WORKING TO SAVE LIVES

CytoSorbents Reports Full Third Quarter 2021 Financial and Operational Results

Third Quarter 2021 total revenue was $9.8 million, including product sales of $8.9 million. Core non-COVID-19 product sales increased 3% Y-Y to approximately $7.8 million.

MONMOUTH JUNCTION, N.J., November 4, 2021 — 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, reports full financial and operating results for the quarter ended September 30, 2021.

Third Quarter 2021 Financial Results

- Total revenue, including product sales and grant income, for Q3 2021 was $9.8 million, compared to $10.5 million in Q3 2020, a decrease of 7%.
- Q3 2021 CytoSorb product sales were $8.9 million, down 13% compared to $10.2 million in Q3 2020.
- Q3 2021 product sales in Germany were $3.7 million, a decrease of $1.1 million or 24% from product sales of $4.8 million in Germany in Q3 2020.
- Core non-COVID-19 product sales for Q3 2021 were approximately $7.8 million, up 3% from approximately $7.5 million in Q3 2020.
- Estimated Q3 2021 COVID-19 related sales were $1.1 million, compared to an estimated $2.7 million in Q3 2020.
- Q3 2021 product gross margins were 82%, as compared to 74% in Q3 2020.
- The Company maintains a healthy cash balance of $61.0 million at September 30, 2021 with no debt.

Recent Operating Highlights

- In October, CytoSorbents enrolled the first patient in the pivotal U.S. STAR-T (**S**afe and **T**imely **A**ntithrombotic **R**emoval – **T**icagrelor) double-blind, randomized controlled trial in the United States to support FDA marketing approval of the DrugSorb-ATR™

antithrombotic removal system for intraoperative ticagrelor removal during urgent cardiothoracic surgery.

- Following receipt of a second Breakthrough Designation attributed to DrugSorb-ATR for the removal of the market-leading Direct Oral Anticoagulants (DOACs) apixaban and rivaroxaban during urgent cardiothoracic surgery in August, the Company successfully filed an IDE application and received full FDA approval to begin the pivotal STAR-D (**S**afe and **T**imely **A**ntithrombotic **R**emoval – **D**irect Oral Anticoagulants) double-blind, randomized controlled trial in the United States to support marketing approval for this additional indication.
- In September, CytoSorbents presented topline results from the U.S. CTC Registry at the International Symposium on Intensive Care & Emergency Medicine conference in Belgium and hosted a dedicated webinar highlighting the associated findings.
- Results from two investigator-initiated studies evaluating the use of CytoSorb in endocarditis, including the randomized, controlled REMOVE trial were presented at the European Association for Cardio-Thoracic Surgery conference in Spain in October.
- In August, CytoSorbents and Aferetica announced the commercial launch in Italy of the PerSorb™ Adsorber (based on CytoSorbents' ECOS-300CY™ sorbent technology) to remove inflammatory mediators during *ex vivo* perfusion via the PerLife™ Organ Perfusion System at the European Society of Organ Transplantation congress.
- More than 152,000 cumulative CytoSorb devices have been utilized to date, an increase of 38% compared to more than 110,000 devices utilized as of Q3 2020, with more than 6,900 COVID-19 patients treated globally.
- CytoSorb is now distributed in more than 70 countries, adding Thailand and the Ukraine during the quarter.

Fourth Quarter and Full Year 2021 Product Revenue Guidance

- The Company maintains its revised 2021 product revenue guidance provided on October 12, 2021:
    - Q4 2021 product revenue is expected to be similar to Q3 2021 product revenue of $8.9 million.
    - Full year 2021 product revenue of at least $39.3 million, roughly flat compared to 2020 product revenue of $39.5 million. While difficult to predict, 2021 core non-COVID-19 product sales are expected to be approximately $33 to $34 million for the year versus $30.1 million in 2020.

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, "As previously communicated in mid-October, third quarter product sales were negatively affected by a resurgence in COVID-19 cases in Germany in August and a reversal of initially encouraging trends that we saw at the beginning of the quarter. Increased hospital restrictions led to lower-than-expected core non-COVID-19 sales of CytoSorb with fewer elective surgical procedures (where complications such as sepsis are often treated with CytoSorb), fewer ICU patients due to ICU capacity constraints from COVID-19 allocations and ICU staffing shortages caused by healthcare worker burnout, as well as decreased visitor access - impacting the ability of our sales force to generate sales. Meanwhile, during this historically seasonal quarter due to European vacation schedules, the severity of illness and deaths among hospitalized COVID-19 patients was unexpectedly low, resulting in fewer COVID-related CytoSorb sales."

Dr. Chan continued, "As a result, product sales in the third quarter of 2021 were $8.9 million, reflecting lower sales in Germany and an expected decline in international COVID-related sales, taking into account the evolving and migrating pandemic and increasing global vaccinations. Core non-COVID-19 product sales accounted for approximately 88% of our overall product sales. Blended product gross margins were approximately 82% in the third quarter, a significant improvement from approximately 74% in the prior year quarter and a strong result driven by manufacturing efficiencies. Today, the macro environment remains challenging in Germany, but we are proactively working within the current constraints to find creative ways to increase engagement with new and existing customers and to increase awareness of the benefits of CytoSorb in both COVID-19 and core applications. We expect the macro environment to improve over time, though timing is difficult to predict."

Dr. Chan added, "Meanwhile, we are pleased by the latest successes of our U.S clinical development program in pursuit of U.S. commercialization. We recently enrolled our first patient in the pivotal STAR-T trial evaluating the use of DrugSorb-ATR for intraoperative ticagrelor removal during urgent cardiothoracic surgery and are ramping up the number of active sites. In addition, in the span of approximately three months we received a second FDA Breakthrough Device Designation for DrugSorb-ATR, this time to remove the direct oral anticoagulants apixaban and rivaroxaban during urgent cardiothoracic surgery, filed an associated IDE, and received full FDA approval to begin the pivotal STAR-D trial for this application. The successful execution of these activities in such a short timeline is a testament to the strength of the clinical and regulatory talent we have hired over the past 18 months. By the end of this year, we expect to have seven active Company-sponsored studies underway that are designed to generate robust clinical data to support our growth objectives. We continue to have a healthy balance sheet, with approximately $61 million in cash and no debt, and we expect to continue funding activities to

drive growth, including clinical development, sales and marketing infrastructure, and our new, expanded manufacturing facility, which is on track to come online by the end of 2022."

Dr. Chan concluded, "Despite the complexities of COVID-19 on our business, we believe we are well-positioned for long-term growth with an outstanding therapy, CytoSorb, that when used on the right patients, at the right time, with the right dose, works to help save lives. We are boldly trying to solve some of the most complex medical problems in medicine today that claim the lives of millions each year. It is not simple. But with every study, we move closer to unlocking the key. In addition, we believe we have an excellent business model bolstered by strong product gross margins, broad international physician and partner support, a growing body of clinical data, and a solid safety profile with now more than 152,000 treatments utilized across more than 70 countries. We remain confident in our core business both in Germany and internationally and are excited about our pivotal trials in the U.S. that have the potential to open the significant U.S. market and make our therapies available to help even more people."

Clinical Studies Update

- In addition to prior commentary provided in this release, the U.S. **STAR-T** trial is now actively recruiting at multiple sites. Pending any COVID-19 related delays, we expect that the study will complete enrollment in 2022. In addition, study start-up activities have begun for the U.S. **STAR-D** trial, with first patient enrollment expected in the first quarter of 2022.

- The **REFRESH 2-AKI** study in the United States has resumed enrollment at multiple trial centers. The goal of the study is to achieve the milestone of the interim analysis next year, however, the ongoing COVID-19 pandemic is causing enrollment delays associated with postponement or deferral of elective cardiac surgeries and shortage in research staff.

- 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 also been submitted for journal publication.

- The **CYTATION** trial in patients on ticagrelor undergoing emergent cardiothoracic surgery in Germany is actively recruiting patients at all three sites plus a recently added clinical

site in Luxembourg. Pending any uncertainty introduced by COVID-19 related delays, we expect that the study will complete enrollment in 2022.

- 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 recruiting. The speed of enrollment remains uncertain due to COVID-19, however we currently estimate study completion by end of 2023.

- The **Hep-On-Fire** single-arm, multi-center German trial evaluating CytoSorb in patients suffering from acute liver failure due to alcoholic hepatitis received Ethics Committee approval in October. Study start-up activities are ongoing, and we expect that the study will begin enrollment in the first quarter of 2022.

- The **S**afe and **T**imely **A**ntithrombotic **R**emoval **(STAR) Registry** was designed to capture real world clinical and economic outcomes in the antithrombotic removal application. The registry is currently actively enrolling patients, and we estimate that first data readouts from the STAR Registry will begin in 2022.

- The German government-sponsored and investigator-initiated **REMOVE** all-comer endocarditis study presented topline results at the European Association of Cardio-Thoracic Surgery (EACTS) annual meeting in Barcelona, Spain in October 2021. CytoSorbents is working collaboratively with the REMOVE investigators to conduct additional exploratory analyses to potentially identify subgroups that may have benefited from CytoSorb and to also inform potential future studies in this application.

Results of Operations for the Quarter ended September 30, 2021

Revenues

Revenue from product sales was approximately $8,902,000 in the three months ended September 30, 2021, as compared to approximately $10,246,000 in the three months ended September 30, 2020, a decrease of approximately $1,344,000, or 13%. This decrease was driven by a decrease in direct sales of approximately $1,264,000 resulting primarily from lower sales in Germany due to COVID-19 pandemic-driven market conditions. This was driven by a wave in new Delta variant-related COVID-19 cases in Germany, which accelerated through August and has continued to date. This prompted many hospitals throughout Germany to reduce elective surgical procedures, to reserve ICU beds, and to either maintain or reinstitute restrictions such as visitation rights to non-essential visitors, in preparation of COVID-19 hospitalizations. However, unlike prior waves in Germany, the rates of severe COVID-19

illness requiring ICU care, and death have been disproportionately very low. This is being partly attributed to high rates of vaccinations that are associated with reduced severity of illness, reduced need for hospitalization, and risk of death. These factors led to a decrease in both COVID-19 and core non-COVID-19 CytoSorb sales in Germany. Sales to hospitals in the United States under the EUA granted by the FDA amounted to approximately $577,000 for the three months ended September 30, 2021. Though difficult to quantitate, we estimate that approximately $1.1 million of total product sales in the third quarter of 2021 was due to the demand for CytoSorb to treat COVID-19 patients. In addition, the change in the average exchange rate of the Euro to the U.S. dollar did not have a significant impact on product sales during the three months ended September 30, 2021, as compared to the three months ended September 30, 2020.

Grant income was approximately $859,000 for the three months ended September 30, 2021 as compared to approximately $301,000 for the three months ended September 30, 2020, an increase of approximately $558,000, or 185%. This increase was a result of the easing of the COVID-19 pandemic in the United States during the three months ended September 30, 2021 and a corresponding increase in grant related work. During the three months ended September 30, 2020, 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.

Total revenues were approximately $9,760,000 for the three months ended September 30, 2021, as compared to total revenues of approximately $10,547,000 for the three months ended September 30, 2020, a decrease of approximately $787,000, or 7%.

Cost of Revenues

For the three months ended September 30, 2021, and 2020, cost of revenue was approximately $2,463,000 and $2,890,000, respectively, a decrease of approximately $427,000. Product cost of revenue was approximately $1,642,000 and $2,622,000, respectively, for the three months ended September 30, 2021 and 2020, a decrease of approximately $980,000. This decrease was due to lower sales and because certain costs associated with the rapid ramp-up of production during the three months ended September 30, 2020 that did not recur during the three months ended September 30, 2021. Product gross margins were approximately 82% for the three months ended September 30, 2021 as compared to approximately 74% for the three months ended September 30, 2020. The increase in the gross margin percentage in 2021 was due to manufacturing efficiencies achieved during the three months ended September 30, 2021 and the impact of the ramp-up costs incurred during the three months ended September 30, 2020 that did not recur in 2021.

Research and Development Expenses

For the three months ended September 30, 2021, research and development expenses were approximately $4,262,000, as compared to approximately $1,753,000 for the three months ended September 30, 2020, an increase of approximately $2,509,000. This increase was due to an increase in costs associated with our clinical trial activities, including increased employee costs to build out our clinical team, as well as higher rent expense, among other items.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately $7,777,000 for the three months ended September 30, 2021, as compared to approximately $7,282,000 for the three months ending September 30, 2020, an increase of $495,000. This increase is related to an increase in salaries, commissions and sales and marketing costs, increased travel and entertainment costs and an increase in non-cash restricted stock expense related to restricted stock units granted to the Company's executive officers. These increases were partially offset by a decrease in non-cash stock option compensation expense, lower royalty expense due to a decrease in sales, and a decrease in other general and administrative expenses.

Interest Income/(Expense), net

For the three months ended September 30, 2021, net interest income was approximately $13,000, as compared to net interest expense of approximately $261,000 for the three months ended September 30, 2020. This decrease in net interest expense was the result of the payoff of our outstanding term loans with Bridge Bank in December of 2020.

Liquidity and Capital Resources

Since inception, our operations have been primarily financed through the issuance of debt and equity securities. As of September 30, 2021, we had current assets of approximately $72,752,000 including cash on hand of approximately $61,043,000 and current liabilities of approximately $11,070,000. During the period from January 1, 2020 through July 15, 2020, we raised approximately $26,427,000 by utilizing our ATM facility with co-agents Jefferies LLC and B. Riley FBR. In addition, we received net proceeds of approximately $53,800,000 from our underwritten public offering that closed on July 24, 2020. Also, we received approximately $1,127,000 in cash from the approved sale of our net operating losses and research and development credits from the State of New Jersey during the nine months ended September 30, 2021.

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

Fourth Quarter and Full Year 2021 Product Revenue Guidance

The macro environment of the global COVID-19 pandemic continues to add uncertainty to the Company's sales outlook, especially since we are unable to predict the course of the pandemic or predict what impact, if any, the COVID-19 pandemic may have on global sales for the remainder of the year.

The Company maintains its guidance that Q4 2021 product revenue will be similar to Q3 2021 product revenue of $8.9 million.

The Company maintains its guidance for expected full year 2021 product revenue of at least $39.3 million, roughly flat compared to 2020 product revenue of $39.5 million. While difficult to predict, 2021 core non-COVID-19 product sales are expected to be approximately $33 to $34 million for the year versus $30.1 million in 2020.

For additional information, please see the Company's Form 10-Q for the period ended September 30, 2021 filed on November 4, 2021 on http://www.sec.gov.

Conference Call

The company will conduct its third quarter operating and financial 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: 1-877-521-4127
International: 1- 212-231-2900
Conference ID: 21998483

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://viavid.webcasts.com/starthere.jsp?ei=1505348&tp_key=fc4e9855a2

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 152,000 cumulative CytoSorb devices have been utilized to date. 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 is initiating 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** (**S**afe and **T**imely **A**ntithrombotic **R**emoval-**T**icagrelor) 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** (**S**afe and **T**imely **A**ntithrombotic **R**emoval-**D**irect 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, 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, 2021, 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 AND COMPREHENSIVE LOSS
(amounts in thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue:				
CytoSorb sales	$ 8,901	$ 10,246	$ 30,405	$ 27,853
Other sales	1	--	6	69
Total product sales	8,902	10,246	30,411	27,922
Grant income	858	301	1,972	1,127
Total revenue	9,760	10,547	32,383	29,049
Cost of revenue	2,463	2,891	7,924	8,525
Gross profit	7,297	7,656	24,459	20,524
Other Expenses:				
Research and development	4,262	1,754	10,244	6,125
Legal, financial and other consulting	665	580	2,090	1,945
Selling, general and administrative	7,776	7,282	25,308	20,190
Total expenses	12,703	9,616	37,642	28,260
Loss from operations	(5,406)	(1,960)	(13,183)	(7,736)
Other income/(expense):				
Interest income (expense), net	13	(261)	16	(840)
Gain (loss) on foreign currency transactions	(1,013)	1,381	(2,085)	1,417
Total other income (expense), net	(1,000)	1,120	(2,069)	577
Loss before benefit from income taxes	(6,406)	(840)	(15,252)	(7,159)
Benefit from income taxes	--	--	--	--
Net loss	$ (6,406)	$ (840)	$ (15,252)	$ (7,159)
Basic and diluted net loss per common share	$ (0.15)	$ (0.02)	$ (0.35)	$ (0.19)
Weighted average number of shares of common stock outstanding	43,396,464	41,593,218	43,319,507	37,350,564
Net loss	$ (6,406)	$ (840)	$ (15,252)	$ (7,159)
Other comprehensive income (loss):				
Currency translation adjustment	808	(1,047)	1,701	(1,044)
Comprehensive loss	$ (5,598)	$ (1,887)	$ (13,551)	$ (8,203)

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	September 30, 2021 (unaudited)	December 31, 2020
ASSETS:		
Current Assets:		
Cash and cash equivalents	$ 61,043	$ 71,422
Grants and accounts receivable, net	5,241	5,159
Inventories	4,528	2,674
Prepaid expenses and other current assets	1,940	3,198
Total current assets	72,752	82,453
Property and equipment, net	3,799	2,120
Right of use asset	13,651	1,029
Other assets	4,865	4,348
TOTAL ASSETS	$ 95,067	$ 89,950
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current Liabilities:		
Accounts payable	$ 3,358	$ 1,835
Lease liability - current portion	265	447
Accrued expenses and other current liabilities	7,447	7,871
Total current liabilities	11,070	10,153
Lease liability, net of current portion	13,386	582
TOTAL LIABILITIES	24,456	10,735
Total stockholders' equity	70,611	79,215
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 95,067	$ 89,950

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