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 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 March 9, 2023, CytoSorbents Corporation (the "Company") issued a press release announcing its financial results for the quarter and twelve-months ended December 31, 2022. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release of the Company, dated March 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: March 9, 2023

CYTOSORBENTS CORPORATION

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

Exhibit 99.1

CytoSorbents Reports Fourth Quarter and Full Year 2022 Results

Pivotal U.S. and Canada STAR-T Trial enrollment passes halfway mark. Positive sales momentum from Q4 2022 continues in Q1 2023 to date, with expectation of sales growth in 2023

PRINCETON, N.J., March 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 financial and operating results for the quarter and year ended December 31, 2022 and provides its 2023 outlook.

Full Year 2022 Financial Results

- 2022 Total Revenue, which includes Product Sales and Grant Income, was $34.7 million versus $43.2 million in 2021, a decrease of 20%
- 2022 Product sales were $29.4 million versus $40.1 million in 2021, which included $0.3 million and $6.3 million in COVID-19 related Product Sales, respectively
- 2022 Core (non-COVID-19) Product Sales were approximately $29.1 million versus $33.8 million in 2021. This reflects an 11% drop in the average Euro to dollar exchange rate from 1.18 in 2021 to 1.05 in 2022. On a constant currency basis, Core Product Sales in 2022 would have been approximately $32.2 million versus $33.8 million in 2021, a decrease of 4.6%
- The decrease in the average Euro to US dollar exchange rate negatively impacted 2022 product sales by approximately $3.1 million
- 2022 Product Gross Margin was approximately 70%, compared to 80% in 2021 due to manufacturing inefficiencies related to the relocation of our manufacturing operations to our new facility
- We believe the Company remains well-capitalized with cash and cash equivalents of $23.8 million (which includes $1.7 million in restricted cash) at December 31, 2022

Fourth Quarter 2022 Financial Results

- Q4 2022 Total Revenue, which includes Product Sales and Grant Income, was $9.4 million versus $10.8 million in Q4 2021, a decrease of 13%
- Q4 2022 Product Sales were $7.6 million versus $9.7 million in Q4 2021. COVID-19 related sales were negligible in Q4 2022 and an estimated $1.7 million in Q4 2021.
- Core Product Sales in Q4 2022 were $7.6 million compared to $8.0 million in Q4 2021. On a constant currency basis, core Q4 2022 Product Sales would have been $8.5 million, a 6% increase over $8.0 million in Q4 2021
- The decrease in the average Euro to US dollar exchange rate lowed Q4 2022 product sales by approximately $0.9 million.
- Q4 2022 product sales of $7.6 million rose 18% sequentially from $6.5 million in Q3 2022
- Q4 2022 product gross margin was approximately 75%, compared to 78% in Q4 2021 due to manufacturing inefficiencies related to the relocation of our manufacturing operations to our new facility, and other factors

Recent Operating Highlights

- Cumulative CytoSorb treatments delivered exceeded 195,000 at the end of 2022, up 20% from the end of 2021, and marking the 10^{th} year of CytoSorb commercialization
- The pivotal STAR-T randomized controlled trial achieved its first milestone of 40 patients enrolled, out of a target 120 patients, triggering a pre-specified Data and Safety Monitoring Board (DSMB) review
- The STAR-T independent DSMB conducted a review of unblinded data from the first 40 patients in the study and recommended the trial continue as planned without any modifications
- Announced that Health Canada has approved the STAR-T protocol, allowing inclusion of Canadian sites into the study
- Welcomed Dr. Richard Whitlock, MD, PhD, Professor of Surgery at McMaster University Medical School, and Canada Research Chair in Cardiovascular Surgery for the Population Health Research Institute, as the Canada Principal Investigator of the STAR-T trial, bringing an outstanding track record of clinical trial execution and a superb network of Canadian clinical trial centers specializing in cardiac surgery studies to the program
- Hemoadsorption was included into the European “Guidelines for the management of severe perioperative bleeding” for the first time, based on published clinical data using our hemoadsorption technology to remove antithrombotic agents and reduce bleeding risk during cardiothoracic surgery

- Appointed Dr. Irina Kulinets as Senior Vice President of Global Regulatory and newest member of the senior management team. She will lead the DrugSorb-ATR regulatory submission for marketing approval to the U.S. FDA and Health Canada. She brings more than 30 years of experience in regulatory affairs and clinical research, where she has had an extensive track record of international regulatory success with the approval/clearance of medical products, including many Class II 510(k) and Class III Premarket Approval (PMA) medical devices
- Strengthened our cash balance with $5 million in a non-dilutive debt financing from Bridge Bank

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents, stated, "We are pleased to provide a brief update from our Stockholder Letter issued on January 31, 2023. If you have not already done so, we encourage you to review the letter, which highlights what we believe is our unique and compelling value proposition, and the proximity of major potential near-term catalysts, including the expected completion of the pivotal STAR-T RCT this year with the intent, with positive data, to submit for U.S. FDA and Health Canada marketing approval, and an expected return to Product Sales growth based on numerous growth initiatives.

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. After achieving the first milestone of 40 patients enrolled in mid-November 2022, study enrollment is now past the halfway point and we believe we will achieve the second milestone of 80 patients enrolled this spring, which will trigger the second pre-specified DSMB review of unblinded data. Enrollment in the study has been accelerating, aided by broad participation of U.S. centers and multiple patients enrolled from initial Canadian centers as well. Because of the current fast pace of the study, we expect to complete enrollment at 120 patients this summer, with database lock, final data analysis, and DSMB closeout review to follow.

If the results of the study are positive, U.S. FDA and Health Canada regulatory submissions are planned following the completion of the study. This is a significant undertaking with preparatory work already in process, now led by our new SVP of Global Regulatory, Dr. Irina Kulinets. Meanwhile, we have developed a detailed launch and commercialization strategy for DrugSorb-ATR, led by COO and President, Vince Capponi, and our VP of US Sales and Marketing, Jim Komsa, and are pursuing our pre-commercial development in parallel to the study.

Other STAR Updates

Our decision to voluntarily pause the pivotal STAR-D (**S**afe and **T**imely **A**ntithrombotic **R**emoval – **D**irect oral anticoagulants) clinical trial has enabled us to focus our resources and those of our study centers on the STAR-T study and to save an anticipated $4M in clinical trial expense this year. That said, with the completion of the STAR-T trial, we intend to resume the STAR-D trial, and leverage the majority of clinical trial centers participating in STAR-T to complete that study quickly. If the results are positive, U.S. FDA and Health Canada marketing approval would double the total addressable market in the U.S. and Canada to more than $1 billion for DrugSorb-ATR as a "one-stop shop" for antithrombotic drug removal in cardiothoracic surgery, and spur sales internationally.

Meanwhile in Europe, the STAR registry that collects real-world evidence on the use of our technology to remove blood thinners during cardiothoracic surgery has now over 200 patients from 12 centers, well ahead of our projected enrollment. Data readouts from the registry commence at the large interventional cardiology conference, EuroPCR in Paris this May, with additional analyses submitted to the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) conferences later this year.

Finally, as we discussed in the press release earlier this week, we were pleased to see for the first time, the inclusion and recommendation of hemoadsorption in the European Guidelines to help manage perioperative bleeding risk in cardiovascular surgery in patients on blood thinning medications, based upon published studies with CytoSorb (a hemoadsorption cartridge). We believe this is a good validating next step in socializing our therapy to the broader surgery community. Positive randomized controlled data from STAR-T, STAR-D, and real-world evidence from the STAR registry are expected to establish our technologies as *the primary* standard-of-care therapy for these major unmet medical need in treatment guidelines worldwide.

Return to Product Sales Growth

In our Stockholder letter, we discuss at length the "perfect storm" of geopolitical, economic, post-pandemic, and company-specific factors that we had to navigate in 2022. Yet despite these challenges, we sill managed to achieve $29.1M in core product sales, that when adjusted for the 11% drop in the Euro, would have been approximately $32.2M, within 5% of 2021 core sales of $33.8M – our highest annual core sales to date, and greater than 30% higher than pre-pandemic product sales of $22.8M in 2019.

We were encouraged by progress in our sales momentum in Q4 2022, which was 18% sequentially higher than Q3 2022, and actually 6% higher than core product sale in Q4 2021 on a constant currency basis. Importantly, we are seeing a continuation of this strength in Q1 2023 to date, which we believe is being driven by strong support, enthusiasm, and receptiveness to new clinical data, of CytoSorb at the customer level - which we believe is a direct result of the long history of positive usage of the therapy in the market. We also believe this has been augmented by our increased ability to meet in-person with customers in hospitals and our focused sales and marketing activities last year. Although many of the macro factors we faced in 2022 still remain, we believe a number of these have abated, and believe our own situation has improved significantly, with many initiatives underway that are expected to contribute to sales growth in 2023.

We expect gains from key programs such as our therapy area focus and leaderhsip in critical care, cardiac surgery, and liver & kidney diseases, our "Right patient, right dose, right time" marketing campaign, our standalone blood pump initiative, our global marketing agreement with Fresenius Medical Care, and our preferred supplier agreements with the top two largest private hospital networks in Germany, Asklepios and Helios. Also, we expect a positive impact of new clinical data and publications in the treatment of numerous illnesses, including:

- External new publication by one of the pioneers of early intervention with CytoSorb and ECMO to treat severe acute respiratory distress syndrome (ARDS), this time in COVID-19, supporting the findings of our CytoSorb Therapy in COVID-19 (CTC) Registry data on "Enhanced lung rest"
- Acute liver disease, and superiority of CytoSorb over the leading liver dialysis platform
- Lower sepsis-related and overall mortality in Staph aureus endocarditis
- Reduction in bleeding risk by removal of the market leading blood thinner Eliquis® (apixaban, Pfizer, BMS) during emergency cardiothoracic surgery
- Exacerbations of autoimmune diseases with, for example, another published use of CytoSorb to successfully treat complications of a severe exacerbation of the autoimmune disease, systemic lupus erythematous ("Lupus")
- Positive clinical results of the final analysis of the International CytoSorb Registry (precursor to the new COSMOS registry)

We also expect a restoration of product gross margins back to more historic levels of 75-80+% as current demand has worked down finished goods inventory and begun to drive volume manufacturing out of the new manufacturing facility. As evidence of this, our Q4 2022 product gross margins were 75%, up from a recent low of 64% in Q3 2022 (55% with one time charges) primarily related to manufacturing inefficiencies related to the relocation of our manufacturing operations to our new facility. This improved gross margin is expected to significantly reduce our cash flow needs. Meanwhile, we expect to report more normalized year-over-year comparisons in 2023, given that the Euro likely bottomed in Q3 2022, and going forward, we will not need to distinguish core versus COVID-19 related product sales, as COVID-19 sales in 2022 were nominal.

Finally, we expect more government-led economic relief for hospitals throughout Europe to help avert a healthcare crisis, and a gradual improvement in staffing shortages, which will help hospitals generate more procedure-based revenue and open up more hospital ward and ICU beds, which would help us as well. In addition, we expect consolidation of smaller hospitals into the larger hospitals where we conduct the majority of our business.

Reduced Cash Burn with Tight Control Over Expenses

We ended the year with $23.8M in cash, including restricted cash and $5M in debt at attractive terms. In 2023, we expect to significantly reduce our cash burn through a combination of:

- Improved sales
- Restoration of product gross margins to 75-80+%
- No major capital expenditures
- Reduced fixed overhead following consolidation of all U.S. operations to our new Princeton, NJ headquarters and manufacturing facility last year
- Expected realization of annualized cost savings from the impact of our 10% workforce reduction in 2022
- Monetizing our New Jersey net operating losses
- Executing on our $11.5M grant backlog to reduce R&D overhead, and
- Significantly reduced operating and clinical trial expenses

Because of this, we believe our current cash position is more than sufficient to drive our 2023 operating plan."

Dr. Chan concluded, "2023 is a very different year from last year, and believe we are now well-positioned to get to the two most important objectives we have as a company: Successful and timely completion of the STAR-T RCT in the U.S. and Canada and the potential to commercially open the vital U.S. and Canadian markets, and a return to growth of our main commercial CytoSorb business internationally. We thank you for your support and look forward to the next update."

Results of Operations

Comparison of the year ended December 31, 2022 and 2021

Revenues:

For the year ended December 31, 2022, we generated total revenue, which includes product revenue and grant income, of approximately $34,689,000 as compared to revenues of approximately $43,166,000 for the year ended December 31, 2021, a decrease of approximately $8,477,000, or 20%. Revenue from product sales was approximately $29,360,000 for the year ended December 31, 2022, as compared to approximately $40,109,000 in the year ended December 31, 2021, a decrease of approximately $10,749,000 or 27%. Direct sales decreased by approximately $8,983,000 and distributor sales decreased by approximately $1,766,000 during the year ended December 31, 2022 as compared to the year ended December 31, 2021. Sales to hospitals in the United States under the EUA granted by the FDA amounted to approximately $300,000 for the year ended December 31, 2022, as compared to approximately $1,690,000 in 2021. Though difficult to quantify, we estimate that approximately $300,000 and approximately $6,300,000 of total product sales during the years ended December 31, 2022 and 2021 was due to the demand for CytoSorb to treat COVID-19 patients. In addition, as a result of the decrease in the average exchange rate of the Euro to the U.S. dollar, 2022 product sales were negatively impacted by approximately $3,127,000. For the year ended December 31, 2022, the average exchange rate of the Euro to the U.S. dollar was $1.05 as compared to an average exchange rate of $1.18 for the year ended December 31, 2021.

Grant income was approximately $5,329,000 for the year ended December 31, 2022 as compared to approximately $3,057,000 for the year ended December 31, 2021, an increase of approximately $2,272,000, or 74%. During the year ended December 31, 2021, our research and development employees were either deployed to work-from-home status or reassigned to assist in activities related to increasing the production of CytoSorb. In 2022, research and development employees were assigned primarily to grant related activities.

Cost of Revenue:

For the years ended December 31, 2022 and 2021, cost of revenue was approximately $13,956,000 and $11,047,000, respectively, an increase of approximately $2,909,000. This increase was due to an increase in grant cost of revenue of approximately $2,210,000 due to the increase in billable hours charged to our grant related projects. Product cost of revenues increased approximately $698,000 during the year ended December 31, 2022 as compared to the year ended December 31, 2021. This increase was primarily due to an equipment failure of a refrigeration unit at our new manufacturing facility that caused a net write-off (after insurance proceeds) of approximately $300,000 of work-in-process inventory (see Note 2 to the financial statements) and inefficiencies associated with lower production due to a decrease in production volume and inefficiencies associated with relocating our production activities to the new facility. Product gross margins were approximately 70% for the year ended December 31, 2022 and approximately 80% for the year ended December 31, 2021.

Gross Profit:

Gross profit was approximately $20,733,000 for the year ended December 31, 2022, a decrease of approximately $11,385,000 or 35%, versus gross profit of $32,118,000 in 2021. This decrease is attributed to lower sales, the inventory write-off related to an equipment failure and inefficiencies associated with the process of relocating our production activities to the new facility as discussed above.

Research and Development Expenses:

Our research and development costs were approximately $15,119,000 and $16,381,000 for the years ended December 31, 2022 and 2021, respectively, a decrease of approximately $1,262,000, or 8%. This decrease was due to a decrease in clinical trial related costs of approximately $2,448,000, due primarily to the temporary pause of our STAR-D clinical trial in the U.S. and the discontinuation of the Hep-On-Fire clinical trial in Germany, a decrease in rent expense to research and development of approximately $685,000 related to our new facility and a decrease in non-grant related research and development costs of approximately $187,000. These decreases were offset by an increase in salaries related to our clinical trial activities of approximately $1,694,000 due to the hiring of additional clinical expertise and an increase in other research and development labor costs of approximately $364,000 related to the hiring of additional scientific expertise.

Legal, Financial and Other Consulting Expenses:

Our legal, financial and other consulting costs were approximately $2,848,000 and $2,732,000 for the years ended December 31, 2022 and 2021, respectively, an increase of approximately $116,000, or 4%. This increase was due to an increase in legal fees of approximately $685,000 due to the abandonment of certain issued patents and patent applications and an increase in accounting fees of approximately $169,000. These increases were offset by a decrease in consulting fees of approximately $396,000 and a decrease in hiring fees of approximately $342,000.

Selling, General and Administrative Expenses:

Our selling, general and administrative expenses were approximately $34,288,000 and $35,750,000 for the years ended December 31, 2022 and 2021, respectively, a decrease of approximately $1,462,000, or 4%. This decrease was due to a decrease of salary and commission costs of approximately $594,000 due to a reduction in commissions due to lower sales, a decrease in royalty expense of approximately $915,000 due to lower sales, a decrease in non-cash restricted stock expense of approximately $1,771,000 related to restricted stock units granted to the Company's executive officers, a decrease in non-cash stock compensation expense of approximately $597,000 and a decrease in other general and administrative expenses of approximately $324,000. These decreases were offset by an increase sales and marketing costs, which include advertising and conference attendance, of approximately $797,000, an increase in travel and entertainment costs of approximately $530,000 and an increase in occupancy costs of approximately $1,412,000 related to the rent expense on our new manufacturing facility.

Gain (Loss) on Foreign Currency Transactions:

For the year ended December 31, 2022, the loss on foreign currency transactions was approximately $2,449,000, as compared to a loss on foreign currency transactions of approximately $2,578,000 for the year ended December 31, 2021. The 2022 loss is directly related to the decrease of 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 at December 31, 2022 as compared to $1.14 per Euro at December 31, 2021. The 2021 loss is directly related to the decrease in the exchange rate of the Euro as of December 31, 2021, as compared to December 31, 2020. The exchange rate of the Euro to the U.S. dollar was $1.14 per Euro at December 31, 2021 as compared to $1.22 per Euro at December 31, 2020.

Benefit from Income Taxes:

Our benefit from income taxes was approximately $1,093,000 and $736,000 for the years ended December 31, 2022 and 2021, 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.

Comparison of the year ended December 31, 2021 and 2020

Revenues:

For the year ended December 31, 2021, we generated total revenue, which includes product revenue and grant income, of approximately $43,166,000 as compared to revenues of approximately $41,005,000 for the year ended December 31, 2020, an increase of approximately $2,161,000, or 5%. Revenue from product sales was approximately $40,109,000 for the year ended December 31, 2021, as compared to approximately $39,453,000 in the year ended December 31, 2020, an increase of approximately $656,000 or 2%. Direct sales increased by approximately $361,000 and distributor sales increased by approximately $295,000 during the year ended December 31, 2021 as compared to the year ended December 31, 2020. Sales to hospitals in the United States under the EUA granted by the FDA amounted to approximately $1,690,000 for the year ended December 31, 2021, as compared to approximately $1,341,000 in 2020. Though difficult to quantify, we estimate that approximately $6.3 million and $9.4 million of total product sales during the years ended December 31, 2021 and 2020 was due to the demand for CytoSorb to treat COVID-19 patients. In addition, as a result of the increase in the average exchange rate of the Euro to the U.S. dollar, sales were positively impacted by approximately $1,207,000. For the year ended December 31, 2021, the average exchange rate of the Euro to the U.S. dollar was $1.18 as compared to an average exchange rate of $1.14 for the year ended December 31, 2020.

Cost of Revenue:

For the years ended December 31, 2021 and 2020, cost of revenue was approximately $11,047,000 and $11,052,000, respectively, a decrease of approximately $5,000. Product cost of revenues decreased approximately $1,447,000 during the year ended December 31, 2021 as compared to the year ended December 31, 2020. This decrease was related to certain costs associated with the rapid ramp-up of production during the year ended December 31, 2020 that did not recur during the year ended December 31, 2021. These decreases were offset by the negative impact of non-recurring costs related to prior years tariffs as a result of an audit by the German Customs Authorities of approximately $732,000 and the offsetting non-recurring positive impact of the Employee Retention Tax Credit of approximately $388,000, both of which were recorded in the first quarter of 2021. Product gross margins were approximately 80% for the year ended December 31, 2021 and approximately 76% for the year ended December 31, 2020.

Gross Profit:

Gross profit was approximately $32,118,000 for the year ended December 31, 2021, an increase of approximately $2,166,000 or 7%, over gross profit of $29,952,000 in 2020. This increase is attributed to the reasons discussed above.

Research and Development Expenses:

Our research and development costs were approximately $16,381,000 and $8,811,000 for the years ended December 31, 2021 and 2020, respectively, an increase of approximately $7,570,000, or 86%. This increase was due to an increase in clinical trial and related costs of approximately $4,670,000, due primarily to the start-up of our STAR-T and STAR-D clinical trials in the U.S. and our PROCYSS and Hep-On-Fire clinical trials in Germany, an increase in salaries related to our clinical trial activities of approximately $1,620,000 due to the hiring of additional clinical expertise, an increase in rent expense of approximately $943,000 related to rent expense on our new facility, an increase in other research and development labor costs of approximately $294,000 related to the hiring of additional scientific expertise and an increase in other research and development costs of approximately $43,000.

Legal, Financial and Other Consulting Expenses:

Our legal, financial and other consulting costs were approximately $2,732,000 and $3,048,000 for the years ended December 31, 2021 and 2020, respectively, a decrease of approximately $316,000, or 10%. This decrease was due to due to a decrease in hiring fees of approximately $319,000, a decrease in legal fees of approximately $263,000, and a decrease in accounting fees of approximately $28,000. These increases were offset by an increase in consulting fees of approximately $294,000 related to certain corporate initiatives.

Selling, General and Administrative Expenses:

Our selling, general and administrative expenses were approximately $35,750,000 and $28,464,000 for the years ended December 31, 2021 and 2020, respectively, an increase of approximately $7,286,000, or 26%. This increase is related to an increase in salaries, commissions and related costs of approximately $4,476,000, an increase in non-cash restricted stock expense of approximately $989,000 related to restricted stock units granted to the Company’s executive officers, an increase in non-cash stock option compensation expense of approximately $507,000, an increase in commercial insurance of approximately $280,000, an increase in sales and marketing costs, which include advertising and conference attendance of approximately $1,152,000 and an increase in travel and entertainment costs of approximately $121,000. These increases were offset by a decrease in contracted public relations costs of approximately $210,000 and a decrease in other general and administrative expenses of approximately $29,000.

Interest Expense, Net:

For the year ended December 31, 2021, interest income, net was approximately $28,000, as compared to interest expense, net of approximately $1,201,000 for the year ended December 31, 2020. This decrease in net interest expense of approximately $1,229,000 was the result of the payoff of our outstanding term loans with Bridge Bank in December of 2020.

Gain (Loss) on Foreign Currency Transactions:

For the year ended December 31, 2021, the loss on foreign currency transactions was approximately $2,578,000, as compared to a gain on foreign currency transactions of approximately $2,607,000 for the year ended December 31, 2020. The 2021 loss is directly related to the decrease of the exchange rate of the Euro at December 31, 2021 as compared to December 31, 2020. The exchange rate of the Euro to the U.S. dollar was $1.14 per Euro at December 31, 2021 as compared to $1.22 per Euro at December 31, 2020. The 2020 gain is directly related to the increase in the exchange rate of the Euro at December 31, 2020, as compared to December 31, 2019. The exchange rate of the Euro to the U.S. dollar was $1.22 per Euro at December 31, 2019 as compared to $1.12 per Euro at December 31, 2019.

Benefit from Income Taxes:

Our benefit from income taxes was approximately $736,000 and $1,127,000 for the years ended December 31, 2021 and 2020, 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 private and public placement of our debt and equity securities. At December 31, 2022, we had current assets of approximately $33,760,000 including cash, cash equivalents and restricted cash on hand of approximately $23,832,000 and had current liabilities of approximately $9,715,000. All of the $25 million of our total shelf amount allocated to our ATM facility was available as of December 31, 2022. On December 27, 2022, we drew down the first $5 million tranche of the Term C loans available under the terms of our Amended Loan and Security Agreement with Bridge Bank. Also, we expect to receive approximately $1,093,000 in cash from the approved sale of our net operating losses and research and development credits from the State of New Jersey in the first half of 2023.

As of December 31, 2022, cash, cash equivalents and restricted cash were $23.8 million compared to $53.8 million as of December 31, 2021. After taking into account the $5 million related to our debt drawdown, our 2022 cash burn was approximately $35.0 million. This cash burn was due to lower-than-expected sales volumes, product gross margins that were lower due to decreased production volumes and operating efficiencies associated with the move to our new manufacturing facility, capital expenditures of approximately $6.3 million related to our new facility and other factors (e.g. a delay in realizing savings from cost cutting due to notice periods and labor laws in Europe). A reduction in product gross margins from 80% in 2021 to 70% in 2022, unfavorably impacted our cash burn by approximately $2.9 million. We expect product gross margins to return to previous levels as we transition production fully to the new facility by the end of this year, end the lease at our Deer Park Drive facility, and begin to capture anticipated manufacturing efficiencies driven by expected improvement in market conditions and increased product demand.

We are also managing our resources proactively, continuing to invest in key areas such as our U.S. clinical program. while driving cost-cutting throughout our Company. At the beginning of Q2 2022, we began instituting tighter cost controls and have reduced our headcount (including full and part-time employees and consultants) internationally by 10%, with the goal of reducing our cash burn. In addition, we have shifted our R&D headcount to funded grant programs, where we have an $11.5 million backlog as of December 31, 2022. Some of our costs savings of our headcount reduction are not yet visible in our results due to notice periods and labor laws in Europe but will be reflected in our 2023 operating budget. Meanwhile, we are working diligently to prioritize activities that we believe have a near-term return on investment and advance our strategic priorities, which cutting non-core or non-essential activities and spend. Our goal is, through a combination of driving an increase in sales and gross margin, and cutting costs, to significantly reduce our cash burn and to extend our operating runway with the resources we have.

Based upon the foregoing, we believe that we have sufficient cash to fund the Company’s operations beyond twelve months from the issuance of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K

Conference Call Details:

Date: Thursday, March 9, 2023
Time: 4:30 PM Eastern Time
Participant Dial-In: 1-201-389-0879
Conference ID: 13736064

Live Presentation Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1596520&tp_key=3635996201

It is recommended that participants dial in approximately 10 minutes prior to the start of the call. There will also be a simultaneous live webcast of the conference call that can be accessed through the following audio feed link: : https://viavid.webcasts.com/starthere.jsp?ei=1596520&tp_key=3635996201

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, 2022, filed on March 9, 2023, on http://www.sec.gov.

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 2022, more than 195,000 CytoSorb devices have been used cumulatively. CytoSorb was originally launched in the European Union under CE mark as the first cytokine adsorber. Additional CE mark extensions were granted for bilirubin and myoglobin removal in clinical conditions such as liver disease and trauma, respectively, and for ticagrelor and rivaroxaban removal in cardiothoracic surgery procedures. CytoSorb has also received FDA Emergency Use Authorization in the United States for use in adult critically ill COVID-19 patients with impending or confirmed respiratory failure. The DrugSorb™-ATR antithrombotic removal system, based on the same polymer technology as CytoSorb, also received two FDA Breakthrough Device Designations, one for the removal of ticagrelor and another for the removal of the direct oral anticoagulants (DOAC) apixaban and rivaroxaban in a cardiopulmonary bypass circuit during urgent cardiothoracic procedures. The Company is currently conducting the FDA-approved, randomized, controlled STAR-T (Safe and Timely Antithrombotic Removal-Ticagrelor) study of 120 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™, DrugSorb™-ATR, ContrastSorb, and others. For more information, please visit the Company's websites at www.cytosorbents.com and www.cytosorb.com or follow us on Facebook and Twitter.

Forward-Looking Statements

This press release includes forward-looking statements intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, future targets and outlooks for our business, 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 anticipated timing for completion of our STAR-T clinical trial and regulatory submissions, 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)

	Year ended December 31,		
	2022	2021	2020
Revenue:			
CytoSorb sales	$ 28,573	$ 39,997	$ 39,342
Other sales	787	112	110
Total product sales	29,360	40,109	39,452
Grant income	5,329	3,057	1,552
Total revenue	34,689	43,166	41,004
Cost of revenue	13,956	11,048	11,052
Gross profit	20,733	32,118	29,952
Other Expenses:			
Research and development	15,119	16,381	8,810
Legal, financial and other consulting	2,848	2,732	3,048
Selling, general and administrative	34,288	35,750	28,464
Total expenses	52,255	54,863	40,322
Loss from operations	(31,522)	(22,745)	(10,370)
Other income (expense):			
Interest income (expense), net	133	28	(1,201)
Gain (loss) on foreign currency transactions	(2,449)	(2,578)	2,607
Miscellaneous income	(67)	---	---
Total other income (expense), net	(2,383)	(2,550)	1,406
Loss before benefit from income taxes	(33,905)	(25,295)	(8,964)
Benefit from income taxes	1,092	736	1,127
Net loss	$ (32,813)	$ (24,559)	$ (7,837)
Basic and diluted net loss per common share	$ (0.75)	$ (0.57)	$ (0.20)
Weighted average number of shares of common stock outstanding	43,573,215	43,359,186	38,818,990
Net loss	$ (32,813)	$ (24,559)	$ (7,837)
Other comprehensive income (loss):			
Currency translation adjustment	1,804	2,260	(2,260)
Comprehensive loss	$ (31,009)	$ (22,299)	$ (10,097)

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	December 31, 2022	December 31, 2021
ASSETS:		
Current Assets:		
Cash and cash equivalents	$ 22,145	$ 52,138
Grants and accounts receivable, net	5,665	4,523
Inventories	3,461	4,766
Prepaid expenses and other current assets	2,489	2,872
Total current assets	33,760	64,299
Property and equipment, net	10,743	5,151
Restricted Cash	1,687	1,687
Right of use asset	12,604	13,423
Other assets	4,438	4,959
TOTAL ASSETS	$ 63,232	$ 89,519
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current Liabilities:		
Accounts payable	$ 1,655	$ 2,805
Lease liability - current portion	109	571
Accrued expenses and other current liabilities	7,951	10,314
Total current liabilities	9,715	13,690
Lease liability, net of current portion	13,142	13,251
Long-term debt	5,000	----
TOTAL LIABILITIES	27,857	26,941
Total stockholders' equity	35,375	62,578
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 63,232	$ 89,519

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