



# CytoSorbents™

Working to Save Lives Through Blood Purification

## CytoSorbents Continues Strong Growth in Q1 2016

*Record quarterly sales up 127% from a year ago with continued consecutive quarterly growth*

MONMOUTH JUNCTION, N.J., May 9, 2016 - CytoSorbents Corporation (NASDAQ: CTSO), a critical care immunotherapy leader commercializing its flagship CytoSorb® blood purification cartridge to prevent or treat deadly inflammation and organ failure in critically-ill and cardiac surgery patients around the world, reports financial and operational results for the quarter ending March 31, 2016.

### **First Quarter 2016 Financial Highlights:**

- CytoSorb® product sales for Q1 2016 were a record \$1.6 million. This represents an increase of approximately 127% over Q1 2015 product sales of \$0.7 million, as a result of solid increases in both direct and distributor sales
- The annualized product sales run rate, as of Q1 2016, was approximately \$6.4 million, as compared to an annualized product sales run rate of approximately \$2.8 million in Q1 2015
- Total revenue for the first quarter of 2016 was \$1.8 million, which includes both product sales and grant revenue
- Overall gross margin rose to approximately \$1.0 million in Q1 2016, an increase of approximately \$0.6 million compared to approximately \$0.4 million in Q1 2015
- Product gross margin for Q1 2016 was approximately 62% compared to approximately 59% for Q1 2015
- These results represent the third consecutive quarter of record sales, as well as the fourth consecutive quarter of increases in product sales, overall

### **First Quarter 2016 Operational Highlights:**

- Approximately 12,000 human treatments have been performed with CytoSorb® worldwide in critical care illnesses and cardiac surgery
- The U.S.-based REFRESH I feasibility and safety study in complex cardiac surgery patients is nearly two-thirds enrolled with completion of enrollment expected in mid-2016
- Conducted another successful [International CytoSorb® Users](#) meeting in Brussels, Belgium, bringing together 107 people from 23 countries worldwide to learn from and share their CytoSorb® treatment experiences with each other, with presentations on key studies in refractory septic shock, septic shock, early use in sepsis, and the intraoperative use in cardiac surgery
- Exhibited at multiple critical care conferences including the 36<sup>th</sup> International Symposium on Intensive Care and Emergency Medicine (ISICEM) in Brussels, Belgium

where we had the largest attendance ever (>300 attendees) at our sponsored research symposium and multiple international posters accepted for presentation, the Symposium for Intensive Care Medicine + Intensive Care Conference in Bremen, Germany, and the 45<sup>th</sup> Society of Critical Care Medicine Congress (SCCM) in Orlando, Florida

- Numerous publications in peer-reviewed journals have been published confirming safety and correlating CytoSorb® treatment and reductions in cytokines with clinical benefit, such as hemodynamic stabilization, in a wide range of patients
- Completed the first interim data analysis from the International CytoSorb Registry, currently with 107 hospital centers registered
- Awarded a \$150K Phase I SBIR contract to develop blood purification countermeasures to reduce mycotoxins, such as aflatoxin, in whole blood, due to either bio-warfare exposure or disseminated fungal infections
- Met with investors and presented at several investment conferences, including the BIO CEO & Investor conference, Needham Healthcare Conference, Biotech Showcase, and Source Capital conference
- Recruited Dr. Volker Humbert, an experienced critical care physician and anesthesiologist, as Senior Manager of Clinical Affairs, tasked with providing comprehensive medical support and education to CytoSorb users worldwide

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, “We are pleased to report another record quarter of CytoSorb® sales, which reflects the continued and growing usage of CytoSorb® by clinicians in a wide variety of clinical indications, particularly sepsis and cardiac surgery. At our recent 3<sup>rd</sup> International CytoSorb® Users Meeting, and our recent critical care conferences in Germany and Belgium, it was extremely gratifying to witness the expanding list of applications where CytoSorb® is being successfully used to help save lives.”

“For the remainder of 2016,” Dr. Chan continued, “we anticipate increased momentum in our core business, including potential:

- Accelerated growth in CytoSorb® sales
- Increased sales contributions by existing strategic partners, including Fresenius Medical Care, that has confirmed the pending launch of CytoSorb® in its exclusive territories later this month
- Initiation of sales by existing distributors based upon completed product registrations
- New strategic partnerships
- A completion of REFRESH I by mid-year with database lock and announcement of top-line data in Q3 2016
- More clinical data from investigator-initiated studies and our International CytoSorb® registry
- Additional publications of clinical studies involving CytoSorb®
- New grant opportunities for CytoSorbents’ technologies

- Strengthening of our balance sheet in a way that makes most sense for the company and its shareholders
- Greater market awareness of our company amongst both retail and fundamental institutional investors

We continue to work aggressively to drive to a potential inflection point in our business, operating cash flow breakeven, and the success of our company.”

“Please join us on our previously announced earnings call today at 4:45PM EST where we will cover our progress and discuss some of the recent clinical studies in more detail. We will also respond to questions from the audience during our live Q&A session. The investor presentation and a written transcript of the conference call will be available within a week of the webcast.”

***Conference Call Details:***

Date: Monday, May 9, 2016

Time: 4:45 PM Eastern

Participant Dial-In: 1-719-325-2138

Live Presentation Webcast: <http://public.viavid.com/index.php?id=119325>

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=119325>

An archived recording of the conference call will be available within a week under the Investor Relations section of the Company's website at <http://www.cytosorbents.com/invest.htm>

***Three Months Ended March 31, 2016 Financial Results***

***Revenues:***

Revenue from product sales was approximately \$1,597,000 in the three months ended March 31, 2016, as compared to approximately \$704,000 in the three months ended March 31, 2015, an increase of approximately \$893,000, or 127%. This increase was largely driven by an increase in direct sales from both new customers and repeat orders from existing customers, along with an increase in distributor sales.

Grant income was approximately \$213,000 for the three months ended March 31, 2016 as compared to approximately \$19,000 for the three months ended March 31, 2015 as a result of revenue recognized from new grants and billable milestones achieved on existing grants.

As a result of the increases in both product sales and grant income, for the three months ended March 31, 2016, we generated total revenue of approximately \$1,810,000, as compared to

revenues of approximately \$723,000, for the three months ended March 31, 2015, an increase of approximately \$1,087,000, or 150%.

***Cost of Revenues:***

For the three months ended March 31, 2016 and 2015, cost of revenue was approximately \$819,000 and \$304,000, respectively, an increase of approximately \$515,000. Product cost of revenues increased approximately \$321,000 during the three months ended March 31, 2016 as compared to the three months ended March 31, 2015 due to increased sales. Product gross margins were approximately 62% for the three months ended March 31, 2016, as compared to approximately 59% for the three months ended March 31, 2015. In addition, direct labor and other costs being deployed toward grant-funded activities, increased approximately \$194,000, which has the effect of increasing the amount of costs allocated to cost of revenue.

***Research and Development Expenses:***

For the three months ended March 31, 2016, research and development expenses were approximately \$856,000 as compared to research and development expenses of approximately \$951,000 for the three months ended March 31, 2015. The decrease of approximately \$95,000 in research and development expenses was primarily due to an increase of \$194,000 of direct labor and other costs being deployed toward grant-funded activities, which had the effect of decreasing the amount of our non-reimbursable research and development costs. In addition, costs related to our non-clinical research and development activities decreased by approximately \$69,000. These decreases were offset by increases in salaries and other costs related to our various clinical studies and trials of approximately \$168,000 during the three months ended March 31, 2016 as compared to the three months ended March 31, 2015.

***Legal, Financial and Other Consulting Expense:***

Legal, financial, and other consulting expenses were approximately \$255,000 for the three months ended March 31, 2016, as compared to approximately \$216,000 for the three months ended March 31, 2015. The increase of approximately \$39,000 was due to an increase in accounting and auditing fees of approximately \$47,000 due to fees incurred related to the initial audit of our internal controls as required by The Sarbanes-Oxley Act of 2002 and an increase in legal fees of approximately \$29,000. These increases were offset by approximately \$37,000 in employment agency and consulting fees incurred in 2015 related to the hiring of senior level personnel that did not recur in 2016.

***Selling, General and Administrative Expense:***

Selling, general, and administrative expenses were approximately \$1,970,000 for the three months ended March 31, 2016, as compared to approximately \$1,515,000 for the three months ending March 31, 2015. The increase of approximately \$455,000 in selling, general, and administrative expenses was due to an increase in salaries, commissions, and related costs of

approximately \$241,000 due to headcount additions and increases in product sales, an increase in royalty expenses of approximately \$62,000 due to the increase in sales, additional sales and marketing costs, which include advertising and conferences, of approximately \$85,000, and an increase in travel and entertainment costs and other expenses of approximately \$67,000 due to the increased volume.

***Gain (Loss) on Foreign Currency Transactions:***

For the three months ended March 31, 2016, the gain on foreign currency transactions was approximately \$232,000 as compared to a loss of approximately \$449,000 for the three months ended March 31, 2015. The 2016 first quarter gain is directly related to the increase in the exchange rate of the Euro at March 31, 2016 as compared to December 31, 2015. The exchange rate of the Euro to the U.S. dollar was \$1.14 per Euro at March 31, 2016 as compared to \$1.08 per Euro at December 31, 2015.

***Change in Warrant Liability:***

We recognize warrants as liabilities at their fair value on the date of the grant because of price adjustment provisions in the warrants, then measure the fair value of the warrants on each reporting date, and record a change to the warrant liability as appropriate. The change in warrant liability resulted in other income of approximately \$18,000 for the three months ended March 31, 2016, and a charge to other expense of approximately \$2,008,000 for the three months ended March 31, 2015. The change in warrant liability was a result of the change in the fair value of the warrant liability from December 31, 2015 to March 31, 2016 and from December 31, 2014 to March 31, 2015.

**Liquidity and Capital Resources**

Since inception, our operations have been primarily financed through the private placement of debt and equity securities. At March 31, 2016, we had current assets of approximately \$8,041,000 including cash on hand and short-term investments of approximately \$6,027,000 and current liabilities of approximately \$3,248,000. We believe we have sufficient cash to fund our operations into the fourth quarter of 2016; however, we may need to raise additional capital to fully fund pivotal trials in the United States and/or Germany. We will be better able to assess this need once the specific protocols are finalized with appropriate regulatory bodies. In addition, we may require additional capital to support our sales and marketing efforts, to fund clinical studies, to expand our production capacity, to further develop our products, and for general working capital purposes.

***2016 Second Quarter Revenue Guidance***

CytoSorbents has not historically given financial guidance on quarterly results until the quarter has been completed. However, we continue to expect our second quarter 2016 product sales to meet or exceed the level of sales achieved in the second quarter of 2015.

For additional information please see the Company's Form 10-Q for the quarter ended March 31, 2016 filed on May 9, 2016 on <http://www.sec.gov>.

### **About CytoSorbents Corporation (NASDAQ: [CTSO](#))**

CytoSorb® is approved in the European Union with distribution in 32 countries around the world, as a safe and effective 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 such as sepsis, burn injury, trauma, lung injury, and pancreatitis, as well as in cancer immunotherapy. 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, such as cytokines and free hemoglobin, which can lead to post-operative complications, including multiple organ failure. CytoSorb® has been used safely in more than 12,000 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. The Company has numerous products under development based upon this unique blood purification technology, protected by 32 issued U.S. patents and multiple applications pending, including HemoDefend™, ContrastSorb, DrugSorb, and others. Additional information is available for download on the Company's websites: <http://www.cytosorbents.com> and <http://www.cytosorb.com>

### **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 9, 2016, 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)

	<b>Three months ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Revenues		
Sales	\$ 1,597	\$ 704
Grant income	213	19
Other revenue	--	1
Total revenues	<u>1,810</u>	<u>724</u>
Cost of revenue	<u>819</u>	<u>305</u>
Gross profit	991	419
Other Expenses:		
Research and development	856	951
Legal, financial and consulting	255	216
Selling, general and administrative	1,970	1,515
Total expenses	<u>3,081</u>	<u>2,682</u>
Loss from operations	<u>(2,090)</u>	<u>(2,263)</u>
Other income/(expense):		
Interest income/(expense)	4	3
Gain (loss) on foreign currency transactions	232	(449)
Change in warrant liability	18	(2,008)
Total other income/(expense), net	<u>254</u>	<u>(2,454)</u>
Net loss before benefit from income taxes	(1,836)	(4,717)
Benefit from income taxes	--	--
Net loss available to common shareholders	<u>\$(1,836)</u>	<u>\$(4,717)</u>
Earnings per share:		
Basic and diluted net loss per share	<u>(\$0.08)</u>	<u>(\$0.19)</u>
Basic and diluted weight average shares outstanding	<u>24,401,167</u>	<u>24,394,474</u>
Net loss	(\$1,836)	(\$4,717)
Other comprehensive loss:		
Currency translation adjustment	(246)	344
Comprehensive loss	<u>(\$2,082)</u>	<u>(\$4,373)</u>

CYTOSORBENTS CORPORATION  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(amounts in thousands)

	<b>March 31, 2016 (Unaudited)</b>	<b>December 31, 2015</b>
<b>ASSETS:</b>		
Cash and cash equivalents	\$3,537	\$5,316
Short-term investments	2,490	2,192
Grants and accounts receivable, net	760	649
Inventories	1,060	1,191
Prepaid expenses and other current assets	194	512
Total current assets	<u>8,041</u>	<u>9,860</u>
Property and equipment, net	569	557
Other assets	902	837
<b>TOTAL ASSETS</b>	<u><u>\$9,512</u></u>	<u><u>\$11,254</u></u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Accounts payable	\$ 860	\$ 685
Accrued expenses and other current liabilities	770	723
Deferred revenue	--	--
Warrant liability	1,618	1,636
Total current liabilities	<u>3,248</u>	<u>3,044</u>
Total Stockholders' Equity	<u>6,264</u>	<u>8,210</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u><u>\$9,512</u></u>	<u><u>\$11,254</u></u>

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**Cytosorbents Contact:**

Amy Vogel

Investor Relations

(732) 329-8885 ext. \*825

[avogel@cytosorbents.com](mailto:avogel@cytosorbents.com)

**Investor Contact:**

Lee Roth

The Ruth Group

646-536-7012

[lroth@theruthgroup.com](mailto:lroth@theruthgroup.com)