



WORKING TO SAVE LIVES

CytoSorbents Reports Fourth Quarter and Full Year 2021 Results and Provides 2022 Outlook

2021 total revenue was \$43.2 million, including product sales of \$40.1 million. Core non-COVID-19 product sales increased approximately 13% Y-Y to \$33.8 million.

2022 marks the 10th anniversary of CytoSorb® commercialization

MONMOUTH JUNCTION, N.J., March 8, 2022 — [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 audited financial and operating results for the quarter and year ended December 31, 2021 and provides its 2022 outlook.

Full Year 2021 Financial Results

- 2021 Total revenue, including product sales and grant income, was \$43.2 million, up 5% compared to \$41.0 million in 2020.
- 2021 Product sales were \$40.1 million, up 2% from \$39.5 million in 2020.
- Core non-COVID-19 product sales in 2021 were \$33.8 million, an approximate 13% increase from \$30.0 million in 2020.
- Direct sales in Germany grew to \$21.0 million in 2021, a 4% increase from \$20.3 million in 2020.
- Estimated COVID-19 related sales in 2021 were \$6.3 million, versus \$9.4 million in 2020.
- 2021 product gross margin was approximately 80%, compared to 76% in 2020.
- The Company remains well-capitalized with cash and cash equivalents of \$53.8 million, including \$1.7 million in restricted cash at December 31, 2021, and no debt.
- Received approval for the sale of our 2020 New Jersey NOL and R&D tax credits, expected to generate cash proceeds of approximately \$0.7M, to be received in first half 2022.

Fourth Quarter 2021 Financial Results

- Total revenue, including product sales and grant income, for Q4 2021 was \$10.8 million, a decrease of 10% compared to \$12.0 million in Q4 2020.
- Q4 2021 product sales were \$9.7 million, rose 9% sequentially from \$8.9 million in Q3 2021, but down 16% compared to \$11.5 million in Q4 2020.
- Q4 2021 direct sales in Germany were \$5.3 million, up 45% from \$3.7 million in Q3 2021, but lower than sales of \$6.0 million in Germany in Q4 2020.
- Core non-COVID-19 product sales for Q4 2021 were approximately \$8.0 million, or 82% of product sales, versus approximately \$8.9 million, or 77% of product sales in Q4 2020.
- Estimated Q4 2021 COVID-19 related sales were \$1.7 million, compared to an estimated \$2.6 million in Q4 2020.
- Q4 2021 product gross margin was 78%, down slightly from 81% in Q4 2020, due mainly to a scheduled manufacturing plant shut down for planned maintenance and year-end inventory count.

2021 Operating Highlights

- More than 162,000 cumulative CytoSorb devices have been utilized worldwide as of December 31, 2021, an increase of 34% compared to more than 121,000 devices utilized as of the end of 2020. More than 7,600 COVID-19 patients have been treated globally since the pandemic began. CytoSorb is now commercialized in more than 70 countries around the world, following the addition of Korea, Singapore, and Thailand, among others in 2021.
- Significant progress was made in pursuit of U.S. FDA marketing approval of DrugSorb™-ATR for the intraoperative removal of antithrombotic drugs during urgent cardiothoracic surgery.
 - Initiation of two pivotal double-blind, randomized controlled trials, the STAR-T (Safe and Timely Antithrombotic Removal – Ticagrelor) and STAR-D (Safe and Timely Antithrombotic Removal – Direct Oral Anticoagulants) trials, following FDA IDE approval for both trials and receipt of a second FDA Breakthrough Device Designation for DrugSorb-ATR.
- Advanced the scientific body of knowledge and understanding of the benefits of CytoSorb use worldwide with 50 new peer-reviewed publications and 36 separate Cases of the Week in 2021 highlighting retrospective and prospective analyses of CytoSorb use in critical care, cardiac surgery, organ failure and other uses. Some highlights include:
 - [Topline results](#) from the [U.S. CTC Registry](#) demonstrating high survival in 52 critically ill patients with refractory respiratory failure on CytoSorb with ECMO

(extracorporeal membrane oxygenation) from 5 U.S. ECMO centers were presented at both a dedicated [webinar](#) and at the International Symposium on Intensive Care & Emergency Medicine conference in Belgium, which were subsequently published in [Frontiers in Medicine](#).

- Multiple large cases series from the international community highlighting the use of CytoSorb in more than 110 critically ill COVID-19 patients with severe or refractory respiratory failure requiring ECMO or CRRT, and high observed survival, published in multiple peer reviewed journals such as [Artificial Organs](#), [American Journal of Respiratory and Critical Care Medicine](#), [Artificial Organs](#), [Journal of Cardiac Surgery](#), and the [International Journal of Artificial Organs](#)
- Results from [two large investigator-initiated studies](#) evaluating the intraoperative use of CytoSorb in a total of 337 patients with infective endocarditis, with both supporting the safety of CytoSorb in this application, and one demonstrating a significant reduction in sepsis-related mortality.
- The [first documented use](#) of CytoSorb to treat severe, refractory neurotoxicity after CAR T-cell immunotherapy for primary refractory high-grade B-cell lymphoma.
- The publication in the [Journal of Clinical Medicine](#) of the largest case series of 109 critically ill liver disease patients with high baseline expected mortality, treated with CytoSorb, collected from the CytoSorb International Registry, demonstrating a significant reduction in bilirubin, a common toxin in these patients and an approved indication for CytoSorb
- Continued to advance partnerships to increase availability and drive growth of CytoSorbents' products worldwide.
 - Established a [global co-marketing relationship](#) with B. Braun Avitum AG, one of the largest medical device companies in the world, to jointly market CytoSorb with the new OMNI® continuous blood purification platform and OMNiset® Plus bloodline set.
 - Announced the [commercial launch](#) in Italy of the PerSorb™ adsorber, which is based on the ECOS-300CY™ sorbent technology to remove inflammatory mediators during *ex vivo* organ perfusion, in combination with Aferetica's PerLife™ Organ Perfusion System in August 2021.
- Began construction on the Company's new global headquarters and state-of-the-art manufacturing facility following the lease of a 48,500 square foot [mixed-use facility in Princeton, New Jersey](#). The new production facility was designed to support annual sales of up to \$400 million while improving product gross margins and allowing space for future product line expansions. We expect to complete the certification audit in the first half of

2022, and commercial production of CytoSorb expected to commence in the second half of 2022.

2022 Outlook

- We expect continued and progressive improvement in our underlying core non-COVID-19 business in 2022, with growth of 20% or more in 2022 core product sales, compared to \$33.8 million in 2021 core sales. This expectation assumes:
 - A gradual recovery of normalized hospital activity and sales access in Germany and other key countries
 - No major economic slowdowns caused by new variants of COVID-19
 - Little to no contribution to sales from Russia and neighboring countries that might be impacted by the war. In 2021, sales from these geographies represented less than 4% of total product sales
- We expect limited COVID-19 related sales in 2022 compared to an estimated \$6.3 million in COVID-19 related product sales in 2021, as high rates of vaccination and natural immunity have reduced the severity of COVID-19 illness and need for hospitalization and ICU care, and with it the use of CytoSorb in these patients.

For a more detailed discussion of 2021 and our 2022 strategy, please refer to our [annual stockholder letter, issued January 18, 2022](#).

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, “CytoSorbents is the pioneer and leader in acute care hemoadsorption. This year, we celebrate the 10th anniversary of CytoSorb commercialization, during which time we have grown our business substantially, with more than 162,000 cumulative CytoSorb devices delivered to more than 70 countries worldwide. Our blood purification technologies help to treat patients who suffer from many of the most difficult and deadly medical conditions that physicians face on a daily basis. These are illnesses for which few, if any, therapies are effective, leading to millions of deaths each year. This is no easy task, but when used in the right patient, at the right time, with the right dose, our CytoSorb therapy is associated with exciting and often dramatic positive outcomes, which has driven adoption and usage around the globe. In fact, the scientific body of knowledge regarding CytoSorb use continues to grow with Company-sponsored and investigator-initiated studies, making CytoSorb the most published cytokine adsorption therapy worldwide. With every study - positive, neutral, or negative - we continue to learn who we can treat and how to achieve the best possible outcomes for these critically ill patients. And now with DrugSorb™-ATR in U.S. clinical trials for antithrombotic drug removal during cardiothoracic surgery to reduce perioperative bleeding, and the ECOS-300CY® cartridge approved in the E.U. for cytokine removal during *ex vivo* organ

perfusion with the goal of improving the function of organs destined for transplant, we have even greater opportunities to impact human health.”

Dr. Chan continued, “In 2021, as discussed in detail in our [annual stockholder letter](#) in January, we had a good year despite a challenging operational environment with the ebbs and flows caused by the COVID-19 pandemic. Total revenue and product sales were slightly ahead of our record results in 2020, highlighted by an approximate 13% increase in core non-COVID-19 product sales as we worked to offset the anticipated decline in COVID-19 related sales. Product gross margins remained strong at approximately 80% and we ended the year with a solid cash balance of nearly \$54 million that is intended to fuel our future growth initiatives, fund the opening of the critical U.S. market, and propel us to profitability.”

Dr. Chan added, “Looking forward in 2022, it is too early to predict how our business may be impacted by the ongoing effects of COVID-19 and the new geopolitical uncertainty caused by the Russia-Ukraine war. However, as it relates to COVID-19, we believe that 2022 will bring a near normalization of our operating environment with the most severe impacts of COVID in the rearview mirror. While the pace and timing are difficult to predict, we believe the trajectory of COVID-19 has followed other major viral pandemics, including the devastating 1918-1919 Spanish influenza epidemic almost a century ago to the year, that lasted roughly 2 years without the benefit of a flu vaccine. Mass immunity to COVID-19 from widespread vaccinations and natural infections have led to plummeting new infections from the Omicron variant in many countries, though note that infection rates are still near all-time highs in Germany and Austria and have only recently just peaked. However, taking other major E.U. countries as a guide, COVID-19 infections should rapidly fall in Germany and Austria over the next month or two, and Germany has already declared its intent to lift social restrictions by late-March. Turning to the Russia-Ukraine war, we are saddened for the people affected by this tragic turn of events and are unable to predict how it may evolve. With the current turmoil and economic and trade sanctions, we have assumed little to no sales from this region in 2022, which in 2021 only represented less than 4% of our product sales. Regardless, we remain focused on factors that are within our control and at the end of the day our priority is to help save lives.”

Dr. Chan continued, “In 2022, we will continue to remain disciplined in our focus, execution, investment, and control of expenses to drive progress in 4 major areas.

- Our main priority is to open the U.S. market by obtaining FDA Marketing approval for DrugSorb™-ATR to remove ticagrelor and/or direct oral anticoagulants (DOACs) during cardiothoracic surgery, a potential total addressable market of \$500M to \$1 billion in the U.S. alone. To do so, we intend to complete enrollment of the 120-patient U.S. STAR-T

pivotal, randomized, controlled trial (RCT) within 12 months from today, and the 120-patient U.S. STAR-D pivotal RCT within 12-18 months of first patient enrollment. If successful, these studies will support our marketing approval application to the FDA under FDA Breakthrough Device Designation.

- Second, we are targeting growth of 20% or more in core CytoSorb sales for the entire year, driven by major investments in our sales infrastructure and key personnel, and by broad existing and new applications ranging from sepsis, trauma, liver failure, acute respiratory distress syndrome, antithrombotic drug removal, and inevitable surgical complications from the significant backlog of surgical procedures. This forecast takes into account the expected evolution of the COVID-19 pandemic and the potential impact of the Russia-Ukraine war.
- Third, we expect to complete and begin CytoSorb production later this year from our new manufacturing facility, which will become our headquarters in Princeton, New Jersey, currently under construction. This facility is expected to help expand product gross margins while supplying enough product to support future annual product sales of up to \$400 million.
- Finally, we plan to expand our strategic partnerships, both new and existing, to maximize the synergy between our technology and those of our partners, while creating new global opportunities for growth.

We believe these initiatives will lead to sustainable and significant value creation for our Company and our shareholders.”

Dr. Chan concluded, “Over the past decade, we have been working tirelessly to help save the lives of patients all over the world with our CytoSorb blood purification technology and to “Change Medicine” for the better. During the pandemic, under FDA Emergency Use Authorization, we have had the opportunity here in the United States to personally train and guide U.S. clinicians on how to use CytoSorb in the most critically ill COVID-19 patients with acute respiratory distress syndrome and refractory respiratory failure on ECMO. We were tremendously gratified to learn that in 52 such patients from 5 major U.S. ECMO centers, using CytoSorb helped roughly 7 out of 10 patients survive their life-threatening ordeal and make it back home to their families. What we are doing is meaningful and important and we are proud to work with all of our healthcare worker, hospital, and distributor/strategic partners to bring this vital therapy to patients in need. We have accomplished a lot over the last 10 years, but we are even more excited about the next ten.”

Clinical Studies Update

Cardiac Surgery

- The U.S. double-blind, randomized, controlled **STAR-T (Safe and Timely Antithrombotic Removal – Ticagrelor)** clinical study evaluating the removal of ticagrelor by DrugSorb-ATR in a cardiopulmonary bypass circuit to reduce the likelihood of serious perioperative bleeding during urgent cardiac surgery enrolled the first patient in October 2021. The study is now actively recruiting patients at multiple sites and we expect the study to reach its first scheduled milestone of the first Data Safety Monitoring Board (DSMB) meeting after 33% of patients are enrolled this summer. Enrollment is expected to be complete within 12 months from today.
- The U.S. double-blind, randomized controlled **STAR-D (Safe and Timely Antithrombotic Removal – Direct Oral Anticoagulants)** clinical study evaluating the removal of the Direct Oral Anticoagulants (DOACs) apixaban and rivaroxaban by DrugSorb-ATR in a cardiopulmonary bypass circuit to reduce the likelihood of serious perioperative bleeding during urgent cardiac surgery has activated its first sites. We expect the first patient to be enrolled in the first quarter of 2022 with target study enrollment completion in 12-18 months following the first patient enrolled.
- The international **Safe and Timely Antithrombotic Removal (STAR) Registry** is designed to capture real world clinical and health economic outcomes with intraoperative antithrombotic drug removal. The STAR Registry is actively enrolling in the U.K. and Germany and is planned to expand to additional EU countries before the end of 2022. The intent of the Registry is to report outcomes at international conferences and submit the results for publication on a rolling basis as enrollment progresses.
- As previously announced, the decision was made in January 2022 to stop the randomized, controlled, multi-center **REFRESH 2-AKI** study designed to evaluate intraoperative use of two CytoSorb devices as a therapy to reduce the incidence and severity of acute kidney injury following cardiac surgery. The study was stopped for business reasons to shift resource allocation to the prioritized U.S. STAR-T and STAR-D trials discussed above. Importantly, there were no safety issues in the REFRESH 2-AKI trial.
- The single arm **TISORB** study executed in the U.K. and the single arm **CYTATION** study in Germany evaluating ticagrelor removal during cardiac surgery were both stopped in 2021. The decision was made since the larger, far more rigorous double blind RCT STAR-T will generate much higher quality data on ticagrelor removal and is powered to also report clinical outcomes rendering these two single arm studies redundant. Once again, it is

important to emphasize that this was a business decision to enhance the focus and resource allocation to the STAR programs and that there were no safety concerns in either of the two stopped studies as confirmed by the independent DSMBs of each study.

Critical Care

- Primary results from the CytoSorb Therapy in COVID-19 (**CTC**) Registry demonstrating high 90-day survival in critically ill COVID-19 patients with acute respiratory distress syndrome (ARDS) treated with both extracorporeal membrane oxygenation (ECMO) and CytoSorb under FDA Emergency Use Authorization were presented at the International Symposium of Intensive Care Medicine (ISICEM) conference at the end of August 2021 in Brussels, Belgium, and have been published in the peer reviewed journal, [Frontiers in Medicine](#). The CTC Registry has completed enrollment at 100 patients and the final results will also be submitted for publication.
- The German **PROCYSS** multicenter, randomized controlled trial evaluating the ability of CytoSorb to restore hemodynamic stability in patients with refractory septic shock is now actively enrolling. The speed of enrollment remains uncertain due to COVID-19, however, we estimate that the next important milestone of the interim analysis after 50% enrollment will occur in 2023.
- The German **Hep-On-Fire** multicenter, single-arm trial evaluating CytoSorb in patients suffering from acute liver failure due to alcoholic hepatitis received Ethics Committee approval in October 2021 and study start-up activities are ongoing. We expect that the study will begin enrollment in the first half of 2022 and complete enrollment in 2023.
- The international **COSMOS Registry** was designed to capture real world outcomes and device utilization patterns across multiple critical care indications including but not limited to sepsis, acute respiratory failure, postoperative vasoplegia, acute liver failure, and acute pancreatitis. The Registry is undergoing start-up activities and scheduled to begin enrollment in the first half of 2022 with the goal of being active in multiple countries in 2023. The intent of the Registry is to report outcomes at international conferences and submit the results for publication on a rolling basis as enrollment progresses.

Results of Operations for the year ended December 31, 2021

Revenues

Total revenue, including product revenue and grant income, for the year ended December 31, 2021 was \$43.2 million, a 5% increase from \$41.0 million for the year ended December 31, 2020. Product sales in 2021 were \$40.1 million in 2021, a 2% increase from \$39.5 million in 2020. COVID-19 relates sales in 2021 were estimated to be \$6.3 million compared to \$9.4 million in 2020. Core non-COVID-19 sales grew approximately 13% from \$30.1 million in 2020 to \$33.8 million in 2021.

Cost of Revenues

Cost of revenue for the year ended December 31, 2021 was \$11.0 million compared to \$11.1 million for the year ended December 31, 2020. Product gross margins were approximately 80% for the year ended December 31, 2021, compared to 76% for the year ended December 31, 2020, due to certain costs associated with the rapid ramp-up of production during 2020 that did not recur during 2021.

Operating Expenses

Operating expenses for the year ended December 31, 2021 amounted to \$54.9 million, a 36% increase from \$40.3 million for the year ended December 31, 2020. Research and development expenses increased from \$8.8 million in 2020 to \$16.4 million in 2021 due primarily to an increase in clinical trial and related costs associated with the start of our STAR-T and STAR-D clinical trials in the U.S. and our PROCYSS and Hep-on-Fire clinical trials in Germany. Selling, General & Administrative (SG&A) expenses increased 26% to \$35.8 million in 2021 from \$28.5 million in 2020 due primarily to an increase in salaries, commissions, and related costs of \$4.5 million, an increase in non-cash restricted stock expense of \$1.0 million related to restricted stock units granted to the Company's executive officers and an increase of \$0.5 million in non-cash stock option compensation expense, among other items. Legal, financial, and other consulting expense decreased 10% in 2021 to \$2.7 million compared to \$3.0 million in 2020.

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, 2021, we had current assets of approximately \$64.3 million including cash, cash equivalents and restricted cash on hand of approximately \$53.8 million and had current liabilities of approximately \$13.7 million. As of December 31, 2021, \$25 million of our total shelf amount was allocated to our ATM facility, all of which is still available. Also, we expect to receive approximately \$736,000 in cash from the approved sale of our 2020 net operating losses and research and development credits from the State of New Jersey in the first half of 2022.

We believe that we have sufficient cash to fund our operations and clinical trial activities well into the future.

Results of Operations for the Quarter ended December 31, 2021

Revenues

Total revenue, including product revenue and grant income, for the fourth quarter of 2021 was \$10.8 million, down 10% from \$12.0 million in the fourth quarter of 2020. Product sales in the fourth quarter of 2021 were \$9.7 million, down 16% from \$11.5 million in the fourth quarter of 2020. COVID-19 relates sales in the fourth quarter of 2021 were estimated to be \$1.7 million compared to \$2.6 million in the fourth quarter of 2021. Core, Non-COVID-19 sales declined 10% from \$8.9 million in the fourth quarter of 2020 to \$8.0 million in the fourth quarter of 2021.

Cost of Revenues

Cost of revenue for the fourth quarter of 2021 was \$3.1 million compared to \$2.5 million for the fourth quarter of 2020. Product gross margin was approximately 78% for the fourth quarter of 2021, compared to approximately 81% for the fourth quarter of 2020, due mainly to a scheduled manufacturing plant shut down for planned maintenance and year-end inventory count.

Operating Expenses

Operating expenses for the fourth quarter of 2021 amounted to \$17.2 million, a 43% increase from \$12.1 million for the fourth quarter of 2020. Research and development expenses increased from \$2.7 million in the fourth quarter of 2020 to \$6.1 million in the fourth quarter of 2021 due primarily to an increase in clinical trial and related costs associated with the start of our STAR-T and STAR-D clinical trials in the U.S. and our PROCYSS and Hep-on-Fire clinical trials in Germany. Selling, General & Administrative (SG&A) expenses increased 26% to \$10.4 million in the fourth quarter of 2021 from \$8.3 million in the fourth quarter of 2020 due primarily to an increase in salaries, commissions, and related costs of \$1.5 million, and an increase in sales and marketing costs, which include advertising and conference attendance of approximately \$0.6 million, among other items. Legal, financial, and other consulting expense declined 42% in the fourth quarter of 2021 to \$0.6 million compared to \$1.1 million in the fourth quarter of 2020.

2022 Outlook

The macro environment in which we operate remains difficult to predict given the complex drivers of our business and global nature of our operations.

We expect COVID-19 cases and hospitalizations worldwide to continue to decline and expect to reach a more normalized operating environment as the year progresses, as high rates of vaccination and natural immunity have reduced the severity of COVID-19 illness and need for hospitalization and ICU care, and with it the use of CytoSorb in these patients. Our 2022 outlook assumes a gradual recovery of normalized hospital activity in Germany and other key countries and no major economic slowdowns as a result of new variants of COVID-19. As a result, we expect limited COVID-19 related product sales in 2022 compared to an estimated \$6.3 million in COVID-19 related product sales in 2021.

In addition, given our global presence, the Russia-Ukraine war presents a unique challenge, and we are unable to predict at this time how this situation may evolve. We believe we currently have limited exposure, where in 2021, product sales generated from Russia and neighboring countries potentially impacted by the conflict amounted to less than 4% of product revenue.

Assuming little, to no sales in 2022 from Russia and neighboring countries that might be impacted by the war, we expect growth of 20% or more in 2022 core, non-COVID-19 sales, compared to \$33.8 million in core, non-COVID-19 product sales generated in 2021.

For additional information, please see the Company's Form 10-K for the period ended December 31, 2021, to be subsequently filed with the SEC at <http://www.sec.gov>.

Conference Call

The company will conduct its fourth quarter and full year results call today at 4:30 p.m. Eastern time. It will be archived for replay following the conference call.

Conference Call Details:

Toll free: 1-877-451-6152

International: 1-201-389-0879

Conference ID: 13726520

It is recommended that participants dial in approximately 10 minutes prior to the start of the call. There will be a simultaneous live webcast of the conference call that can be accessed through the following audio feed link:

https://viaid.webcasts.com/starthere.jsp?ei=1525680&tp_key=7f828ec8e8

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 intensive care and cardiac surgery using blood purification. Its flagship product, [CytoSorb®](#), is approved in the European Union with distribution in more than 70 countries around the world as an extracorporeal cytokine adsorber designed to reduce the “cytokine storm” or “cytokine release syndrome” seen in common critical illnesses that may result in massive inflammation, organ failure and patient death. These are conditions where the risk of death can be extremely high, yet few to no effective treatments exist. CytoSorb is also being used during and after cardiothoracic surgery to remove inflammatory mediators that can lead to post-operative complications, including multiple organ failure. More than 162,000 cumulative CytoSorb devices have been utilized as of December 31, 2021. CytoSorb was originally introduced into the European Union under CE-Mark as a first-in-kind cytokine adsorber. Additional CE-Mark label expansions were received for the removal of bilirubin and myoglobin in clinical conditions such as liver disease and trauma, respectively, and both [ticagrelor](#) and [rivaroxaban](#) during cardiothoracic surgery. CytoSorb has also received [FDA Emergency Use Authorization](#) in the United States for use in adult critically ill COVID-19 patients with imminent or confirmed respiratory failure. The DrugSorb-ATR™ Antithrombotic Removal System, which is based on the same polymer technology as CytoSorb, has also been granted [FDA Breakthrough Designation](#) for the removal of ticagrelor, as well as [FDA Breakthrough Designation](#) for the removal of the direct oral anticoagulant (DOAC) drugs, apixaban and rivaroxaban, in a cardiopulmonary bypass circuit during urgent cardiothoracic surgery. The Company has initiated two FDA approved pivotal trials designed to support U.S. marketing approval of DrugSorb-ATR. The first is the 120-patient, 20 center **STAR-T (Safe and Timely Antithrombotic Removal-Ticagrelor)** randomized, controlled trial evaluating the ability of intraoperative DrugSorb-ATR use to reduce perioperative bleeding risk in patients on ticagrelor undergoing cardiothoracic surgery. The second is the 120-patient, 25 center **STAR-D (Safe and Timely Antithrombotic Removal-Direct Oral Anticoagulants)** randomized, controlled trial, evaluating the intraoperative use of DrugSorb-ATR to reduce perioperative bleeding risk in patients undergoing cardiothoracic surgery on direct oral anticoagulants, including apixaban and rivaroxaban.

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 more than \$39.5 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, expectations regarding the future impacts of COVID-19 or the ongoing conflict between Russia and the Ukraine, 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 2021 Form 10-K filed with the SEC on March 9, 2021 and our 2022 Annual Report on Form 10-K, to be subsequently filed with the SEC, 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 December 31,		Year ended December 31,	
	2021	2020	2021	2020
Revenue:				
CytoSorb sales	\$ 9,592	\$ 11,489	\$ 39,997	\$ 39,342
Other sales	106	42	112	110
Total product sales	<u>9,698</u>	<u>11,531</u>	<u>40,109</u>	<u>39,452</u>
Grant income	<u>1,084</u>	<u>425</u>	<u>3,057</u>	<u>1,552</u>
Total revenue	<u>10,782</u>	<u>11,956</u>	<u>43,166</u>	<u>41,004</u>
Cost of revenue	<u>3,123</u>	<u>2,527</u>	<u>11,048</u>	<u>11,052</u>
Gross profit	<u>7,659</u>	<u>9,429</u>	<u>32,118</u>	<u>29,952</u>
Other Expenses:				
Research and development	6,137	2,686	16,381	8,810
Legal, financial and other consulting	641	1,103	2,732	3,048
Selling, general and administrative	<u>10,442</u>	<u>8,274</u>	<u>35,750</u>	<u>28,464</u>
Total expenses	<u>17,220</u>	<u>12,063</u>	<u>54,863</u>	<u>40,322</u>
Loss from operations	<u>(9,561)</u>	<u>(2,634)</u>	<u>(22,745)</u>	<u>(10,370)</u>
Other income/(expense):				
Interest income (expense), net	12	(361)	28	(1,201)
Gain (loss) on foreign currency transactions	<u>(493)</u>	<u>1,190</u>	<u>(2,578)</u>	<u>2,607</u>
Total other income (expense), net	<u>(481)</u>	<u>829</u>	<u>(2,550)</u>	<u>1,406</u>
Loss before benefit from income taxes	<u>(10,043)</u>	<u>(1,805)</u>	<u>(25,295)</u>	<u>(8,964)</u>
Benefit from income taxes	<u>736</u>	<u>1,127</u>	<u>736</u>	<u>1,127</u>
Net loss	<u>\$ (9,307)</u>	<u>\$ (678)</u>	<u>\$ (24,559)</u>	<u>\$ (7,837)</u>
Basic and diluted net loss per common share	<u>\$ (0.21)</u>	<u>\$ (0.02)</u>	<u>\$ (0.57)</u>	<u>\$ (0.20)</u>
Weighted average number of shares of common stock outstanding	<u>43,476,926</u>	<u>43,192,127</u>	<u>43,359,186</u>	<u>38,818,990</u>
Net loss	\$ (9,307)	\$ (678)	\$ (24,559)	\$ (7,837)
Other comprehensive income (loss):				
Currency translation adjustment	558	(1,217)	2,260	(2,260)
Comprehensive loss	<u>\$ (8,749)</u>	<u>\$ (1,895)</u>	<u>\$ (22,299)</u>	<u>\$ (10,097)</u>

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	<u>December 31,</u> 2021	<u>December 31,</u> 2020
ASSETS:		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 52,138	\$ 71,422
Grants and accounts receivable, net	4,523	5,159
Inventories	4,766	2,674
Prepaid expenses and other current assets	<u>2,872</u>	<u>3,198</u>
Total current assets	64,299	82,453
Property and equipment, net	5,151	2,120
Restricted Cash	1,687	-
Right of use asset	13,423	1,029
Other assets	<u>4,959</u>	<u>4,348</u>
TOTAL ASSETS	\$ <u>89,519</u>	\$ <u>89,950</u>
LIABILITIES AND STOCKHOLDERS' EQUITY:		
<i>Current Liabilities:</i>		
Accounts payable	\$ 2,805	\$ 1,835
Lease liability - current portion	571	447
Accrued expenses and other current liabilities	<u>10,314</u>	<u>7,871</u>
Total current liabilities	13,690	10,153
Lease liability, net of current portion	<u>13,251</u>	<u>582</u>
TOTAL LIABILITIES	26,941	10,735
Total stockholders' equity	<u>62,578</u>	<u>79,215</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ <u>89,519</u>	\$ <u>89,950</u>

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