 2.5 months of the study with a lot of work ongoing, we expect to formally complete the study shortly and drive data cleaning and database lock in the next several months. This will be followed by statistical analysis of the data, which we believe will enable us to achieve our goal of announcing topline data before year-end. Meanwhile, our regulatory personnel have been coordinating the resources of the company to assemble the regulatory dossier needed to submit for marketing approval to U.S. FDA and Health Canada, which we plan to do as soon as possible assuming positive clinical study data. We plan to follow this with a formal presention of the data at a major U.S. cardiovascular conference. With improved visibility on future approval, we expect to execute our pre-commercialization strategy and begin building our sales and marketing infrastructure next year.

DrugSorb-ATR targets a large and growing market opportunity that exists today and we expect it to further accelerate as low-cost generic versions of ticagrelor become available starting in 2024. For example, the need to remove Brilinta® (ticagrelor, AstraZeneca) in patients with acute coronary syndrome who have received dual anti-platelet therapy (aspirin and a P2Y12 platelet inhibitor), but now require coronary artery bypass graft (CABG) surgery, is highlighted by the rapid speed of patient enrollment in the U.S. and Canadian STAR-T trial. Today, physicians have the choice of using different P2Y12 anti-platelet drugs, including Brilinta®, Plavix® (clopidogrel, BMS/Sanofi), and Effient® (prasugrel, Eli Lilly, Daiichi Sankyo, UBE). Although Brilinta has superior antithrombotic efficacy to Plavix, Plavix is still widely used because it is generic and less expensive. However, since Brilinta is expected to become generic ticagrelor in 2024, we believe it will take market share from both Plavix and Effient as the price of ticagrelor drops. In addition, if DrugSorb-ATR is approved to remove Brilinta, Brilinta will become the only P2Y12 platelet inhibitor with a solution available to allow timely surgery in patients on the drug – a powerful marketing message to prescribing cardiologists and emergency room physicians who know that 5-10% of patients with acute coronary syndrome treated with a P2Y12 inhibitor will not be candidates for stent placement and will require surgery and be at high risk of potentially fatal perioperative bleeding.

The preference for Brilinta (ticagrelor) by U.S. cardiologists has been highlighted recently in the prestigious JAMA Network Open publication, entitled, “Assessing the Clinical Treatment Dynamics of Antiplatelet Therapy Following Acute Coronary Syndrome and Percutaneous Coronary Intervention in the US” where in a cohort study of more than 62,000 patients from 2010-2019 demonstrated that “ticagrelor has emerged as the most commonly prescribed P2Y12 inhibitor” following acute coronary syndrome and percutaneous coronary intervention. The rise of ticagrelor usage in this setting can be easily seen in Figure 1, where in 2019, ticagrelor was the drug of choice in 60.4% of cases, while clopidogrel (Plavix®) dropped to 29.6%, and prasugrel (Effient®) dropped to 10.0% of cases. We believe this trend bodes well for DrugSorb-ATR and supports our contention that the U.S. and Canadian ticagrelor market will expand over time.

With STAR-T enrollment complete, our clinical team is now focused on the activities leading up to the analysis of the results, and if positive, preparation of the documentation needed for our planned U.S. and Health Canada regulatory submissions for DrugSorb-ATR. When appropriate, we plan to continue our STAR (Safe and Timely Antithrombotic Removal) program with the resumption of the STAR-D trial, that will evaluate the use of DrugSorb-ATR to remove the direct oral anticoagulant (DOAC) Factor Xa inhibitors, Eliquis and Xarelto (among the highest revenue generating pharmaceuticals in the world), and to reduce bleeding risk in cardiothoracic surgery patients on these agents. We plan to leverage the same site network as in STAR-T and based on their feedback that they routinely encounter patients on DOACs needing cardiac surgery and their proven track record of trial execution, we believe the STAR-D trial can be run quickly and cost-effectively.

Finally, CMS recently announced details surrounding the Transitional Coverage for Emerging Technologies (TCET) program and are currently in the public comment period. The current proposed program falls short of what was widely anticipated by the medical device community and its trade organization, Advamed, providing a transparent pathway for securing dedicated CMS national coverage of FDA Breakthrough Designated Devices within 6 months of FDA clearance or approval, but departing from the automatic four-year national coverage upon FDA approval of qualified Breakthrough Devices that was discussed by CMS previously. We expect there to be ongoing discussion and possible modification of the program. We believe DrugSorb-ATR, as a Breakthrough Designated Device whose core target population falls squarely in the age group covered by Medicare, would still be an excellent candidate for this TCET program and we will continue to follow the story as it develops. Meanwhile, the STAR-T trial is expected to provide significant health economics data to support reimbursement through traditional private and public insurance pathways.

2. Return to Sales Growth for CytoSorb

CytoSorb targets the massive critical care and cadiac surgery markets outside the U.S., helping to control deadly inflammation and other life-threatening conditions such as sepsis, lung injury, trauma, burn injury, liver failure, complications of surgery, cytokine release syndrome in cancer immunotherapy, and many others. Following a post-COVID slowdown in hospital-based markets globally in 2022, we are pleased to report our third consecutive quarter of sequential product sales growth and a 10% increase in Q2 2023, year-over-year. With many new growth initiatives, and importantly new leadership in key positions in our therapy area verticals and our overall commercialization organization, we anticipate further momentum of our business over time. Importantly, product gross margins have rebounded 700 basis points to 74%, a trend consistent with our guidance of returning to 75-80% product gross margins on a quarterly basis this year. Our new manufacturing facility is fully online and producing CytoSorb devices in volume.

We believe there is now no question of what we have known for years - that CytoSorb is a powerful treatment of cytokine storm, particularly following the landmark publication in the journal Critical Care, describing the excellent effect of CytoSorb on reducing systemic cytokine levels in a well-controlled human endotoxin challenge model. We have learned a lot over the past 11 years of CytoSorb commercialization and the more than 200,000 human treatments administered to date in patients that are literally battling between life and death. Every study that has been published - positive, neutral, or negative - has taught us more about how to best treat patients with CytoSorb. We have distilled it down to the very simple message of "***Right Patient, Right Timing, Right Dose.***"

The concept of treating the right patient at the right time with the right dose to have good clinical outcomes is, in fact, relevant to most therapies. For example, antibiotics are some of the most commonly used drugs in the intensive care unit and are a perfect analogy for CytoSorb. Certainly you need antibiotics to kill the pathogen and to survive a life-threatening infection, just as you need to control the deadly massive inflammatory response in sepsis with CytoSorb. But despite antibiotics and the best standard of care (excluding CytoSorb), approximately 20-25% of patients with sepsis and organ dysfunction will die, and 35-50% of patients with septic shock will still die. A lot of these failures can be traced back to not following the "Right Patient, Right Timing, Right Dose" mantra. For example, if a patient with an infection is misdiagnosed and treated with the wrong antibiotic, it will not work (e.g. treating COVID-19 with penicillin instead of Paxlovid®). Or if an infection is not treated with antibiotics until the infection has spiraled out of control and the patient develops sepsis – then this is 'too little too late.' Or if the dose of the antibiotic is not adjusted for the severity of illness, the antibiotic may not work optimally.

This is why for the past several years, thanks to the observations of many dedicated CytoSorb users around the world, we have been emphasizing the "Right patient, right timing, and right dose" with the early and aggressive treatment of patients with clear evidence of hyperinflammation. Many of the older studies, for example, used CytoSorb relatively late in patients that had already developed kidney failure and were on dialysis, a generally later stage complication in critical illness that itself increases the risk of death, making it more difficult to demonstrate a benefit. Other studies did not evaluate the inflammatory status of patients. But when CytoSorb is used early and aggressively in documented hyperinflamed patients, we have seen some outstanding results. This includes the recently published final CTC (CytoSorb Therapy in COVID-19) Registry results in the journal, Critical Care, detailing the clinical outcomes in 100 critically-ill COVID-19 patients with severe inflammation and refractory lung failure using CytoSorb with ECMO to achieve "enhanced lung rest". Overall, 90-day survival was high at 74% and in a post-hoc analysis, patients who were treated before the median treatment time of 87 hours had 82% survival, compared to 66% survival in patients treated after 87 hours. In addition, those treated in the early group had significantly shorter median durations of mechanical ventilation (7 [2–26] vs. 17 [7–37] days, p=0.02), ECMO support (13 [8–24] vs. 29 [14–38] days, p=0.021) and ICU stay (17 [10–40] vs 36 [19–55] days, p=0.002). Importantly, no device-related adverse events were reported. Overall, our results compare favorably to the approximately 50% survival reported by the Extracorporeal Life Support Organization (ECMO) COVID-19 registry looking at ECMO use alone in this population. Our data support the strategy of early combined usage of CytoSorb with ECMO to treat severe ARDS and refractory lung failure and is a prime example of our "hit early, hit hard" treatment philosophy.

To this end, our current Company-sponsored trials, such as the PROCYSS refractory septic shock randomized trial, and the international COSMOS critical illness registry, incorporate our evolving understanding of how to achieve better and more consistent results with CytoSorb. We have also been working to drive earlier usage of CytoSorb in the appropriate patients through a number of different ways, including for example, pursuing a theranostic strategy (i.e. using a diagnostic test to guide patient selection and timing of CytoSorb therapy) as we are doing in our collaboration with Humedics in the field of liver disease, or by selling a simple-to-use, relatively low cost hemoperfusion machine that can run CytoSorb quickly and efficiently, without needing to wait for patients to develop kidney failure and go on dialysis.

3. Reduced Cash Burn and Tight Control Over Expenses

Based upon our various cost controls implemented over the past 12 months, along with an improvement in sales and product gross margins, our quarterly cash burn during the first half of 2023 averaged approximately $4.5 million, down significantly from the average quarterly burn in the first half of 2022 of approximately $11 million. We closed the quarter with approximately $14.8 million in cash and we believe a runway to multiple catalysts for our business."

Dr Chan continued, "Overall, we are excited about completing the STAR-T trial and potentially being on the cusp of reporting topline data by the end of the year and the full data set analysis shortly thereafter. If positive, these data could lead to U.S. FDA and Health Canada marketing approval for DrugSorb-ATR, and importantly, commercial revenue targeting an initial $300 million total addressable market in these two countries alone. Meanwhile, the gradual but steady recovery we are seeing for CytoSorb is expected to build momentum as the hospital markets recover, with anticipated future growth of the therapy in so many different clinical indications addressing multi-billion dollar markets. If we are successful, we believe CytoSorb and DrugSorb-ATR could transform CytoSorbents into a dual U.S. and international growth company, fueled by two major high margin revenue engines, helping to drive significant shareholder value."

Dr. Chan concluded, “Finally we would like to thank former Chairman Al Kraus and CFO Kathy Bloch for their 20 and 10 years of service, respectively, and their countless contributions to the success of the Company, and wish them well in retirement. We also would like to congratulate Michael Bator as our new Chairman of the Board of Directors and to welcome Alex D’Amico as our new Chief Financial Officer.”

Results of Operations

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

Revenues:

Revenue from product sales was approximately $8,072,000 in the three months ended June 30, 2023, as compared to approximately $7,331,000 in the three months ended June 30, 2022, an increase of approximately $741,000, or 10%. Direct sales increased approximately $331,000, or 8%. Distributor sales increased approximately $410,000, or 14%. The increase in the average exchange rate of the Euro to the U.S. dollar positively impacted second quarter 2023 product sales by approximately $187,000. For the three months ended June 30, 2023, the average exchange rate of the Euro to the U.S. dollar was $1.09 was compared to an average exchange rate of $1.06 for the three months ended June 30, 2022. There were no sales related to the demand for CytoSorb to treat COVID-19 patients during the three months ended June 30, 2023, or for the three months ended June 30, 2022.

Grant income was approximately $1,348,000 for the three months ended June 30, 2023, as compared to approximately $1,165,000 for the three months ended June 30, 2022, an increase of approximately $183,000, or 16%. This increase was a result of a strategic decision to deploy our research and development employees exclusively to grant related activities during the three months ended June 30, 2023.

Total revenues were approximately $9,421,000 for the three months ended June 30, 2023, as compared to total revenues of approximately $8,496,000 for the three months ended June 30, 2022, an increase of approximately $925,000, or 11%.

Cost of Revenues:

For the three months ended June 30, 2023, and 2022, cost of revenue was approximately $3,402,000 and $3,551,000, respectively, a decrease of approximately $149,000. Product cost of revenue was approximately $2,093,000 and $2,453,000, respectively, for the three months ended June 30, 2023, and 2022, a decrease of approximately $360,000. 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 second quarter of 2022 that did not recur in the second quarter of 2023. Product gross margins were approximately 74% for the three months ended June 30, 2023, as compared to approximately 67% for the three months ended June 30, 2022.

Research and Development Expenses:

For the three months ended June 30, 2023, research and development expenses were approximately $3,669,000, as compared to research and development expenses of approximately $4,183,000 for the three months ended June 30, 2022, a decrease of approximately $514,000. This decrease was due to a decrease in our clinical trial activities of approximately $627,000 related to the pause of our STAR-D trial in November 2022. This decrease was offset by approximately $70,000 of costs incurred related to pre-production manufacturing activities required to bring the new manufacturing plant to a state of commercial readiness and an increase in non-grant related research and development costs of approximately $43,000.

Legal, Financial, and Other Consulting Expenses:

Legal, financial, and other consulting expenses were approximately $1,185,000 for the three months ended June 30, 2023, as compared to approximately $679,000 for the three months ended June 30, 2022, an increase of approximately $506,000. This increase was due to an increase in legal fees and expected settlement costs of pending litigation of approximately $306,000, other increases in legal expenses of approximately $174,000, and the write-off of certain patent costs and an increase in accounting fees and other consulting fees of approximately $26,000.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were approximately $7,724,000 for the three months ended June 30, 2023, as compared to approximately $8,439,000 for the three months ending June 30, 2022, a decrease of $715,000. This decrease was due to a decrease in non-cash stock compensation expense of approximately $191,000, a decrease in travel and entertainment expenses of approximately $99,000, a decrease in public relations costs of approximately $96,000, a decrease in advertising costs of approximately $82,000, a decrease in royalty expense of approximately $73,000, a decrease in commercial insurance of approximately $56,000, a decrease in salaries, commissions and related costs of approximately $43,000, and a decrease in other general and administrative expenses of approximately $75,000.

Gain (Loss) on Foreign Currency Transactions:

For the three months ended June 30, 2023, the gain on foreign currency transactions was approximately $415,000 as compared to a loss of approximately $2,523,000 for the three months ended June 30, 2022. The 2023 gain was directly related to the increase in the spot exchange rate of the Euro to the U.S. dollar at June 30, 2023 as compared to March 31, 2023. The spot exchange rate of the Euro to the U.S. dollar was $1.091 per Euro at June 30, 2023, as compared to $1.086 per Euro at March 31, 2023. The 2022 loss was directly related to the decrease in the spot exchange rate of the Euro at June 30, 2022 as compared to March 31, 2022. The spot exchange rate of the Euro to the U.S. dollar was $1.05 per Euro as of June 30, 2022, as compared to $1.11 per Euro as of March 31, 2022.

Comparison for the six months ended June 30, 2023, and 2022:

Revenues:

Revenue from product sales was approximately $15,982,000 for the six months ended June 30, 2023, as compared to approximately $15,255,000 for the six months ended June 30, 2022, an increase of approximately $727,000, or 5%. Distributor sales increased by approximately $597,000, or 10%. Overall direct sales increased by approximately $130,000, or 1%. The change in the exchange rate of the Euro to U.S. dollar did not have a significant impact on product sales during the six months ended June 30, 2023.

Grant income was approximately $2,888,000 for the six months ended June 30, 2023, as compared to approximately $1,932,000 for the six months ended June 30, 2022, an increase of approximately $956,000 or 49%. During the six months ended June 30, 2022, 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 2023, research and development employees were assigned exclusively to grant and other research and development activities.

Total revenues were approximately $18,870,000 for the six months ended June 30, 2023, as compared to total revenues of approximately $17,187,000 for the six months ended June 30, 2022, an increase of approximately $1,683,000, or 10%.

Cost of Revenues:

For the six months ended June 30, 2023 and 2022, cost of revenue was approximately $7,396,000 and $5,828,000, respectively, an increase of approximately $1,568,000. Product cost of revenue was approximately $4,624,000 and $4,008,000, respectively, for the six months ended June 30, 2023 and 2022, an increase of approximately $616,000 and grant cost of revenue increased by approximately $952,000. These increases were due primarily to increases in both product sales and grant revenue. Product gross margins were approximately 71% for the six months ended June 30, 2023, and approximately 74% for the six months ended June 30, 2022. The reduction in product gross margin is due primarily to start-up costs associated with our new manufacturing facility in Princeton, New Jersey during the six months ended June 30, 2023.

Research and Development Expenses:

For the six months ended June 30, 2023, research and development expenses were approximately $7,883,000 as compared to research and development expenses of approximately $8,427,000 for the six months ended June 30, 2022, a decrease of approximately $544,000. This decrease was due to a decrease in costs associated with our clinical trial activities of approximately $1,434,000 related to the pause of our STAR-D trial in November 2022, and a decrease in non-grant related research and development activities of approximately $29,000. These decreases were offset by approximately $919,000 of costs incurred related to pre-production manufacturing activities required to bring the new manufacturing plant to a state of commercial readiness.

Legal, Financial, and Other Consulting Expenses:

Legal, financial, and other consulting expenses were approximately $1,854,000 for the six months ended June 30, 2023, as compared to approximately $1,480,000 for the six months ending June 30, 2022. The increase of approximately $374,000 was due an increase in legal fees and expected settlement costs of pending litigation of approximately $306,000 and an increase in employment agency fees of approximately $80,000. These increases were offset by a decrease in consulting fees of approximately $12,000.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were approximately $16,187,000 for the six months ended June 30, 2023, as compared to $17,600,000 for the six months ended June 30, 2022, a decrease of $1,413,000. This decrease was due to a decrease in salaries, commissions and related costs of approximately $683,000, a decrease in non-cash stock compensation expense of approximately $148,000, a decrease in commercial insurance expenses of approximately $131,000, a decrease in travel and entertainment expenses of approximately $127,000, a decrease in public relations costs of approximately $119,000, a decrease in advertising costs of approximately $100,000, a decrease in royalty expense of approximately $68,000 and a decrease in other general and administrative expenses of approximately $37,000.

Gain (Loss) on Foreign Currency Transactions:

For the six months ended June 30, 2023, the gain on foreign currency transactions was approximately $1,076,000 as compared to a loss of approximately $3,736,000 for the six months ended June 30, 2022. The 2023 gain was directly related to the increase in the spot exchange rate of the Euro to the U.S. dollar as of June 30, 2023, as compared to December 31, 2022. The spot exchange rate of the Euro to the U.S. dollar was $1.09 per Euro as of June 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 as of June 30, 2022, as compared to 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 June 30, 2023, we had current assets of approximately $23,644,000 and current liabilities of approximately $10,351,000. As of June 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. We have instituted tight cost controls which are expected to materially reduce our planned cash burn in 2023.

We believe that we have sufficient cash to fund the Company’s operations through 2023. We will need to raise additional capital to support our ongoing operations in the future.

Q2 2023 Earnings Conference Call

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

Conference Call Details:
Date: Tuesday, August 1, 2023
Time: 4:30 PM Eastern Time
Live Presentation Webcast:
https://edge.media-server.com/mmc/p/ux9gjyvu

For those participants who cannot join by webcast, we are pleased to offer a conference call option accessible through the following link:
https://register.vevent.com/register/BIb5f023a4734446ce8e778065c2d484d9

- Click on the call link and complete the online registration form.
- Upon registering you will receive the dial-in info and a unique PIN to join the call, as well as an email confirmation with the details.
- Select a method for joining the call.
- Dial-In: A dial in number and unique PIN are displayed to connect directly from your phone.
- Call Me: Enter your phone number and click “Call Me” for an immediate callback from the system.
- 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 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 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 Q2 2023, more than 212,000 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 is currently completing 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 $48 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 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 June 30,		Six months ended June 30,	
	2023	2022	2023	2022
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue:				
CytoSorb sales	$ 8,066	$ 7,038	$ 15,972	$ 14,905
Other sales	6	293	10	350
Total product sales	8,072	7,331	15,982	15,255
Grant income	1,349	1,165	2,888	1,932
Total revenue	9,421	8,496	18,870	17,187
Cost of revenue	3,402	3,551	7,396	5,828
Gross profit	6,019	4,945	11,474	11,359
Other Expenses:				
Research and development	3,669	4,184	7,883	8,427
Legal, financial and other consulting	1,185	679	1,854	1,480
Selling, general and administrative	7,724	8,439	16,188	17,600
Total expenses	12,578	13,302	25,925	27,507
Loss from operations	(6,559)	(8,357)	(14,451)	(16,148)
Other income/(expense):				
Interest income (expense), net	(9)	24	(72)	32
Gain (loss) on foreign currency transactions	415	(2,523)	1,076	(3,736)
Miscellaneous Income (Expense)	--	(23)	(32)	6
Total other income (expense), net	406	(2,522)	972	(3,698)
Loss before benefit from income taxes	(6,153)	(10,879)	(13,479)	(19,846)
Benefit from income taxes	--	--	--	--
Net loss	$ (6,153)	$ (10,879)	$ (13,479)	$ (19,846)
Basic and diluted net loss per common share	$ (0.14)	$ (0.25)	$ (0.31)	$ (0.46)
Weighted average number of shares of common stock outstanding	44,015,380	43,560,481	43,758,888	43,524,414
Net loss	$ (6,153)	$ (10,879)	$ (13,479)	$ (19,846)
Other comprehensive income (loss):				
Currency translation adjustment	(393)	2,053	(1,001)	3,016
Comprehensive loss	$ (6,546)	$ (8,826)	$ (14,480)	$ (16,830)

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	June 30, 2023	December 31, 2022
ASSETS:		
Current Assets:		
Cash and cash equivalents	$ 13,151	$ 22,145
Grants and accounts receivable, net	7,025	5,665
Inventories	2,046	3,461
Prepaid expenses and other current assets	1,422	2,489
Total current assets	23,644	33,760
Property and equipment, net	10,502	10,743
Restricted Cash	1,687	1,687
Right of use asset	12,334	12,604
Other assets	4,278	4,438
TOTAL ASSETS	$ 52,445	$ 63,232
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current Liabilities:		
Accounts payable	$ 2,836	$ 1,655
Lease liability - current portion	114	109
Accrued expenses and other current liabilities	7,401	7,951
Total current liabilities	10,351	9,715
Lease liability, net of current portion	12,978	13,142
Long-term debt	5,021	5,000
TOTAL LIABILITIES	28,350	27,857
Total stockholders' equity	24,095	35,375
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 52,445	$ 63,232

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