CytoSorbents Reports First Quarter 2023 Results

Pivotal U.S. and Canada STAR-T Trial enrollment enters the last third of the study. Strong customer demand from Q4 2022 continued into Q1 2023, with current expectation of overall sales growth in 2023

PRINCETON, N.J., May 2, 2023 — CytoSorbents Corporation (NASDAQ: CTSO), a leader in the treatment of life-threatening conditions in the intensive care unit and cardiac surgery using blood purification via its proprietary polymer adsorption technology, today reported unaudited financial and operating results for the quarter ended March 31, 2023.

First Quarter 2023 Financial Results

- Total revenue, including product sales and grant income, for Q1 2023 was $9.4 million, an increase of 9% compared to $8.7 million in Q1 2022
- Q1 2023 product sales were $7.9 million versus $7.9 million in Q1 2022. There were no COVID-related sales this quarter, compared to approximately $300K of COVID-related sales in Q1 2022
- Currency effects negatively impacted Q1 2023 sales by approximately $349K. Constant currency core product sales in Q1 2023 were $8.3 million, an increase of $635K or 8.3%, over core products sales of $7.6 million in Q1 2022
- Q1 2023 represents the second consecutive period of sequential quarterly product sales growth, and the first time that Q1 core product sales sequentially exceeded seasonally strong core Q4 sales in the past five years, which we believe represents a positive indicator of improving business
- Q1 2023 product gross margin was approximately 68%, compared to 80% in Q1 2022 due to start-up activities of our new manufacturing facility
- We believe the Company remains well-capitalized with cash and cash equivalents of $20.7 million (which includes $1.7 million in restricted cash) as of March 31, 2023

Recent Operating Highlights

- We have now surpassed 200,000 cumulative human treatments globally after achieving 100,000 cumulative CytoSorb treatments in August 2020 less than 3 years ago. As of the end of Q1 2023, there have been more than 203,000 CytoSorb cumulative treatments delivered across more than 75 countries worldwide
- The pivotal STAR-T randomized controlled trial achieved its second milestone of 80 patients enrolled on schedule in mid-April 2023, following the first milestone of 40 patients enrolled in November 2022, triggering a second pre-specified Data and Safety Monitoring Board (DSMB) review, which is expected to complete in the next few months. The trial continues to enroll well and is now in its last stage of enrollment, which is expected to complete this summer
- Our Board Chairman, Al Kraus, announced his intent to retire at the end of his term in June 2023, following 20 years of leadership with the Company at age 78. He will continue to consult for the Company as needed. Pending the results of the 2023 Annual Meeting, current Board Director Michael Bator will succeed Al Kraus as Chairman of the Board
- Highlighted a landmark publication in the high impact, peer-reviewed journal, Critical Care, underscoring the power of CytoSorb to reduce cytokine storm during systemic hyperinflammation caused by a very important toxin in half of sepsis cases, in a well-controlled, balanced, and definitive human study
- Hosted a successful and highly attended scientific symposium and exhibition at the 42nd International Symposium on Intensive Care & Emergency Medicine (ISICEM 2023) in Brussels, Belgium in March 2023, where data from the latest studies were presented and live-streamed, detailing the effect of CytoSorb in treating cytokine storm and deadly inflammation in diseases such as sepsis, shock, and acute respiratory distress syndrome (ARDS), including the study above which was the centerpiece of the session

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, "We believe we have started 2023 with favorable momentum and are pleased with the continued execution of three key goals described in the shareholder letter earlier this year.

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

The STAR-T (**S**afe and **T**imely **A**ntithrombotic **R**emoval - **T**icagrelor) pivotal, randomized controlled trial is designed to support U.S. FDA and Health Canada marketing approval of DrugSorb-ATR with the goal of demonstrating that DrugSorb-ATR reduces the risk of perioperative bleeding in patients undergoing cardiothoracic surgery on Brilinta® (ticagrelor, AstraZeneca). The STAR-T trial is enrolling well with recruitment by nearly all trial sites, both here

in the U.S. and in Canada, and has recently outpaced our own internal projections. Should these trends continue, we expect to enroll the final third of the study this summer and have topline data by year-end that if positive, we believe would support the application for FDA and Health Canada marketing approval of DrugSorb-ATR.

As discussed recently, the rapid pace of enrollment of STAR-T led us to elect to forego a formal interim analysis on the first 80 patients. To fully understand this decision, it is important to clarify that the original intent of this interim analysis was to provide the opportunity to stop the trial early, an important option if enrollment was expected to be slow or delayed. However, the current enrollment pace is brisk and our projections suggest that the trial will likely be completed by the time a formal interim analysis - that requires fully monitored, cleaned, locked, and adjudicated data - would have been completed. Accordingly, a trial that is fully enrolled cannot be stopped early and as such we are now focusing our efforts on the final analysis. We believe it is also important to emphasize that there are no other considerations or information underlying this decision and that the STAR-T study data remain fully-blinded. The next milestone for the STAR-T trial is the second independent Data and Safety Monitoring Board (DSMB) safety evaluation after the first 80 patients which we expect to be completed in the next 2-3 months. As previously disclosed, the DSMB recommendation after the safety evaluation of the first 40 patients was to continue the study as planned without any modifications.

In parallel to the clinical study, Dr. Irina Kulinets, Senior Vice President of Global Regulatory, is leading the execution of the regulatory strategy for DrugSorb-ATR that at this stage includes strengthening her team, planning for future regulatory submissions, and driving interdepartmental alignment and responsibilities to meet our regulatory objectives and timelines.

Finally, we spoke previously of a pending proposal from Centers for Medicare & Medicaid Services (CMS) for Transitional Coverage of Emerging Technology (TCET) that could establish four years of U.S. Medicare coverage to breakthrough medical devices approved by the FDA. This proposal was expected in April 2023, and is still expected imminently. We believe that DrugSorb®-ATR, as an FDA Breakthrough Designated Device that targets many patients in the Medicare population undergoing open heart surgery and at high risk of unwanted bleeding due to blood thinners, could be well-suited for such a program.

2. Return to Sales Growth

We believe the achievement of sequential growth in Q1 2023 product sales from the prior quarter, and 8% quarterly core product sales growth year-over-year on a constant currency basis,

represent an encouraging sign towards our goal of returning to sales growth this year. More important than this, however, is the general perception of our employees across each of our business segments of strong customer engagement, excellent feedback on our most recent clinical and scientific data across multiple indications in our therapeutic area verticals, and a trend of improvement in our hospital markets in core countries - though healthcare professional staffing remains a key issue. For example, in Germany, the DIVI Critical Care Society is reporting an increase in regularly operating adult intensive care units, and a concomitant sharp reduction in restricted ICUs – an important, non-quantitative assessment of the supply situation, which is governed by availability of staff, rooms, materials, and other factors. This has correlated with a major drop in COVID-related ICU admissions. If sustained, we believe it is likely that the mandate to have emergency reserve ICU beds for COVID-19 will also likely be lifted, freeing additional ICU capacity throughout the country. We expect this to translate into the ability to accept more non-COVID critically ill patients to the ICU and to do more surgical procedures, such as cardiac surgery, that require ICU postoperative care, which are all drivers of our business. Among our many growth initiatives, we are also seeing good progress in our strategy of expanding into German hospitals within private networks based on our preferred supplier agreements, increasing our accounts in these German networks by 50% last year over 2021.

We believe these improvements are beginning to translate to our own results, where Q1 2023 demand was brisk, working down our finished goods inventory. In response, we have been ramping production of CytoSorb out of our new manufacturing facility with the goal of meeting demand and replenishing inventory. Our product gross margins for Q1 2023 were 68%, in-line with the average product gross margin in 2022, reflecting the transition from our old to new facility and a number of one-time start-up costs. However, we expect sequential improvements of our product gross margin this year, and again reiterate our expectation of a return of product gross margins to at least 75-80% on a quarterly basis this year.

3. ***Reduced Cash Burn and Tight Control Over Expenses***

Last year, we implemented numerous cost-cutting efforts, disciplined cash management, and a strict 2023 budget to significantly reduce operating expenses and to optimize resource allocation to priority programs and pipeline projects. We are pleased that these changes, along with reductions in capital expenditure spending, led to a significantly lower cash burn in Q1 2023 of approximately $3.1M versus $9.1M cash burn a year ago. We currently do not expect any significant capital expenditures this year which could potentially further reduce our need for cash. We closed Q1 2023 with $20.7M in cash, which is expected to fund our operations for more than a year."

Dr. Chan concluded, “We believe we are on the path to significant growth of our business and are in a much stronger position now than in the second half of last year. We believe we are making excellent progress on our major goals for 2023. In particular, we expect the completion of the STAR-T trial enrollment this summer with topline data later this year, which could be a pivotal milestone for the Company. We are seeing solid improvements and momentum in our core CytoSorb business, giving us optimism that our commercial business is continuing to turn around. And we believe our cost-cutting initiatives are taking hold, leading to a low cash burn quarter and a solid cash position going into Q2 2023. Between now and the end of the year, we expect many exciting developments and thank you for sharing the journey with us.”

Results of Operations

Comparison of the three months ended March 31, 2023 and March 31, 2022

Revenues:

Revenue from product sales was approximately $7,910,000 in the three months ended March 31, 2023, as compared to approximately $7,924,000 in the three months ended March 31, 2022, a decrease of approximately $14,000. As a result of the decrease in the average exchange rate of the Euro to the U.S. dollar, 2023 product sales were negatively impacted by approximately $349,000. For the three months ended March 31, 2023, the average exchange rate of the Euro to the U.S. dollar was $1.07 as compared to an average exchange rate of $1.12 for the three months ended March 31, 2022. Direct sales decreased approximately $202,000, or 4%. Distributor sales increased approximately $188,000, or 7%. There were no sales to hospitals in the United States under the EUA granted by the FDA for the three months ended March 31, 2023, as compared to sales of approximately $155,000 in the first quarter of 2022. There were no sales related to the demand for CytoSorb to treat COVID-19 patients during the three months ended March 31, 2023 as compared to approximately $300,000 in the first quarter of 2022.

Grant income was approximately $1,539,000 for the three months ended March 31, 2023 as compared to approximately $767,000 for the three months ended March 31, 2022, an increase of approximately $772,000, or 101%. This increase was a result of a strategic decision to deploy our research and development employees exclusively to grant related activities during the three months ended March 31, 2023. In addition, revenue earned on new grant awards was approximately $312,000 during the three months ended March 31, 2023.

Total revenues were approximately $9,449,000 for the three months ended March 31, 2023, as compared to total revenues of approximately $8,691,000 for the three months ended March 31, 2022, an increase of approximately $758,000, or 9%.

Cost of Revenues:

For the three months ended March 30, 2023 and 2022, cost of revenue was approximately $3,994,000 and $2,278,000, respectively, an increase of approximately $1,716,000. Product cost of revenues increased approximately $976,000 during the three months ended March 31, 2023 as compared to the three months ended March 31, 2022. This increase was due to start-up activities related to our new manufacturing facility. Product gross margins were approximately 68% for the three months ended March 31, 2023, as compared to approximately 80% for the three months ended March 31, 2022, also due to start-up activities related to our new manufacturing facility.

Research and Development Expenses:

For the three months ended March 31, 2023, research and development expenses were approximately $4,214,000 as compared to research and development expenses of approximately $4,243,000 for the three months ended March 31, 2022, a decrease of approximately $29,000. This decrease was due to a decrease in clinical trial costs of approximately $807,000 related to the pause of our STAR-D trial in November 2022, and a decrease in non-grant related research and development activities of approximately $72,000. These decreases were offset by approximately $850,000 of costs incurred related to pre-production manufacturing activities required to bring the new manufacturing plant to a state of commercial readiness.

Legal, Financial and Other Consulting Expenses:

Legal, financial and other consulting expenses were approximately $669,000 for the three months ended March 31, 2023, as compared to approximately $801,000 for the three months ended March 31, 2022, a decrease of approximately $132,000. This decrease was due to a decrease in legal fees of approximately $174,000 related to the abandonment of certain patent applications in 2022 and a decrease in accounting and other consulting costs of approximately $33,000. These decreases were offset by an increase in employment agency fees of approximately $75,000.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were approximately $8,463,000 for the three months ended March 31, 2023, as compared to approximately $9,161,000 for the three months ending March 31, 2022, a decrease of approximately $698,000. This decrease was due to a decrease in salaries, commissions and related costs of approximately $641,000, a decrease in commercial insurance expenses of approximately $76,000, a decrease in travel and entertainment expenses of approximately $28,000, a decrease in public relations costs of approximately $23,000, a decrease in advertising costs of approximately $18,000 and a decrease in other general and administrative expenses of approximately $46,000. These decreases were offset by increases in non-cash stock compensation and non-cash restricted stock expense of approximately $134,000.

Gain (Loss) on Foreign Currency Transactions:

For the three months ended March 31, 2023, the gain on foreign currency transactions was approximately $661,000 as compared to a loss of approximately $1,213,000 for the three months ended March 31, 2022. The 2023 gain was directly related to the increase in the spot exchange rate of the Euro to the U.S. dollar as of March 31, 2023 as compared to December 31, 2022. The spot exchange rate of the Euro to the U.S. dollar was $1.09 per Euro as of March 31, 2023, as compared to $1.07 per Euro as of December 31, 2022.

Interest Expense, net:

For the three months ended March 31, 2023, interest expense was approximately $63,000, as compared to interest income of approximately $8,000 for the three months ended March 31, 2022. The change was the result of interest incurred related to the draw down of the $5,000,000 Term Loan with Bridge Bank in December 2022.

Liquidity and Capital Resources

Since inception, our operations have been primarily financed through the issuance of debt and equity securities. As of March 31, 2023, we had current assets of approximately $28,165,000 and current liabilities of approximately $10,436,000. As of March 31, 2023, $25 million of our total shelf amount was allocated to our ATM facility, of which approximately $24.3 million is still available. In April of 2023, we received approximately $1.0 million in cash from the approved sale of our net operating losses and research and development credits from the State of New Jersey.

We are also managing our resources proactively, continuing to invest in key areas such as our U.S. pivotal STAR-T clinical trial. We have instituted tighter cost controls which are expected to materially reduce our cash burn in 2023.

We believe that we have sufficient cash to fund the Company's operations beyond twelve months from the issuance of these financial statements.

Conference Call Details:
Date: Tuesday, May 2, 2023
Time: 4:30 PM Eastern Time
Participant Dial-In: 201-389-0879
Conference ID: 13738513
Live Presentation Webcast:
https://viavid.webcasts.com/starthere.jsp?ei=1612750&tp_key=e42d46cec2

It is recommended that participants dial in approximately 10 minutes prior to the start of the call. There will also be a simultaneous live webcast of the conference call that can be accessed through the following audio feed link: :
https://viavid.webcasts.com/starthere.jsp?ei=1612750&tp_key=e42d46cec2

An archived recording of the conference call will be available under the Investor Relations section of the Company's website at http://cytosorbents.com/investor-relations/financial-results/.

For additional information, please see the Company's Form 10-K for the period ended December 31, 2022, filed on March 9, 2023, on http://www.sec.gov.

About CytoSorbents Corporation (NASDAQ: CTSO)

CytoSorbents Corporation is a leader in the treatment of life-threatening conditions in the intensive care unit and in cardiac surgery through blood purification. Its lead product, CytoSorb®, is approved in the European Union and distributed in 75 countries worldwide. It is an extracorporeal cytokine adsorber that reduces "cytokine storm" or "cytokine release syndrome" in common critical illnesses that can lead to massive inflammation, organ failure and patient death. In these diseases, the risk of death can be extremely high, and there are few, if any, effective treatments. CytoSorb is also used during and after cardiothoracic surgery to remove antithrombotic drugs and inflammatory mediators that can lead to postoperative complications,

including severe bleeding and multiple organ failure. As of March 31, 2023, more than 203,000 CytoSorb devices have been used cumulatively. CytoSorb was originally launched in the European Union under CE mark as the first cytokine adsorber. Additional CE mark extensions were granted for bilirubin and myoglobin removal in clinical conditions such as liver disease and trauma, respectively, and for ticagrelor and rivaroxaban removal in cardiothoracic surgery procedures. CytoSorb has also received FDA Emergency Use Authorization in the United States for use in adult critically ill COVID-19 patients with impending or confirmed respiratory failure. The DrugSorb™-ATR antithrombotic removal system, based on the same polymer technology as CytoSorb, also received two FDA Breakthrough Device Designations, one for the removal of ticagrelor and another for the removal of the direct oral anticoagulants (DOAC) apixaban and rivaroxaban in a cardiopulmonary bypass circuit during urgent cardiothoracic procedures. The Company is currently conducting the FDA-approved, randomized, controlled STAR-T (Safe and Timely Antithrombotic Removal-Ticagrelor) study of 120 patients at approximately 30 centers in U.S. and Canada to evaluate whether intraoperative use of DrugSorb-ATR can reduce the perioperative risk of bleeding in patients receiving ticagrelor and undergoing cardiothoracic surgery. This pivotal study is intended to support U.S. FDA and Health Canada marketing approval for DrugSorb-ATR in this application.

CytoSorbents' purification technologies are based on biocompatible, highly porous polymer beads that can actively remove toxic substances from blood and other bodily fluids by pore capture and surface adsorption. Its technologies have received non-dilutive grant, contract, and other funding of approximately $48 million from DARPA, the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI), the U.S. Army, the U.S. Air Force, U.S. Special Operations Command (SOCOM), Air Force Material Command (USAF/AFMC), and others. The Company has numerous marketed products and products under development based upon this unique blood purification technology protected by many issued U.S. and international patents and registered trademarks, and multiple patent applications pending, including ECOS-300CY®, CytoSorb-XL™, HemoDefend-RBC™, HemoDefend-BGA™, VetResQ®, K^{+}ontrol™, DrugSorb™, 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, statements about potential exposures resulting from our

cash positions, representations and contentions, and are not historical facts and typically are identified by use of terms such as “may,” “should,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “continue” and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements in this press release represent management’s current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. Factors which could cause or contribute to such differences include, but are not limited to, the risks discussed in our Annual Report on Form 10-K, filed with the SEC on March 9, 2023, as updated by the risks reported in our Quarterly Reports on Form 10-Q, and in the press releases and other communications to shareholders issued by us from time to time which attempt to advise interested parties of the risks and factors which may affect our business. We caution you not to place undue reliance upon any such forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, other than as required under the Federal securities laws.

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except per share data)

	For the Three Months Ended	
	3/31/23	3/31/22
Revenue:		
CytoSorb sales	$ 7,906	$ 7,867
Other sales	4	58
Total product sales	7,910	7,925
Grant income	1,539	767
Total revenue	9,449	8,692
Cost of revenue	3,994	2,278
Gross profit	5,455	6,414
Operating Expenses:		
Research and development	4,215	4,243
Legal, financial and other consulting	669	801
Selling, general and administrative	8,463	9,161
Total operating expenses	13,347	14,205
Loss from operations	(7,892)	(7,791)
Other income (expense):		
Interest income (expense), net	(63)	8
Gain on foreign currency transactions	661	(1,213)
Miscellaneous income/(expense)	(32)	30
Total other income (expense), net	566	(1,175)
Loss before benefit from income taxes	(7,326)	(8,966)
Benefit from income taxes	---	---
Net loss	(7,326)	(8,966)
Earnings per share:		
Basic and diluted loss per share	$ (0.17)	$ (0.21)
Weighted average share outstanding	43,676,435	43,487,946
Net Loss	$ (7,326)	$ (8,966)
Other comprehensive income:		
Foreign currency translation adjustment	(608)	963
Comprehensive loss	$ (7,934)	$ (8,003)

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	March 31, 2023	December 31, 2022
ASSETS:		
Current Assets:		
Cash and cash equivalents	$ 19,048	$ 22,145
Grants and accounts receivable, net	5,528	5,665
Inventories	1,726	3,461
Prepaid expenses and other current assets	1,863	2,489
Total current assets	28,165	33,760
Property and equipment, net	10,695	10,743
Restricted Cash	1,687	1,687
Right of use asset	12,470	12,604
Other assets	4,446	4,438
TOTAL ASSETS	$ 57,463	$ 63,232
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current Liabilities:		
Accounts payable	$ 2,995	$ 1,655
Lease liability - current portion	112	109
Accrued expenses and other current liabilities	7,329	7,951
Total current liabilities	10,436	9,715
Lease liability, net of current portion	13,061	13,142
Long-term debt	5,011	5,000
TOTAL LIABILITIES	28,508	27,857
Total stockholders' equity	28,955	35,375
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 57,463	$ 63,232

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