



CytoSorbents

Working to Save Lives Through Blood Purification

CytoSorbents Reports First Quarter 2019 Financial Results and Provides Second Quarter 2019 Guidance

MONMOUTH JUNCTION, N.J., May 7, 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 March 31, 2019.

First Quarter 2019 Financial Results:

- Total revenue for Q1 2019 was \$5.2 million, including both product sales and grant income, compared to \$4.9 million in Q1 2018
- Product sales for Q1 2019 were \$4.6 million, compared to \$4.4 million for Q1 2018. Adjusted first quarter 2019 product sales would have been approximately \$4.9 million, after reflecting changes in the Euro to dollar exchange rate between periods
- Direct sales continue to expand and achieved new highs, reflecting 18% quarterly growth year-over-year, and 4% sequential growth compared to Q4 2018. Results do not yet materially reflect additions to the sales infrastructure, and new direct territories added in Q1 2019
- Distributor sales were affected by anticipated short-term issues from three distributors. [As disclosed previously](#), Fresenius Medical Care is transitioning to new exclusive sales territories (e.g. Mexico, South Korea, Czech Republic) while maintaining France and Finland, and did not order in Q1 2019 as it sells through non-transferable European product inventory. Meanwhile, two other distributors temporarily paused from ordering to rebalance inventory, but have strong and growing end user demand for CytoSorb. We expect these issues to resolve before or during the second half of 2019
- Product gross margins for Q1 2019 and Q1 2018 were 74%
- Strong cash position of \$19.6 million at March 31, 2019

First Quarter 2019 Operational Highlights:

- Exceeded 61,000 cumulative CytoSorb treatments delivered, an increase from 40,000 a year ago

- [Expanded partnership with Fresenius Medical Care](#) to include an expansion of its exclusive distribution agreement to sell CytoSorb in Mexico, South Korea, and the Czech Republic, while maintaining France and Finland
- Following a review of the first 50 patients, the independent Data Safety Monitoring Board (DSMB) and Scientific Advisory Board (SAB) [recommended continuation](#) of the German government-funded [REMOVE endocarditis trial](#). The trial has now enrolled 180 patients, or nearly 75% of the targeted 250 patients, at 15 active sites
- The [REFRESH 2-AKI company-sponsored pivotal trial](#) has increased enrollment to 79 patients at 23 clinical trial sites, and has attained approximately 20% of a targeted 400 patient enrollment
- HemoDefend-RBC tooling delays have been resolved, parts have been manufactured, and clinical trial devices are being assembled. Meanwhile, an FDA investigational device exemption (IDE) submission is targeted for the second half of this year. A contract research organization (CRO) has been selected to manage the pivotal trial and has begun clinical site negotiations
- Hosted the [6th International CytoSorb Users Meeting](#) in Brussels, Belgium, in connection with the [39th International Symposium of Intensive Care and Emergency Medicine \(ISICEM\)](#)

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents Corporation stated, “Q2 2019 product sales are expected to return to our historical growth trajectory, and are anticipated to be the highest quarterly product sales reported in our history. In addition, we continue to forecast strong revenue growth for all of 2019, despite a slow start in Q1, based on numerous growth opportunities we see.”

Dr. Chan continued, “Specifically, we anticipate CytoSorb direct sales will continue strengthening and accelerate into the second half of this year, driven by organic growth, our investments in a larger direct sales team - particularly in Germany, reimbursement, contributions from new direct territories including Poland, Netherlands, and Scandinavia, new clinical data and applications, and other catalysts.”

“In addition, we believe the factors that impacted Q1 indirect sales are short-term and specific to the three distributors as described above. For example, Fresenius (FMC) is selling through its European inventory of CytoSorb in France and Finland, while it begins sales in the Czech Republic and pursues registration of CytoSorb in both Mexico and South Korea. It is expected that FMC will order new CytoSorb devices for these countries once registration is achieved. We are encouraged that each of these customers has increased their commitment to selling CytoSorb, including aggressively pursuing new indications, increasing resource allocation, and working closely with our company to drive success. Importantly, we see end-user demand increasing in their territories, based on the excellent foundation they have established. Over the next several quarters, we expect a resumption of ordering from all three groups. Of special note, we do not require these orders to achieve our guidance for Q2 2019.” Dr. Chan concluded, “Lastly, we reiterate our guidance on expanding our blended product gross margins to 80% on a quarterly basis this year.”

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

Conference Call Details:

Date: Tuesday, May 7, 2019

Time: 4:45 PM Eastern Time

Participant Dial-In: 877-451-6152

Conference ID: 13690052

Live Presentation Webcast: <http://public.viavid.com/index.php?id=134206>

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=134206>

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, 2019 and 2018:

Revenues:

Revenue from product sales was approximately \$4,577,000 in the three months ended March 31, 2019, as compared to approximately \$4,433,000 in the three months ended March 31, 2018 an increase of approximately \$144,000, or 3%. This increase was driven by an increase in direct sales of approximately \$624,000 resulting from sales to both new customers and repeat orders from existing customers, offset by a decrease in distributor sales of approximately \$480,000. In addition, first quarter 2019 sales were negatively impacted by \$363,000 as a result of the decrease in the average exchange rate of the Euro. For the three months ended March 31, 2019, the average exchange rate of the Euro to the U.S. dollar was \$1.14 as compared to an average exchange rate of \$1.23 for the three months ended March 31, 2018.

Grant income was approximately \$615,000 for the three months ended March 31, 2019 as compared to approximately \$491,000 for the three months ended March 31, 2018, an increase of approximately \$124,000 or 25%. This increase was a result of timing of certain grant revenue and income recognized from a new grant.

Total revenues were approximately \$5,192,000 for the three months ended March 31, 2019, as compared to total revenues of approximately \$4,925,000 for the three months ended March 31, 2018, an increase of approximately \$267,000, or 5%.

Cost of Revenues:

For the three months ended March 31, 2019 and 2018, cost of revenue was approximately \$1,739,000 and \$1,568,000, respectively, an increase of approximately \$171,000. Product cost of revenues increased approximately \$52,000 during the three months ended March 31, 2019 as compared to the three months ended March 31, 2018 due to increased sales. Product gross margins were approximately 74% for each of the three months ended March 31, 2019 and 2018.

Research and Development Expenses:

For the three months ended March 31, 2019, research and development expenses were approximately \$2,419,000 as compared to research and development expenses of approximately \$1,725,000 for the three months ended March 31, 2018. The increase of approximately \$694,000 was due to an increase in clinical trial costs of approximately \$888,000, which is primarily related to our REFRESH 2-AKI trial and an increase in non-clinical research and development salary related costs of approximately \$9,000. These increases were offset by an increase in direct labor and other costs being deployed toward grant-funded activities of approximately \$118,000, which had the effect of decreasing the amount of our non-reimbursable research and development costs, a decrease in new product development costs of approximately \$67,000 and a decrease of other non-clinical research and development costs of approximately \$18,000.

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting expenses were approximately \$562,000 for the three months ended March 31, 2019, as compared to approximately \$416,000 for the three months ended March 31, 2018. The increase of approximately \$146,000 was due to an increase in legal fees of approximately \$167,000 related to patent matters and certain corporate initiatives and an increase in consulting fees of approximately \$18,000. These increases were offset by a decrease in employment agency fees of approximately \$36,000 and a decrease in accounting fees of approximately \$3,000.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately \$4,758,000 for the three months ended March 31, 2019, as compared to approximately \$4,317,000 for the three months ending March 31, 2018. The increase of \$441,000 was due to an increase in salaries, commissions and related costs of approximately \$424,000, an increase in travel and entertainment and other costs of approximately \$142,000, additional sales and marketing costs, which include advertising and conferences of approximately \$88,000, an increase in royalty expenses of approximately \$7,000 due to the increase in product sales, an increase in rent expense of approximately \$11,000 related to the expansion of manufacturing and office facilities and an increase in other general and administrative cost increases of approximately \$21,000. These increases were offset by a decrease in non-cash stock compensation of approximately \$252,000.

Interest Expense, net:

For the three months ended March 31, 2019, interest expense was approximately \$205,000, as compared to interest expense of approximately \$239,000 for the three months ended March 31, 2018. This decrease in interest expense of approximately \$34,000 is due to an increase in interest earned on our cash balances during the three months ended March 31, 2019.

Gain (Loss) on Foreign Currency Transactions:

For the three months ended March 31, 2019, the loss on foreign currency transactions was approximately \$(393,000) as compared to a gain of approximately \$358,000 for the three months ended March 31, 2018. The 2019 loss is directly related to the decrease in the exchange rate of the Euro to the U.S. dollar at March 31, 2019 as compared to December 31, 2018. The exchange rate of the Euro to the U.S. dollar was \$1.12 per Euro at March 31, 2019, as compared to \$1.15 per Euro at December 31, 2018. The 2018 gain is directly related to the increase in the exchange rate of the Euro at March 31, 2018 as compared to December 31, 2017. The exchange rate of the Euro to the U.S. dollar was \$1.23 per Euro at March 31, 2017 as compared to \$1.07 per Euro at December 31, 2017.

History of Operating Losses:

We have experienced substantial operating losses since inception. As of March 31, 2019, we had an accumulated deficit of approximately \$174,408,000, which included losses of approximately \$4,884,000 and \$2,982,000 for the three-month periods ended March 31, 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 March 31, 2019, we had current assets of approximately \$24,828,000 including cash on hand of approximately \$19,647,000, and current liabilities of approximately \$6,711,000.

We believe that we have sufficient cash to fund our operations into 2020.

2019 Second Quarter Revenue Guidance

CytoSorbents has not historically given specific financial guidance on quarterly results until the quarter has been completed. However, Q2 2019 product sales are expected to return to our historical growth trajectory, and are anticipated to be the highest quarterly product sales reported in our history.

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 61,000 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)

	For the Three Months Ended	
	<u>3/31/19</u>	<u>3/31/18</u>
Revenue:		
CytoSorb sales	\$ 4,510	\$ 4,404
Other sales	<u>67</u>	<u>29</u>
Total product sales	4,577	4,433
Grant income	<u>615</u>	<u>491</u>
Total revenue	5,192	4,925
Cost of revenue	<u>1,739</u>	<u>1,568</u>
Gross profit	3,453	3,357
Expenses:		
Research and development	2,419	1,725
Legal, financial and other consulting	561	416
Selling, general and administrative	<u>4,758</u>	<u>4,317</u>
Total operating expenses	<u>7,738</u>	<u>6,458</u>
Loss from operations	(4,285)	(3,101)
Other income(expense):		
Interest expense, net	(205)	(239)
Gain (loss) on foreign currency transactions	<u>(394)</u>	<u>358</u>
Total other income, net	<u>(599)</u>	<u>119</u>
Loss before benefit from income taxes	(4,884)	(2,982)
Benefit from income taxes	-----	-----
Net loss	<u><u>(4,884)</u></u>	<u><u>(2,982)</u></u>
Earnings per share:		
Basic and diluted loss per share	\$ <u>(0.15)</u>	\$ <u>(0.10)</u>
Weighted average share outstanding	<u>31,931,215</u>	<u>29,351,174</u>
Net Loss	\$ (4,884)	\$ (2,982)
Other comprehensive income:		
Currency translation adjustment	<u>306</u>	<u>(330)</u>
Comprehensive loss	<u><u>(4,578)</u></u>	<u><u>(3,312)</u></u>

CYTOSORBENTS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	March 31, 2019	December 31, 2018
ASSETS:		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 19,647	\$ 22,369
Grants and accounts receivable, net	3,267	3,943
Inventories	1,214	833
Prepaid expenses and other current assets	700	1,119
Total current assets	24,828	28,264
Property and equipment, net	1,897	1,730
Right of use asset	1,359	1,450
Other assets	2,911	2,753
TOTAL ASSETS	\$ 30,995	\$ 34,197
 LIABILITIES AND STOCKHOLDERS' EQUITY:		
<i>Current Liabilities:</i>		
Accounts payable	\$ 1,841	\$ 1,486
Current maturities of long-term debt	1,667	667
Lease liability - current portion	389	378
Accrued expenses and other current liabilities	2,815	4,385
Total current liabilities	6,712	6,916
Long-term debt, net of current maturities and debt issuance costs	8,298	9,275
Lease liability, net of current portion	970	1,071
TOTAL LIABILITIES	15,980	17,262
Total stockholders' equity	15,015	16,935
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 30,995	\$ 34,197

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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

European Public Relations Contact:

Lucy Turpin Communications GmbH

Thomas Hahnel | Eva Hildebrandt

+49 89 417761-10/14

CytoSorbents@lucyturpin.com