CytoSorbents Reports First Quarter 2021 Financial and Operational Results

Total revenue increased to $10.6M. Q1 2021 CytoSorb product sales grew 24% to $10.1M versus $8.2M a year ago

MONMOUTH JUNCTION, N.J., May 4, 2021 — CytoSorbents Corporation (NASDAQ: CTSO), a critical care leader using its CytoSorb® blood purification technology to treat life-threatening conditions in critically-ill and cardiac surgery patients around the world, reports financial and operating results for the quarter ended March 31, 2021.

First Quarter 2021 Financial Results:

- Total revenue for Q1 2021 was $10.6 million, including both product sales and grant income, compared to $8.7 million in Q1 2020, an increase of 22%
- Q1 2021 CytoSorb product sales was $10.1 million, an increase of approximately $2.0 million over Q1 2020 product sales of $8.2 million, an increase of 24%. Estimated COVID-19 related sales for Q1 2021 were approximately $1.8 million, compared to $1.6 million in Q1 2020
- Gross profit margin rose to $7.8 million in Q1 2021, as compared to $6.3 million in Q1 2020
- Q1 2021 Product gross margins were 77%. Excluding the non-recurring negative impact of 2018, 2019 and 2020 tariff adjustments of approximately $732K and the offsetting non-recurring positive impact of the Employee Retention Tax Credit of $388K, product gross profit margins were 81% in Q1 2021, as compared to 76% in Q1 2020
- Trailing twelve months product sales rose to $41.4M at March 31, 2021, an increase of $15.1M or 57% over trailing twelve months product sales of $26.3M at March 31, 2020
- Healthy cash balance of $68.5M at March 31, 2021

Q1 2021 Operating Highlights:

- Exceeded 131,000 cumulative CytoSorb treatments delivered, up from 88,000 in Q1 2020, an increase of 49%, with an estimated 5,750 COVID-19 patients treated across 30+ countries to date

- Filed and later received U.S. FDA conditional approval of an Investigational Device Exemption (IDE) protocol to conduct the U.S. STAR-T (**S**afe and **T**imely **A**ntithrombotic **R**emoval of **T**icagrelor) randomized controlled trial. This trial was designed to support U.S. FDA approval under Breakthrough Designation
- We are pleased to announce that the U.S. STAR-T trial will be led by two luminaries in the field of cardiovascular medicine who will serve as Co-Principal Investigators:
    - Dr. Michael Mack, MD – Medical Director of Cardiothoracic Surgery for Baylor Scott & White Health and the chairman of BSW The Heart Hospital – Plano Research Center. He is a pioneer in the field of cardiothoracic surgery and a world-renowned clinical researcher and physician who has performed more than 7,000 cardiac surgeries and authored over 400 publications, and has been instrumental in key advances in the treatment of cardiovascular disease.
    - Dr. C. Michael Gibson, MS, MD – President and CEO of the combined non-profit Baim and PERFUSE research institutes at Harvard Medical School that has led over 1,000 studies, published 3,000 manuscripts, and led 60 FDA submissions from their worldwide network. Dr. Gibson is an interventional cardiologist and an internationally recognized thought leader in cardiovascular clinical trials and the regulatory process and has led Phase I-4 clinical trials, and cardiology megatrials totaling more than 180,000 patients which eventuated in international approval of drugs like prasugrel (Effient®, Daiichi Sankyo, Eli Lilly) and rivaroxaban (Xarelto®, Bayer, Jannsen), and betrixaban (Bevyxxa®, AstraZeneca)
- Announced a global co-marketing agreement with B. Braun Avitum AG, the third largest dialysis company in the world with €7.5 billion in worldwide revenue, to promote CytoSorb® with their OMNI® Continuous Blood purification platform
- Appointed two key hires:
    - Mr. James Komsa as Vice President – U.S. Sales and Marketing to manage U.S. sales of CytoSorb under the FDA Emergency Use Authorization for COVID-19 patients, and potential U.S. approval of the technology for antithrombotic removal during cardiothoracic surgery. Formerly a VP at Medtronic
    - Dr. David D. Cox, PhD, MBA as Vice President – Global Regulatory Affairs to help drive regulatory approval in the U.S. and lead CytoSorbents global regulatory initiatives. Formerly VP of Regulatory Affairs at Integra LifeSciences
- The Korean Ministry of Food and Drug Safety (KMFDS) approved CytoSorb for all equivalent European Union (E.U.) approved indications, in collaboration with partner, Fresenius Medical Care
- Health Canada authorized CytoSorb for the importation, sale, and use in hospitalized COVID-19 patients, with CytoSorb distributed by ebbtides medical
- United Kingdom's National Institute of Health and Care Excellence (NICE) issued a Medtech Innovation Briefing on CytoSorb for reducing the risk of bleeding during cardiac surgery
- Executed the lease on our new 48,500 sq ft. U.S. corporate headquarters and future manufacturing center at 305 College Road East, Princeton, New Jersey, intended to

support volume production capacity of $350-400 million in CytoSorb sales and product gross margins in excess of 85%
- Opened the new CytoSorbents Logistics Hub Europe, an expanded warehouse and distribution facility
- Conducted multiple webinars using CytoSorb in:
    - Liver dialysis therapy and how it surpasses other technologies
    - Removal of anti-thrombotic or blood thinner medications and the reduction in bleeding complication and costs, the potential to reduce re-thoracotomies (re-operations), and why this application is relevant
    - Post-cardiac surgery to control post-operative complications such as shock
    - Multiple separate applications in septic shock, in COVID-19 patients, in muscle injury and rhabdomyolysis, valve replacement for infective endocarditis, in major aortic surgery, and extracorporeal membrane oxygenation (ECMO) – here and here.

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, "Product sales grew by a healthy 24% in Q1 2021 compared to a year ago, aided by 27% growth in our core non-COVID-19 business and 79% growth in distributor and partner sales overall. We believe that Q1 2021 sales would have been even higher, but were hampered for most of the quarter by restrictions and lockdowns throughout Europe in many of our core markets, coupled with rapidly declining new COVID-19 infections and hospitalizations globally throughout the first two months of the quarter. COVID-19 related sales for Q1 2021 were approximately $1.8M, down from an average of $2.6M in the prior three quarters. However, March brought another dreaded COVID-19 wave to Europe, Latin America, the Middle East, and India, resulting in a massive spike in new worldwide infections and a strengthening of COVID-19 related orders of CytoSorb, despite a continuation of lockdowns and restrictions."

"Once the COVID-19 pandemic diminishes, we believe we will continue our multi-year cycle of sales growth based on the breadth and strength of our core non-COVID-19 businesses in critical care and cardiac surgery and the growing body of evidence generated by our clinical programs. The accelerated adoption of CytoSorb around the world that we are seeing due to COVID-19 and new exciting applications, such as liver dialysis therapy and anti-thrombotic drug removal during cardiac surgery, are expected to accelerate this growth phase. Because of this, we continue to invest in our commercialization team, new manufacturing facilities, and importantly, Company-sponsored clinical studies designed to support inclusion of our therapy into global standard treatment guidelines."

"To this end, we have made excellent progress in our clinical programs. The U.S. STAR-T trial is our current clinical priority, as we believe it provides the shortest, lowest risk, and most visible path to potential U.S. regulatory approval. Our FDA conditional IDE approval gave us the green light to complete our operational readiness activities and begin anticipated enrollment of the study in Q3 2021. We have already evaluated and received verbal agreement from all of our clinical trial centers to participate in the study, selected a contract research organization, and

established a Data and Safety Monitoring Board (DSMB) and Clinical Evaluation Committee (CEC). We are now proceeding with clinical trial agreements and ethics committee review at these trial sites. Most importantly, today we are pleased to announce STAR-T trial leadership by two seminal figures in cardiovascular clinical research, Dr. Michael Mack and Dr. C. Michael Gibson. Their guidance and involvement in the study design has already proven invaluable. We look forward to sharing more detail of the study once the IDE is fully approved."

"Meanwhile, we continue to make progress on our other studies:

- The U.S. REFRESH 2-AKI pivotal trial has now restarted, with 50% of study sites now active and screening, with the remaining sites expected to be active, pending COVID-19 restrictions, by the end of this quarter
- The CTC COVID-19 Registry data entry and interim analysis on more than 50 critically ill U.S. COVID-19 patients with acute respiratory distress syndrome (ARDS) on ECMO plus CytoSorb is nearing completion with a publication submission expected this quarter
- The CyTATION ticagrelor removal trial enrolled its first patients in the first quarter and will continue, led by the pioneers of this therapeutic approach in Germany, and is expected to provide important additional information to STAR-T. However, we have decided to close our single arm, multi-center U.K. TISORB study, due to protracted COVID-19 related delays in enrollment and the ongoing U.K. lockdown, as previously disclosed, in favor of redirecting those financial and personnel resources towards the U.S. STAR-T trial
- The PROCYSS refractory septic shock and the HepOnFire acute alcoholic hepatitis pilot studies are moving forward and are on target to begin patient enrollment in Q4 2021
- We continue to expect to see topline data from the REMOVE endocarditis trial this quarter"

Dr. Chan concluded, "Finally, we recently added a new warehouse and product distribution center in Berlin, Germany to help manage our increased international product volumes and logistics. We are also excited to move forward with construction of our manufacturing facility and building improvements of our new corporate headquarters in Princeton, New Jersey. With a modest capital expenditure of $6-7M, this new production plant is expected to quintuple our capacity to support $350-400M in sales, while helping to significantly improve our product gross margins and potential future profitability. Pending COVID-19 restrictions, most of our non-manufacturing staff are expected to move into the new building during the summer, with a staged transition of our manufacturing teams to the new building by the end of 2022 as the Princeton manufacturing facility is expected to be completed, validated, and comes on line."

"Please join us on our earnings conference call today, details for which are below."

Conference Call Details:

Date: Tuesday, May 4, 2021
Time: 4:45 PM Eastern Time
Participant Dial-In: 1-877-451-6152

Conference ID: 13718834
Live Presentation Webcast: http://public.viavid.com/index.php?id=144427

It is recommended that participants dial in approximately 10 minutes prior to the start of the call. There will also be a simultaneous live webcast of the conference call that can be accessed through the following audio feed link: http://public.viavid.com/index.php?id=144427

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/.

Results of Operations

Comparison for the three months ended March 31, 2021 and 2020:

Revenues:

Revenue from product sales was approximately $10,143,000 in the three months ended March 31, 2021, as compared to approximately $8,156,000 in the three months ended March 31, 2020, an increase of approximately $1,987,000, or 24%. This increase was driven by an increase in direct sales of approximately $608,000 resulting from sales to both new customers and repeat orders from existing customers and an increase in distributor sales of approximately $1,379,000. Sales to hospitals in the United States under the EUA granted by the FDA amounted to approximately $304,000 for the three months ended March 31, 2021. Though difficult to quantitate, we estimate that approximately $1.8 million of total product sales in the first quarter of 2021 was due to the demand for CytoSorb to treat COVID-19 patients. In addition, as a result of the increase in the average exchange rate of the Euro to the U.S. dollar, 2021 product sales were positively impacted by approximately $790,000. For the three months ended March 31, 2021, the average exchange rate of the Euro to the U.S. dollar was $1.21 as compared to an average exchange rate of $1.10 for the three months ended March 31, 2020.

Grant income was approximately $455,000 for the three months ended March 31, 2021 as compared to approximately $551,000 for the three months ended March 31, 2020, a decrease of approximately $96,000 or 17%. This decrease was a result of delays in grant related work caused by the COVID-19 pandemic as 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 $10,599,000 for the three months ended March 31, 2021, as compared to total revenues of approximately $8,707,000 for the three months ended March 31, 2020, an increase of approximately $1,892,000, or 22%.

Cost of Revenues:

For the three months ended March 30, 2021 and 2020, cost of revenue was approximately $2,751,000 and $2,385,000, respectively, an increase of approximately $366,000. Product cost of revenues increased approximately $354,000 during the three months ended March 31, 2021 as compared to the three months ended March 31, 2020 primarily as a result of increased sales. Product gross margins were approximately 77% for the three months ended March 31, 2021 and approximately 76% for the three months ended March 31, 2020. The increase in the gross margin percentage in 2021 was due manufacturing efficiencies achieved during the three months ended March 31, 2021 and the receipt of approximately $388,000 related to the Employee Retention Tax Credit under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). These increases were offset by the impact of costs related to prior years tariffs as a result of an audit by the German Customs Authorities. Excluding the non-recurring negative impact of the 2018, 2019 and 2020 tariff adjustments of approximately $732,000 and the offsetting non-recurring positive impact of the Employee Retention Tax Credit which were recorded in the first quarter of 2021, product gross margins were approximately 81% for the three months ended March 31, 2021. Please see Note 6 to the financial statements for details related to this matter.

Research and Development Expenses:

For the three months ended March 31, 2021, research and development expenses were approximately $2,282,000 as compared to research and development expenses of approximately $1,965,000 for the three months ended March 31, 2021, an increase of approximately $317,000. This increase was due to an increase in salaries related to our clinical trial activities of approximately $333,000 due to the hiring of additional personnel dedicated to the design of protocol and the anticipated start of a clinical trial in the United States for the removal of ticagrelor in emergent and urgent cardiac surgery patients and an increase in non-grant related research and development costs of approximately $65,000. These increases were offset by a decrease in new product development costs of approximately $81,000.

Legal, Financial and Other Consulting Expenses:

Legal, financial and other consulting expenses were approximately $708,000 for the three months ended March 31, 2021, as compared to approximately $519,000 for the three months ended March 31, 2020. The increase of approximately $189,000 was due to an increase in hiring fees of approximately $151,000 due to the hiring of certain senior level personnel and an increase in consulting fees of approximately $111,000 primarily related to certain financial advisory fees and information systems consulting. These increases were offset by decreases in legal fees of approximately $60,000 and accounting fees of approximately $13,000.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were approximately $7,710,000 for the three months ended March 31, 2021, as compared to approximately $6,317,000 for the three months ending March 31, 2020, an increase of $1,393,000. This increase is related to an increase in salaries, commissions and other employee-related costs of approximately $1,551,000, an

increase in royalty expenses of approximately $156,000 due to the increase in product sales, an increase in commercial insurance of approximately $75,000 and an increase other general and administrative expenses of approximately $50,000. These increases were offset by reductions in sales and marketing costs, which include advertising and conference attendance of approximately $151,000 and travel and entertainment costs of approximately $190,000 due primarily to travel restrictions related to the COVID-19 pandemic and a decrease in non-cash stock option and restricted stock expense of approximately $98,000.

Interest Expense, net:

For the three months ended March 31, 2021, net interest expense was approximately $10,000, as compared to net interest expense of approximately $306,000 for the three months ended March 31, 2020. This decrease in net interest expense of approximately $296,000 was the result of the payoff of our outstanding term loans with Bridge Bank in December of 2020.

Gain (Loss) on Foreign Currency Transactions:

For the three months ended March 31, 2021, the loss on foreign currency transactions was approximately $1,306,000 as compared to a loss of approximately $668,000 for the three months ended March 31, 2020. The 2021 loss was directly related to the decrease in the spot exchange rate of the Euro to the U.S. dollar at March 31, 2021 as compared to December 31, 2020. The spot exchange rate of the Euro to the U.S. dollar was $1.17 per Euro at March 31, 2021, as compared to $1.22 per Euro at December 31, 2020. The 2020 loss was directly related to the decrease in the spot exchange rate of the Euro at March 31, 2020 as compared to December 31, 2019. The spot exchange rate of the Euro to the U.S. dollar was $1.10 per Euro at March 31, 2020, as compared to $1.12 per Euro at December 31, 2019.

History of Operating Losses

We have experienced substantial operating losses since inception. As of March 31, 2021, we had an accumulated deficit of approximately $200,794,000, which included losses of approximately $4,168,000 and $3,453,000 for the three-month periods ended March 31, 2021 and 2020, respectively. Historically, losses have resulted principally from costs incurred in the research and development of our polymer technology, clinical studies, and general and administrative expenses.

Liquidity and Capital Resources

Since inception, our operations have been primarily financed through the issuance of debt and equity securities. At March 31, 2021, we had current assets of approximately $79,635,000 including cash on hand of approximately $68,468,000 and current liabilities of approximately $9,759,000. 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 expect to receive 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 in the second quarter of 2021.

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

2021 Second Quarter Guidance

CytoSorbents has not historically given specific financial guidance on quarterly results until the quarter has been completed. However, should current underlying order patterns continue, with strength in our core business and global demand for CytoSorb to treat COVID-19 patients, as well as our ability to continue to scale up and produce CytoSorb, we expect our second quarter 2021 product sales will exceed product sales reported in the second quarter of 2020. We believe the COVID-19 pandemic has increased awareness and usage of CytoSorb as a treatment of cytokine storm in many countries worldwide. We cannot predict what the lasting impact of this exposure will have on our long-term business, if any, and sales of CytoSorb may return to historical levels when the pandemic is over.

For additional information, please see the Company's Form 10-Q for the period ended March 31, 2021 filed on May 4, 2021 on http://www.sec.gov.

About CytoSorbents Corporation (NASDAQ: CTSO)

CytoSorbents Corporation is a leader in critical care immunotherapy, specializing in blood purification. Its flagship product, CytoSorb® is approved in the European Union with distribution in 67 countries around the world, as an extracorporeal cytokine adsorber designed to reduce the "cytokine storm" or "cytokine release syndrome" that could otherwise cause massive inflammation, organ failure and death in common critical illnesses. These are conditions where the risk of death is extremely high, yet no effective treatments exist. CytoSorb® has been used in more than 131,000 human treatments to date. CytoSorb has received FDA Emergency Use Authorization in the United States for use in critically-ill COVID-19 patients with imminent or confirmed respiratory failure, in defined circumstances. CytoSorb has also been granted FDA Breakthrough Designation for the removal of ticagrelor in a cardiopulmonary bypass circuit during emergent and urgent cardiothoracic surgery.

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 $39.5 million from DARPA, the U.S. Army, the U.S. Department of Health and Human Services, the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI), U.S. Special Operations Command (SOCOM), the U.S. Army, U.S. Special

Operations Command (USSOCOM), the U.S. Air Force, Air Force Material Command (USAF/AFMC) and others. The Company has numerous products under development based upon this unique blood purification technology protected by many issued U.S. and international patents and multiple applications pending, including CytoSorb-XL™, HemoDefend™, VetResQ™, K⁺ontrol™, ContrastSorb, DrugSorb, 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, including statements about our product sales, our cash runway, expected revenues and the impact of the COVID-19 pandemic on the Company, its operations and use of CytoSorb internationally, 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
(amounts in thousands, except per share data)

	For the Three Months Ended	
	3/31/21	3/31/20
Revenue:		
CytoSorb sales	$ 10,143	$ 8,156
Other sales	---	---
Total product sales	10,143	8,156
Grant income	456	551
Total revenue	10,599	8,707
Cost of revenue	2,751	2,385
Gross profit	7,848	6,322
Expenses:		
Research and development	2,282	1,965
Legal, financial and other consulting	708	519
Selling, general and administrative	7,710	6,317
Total operating expenses	10,700	8,801
Loss from operations	(2,852)	(2,479)
Other expense:		
Interest expense, net	(10)	(306)
Loss on foreign currency transactions	(1,306)	(668)
Total other expense, net	(1,316)	(974)
Loss before benefit from income taxes	(4,168)	(3,453)
Benefit from income taxes	---	---
Net loss	(4,168)	(3,453)
Earnings per share:		
Basic and diluted loss per share	$ (0.10)	$ (0.10)
Weighted average share outstanding	43,242,791	33,981,262
Net Loss	$ (4,168)	$ (3,453)
Other comprehensive income:		
Currency translation adjustment	1,158	610
Comprehensive loss	$ (3,010)	$ (2,843)

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	March 31, 2021	December 31, 2020
ASSETS:		
Current Assets:		
Cash and cash equivalents	$ 64,468	$ 71,422
Grants and accounts receivable, net	5,019	5,159
Inventories	3,108	2,674
Prepaid expenses and other current assets	3,040	3,198
Total current assets	79,635	82,453
Property and equipment, net	2,405	2,120
Right of use asset	924	1,029
Other assets	4,515	4,348
TOTAL ASSETS	$ 87,479	$ 89,950
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current Liabilities:		
Accounts payable	$ 1,677	$ 1,835
Current maturities of long–term debt	---	---
Lease liability - current portion	463	447
Accrued expenses and other current liabilities	7,619	7,871
Total current liabilities	9,759	10,153
Long-term debt, net of current maturities and debt issuance costs	---	---
Lease liability, net of current portion	461	582
TOTAL LIABILITIES	10,220	10,735
Total stockholders' equity	77,259	79,215
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 87,479	$ 89,950

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