



CytoSorbents

Working to Save Lives Through Blood Purification

CytoSorbents Reports Record Second Quarter 2019 Financial Results

Q2 2019 Total Revenue was \$6.2 million, with record quarterly product sales of \$5.9 million and product gross margins of 76%

MONMOUTH JUNCTION, N.J., August 6, 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 June 30, 2019.

Second Quarter 2019 Financial Results:

- Total Q2 2019 revenues were \$6.2 million, including both product sales and grant income, an increase of approximately 8% from \$5.8 million in Q2 2018
- Product sales for Q2 2019 were approximately \$5.9 million, compared to \$5.2 million for Q2 2018, an increase of approximately 12%. Q2 2019 product sales would have been approximately \$6.2 million, or \$357,000(18%) higher than a year ago, had the Euro remained unchanged
- Product gross margins for Q2 2019 increased to 76%, compared to 74% in Q2 2018
- Executed a loan amendment with Bridge Bank which provided an additional \$5 million in debt financing which was received on July 31, 2019, extending the interest-only period of the entire term loan to October 2020, provided certain financial targets are met
- Strong cash position with \$16.3M at the end of the quarter, and approximately \$20 million at the end of July, reflecting the additional proceeds from debt

Second Quarter 2019 Operational Highlights:

- 67,000+ cumulative CytoSorb treatments have been delivered, up from 46,000 a year ago
- CytoSorb product registration has been submitted in Mexico and South Korea with partner Fresenius Medical Care, with concurrent initiation of commercialization planning and pre-launch activities including conferences, marketing, and key opinion leader events. Feedback on the status of registration is expected before the end of this year
- Publication of the [U.S. REFRESH I study](#) in [Seminars in Thoracic and Cardiovascular Surgery](#), a journal of the [American Association for Thoracic Surgery \(AATS\)](#) and an associated [editorial commentary](#) on the clinical trial and the potential clinical importance and value that CytoSorb could have in complex cardiac surgery with future studies

- Enrollment in the 400 patient U.S. [REFRESH 2-AKI](#) pivotal randomized, controlled trial is currently at 109 patients with 24 active sites
- The German government-funded [REMOVE](#) endocarditis trial is approximately 90% enrolled, with 222 patients out of a target 250 patients at 15 clinical sites. Completed enrollment is expected by year-end
- The HemoDefend-RBC program remains on track for an investigational device exemption (IDE) submission to the FDA this year, enabling the start of the U.S. pivotal trial

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents Corporation, stated, “Q2 2019 product sales rebounded significantly over the past quarter, achieving our guidance as the best quarter of product sales since we began commercialization, and in-line with our historical product sales trajectory of growth. Results were aided by the resumption of ordering from one of our major distributors. We also attained blended product gross margins of 76%, an increase of 200 basis points from the prior quarter, primarily resulting from continued efficiencies in manufacturing, and closing in on our goal of 80% on a quarterly basis this year.”

“The new loan amendment with Bridge Bank has expanded our effective working capital position by approximately \$9 million, including deferment of principal repayments, and will allow us to continue making the investments in our business that will drive future growth. We expect that product sales in the second half of this year will solidly exceed product sales in the first half, catalyzed by the impact of our expanding sales team, organic growth in existing markets, increased international expansion, publication of new clinical data in a wide variety of clinical applications, and increased partner support.”

Dr. Chan concluded, “Lastly, in the independent editorial commentary to the REFRESH I paper that was recently published, we were pleased to note that the authors described the complications of extended cardiopulmonary bypass – including the activation of inflammation, release of free hemoglobin due to hemolysis, and organ injury and failure - as the ‘Achilles heel of complex cardiac surgery’, and that the ‘holy grail of research in this subject would be to find something able to mitigate or eliminate the mediators responsible for these potentially catastrophic downstream effects of prolonged cardiopulmonary bypass.’ In reality, CytoSorb has demonstrated utility in so many different life-or-death applications in critical care and cardiac surgery, that we believe we are one of the leading innovators in bringing game-changing advances to medicine.”

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

Conference Call Details:

Date: Tuesday, August 6, 2019

Time: 4:45 PM Eastern Time

Participant Dial-In: 877-451-6152

Conference ID: 13692360

Live Presentation Webcast: <http://public.viavid.com/index.php?id=135206>

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=135206>

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 June 30, 2019 and 2018:

Revenues:

Revenue from product sales was approximately \$5,850,000 in the three months ended June 30, 2019, as compared to approximately \$5,246,000 in the three months ended June 30, 2018, an increase of approximately \$604,000, or 12%. This increase was driven by an increase in direct sales of approximately \$520,000 resulting from sales to both new customers and repeat orders from existing customers and an increase in distributor sales of approximately \$84,000. In addition, sales were negatively impacted by approximately \$357,000 as a result of the decrease in the average exchange rate of the Euro to the U.S. dollar. For the three months ended June 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 three months ended June 30, 2018.

Grant income was approximately \$382,000 for the three months ended June 30, 2019 as compared to approximately \$510,000 for the three months ended June 30, 2018, a decrease of approximately \$128,000 or 25%. This decrease was a result of timing of certain grant revenue.

Total revenues were approximately \$6,233,000 for the three months ended June 30, 2019, as compared to total revenues of approximately \$5,755,000 for the three months ended June 30, 2018, an increase of approximately \$478,000, or 8%.

Cost of Revenues:

For the three months ended June 30, 2019 and 2018, cost of revenue was approximately \$1,834,000 and \$1,786,000, respectively, an increase of approximately \$48,000. Product cost of revenues increased approximately \$31,000 during the three months ended June 30, 2019 as compared to the three months ended June 30, 2018 due to increased sales. Product gross margins were approximately 76% for the three months ended June 30, 2019 and approximately 74% for the three months ended June 30, 2018.

Research and Development Expenses:

For the three months ended June 30, 2019, research and development expenses were approximately \$2,930,000 as compared to research and development expenses of approximately \$1,576,000 for the three months ended June 30, 2018. The increase of approximately \$1,354,000 was due to an increase in clinical trial costs of approximately \$1,215,000, which is primarily related to our REFRESH 2-AKI trial, an increase in non-clinical research and development salary related costs of approximately \$11,000 and an increase in other non-clinical research and development costs of approximately \$150,000. These increases were offset by an increase in direct labor and other costs being deployed toward grant-funded activities of approximately \$18,000, which had the effect of decreasing the amount of our non-reimbursable research and development costs, and a decrease in new product development costs of approximately \$4,000.

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting expenses were approximately \$592,000 for the three months ended June 30, 2019, as compared to approximately \$458,000 for the three months ended June 30, 2018. The increase of approximately \$134,000 was due to an increase in legal fees of approximately \$28,000 related to patent matters and certain corporate initiatives, an increase in consulting fees of approximately \$55,000, an increase in employment agency fees of approximately \$31,000 and an increase in accounting fees of approximately \$20,000.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately \$4,507,000 for the three months ended June 30, 2019, as compared to approximately \$6,124,000 for the three months ending June 30, 2018, a decrease of \$1,617,000. The decrease of \$1,617,000 was due to a decrease in non-cash stock compensation of approximately \$2,228,000, a decrease in travel and entertainment costs of approximately \$64,000 and a decrease in other general and administrative expenses of approximately \$70,000. These decreases were offset by an increase in salaries, commissions and related costs of approximately \$588,000, additional sales and marketing costs, which include advertising and conferences of approximately \$92,000, an increase in royalty expenses of approximately \$53,000 due to the increase in product sales and an increase in rent expense of approximately \$12,000 related to the expansion of manufacturing and office facilities.

Interest Expense, net:

For the three months ended June 30, 2019, interest expense was approximately \$215,000, as compared to interest expense of approximately \$840,000 for the three months ended June 30, 2018. This decrease in interest expense of approximately \$625,000 was primarily a result of the settlement of the Success Fee with Bridge Bank in the amount of \$637,000 that became due in May 2018 in accordance with the terms of the 2016 Success Fee Letter with Bridge Bank.

Gain (Loss) on Foreign Currency Transactions:

For the three months ended June 30, 2019, the gain on foreign currency transactions was approximately \$297,000 as compared to a loss of approximately \$(794,000) for the three months ended June 30, 2018. The 2019 gain was directly related to the increase in the spot exchange rate of the Euro to the U.S. dollar at June 30, 2019 as compared to March 31, 2018. The spot exchange rate of the Euro to the U.S. dollar was \$1.14 per Euro at June 30, 2019, as compared to \$1.12 per Euro at March 31, 2019. The 2018 loss was directly related to the decrease in the spot exchange rate of the Euro at June 30, 2018 as compared to March 31, 2018. The spot exchange rate of the Euro to the U.S. dollar was \$1.17 per Euro at June 30, 2018, as compared to \$1.23 per Euro at March 31, 2018.

Comparison for the six months ended June 30, 2019 and 2018:

Revenues:

Revenue from product sales was approximately \$10,427,000 in the six months ended June 30, 2019, as compared to approximately \$9,679,000 in the six months ended June 30, 2018, an increase of approximately \$748,000, or 8%. This increase was driven by an increase in direct sales of approximately \$1,160,000 resulting from sales to both new customers and repeat orders from existing customers, offset by a decrease in distributor sales of approximately \$412,000. In addition, sales were negatively impacted by approximately \$737,000 as a result of the decrease in the average exchange rate of the Euro to the U.S. dollar. For the six months ended June 30, 2019, the average exchange rate of the Euro to the U.S. dollar was \$1.13 as compared to an average exchange rate of \$1.21 for the six months ended June 30, 2018.

Grant income was approximately \$997,000 for the six months ended June 30, 2019 as compared to approximately \$1,001,000 for the six months ended June 30, 2018, a decrease of approximately \$4,000 or less than 1%.

Total revenues were approximately \$11,424,000 for the six months ended June 30, 2019, as compared to total revenues of approximately \$10,680,000 for the six months ended June 30, 2018, an increase of approximately \$744,000, or 7%.

Cost of Revenues:

For the six months ended June 30, 2019 and 2018, cost of revenue was approximately \$3,573,000 and \$3,353,000, respectively, an increase of approximately \$220,000. Product cost of revenues increased approximately \$83,000 during the six months ended June 30, 2019 as compared to the six months ended June 30, 2018 due to increased sales. Product gross margins were approximately 75% for the six months ended June 30, 2019 and approximately 74% for the six months ended June 30, 2018.

Research and Development Expenses:

For the six months ended June 30, 2019, research and development expenses were approximately \$5,348,000 as compared to research and development expenses of approximately \$3,356,000 for the six months ended June 30, 2018. The increase of approximately \$1,992,000 was due to increase in clinical trial costs of approximately \$1,993,000, which is primarily related to our REFRESH 2-AKI trial, an increase in non-clinical research and development salary related costs of approximately \$20,000 and an increase in other non-clinical research and development costs of approximately \$186,000. These increases were offset by an increase in direct labor and other costs being deployed toward grant-funded activities of approximately \$136,000, which had the effect of decreasing the amount of our non-reimbursable research and development costs, and a decrease in new product development costs of approximately \$71,000.

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting expenses were approximately \$1,154,000 for the six months ended June 30, 2019, as compared to approximately \$874,000 for the six months ended June 30, 2018. The increase of approximately \$280,000 was due to an increase in legal fees of approximately \$194,000 related to patent matters and certain corporate initiatives, an increase in consulting fees of approximately \$73,000, and an increase in accounting fees of approximately \$17,000. These increases were offset by a decrease in employment agency fees of approximately \$4,000.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately \$9,265,000 for the six months ended June 30, 2019, as compared to approximately \$10,385,000 for the six months ending June 30, 2018. The decrease of \$1,120,000 was due to a decrease in non-cash stock compensation of approximately \$2,426,000 and other general and administrative expenses of approximately \$140,000. These decreases were offset by an increase in salaries, commissions and related costs of approximately \$1,142,000, an increase in travel and entertainment and other costs of approximately \$33,000, additional sales and marketing costs, which include advertising and conferences of approximately \$189,000, an increase in royalty expenses of approximately \$60,000 due to the increase in product sales and an increase in rent expense of approximately \$22,000 related to the expansion of manufacturing and office facilities.

Interest Expense, net:

For the six months ended June 30, 2019, interest expense was approximately \$420,000, as compared to interest expense of approximately \$1,079,000 for the six months ended June 30, 2018. This decrease in interest expense of approximately \$659,000 was primarily a result of the settlement of the Success Fee with Bridge Bank in the amount of \$637,000 that became due in May 2018 in accordance with the terms of the 2016 Success Fee Letter with Bridge Bank and interest earned on our cash balances during the six months ended June 30, 2019.

Gain (Loss) on Foreign Currency Transactions:

For the six months ended June 30, 2019, the loss on foreign currency transactions was approximately \$96,000 as compared to a loss of approximately \$435,000 for the six months ended June 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 June 30, 2019 as compared to December 31, 2018. The spot exchange rate of the Euro to the U.S. dollar was \$1.14 per Euro at June 30, 2019, as compared to \$1.15 per Euro at December 31, 2018. The 2018 loss was directly related to the decrease in the spot exchange rate of the Euro at June 30, 2018 as compared to the December 31, 2017. The spot exchange rate of the Euro to the U.S. dollar was \$1.17 per Euro at June 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 June 30, 2019, we had an accumulated deficit of approximately \$177,955,000, which included losses of approximately \$8,431,000 and \$8,803,000 for the six-month periods ended June 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 June 30, 2019, we had current assets of approximately \$22,214,000 including cash on hand of approximately \$16,342,000 and current liabilities of approximately \$6,919,000. 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.

2019 Third Quarter Revenue Guidance:

CytoSorbents has not historically given specific financial guidance on quarterly results until the quarter has been completed. However, we expect our third quarter 2019 product sales will exceed sales reported in the third 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 55 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 trial – a multi-center, randomized controlled, clinical trial 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 67,000 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 \$26 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), 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 June 30,		Six months ended June 30,	
	2019	2018	2019	2018
	<u>(Unaudited)</u>	<u>(Unaudited)</u>	<u>(Unaudited)</u>	<u>(Unaudited)</u>
Revenue:				
CytoSorb sales	\$ 5,850	\$ 5,187	\$ 10,360	\$ 9,591
Other sales	--	59	67	88
Total product sales	<u>5,850</u>	<u>5,246</u>	<u>10,427</u>	<u>9,679</u>
Grant income	382	510	997	1,001
Total revenue	<u>6,232</u>	<u>5,756</u>	<u>11,424</u>	<u>10,680</u>
Cost of revenue	<u>1,834</u>	<u>1,786</u>	<u>3,573</u>	<u>3,353</u>
Gross profit	4,398	3,970	7,851	7,327
Other Expenses:				
Research and development	2,930	1,576	5,348	3,356
Legal, financial and other consulting	592	458	1,153	874
Selling, general and administrative	4,506	6,124	9,265	10,386
Total expenses	<u>8,028</u>	<u>8,158</u>	<u>15,766</u>	<u>14,616</u>
Loss from operations	(3,630)	(4,188)	(7,915)	(7,289)
Other income/(expense):				
Interest expense, net	(214)	(840)	(420)	(1,079)
Gain (loss) on foreign currency transactions	297	(793)	(96)	(435)
Total other income/(expense), net	<u>83</u>	<u>(1,633)</u>	<u>(516)</u>	<u>(1,514)</u>
Loss before benefit from income taxes	(3,547)	(5,821)	(8,431)	(8,803)
Benefit from income taxes	--	--	--	--
Net loss	<u>\$ (3,547)</u>	<u>\$ (5,821)</u>	<u>\$ (8,431)</u>	<u>\$ (8,803)</u>
Basic and diluted net loss per common share	<u>\$ (0.11)</u>	<u>\$ (0.19)</u>	<u>\$ (0.26)</u>	<u>\$ (0.30)</u>
Weighted average number of shares of common stock outstanding	<u>32,266,861</u>	<u>30,302,065</u>	<u>32,099,834</u>	<u>29,827,436</u>
Net loss	\$ (3,547)	\$ (5,821)	\$ (8,431)	\$ (8,803)
Other comprehensive income (loss):				
Currency translation adjustment	(250)	662	57	332
Comprehensive income (loss)	<u>\$ (3,797)</u>	<u>\$ (5,159)</u>	<u>\$ (8,374)</u>	<u>\$ (8,471)</u>

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	<u>June 30, 2019 (Unaudited)</u>	<u>December 31, 2018 (As adjusted)</u>
ASSETS		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 16,341	\$ 22,369
Grants and accounts receivable, net	3,450	3,943
Inventories	1,463	833
Prepaid expenses and other current assets	<u>960</u>	<u>1,119</u>
Total current assets	22,214	28,264
Property and equipment, net	1,924	1,730
Right of use asset	1,265	1,450
Other assets	<u>3,080</u>	<u>2,753</u>
TOTAL ASSETS	\$ <u>28,483</u>	\$ <u>34,197</u>
LIABILITIES AND STOCKHOLDERS' EQUITY:		
<i>Current Liabilities:</i>		
Accounts payable	\$ 2,150	\$ 1,486
Current maturities of long-term debt	833	667
Lease liability – current portion	400	378
Accrued expenses and other current liabilities	<u>3,536</u>	<u>4,386</u>
Total current liabilities	6,919	6,917
Long-term debt, net of current maturities and debt issuance costs	9,155	9,274
Lease liability, net of current portion	<u>866</u>	<u>1,071</u>
TOTAL LIABILITIES	16,940	17,262
Total stockholders' equity	<u>11,543</u>	<u>16,935</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ <u>28,483</u>	\$ <u>34,197</u>

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