



CytoSorbents

Working to Save Lives Through Blood Purification

CytoSorbents Reports Third Quarter 2019 Financial Results

MONMOUTH JUNCTION, N.J., November 5, 2019 — [CytoSorbents Corporation](#) (NASDAQ: CTSO), a critical care immunotherapy leader using its [CytoSorb®](#) blood purification technology to treat deadly inflammation in critically-ill and cardiac surgery patients around the world, reports financial and operational results for the quarter ending September 30, 2019.

Third Quarter 2019 Financial Results:

- Total Q3 2019 revenues were \$6.1 million, including both product sales and grant income, an increase of approximately 6%, up from \$5.7 million in Q3 2018
- Product sales for Q3 2019 were approximately \$5.7 million, compared to \$5.1 million for Q3 2018, an increase of approximately 12%
- Excluding the change in the Euro to dollar exchange rate from Q3 2018 to Q3 2019, CytoSorb product sales would have been approximately \$239,000 higher than actually reported, or approximately \$6.0 million, an increase of 18% over Q3 2018 product sales
- Blended product gross margins for Q3 2019 rose to 77%, compared to 72% for Q3 2018, and 76% from Q2 2019
- Cash and cash equivalents were approximately \$16 million at the end of the quarter

Third Quarter 2019 Operational Highlights:

- More than 73,000 CytoSorbents treatments delivered cumulatively, up from 51,000 a year ago
- [Received renewal of CytoSorb CE Mark through May 2024 and annual ISO 13485:2016 certification through September 2022](#)
- [Publication of a key study demonstrating 28-day mortality benefit and the potential for CytoSorb to save 19 additional lives out of every 100 patients with septic shock on continuous renal replacement therapy](#)
- [Initiation of first study to evaluate the use of CytoSorb as a treatment of cytokine release syndrome in CAR T-cell immunotherapy](#)
- [Extended CytoSorb distribution to a total of 58 countries, with Latin America expansion to Brazil, Colombia, and Costa Rica](#)

- Two of the three distributor/partners discussed in the Q1 2019 earnings call ordered in Q3 2019
- Near completion of the Germany-funded [REMOVE endocarditis randomized controlled trial](#), with the achievement of the targeted enrollment of 250 patients. Well-ahead of schedule, the trial will continue to enroll up to 15 additional patients to account for potential dropouts, which is expected to be completed by the end of 2019
- Advancement of the U.S. pivotal [REFRESH 2-AKI trial](#), currently at 144 patients enrolled of a total of 400 patients, and positioned to exceed end-of-year enrollment target of 150
- Continued expectation to file HemoDefend IDE to FDA before year end
- [Strengthened cash position with addition of \\$5M of debt from Bridge Bank with interest-only period extended to November 2020, provided certain conditions are met](#)

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, “Product sales for the third quarter were just shy of our record Q2 2019 results, despite the summer seasonality and foreign exchange effects. In addition, our blended product gross margins were 77%, nearing our guidance of achieving 80% blended product gross margins on a quarterly basis this year. Though encouraging, we expect the growth in 2020 to be far more robust, driven by a number of important catalysts. Importantly, we have the following already in place:

- What we believe to be strong underlying demand for CytoSorb in Germany and other countries, with our limited ability to harvest the opportunity in 2019 due to a lack of manpower and challenge in the timely hiring of the right people
- We have invested heavily in our expansion and have increased headcount at the company by approximately 50% in the past year, with most of the key people joining in the past 3-6 months. We have doubled customer facing sales representatives and market specialists, and brought on others who have a direct impact on sales including new sales and marketing directors, and specialists in application and clinical support, reimbursement, manufacturing, and others
- Increased the number of direct sales countries from 5 to 10, where CytoSorb is sold to hospitals directly with our own sales reps, leveraging our focused product messaging and positioning, higher product gross margins, and market development that has taken place for the better part of a year
- Expanded distribution of CytoSorb to 58 countries, with a number of new countries expected to achieve product registration and contribute to sales in 2020, including Mexico, South Korea, Brazil, Colombia, and others
- New published data in major current indications such as septic shock, ECMO, and cardiac surgery, as well as investigational applications, such as anti-thrombotic drug removal in patients undergoing emergency cardiac surgery that was recently reported to [reduce perioperative bleeding risk](#) and [reduce costs](#)
- Potential new data from the REMOVE endocarditis trial that is expected to read out in mid-2020, the recently announced [U.K. TISORB trial](#) using CytoSorb to remove the anti-platelet drug ticagrelor in emergency cardiac surgery patients and an associated companion study, and data from a number of investigator-initiated studies

- Increased commitment from strategic partnerships to expand CytoSorb commercialization

Dr. Chan continued, “We expect a solid finish to 2019, consistent with our prior guidance that 2H 2019 will be stronger than 1H 2019 and current guidance that Q4 2019 product sales will exceed those in Q4 2018. More importantly, we believe the pieces that we have labored to put into place positions us well to return to more aggressive sales growth of CytoSorb in 2020 and beyond as the leader in this space. In the meantime, we remain committed to our clinical trials program, intended to drive CytoSorb as standard of care in multiple applications.”

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

Conference Call Details:

Date: Tuesday, November 5, 2019

Time: 4:45 PM Eastern Time

Participant Dial-In: 877-451-6152

Conference ID: 13695453

Live Presentation Webcast: <http://public.viavid.com/index.php?id=136487>

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=136487>

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 September 30, 2019 and 2018:

Revenues:

Revenue from product sales was approximately \$5,728,000 for the three months ended September 30, 2019, as compared to approximately \$5,103,000 for the three months ended September 30, 2018, an increase of approximately \$625,000, or 12%. This increase was driven by an increase in direct sales of approximately \$891,000 resulting from sales to both new customers and repeat orders from existing customers, offset by a decrease in distributor sales of approximately \$266,000. In addition, sales were negatively impacted by approximately \$239,000 as a result of the decrease in the average exchange rate of the Euro to the U.S. dollar. For the three months ended September 30, 2019, the average exchange rate of the Euro to the U.S. dollar was \$1.11 as compared to an average exchange rate of \$1.16 for the three months ended September 30, 2018.

Grant income was approximately \$367,000 for the three months ended September 30, 2019 as compared to approximately \$640,000 for the three months ended September 30, 2018, a decrease of approximately \$273,000 or 43%. This decrease was a result of the completion of certain grants prior to the three months ended September 30, 2019 and timing of certain other grant revenue.

Total revenues were approximately \$6,095,000 for the three months ended September 30, 2019, as compared to total revenues of approximately \$5,743,000 for the three months ended September 30, 2018, an increase of approximately \$352,000, or 6%.

Cost of Revenues:

For the three months ended September 30, 2019 and 2018, cost of revenue was approximately \$1,696,000 and \$2,053,000, respectively, a decrease of approximately \$357,000. Product cost of revenues decreased approximately \$66,000 during the three months ended September 30, 2019 as compared to the three months ended September 30, 2018 due to achieved production efficiencies. Product gross margins were approximately 77% for the three months ended September 30, 2019 and approximately 72% for the three months ended September 30, 2018.

Research and Development Expenses:

For the three months ended September 30, 2019, research and development expenses were approximately \$3,185,000 as compared to research and development expenses of approximately \$1,943,000 for the three months ended September 30, 2018. The increase of approximately \$1,242,000 was due to an increase in clinical trial and related costs of approximately \$863,000, which includes expenditures related to our REFRESH 2-AKI study, decreases in direct labor and other costs being deployed toward grant-funded activities of approximately \$290,000, which had the effect of increasing the amount of our non-reimbursable research and development costs and an increase in non-clinical research and development salary related costs of approximately \$104,000.

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting expenses were approximately \$733,000 for the three months ended September 30, 2019, as compared to approximately \$417,000 for the three months ended September 30, 2018. The increase of approximately \$316,000 was due to an increase in legal fees of approximately \$147,000 related to patent matters and certain corporate initiatives and an increase in employment agency fees of approximately \$222,000 related to the hiring of senior level personnel. These increases were offset by a decrease in accounting fees of approximately \$37,000 and a decrease in consulting fees of approximately \$16,000.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately \$6,108,000 for the three months ended September 30, 2019, as compared to approximately \$4,041,000 for the three months ending September 30, 2018, an increase of \$2,067,000. This increase is related to an increase in salaries, commissions and related costs of approximately \$613,000, additional sales and marketing costs, which include advertising and conferences of approximately \$462,000, an increase in royalty expenses of approximately \$46,000 due to the increase in product sales, an increase in non-cash stock compensation of approximately \$529,000 related to options granted and an increase in restricted stock expense of approximately \$481,000 related to restricted stock units granted to the Company executive officers.

Interest Expense, net:

For the three months ended September 30, 2019, interest expense was approximately \$302,000, as compared to interest expense of approximately \$185,000 for the three months ended September 30, 2018. This increase in interest expense of approximately \$117,000 was primarily a result of the additional interest incurred related to the draw down of the \$5,000,000 Term B Loan with Bridge Bank on July 31, 2019.

Gain (Loss) on Foreign Currency Transactions:

For the three months ended September 30, 2019, the non-cash loss on foreign currency transactions was approximately \$956,000 as compared to a loss of approximately \$109,000 for the three months ended September 30, 2018. The 2019 loss was directly related to the decrease in the spot exchange rate of the Euro to the U.S. dollar at September 30, 2019 as compared to June 30, 2019. The spot exchange rate of the Euro to the U.S. dollar was \$1.09 per Euro at September 30, 2019, as compared to \$1.14 per Euro at June 30, 2019. The 2018 loss is directly related to the decrease in the exchange rate of the Euro to the U.S. dollar at September 30, 2018 as compared to June 30, 2018. The exchange rate of the Euro to the U.S. dollar was \$1.16 per Euro at September 30, 2018, as compared to \$1.17 per Euro at June 30, 2018.

Comparison for the nine months ended September 30, 2019 and 2018:

Revenues:

Revenue from product sales was approximately \$16,155,000 for the nine months ended September 30, 2019, as compared to approximately \$14,782,000 for the nine months ended September 30, 2018, an increase of approximately \$1,373,000, or 9%. This increase was driven by an increase in direct sales of approximately \$2,053,000 resulting from sales to both new customers and repeat orders from existing customers, offset by a decrease in distributor sales of approximately \$680,000. In addition, sales were negatively impacted by approximately \$977,000 as a result of the decrease in the average exchange rate of the Euro to the U.S. dollar. For the nine months ended September 30, 2019, the average exchange rate of the Euro to the U.S. dollar was \$1.12 as compared to an average exchange rate of \$1.19 for the nine months ended September 30, 2018.

Grant income was approximately \$1,364,000 for the nine months ended September 30, 2019 as compared to approximately \$1,641,000 for the nine months ended September 30, 2018, a decrease of approximately \$277,000 or 17%.

Total revenues were approximately \$17,519,000 for the nine months ended September 30, 2019, as compared to total revenues of approximately \$16,423,000 for the nine months ended September 30, 2018, an increase of approximately \$1,096,000, or 7%.

Cost of Revenues:

For the nine months ended September 30, 2019 and 2018, cost of revenue was approximately \$5,269,000 and \$5,406,000, respectively, a decrease of approximately \$137,000. Product cost of revenues increased approximately \$17,000 during the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018 due to increased sales, offset by achieved production efficiencies. Product gross margins were approximately 76% for the nine months ended September 30, 2019 and approximately 73% for the nine months ended September 30, 2018.

Research and Development Expenses:

For the nine months ended September 30, 2019, research and development expenses were approximately \$8,533,000 as compared to research and development expenses of approximately \$5,299,000 for the nine months ended September 30, 2018. The increase of approximately \$3,234,000 was due to an increase in clinical trial and related costs of approximately \$2,856,000, which includes expenditures related to our REFRESH 2-AKI study, an increase in non-clinical research and development salary related costs of approximately \$133,000, decreases in direct labor and other costs being deployed toward grant-funded activities of approximately \$154,000, which had the effect of increasing the amount of our non-reimbursable research and development costs and an increase in other non-clinical research and development costs of approximately \$91,000.

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting expenses were approximately \$1,887,000 for the nine months ended September 30, 2019, as compared to approximately \$1,291,000 for the nine months ended September 30, 2018. The increase of approximately \$596,000 was due to an increase in legal fees of approximately \$342,000 related to patent matters and certain corporate initiatives, an increase in employment agency fees of approximately \$217,000 related to the hiring of senior level personnel, and an increase in consulting fees of approximately \$57,000. These increases were offset by a decrease in accounting fees of approximately \$20,000.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately \$15,372,000 for the nine months ended September 30, 2019, as compared to approximately \$14,426,000 for the nine months ending September 30, 2018. The increase of \$946,000 was due to an increase in salaries, commissions and related costs of approximately \$1,790,000, additional sales and marketing costs, which include advertising and conference attendance of approximately \$660,000, an increase in royalty expenses of approximately \$107,000 due to the increase in product sales, and an increase in restricted stock expense of approximately \$273,000 related to restricted stock units granted to the Company's executive officers. These increases were offset by a decrease in non-cash stock compensation of approximately \$1,689,000 and a decrease in travel and entertainment and other general and administrative expenses of approximately \$195,000.

Interest Expense, net:

For the nine months ended September 30, 2019, interest expense was approximately \$722,000, as compared to interest expense of approximately \$1,264,000 for the nine months ended September 30, 2018. This decrease in interest expense of approximately \$542,000 was primarily a result of the settlement of the Success Fee in the amount of \$637,000 that became due in May 2018 in accordance with the terms of the 2016 Success Fee Letter, offset by an increase in interest due to the draw down of the \$5,000,000 Term B Loan with Bridge Bank on July 31, 2019.

Gain (Loss) on Foreign Currency Transactions:

For the nine months ended September 30, 2019, the non-cash loss on foreign currency transactions was approximately \$1,052,000 as compared to a loss of approximately \$544,000 for the nine months ended September 30, 2018. The 2019 loss was directly related to the decrease in the spot exchange rate of the Euro to the U.S. dollar at September 30, 2019 as compared to December 31, 2018. The spot exchange rate of the Euro to the U.S. dollar was \$1.09 per Euro at September 30, 2019, as compared to \$1.15 per Euro at December 31, 2018. The 2018 loss is directly related to the decrease in the exchange rate of the Euro to the U.S. dollar at September 30, 2018 as compared to December 31, 2017. The exchange rate of the Euro to the U.S. dollar was \$1.16 per Euro at September 30, 2018, as compared to \$1.20 per Euro at December 31, 2017.

History of Operating Losses:

We have experienced substantial operating losses since inception. As of September 30, 2019, we had an accumulated deficit of approximately \$184,840,000, which included losses of approximately \$15,316,000 and \$11,808,000 for the nine-month periods ended September 30, 2019 and 2018, 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 September 30, 2019, we had current assets of approximately \$22,351,000 including cash on hand of approximately \$15,978,000 and current liabilities of approximately \$9,302,000. On July 31, 2019, the Company executed an Amendment to its Loan Agreement with Bridge Bank and, simultaneous with this Amendment, received \$5 million in proceeds from an additional term loan. In addition, the Amendment extends the interest-only period of the loan for an additional six months through April 2020, with the ability to further extend the interest-only period for another six months through October 2020 should the Company meet certain conditions. We believe that we have sufficient cash to fund our operations into 2020.

Fourth Quarter 2019 Revenue Guidance

CytoSorbents has not historically given specific financial guidance on quarterly results until the quarter has been completed. However, we expect our fourth quarter 2019 product sales will exceed sales reported in the fourth quarter of 2018. In addition, we expect that second half 2019 product sales will exceed first half 2019 product sales.

For additional information, please see the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 7, 2019 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 58 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®](#) is also being used during and after cardiac surgery to remove inflammatory mediators that can lead to post-operative complications, including multiple organ failure. CytoSorbents is conducting its pivotal REFRESH 2-AKI study – a multi-center, randomized controlled, clinical study intended to support U.S. regulatory approval of CytoSorb for use in a heart-lung machine during complex cardiac surgery to reduce organ injury. CytoSorb® has been used in more than 73,000 human treatments to date.

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 nearly \$29 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 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 7, 2019, 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 September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
	<u>(Unaudited)</u>	<u>(Unaudited)</u>	<u>(Unaudited)</u>	<u>(Unaudited)</u>
Revenue:				
CytoSorb sales	\$ 5,648	\$ 5,103	\$ 16,009	\$ 14,694
Other sales	80	--	146	88
Total product sales	<u>5,728</u>	<u>5,103</u>	<u>16,155</u>	<u>14,782</u>
Grant income	367	640	1,364	1,641
Total revenue	<u>6,095</u>	<u>5,743</u>	<u>17,519</u>	<u>16,423</u>
Cost of revenue	<u>1,696</u>	<u>2,053</u>	<u>5,269</u>	<u>5,406</u>
Gross profit	4,399	3,690	12,250	11,017
Other Expenses:				
Research and development	3,185	1,943	8,533	5,300
Legal, financial and other consulting	733	417	1,887	1,291
Selling, general and administrative	6,108	4,041	15,373	14,426
Total expenses	<u>10,026</u>	<u>6,401</u>	<u>25,793</u>	<u>21,017</u>
Loss from operations	(5,627)	(2,711)	(13,543)	(10,000)
Other expense:				
Interest expense, net	(302)	(185)	(721)	(1,264)
Gain (loss) on foreign currency transactions	(956)	(109)	(1,052)	(544)
Total other expense, net	<u>(1,258)</u>	<u>(294)</u>	<u>(1,773)</u>	<u>(1,808)</u>
Loss before benefit from income taxes	(6,885)	(3,005)	(15,316)	(11,808)
Benefit from income taxes	--	--	--	--
Net loss	<u>\$ (6,885)</u>	<u>\$ (3,005)</u>	<u>\$ (15,316)</u>	<u>\$ (11,808)</u>
Basic and diluted net loss per common share	<u>\$ (0.21)</u>	<u>\$ (0.10)</u>	<u>\$ (0.48)</u>	<u>\$ (0.39)</u>
Weighted average number of shares of common stock outstanding	<u>32,365,700</u>	<u>31,305,620</u>	<u>32,189,430</u>	<u>30,394,326</u>
Net loss	\$ (6,885)	\$ (3,005)	\$ (15,316)	\$ (11,808)
Other comprehensive income:				
Currency translation adjustment	812	99	868	431
Comprehensive loss	<u>\$ (6,073)</u>	<u>\$ (2,906)</u>	<u>\$ (14,448)</u>	<u>\$ (11,377)</u>

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	September 30, 2019 <u>(Unaudited)</u>	December 31, 2018 <u>(As adjusted)</u>
ASSETS		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 15,978	\$ 22,369
Grants and accounts receivable, net	3,448	3,943
Inventories	1,768	833
Prepaid expenses and other current assets	<u>1,157</u>	<u>1,119</u>
Total current assets	22,351	28,264
Property and equipment, net	1,917	1,730
Right of use asset	1,169	1,450
Other assets	<u>3,245</u>	<u>2,753</u>
TOTAL ASSETS	\$ <u>28,682</u>	\$ <u>34,197</u>
LIABILITIES AND STOCKHOLDERS' EQUITY:		
<i>Current Liabilities:</i>		
Accounts payable	\$ 2,072	\$ 1,486
Current maturities of long-term debt	3,125	667
Lease liability – current portion	414	378
Accrued expenses and other current liabilities	<u>3,691</u>	<u>4,386</u>
Total current liabilities	9,302	6,917
Long-term debt, net of current maturities and debt issuance costs	11,891	9,274
Lease liability, net of current portion	<u>755</u>	<u>1,071</u>
TOTAL LIABILITIES	21,948	17,262
Total stockholders' equity	<u>6,734</u>	<u>16,935</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ <u>28,682</u>	\$ <u>34,197</u>

Please Click to Follow Us on [Facebook](#) and [Twitter](#)

Cytosorbents Contact:

Amy Vogel

Investor Relations

(732) 398-5394

avogel@cytosorbents.com

Investor Relations Contact:

Jeremy Feffer

LifeSci Advisors

917-749-1494

jeremy@lifesciadvisors.com

U.S. Public Relations Contact:

Joshua Berkman

Rubenstein Public Relations

212-805-3055

jberkman@rubensteinpr.com