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): January 31, 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 Operations and Financial Condition

On January 31, 2023, CytoSorbents Corporation (the "Company") issued a stockholder letter (the "Letter"), including preliminary unaudited fourth quarter and full-year 2022 revenues and certain other preliminary financial information. A copy of the Letter is included as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.*

Item 8.01 Other Events

The information included in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is incorporated by reference into this Item 8.01.

Item 9.01 Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Stockholder Letter of the Company, dated January 31, 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, as amended, 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: January 31, 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 Issues Stockholder Letter and Reports Preliminary Fourth Quarter and Full Year 2022 Revenue

Cumulative CytoSorb treatments surpassed 195,000. Q4 2022 product sales rebounded from Q3 2022 low. Adjusted for constant currency, Core non-COVID 2022 product sales were within 5% of that achieved in 2021 and greater than 30% increased from pre-pandemic 2019

PRINCETON, N.J., January 31, 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, issues a stockholder letter from its Chief Executive Officer, Dr. Phillip Chan, and announces preliminary unaudited fourth quarter 2022 and full year 2022 results ahead of filing its Form 10-K.

Preliminary Unaudited Full Year 2022 Results

- Cumulative CytoSorb treatments delivered exceeded 195,000 at the end of 2022, up 20% from the end of 2021, and marking the 10th year of CytoSorb commercialization
- Preliminary unaudited 2022 Total Revenue, which includes Product Sales and Grant Revenue, was approximately $34.7 million versus $43.2 million in 2021, and $24.9 million in pre-pandemic 2019
- Overall preliminary unaudited 2022 Product Sales were approximately $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, and versus $22.8 million in pre-pandemic 2019
- 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 would have been approximately $32.2 million versus $33.8 million in 2021, a decrease of 4.6%
- Solid cash balance at the end of 2022 of approximately $23.8 million

Preliminary Unaudited Q4 2022 Results

- Q4 2022 Total Revenue was approximately $9.4 million versus $10.8 million in Q4 2021, and versus $7.4 million in pre-pandemic Q4 2019

- Q4 2022 Product Sales were approximately $7.6 million, which rose 18% sequentially from $6.5 million in Q3 2022, but were lower than the $9.7 million in Q4 2021, which benefitted from $1.7 million in COVID-related sales. Pre-pandemic Q4 2019 Product Sales were $6.6 million.

- Core (non-COVID-19) Product Sales in Q4 2022 were approximately $7.6 million, compared to approximately $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 Company expects to report fully-audited financial results for Q4 2022 and full year 2022 on Thursday, March 9, 2023, with a conference call held at 4:30PM ET. Further details for the earnings call will be provided at a later date.

CytoSorbents 2023: Eyes on the Prize

Dear Stockholders and Friends,

Before I begin, I thought it would be helpful to pause and take stock of where CytoSorbents stands today. In short, we are a NASDAQ-traded medical device company that generated total revenue of approximately $34.7M in 2022, primarily from international sales of our flagship product, CytoSorb®, a unique therapy that is E.U. approved for many life-saving applications in the multi-billion dollar markets of critical care and cardiac surgery. CytoSorb has demonstrated its clinical value through 10 years of commercialization and nearly 200,000 treatments administered across 75 countries around the world. In addition, we are working to enter the U.S. and Canadian markets for the first time with a second product, DrugSorb™-ATR, intended to reduce serious bleeding complications from cardiothoracic surgery associated with the blockbuster blood thinning drug, Brilinta® (AstraZeneca). We anticipate completing enrollment of our pivotal STAR-T registration trial this summer and if positive, intend to file for FDA and Health Canada marketing authorization of DrugSorb-ATR following study completion. We closed 2022 with a strong cash balance of $23.8M, and a grant contract backlog of approximately $11.5M, primarily to fund the development of HemoDefend-BGA for Universal Plasma, another potentially major product in the queue.

We believe our value proposition is unique and compelling, particularly in light of the major unmet medical needs that our products address globally, our high margin “razorblade” business model, the validation of our technology by our customers, strategic partners, and government funding agencies, and the potential proximity of opening and driving sales in the U.S., the largest medical device market in the world, with the potential to significantly accelerate our sales growth and profitability.

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

Antithrombotic, or “blood thinning,” medications are among the most widely prescribed drugs in the world, with millions of people on these agents to reduce the risk of heart attack and stroke. However, patients taking these medications have a higher tendency to bleed, sometimes fatally, particularly when undergoing urgent surgery, suffering an acute injury, or developing a spontaneous bleeding event such as a hemorrhagic stroke or gastrointestinal bleed.

We are in the midst of the pivotal U.S. and Canadian STAR-T (**S**afe and **T**imely **A**ntithrombotic **R**emoval of **T**icagrelor) randomized, controlled trial, 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). DrugSorb-ATR has already received two FDA Breakthrough Device Designations, one to remove Brilinta, and the other to remove direct oral anticoagulants such as Xarelto® (Bayer, Janssen) and Eliquis® (Pfizer, BMS), highlighting the lack of effective approved or cleared therapies in the U.S. to deal with the bleeding risk in surgical patients. Based on actual data on numbers of U.S. and Canadian patients on Brilinta® needing urgent cardiothoracic surgery each year, we estimate the immediate combined total addressable market for DrugSorb-ATR in these two countries is approximately $300-350M currently, and expected to potentially double as Brilinta® becomes generic in 2024. We are already working with many of the leading cardiac surgery centers and surgeons in both the U.S. and Canada that have historically been instrumental in driving innovation in the cardiac surgery field.

In 2023, our goal is to successfully complete the STAR-T trial, finalize our data analysis, and file for U.S. FDA and Health Canada regulatory approval. We believe this would be a game changing win for our company and have been working to put the pieces in place to achieve this. Most recently, we have:

- Enrolled the first third of a total of 120 patients in the STAR-T trial in November 2022, achieving the first of three major milestones in the study
- Received the recommendation by the independent Data and Safety Monitoring Board (DSMB) to continue the trial without modification in December 2022, following an unblinded data review of the first 40 patients

- Obtained Health Canada approval of our STAR-T protocol this month, clearing the way for us to initiate new high volume Brilinta-using centers in the country, which is expected to speed enrollment and completion of the study, while also supporting a Health Canada regulatory submission

- Welcomed Dr. Irina Kulinets, PhD as Senior Vice President of Global Regulatory Affairs and the newest member of the executive management team, to lead the regulatory approval of DrugSorb-ATR for anti-thrombotic removal. Previously, she was the SVP of Regulatory Affairs, Clinical Research, and Quality at Microvention, a global leader in advanced neuroendovascular surgical products. Irina is highly experienced in all aspects of U.S. and international medical device regulatory affairs and has an outstanding track record of successful device approvals across the gamut of low to high-risk medical devices.

Patient enrollment in STAR-T continues to meet expectations. We expect to reach the second milestone of 80 patients enrolled this spring, which will trigger the next unblinded data review by the DSMB, and to complete enrollment of all 120 patients this summer, with database lock and topline data expected shortly thereafter. If positive, FDA and Health Canada regulatory submissions are planned upon the completion of the trial.

Preparing for Commercialization of DrugSorb-ATR

Meanwhile, we have developed a detailed launch and commercialization strategy for DrugSorb-ATR and are pursuing our pre-commercial development in parallel to the clinical study. A key area of focus is how DrugSorb-ATR will be funded. Based upon a number of health economic analyses done in the U.K., Germany, and here in the U.S., the value proposition of DrugSorb-ATR to reduce bleeding complications and their associated costs is dominant, even in the absence of dedicated reimbursement. With approval, we expect rapid adoption under current cardiac surgery payment bundles. That said, the STAR-T randomized, controlled trial is designed to provide valuable health economics data to support market pricing and standard reimbursement of DrugSorb-ATR from both private and government insurers such as Centers for Medicare and Medicaid Services (CMS), where we believe the cost-benefit message is very compelling.

Although we feel very comfortable with the conventional path to obtain reimbursement for DrugSorb-ATR, interestingly, there may soon be another alternative avenue to obtain CMS reimbursement that will only be available to a select group of FDA-approved Breakthrough Devices. We have previously discussed how in January 2021, CMS announced the “Medicare Coverage for Innovative Technologies (MCIT)” rule, that was designed to spur innovation in the medical device industry by offering up to four years of automatic reimbursement for approved or cleared FDA Breakthrough Devices. This would have been very relevant to DrugSorb-ATR as a Breakthrough Device, as many patients on blood thinners who require cardiothoracic surgery are in the targeted Medicare population. Unfortunately, CMS rescinded the rule in late 2021, citing needed improvements to ensure safety, efficacy, and relevance in Medicare patients. In the wake of this disappointing news, leading researchers at Stanford University, including Dr. Joshua Makower, published a paper entitled “The Need for Accelerated Medicare Coverage of Innovative Technologies: Impact on Patient Access and the Innovation Ecosystem.” In the paper, CytoSorbents and DrugSorb-ATR were selected as one of four highlighted Breakthrough technologies, among all other FDA Breakthrough Devices, that exemplified the importance of the MCIT rule to the Medicare population.

Thankfully, there is broad bipartisan support of the MCIT rule, and a modified version of it is included in the proposed CURES 2.0 Act legislation. In addition, in early 2022, CMS announced a new initiative called "Transitional Coverage for Emerging Technologies (TCET)" as a potential replacement for MCIT. TCET is supported by AdvaMed (Advanced Medical Technology Association) – the world's largest medical technology association representing device, diagnostics, and digital technology manufacturers who issued a similar letter supporting a proposed TCET rule in August 2022.

In an article entitled, "A Vision of Medicare Coverage for New and Emerging Technologies – A Consistent Process to Foster Innovation and Promote Value" published in the October 13, 2022 edition of the Journal of the American Medical Association (JAMA), Dr. Lee Fleisher and Jonathan Blum, Centers for Medicare & Medicaid Services (CMS), said that CMS is "committed to making sure Medicare beneficiaries are able to access emerging technologies" and announced plans to develop a new expedited Medicare reimbursement coverage pathway for new and innovative medical devices that are relevant to the Medicare population.

At a Medtech Conference panel in October 2022, Tamara Syrek Jensen, director of the CMS Coverage and Analysis Group, stated that CMS plans to issue a proposed TCET policy by April 2023 and stated "We will have a proposed [rule] out by April of 2023, that is a big priority for my crew." This was reiterated at the November 9-10, 2022 Medical Device Manufacturers Association (MDMA) meeting featuring CMS officials where in a meeting synopsis, a key takeaway was that "TCET is still a CMS priority and policy development is ongoing, expected timeline for the proposed rule is early 2023."

In a press release and open letter to CMS Administrator Chiquita Brooks-LaSure on December 16, 2022, members of Congress urged CMS to issue a proposed rule to streamline Medicare beneficiaries' access to innovative medical devices" and stated, "We firmly believe a successful implementation of a TCET rule should include an independent transitional coverage pathway for breakthrough devices that have been proved safe and effective by the FDA."

Again, we believe DrugSorb-ATR, as an FDA Breakthrough Device whose target population comprises many patients 65 years of age and older in the Medicare population, could be well-suited to a proposed CMS TCET policy. We are encouraged by the continued prioritization of this program by CMS and will continue to follow the progress closely. If it becomes a reality, we will investigate this as an alternate path for CMS coverage. Meanwhile, we continue to be laser-focused on driving DrugSorb-ATR to the finish line.

2. Return to Sales Growth

CytoSorb is a European Union-approved blood purification technology used primarily to treat deadly inflammation that is the key common factor that drives illness severity and risk of death in a wide range of life-threatening conditions in the intensive care unit and cardiothoracic surgery. These are major unmet medical needs that include, for example, sepsis, trauma, shock, lung injury, liver failure, and complications of cardiothoracic surgery, where outside of antibiotics, there is little more than supportive care therapy (e.g. mechanical ventilation, dialysis, vasopressors) to treat them. The number of afflicted patients is being driven by many key trends in healthcare, particularly the aging demographic. Collectively, these conditions afflict tens of millions of people each year, typically killing 20-40% of patients despite the best medical treatment, and often severely debilitating survivors such that many are not alive or back in the ICU in the next year. Sepsis alone is estimated to be responsible for 1 in every 5 deaths worldwide. CytoSorb celebrated its 10th year of commercialization last year, accumulating nearly 200,000 human treatments and hundreds of publications to date, and helping to save many, many lives across 75 countries.

CytoSorb targets a global multi-billion dollar total addressable market each year. To date, among dozens of different applications, nearly half of all CytoSorb treatments were related to sepsis and septic shock. But other applications are expected to gain momentum, particularly:

- Treatment of severe ARDS (acute respiratory distress syndrome) with new exciting survival data in 100 patients from 5 major U.S. ECMO centers, combining CytoSorb with ECMO (extracorporeal membrane oxygenation) in the setting of COVID-19 to achieve “enhanced lung rest” under FDA Emergency Use Authorization

- Treatment of acute liver disease where CytoSorb demonstrated superiority to the leading liver dialysis platform in terms of liver toxin and cytokine removal, and importantly, ease-of-use

- Antithrombotic drug removal with strong adoption by cardiothoracic surgeons in Europe and the pending completion of the STAR-T randomized controlled trial

- Staph aureus endocarditis, driven by the risk of infection of aging implanted prosthetic heart valves as well as the opiate crisis and use of dirty needles

CytoSorbents sells CytoSorb with a direct sales force in 15 countries, and through distributors and partners in 60 other countries. We leverage an attractive "razorblade" disposables business model, where we believe the historic blended product gross margins (mixing higher direct sales margins with lower distributor margins) for CytoSorb are in the top tier for the medical device industry and are more comparable to those seen in the biotechnology and pharmaceutical industries. We are also partnered with some of the leading providers of the blood pump machine "razors", that include industry leaders Fresenius Medical Care (FMC), B Braun, Terumo Cardiovascular, Biocon, and Nikkiso. Late last year, CytoSorb became the "featured solution for cytokine, bilirubin, and myoglobin removal" on FMC's blood pump platforms, helping to "expand the dimension of blood purification" beyond the approximately 10% of ICU patients who require kidney replacement therapy, to the estimated 30-40% of patients in the ICU who suffer from severe, damaging inflammation.

CytoSorb, DrugSorb-ATR, ECOS-300CY® and VetResQ® are now being manufactured at our new, certified, state-of-the-art production facility and headquarters in Princeton, New Jersey. With capacity to support up to $400M in global product sales, the new plant was designed to streamline production, drive manufacturing efficiencies, and ultimately drive down costs of goods sold, and conversely help to expand product gross margins.

We believe the fundamentals of our business and sales model are sound. However, in 2022, we experienced a perfect storm of many geopolitical, economic, post-pandemic, and company-specific factors that contributed to lower-than-expected sales and product gross margins, and higher capital expenditures and operating costs, that made it a challenging year. Some of these factors included:

- Significant weakness in the acute care hospital segment worldwide. As widely reported, the toll of the protracted pandemic led to an exodus of healthcare professionals, particularly nurses, and a shortfall in revenues due to fewer hospital beds, patients, and procedures, coupled with the additional financial strain from inflation and energy costs. Many hospitals in many countries are experiencing major deficits and are facing significant financial hardship

- The 11% drop of the Euro against the U.S. dollar resulting in major currency exchange headwinds as a majority of our sales are based in Euros and converted into dollars
- The impact of high inflation and rapidly rising interest rates that threatened global recession, cascading down into all aspects of our business
- The Russia-Ukraine war that drove both political and economic instability, and fueled skyrocketing energy costs throughout Europe
- The plunge of the stock market that triggered a bear market in many sectors, impacted our stock, and iced new investments and funding
- "Pandemic inflation" resulting in higher-than-expected construction costs to open our new manufacturing facility
- A temporary decline in product gross margin due to the transition to our new Princeton, New Jersey manufacturing facility
- The unusually competitive labor market, resulting in higher labor costs and employee turnover, and
- The simultaneous launch of the two pivotal STAR-T and STAR-D trials that increased our clinical spend

Given these challenges, we still managed to achieve approximately $29.2 million in core product sales last year, that when adjusted for the 11% drop in the Euro, would have been at approximately $32.2M, within 5% of 2021 core sales of $33.8M, and greater than 30% higher than pre-pandemic product sales of $22.8M in 2019.

As we look ahead to 2023, many of the factors that we faced last year still remain, but importantly, we believe a number of these have abated, and we believe our own situation has improved significantly. This year, we expect:

- **Increased Visibility on the Likelihood of DrugSorb-ATR Contributing to Future Sales**

  As we discussed above, every month that goes by, we get closer to the completion of the STAR-T randomized controlled trial, expected this year. High quality clinical efficacy and health economics data from this study, if positive, are expected to support FDA and Health Canada regulatory approval, demonstrate cost savings to the healthcare system to justify reimbursement, and support consideration for inclusion into patient care guidelines. Should these come to pass, we believe DrugSorb-ATR adoption could be swift with it becoming a significant contributor to overall product sales, capturing a portion of the estimated initial total addressable U.S. and Canadian markets of $300-350M annually

- **Rebound of International Product Sales Growth**

  Core product sales for the year, when adjusted for currency exchange differences, were within 5% of that achieved in 2021. In addition, Q4 2022 core product sales were 18% sequentially higher than Q3 2022, and actually 6% higher than core product sales in Q4 2021 on a constant currency basis. We believe this was primarily related to our efforts and ability as a company to get back to selling and marketing our products in person, rather than any significant improvement of the hospital markets. Although too early to draw broad conclusions, we are encouraged by the continued market enthusiasm for our therapy and are projecting stronger product sales this year based upon numerous growth opportunities and initiatives. We expect gains from key programs such as our standalone blood pump initiative, our global marketing agreement with Fresenius Medical Care, our therapy area focus in critical care, cardiac surgery, and liver & kidney diseases, and our preferred supplier agreements with the top two largest private hospital networks in Germany, Asklepios and Helios. We also expect to launch several new sales and marketing initiatives in 2023 that we believe have the potential to drive increased sales of CytoSorb throughout the world. We will have more detail on these programs as the year progresses. Our goal is to more than double our annual ex-U.S. product sales to at least $80M in the next three years

- **Restoration of Product Gross Margins** – In 2022, product gross margins were lower due to scheduled pauses in device production, the combined overhead of two manufacturing facilities, one-time manufacturing issues, and decreased production due to inventory and lower than expected product sales. As most of these issues were non-recurring, we believe product gross margins will return to historic ranges between 75-80% in 2023

- **Full CytoSorb Production from Princeton Facility**

  In December 2022, we consolidated all of our U.S. operations to our Princeton, New Jersey headquarters. The transition was smooth and we are currently beginning full production of CytoSorb out of the new manufacturing facility

- **More Normalized Year-over-Year Comparisons**

  In the past several years, our results have been skewed by two major items: large COVID-19 related product revenue from the first two years of the pandemic, and currency exchange volatility. Going forward, we expect more normalized year-over-year comparisons, with nominal COVID-19 related revenue to compare to last year, and what was a likely bottoming of the Euro in 2022

- **Reduced Cash Burn with Tight Control Over Expenses, and No Major Capital Expenditures**

  In December, we strengthened our cash balance to $23.8M with a non-dilutive $5M term-loan from Bridge Bank. Meanwhile in Q4 2022, we reduced our cash burn significantly and expect our quarterly cash burn to be even lower in 2023 with achievement of budgeted sales. Many of the cost cutting efforts that we took in 2022 will become more apparent. For example, consolidation of our U.S. facilities, where we exited our prior lease at the end of 2022, will save approximately $0.8M this year. The postponement of STAR-D is expected to save $4M in 2023. And annualized savings from the 10% headcount reduction made last year will begin to be realized, particularly in Europe now that mandatory employment notice periods have expired. In addition, we do not expect any major capital expenditures this year, after completing the build out of our manufacturing facility last year

- **Finally, We Expect More Economic Relief for Hospitals Throughout Europe**

  Healthcare is often cited as recession resistant, as there are always people getting sick. However, the pandemic initiated a global healthcare crisis, and eroded the infrastructure and buffer that protected hospitals as the backbone of the healthcare industry. This will likely result in a wave of hospital consolidations with weaker ones being assimilated or closed. But overall, we believe hospitals are such a core part of the economy and provide such a fundamental, basic human right that governments cannot afford, both economically and politically, to let them fail despite occasional rhetoric to the contrary. This is particularly true in most European countries where governments regulate and fund, or heavily subsidize, universal healthcare. For example, Germany pledged financial support for German hospitals to offset the cost of energy in October 2022. In the same month, France announced a 150M Euro relief fund for pediatric services, and earlier this month announced an overhaul to the French health system. At the same time, the U.K. Prime Minister called an emergency meeting in early January 2023 on how to shore up the struggling National Health System (NHS). Although not enough, it highlights the motivation of governments to address this crisis, which ultimately we believe would be good for us

Eyes on the Prize

With everything going on in the world today, it is easy to get distracted by short-term events and uninformed speculation, and to lose sight of the significant value that we have created in this Company, the expected proximity of some potentially game-changing events such as the completion of the STAR-T trial and submission for FDA and Health Canada marketing approval for DrugSorb-ATR, and the long game goal of becoming a highly profitable leader in acute care blood purification.

Despite the significant challenges that we have faced this past year and their impact on our business, we believe we have successfully navigated through some of the most challenging times in our Company's history and believe we are in excellent shape and well-positioned to take the next step in our evolution. We believe we have been able to do so because of our strong fundamentals.

- An outstanding and passionate team of nearly 200 employees worldwide

- A strong network of dedicated users and healthcare professionals in 75 countries globally
- A portfolio of compelling products, including CytoSorb, DrugSorb-ATR, ECOS-300CY, VetResQ, HemoDefend-BGA, and others under commercialization and development that address pressing unmet medical needs, massive markets, and are driven by major trends in healthcare
- An attractive high margin “razorblade” business model
- World-class industry partners
- A solid balance sheet to fund our initiatives
- A new manufacturing facility that is expected to drive further product gross margin expansion while supplying product for years to come, and finally,
- The expected successful completion of the STAR-T trial this year, and if positive, submission for FDA and Health Canada marketing approval, potentially opening up the massive U.S. and Canadian markets – a potential watershed event for our Company

We are grateful to all of you who continue to support CytoSorbents, see the tremendous value we have created, and share our vision of success in the future. Best wishes to you and your families for a happy, healthy, and prosperous New Year!

Dr. Phillip Chan, MD, PhD
Chief Executive Officer
CytoSorbents Corporation

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 FDA marketing approval in the United States 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 10, 2022, as updated by the risks reported in our Quarterly Reports on Form 10-Q, and in the press releases and other communications to shareholders issued by us from time to time which attempt to advise interested parties of the risks and factors which may affect our business. We caution you not to place undue reliance upon any such forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, other than as required under the Federal securities laws.

Please Click to Follow Us on Facebook and Twitter

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