



# CytoSorbents

Working to Save Lives Through Blood Purification

## CytoSorbents Reports Record Quarterly and Full-Year 2016 Revenue

*Company Well-Positioned for Accelerated Growth in 2017*

MONMOUTH JUNCTION, N.J., March 3, 2017 - [CytoSorbents Corporation](#) (NASDAQ: CTSO), a critical care immunotherapy leader commercializing its flagship [CytoSorb®](#) blood filter to prevent or treat deadly inflammation and organ failure in critically-ill and cardiac surgery patients around the world, reports operational and financial results for the fiscal year ending December 31, 2016.

### **2016 Financial Highlights:**

- Total revenue doubled in 2016 to approximately \$9.5 million, which includes both product sales and grant income, from \$4.8 million in 2015
- CytoSorb® product sales increased 103% to \$8.2 million for fiscal 2016 compared to \$4.0 million in fiscal 2015
- Increases in 2016 product sales were driven by 112% growth in direct sales in Germany to approximately \$5.0 million, or 61% of sales, and 91% rest-of-world growth to \$3.2 million, compared to 2015
- Q4 2016 product sales were \$2.6 million, the sixth consecutive quarter of record sales growth, representing a 75% increase over Q4 2015 sales, and a 22% increase over Q3 2016 sales
- Product gross margins expanded to approximately 67% for fiscal 2016, compared to 62% for fiscal 2015, blending higher margin direct sales and lower margin distributor sales
- Revenue run rate has exceeded \$10 million for the first time

### **2016 Operational Highlights:**

- Surpassed 20,000 human CytoSorb® treatments worldwide
- Completed the U.S. REFRESH I safety and feasibility randomized controlled trial. Achieved the primary safety endpoint, identified procedures with very high levels of toxic plasma free hemoglobin that can be used to enrich future studies for those at greatest risk, and demonstrated a statistically significant reduction in key inflammatory mediators in this population
- Expanded distribution of CytoSorb to a total of 42 countries, adding Spain, Portugal, Hungary, Czech Republic, Slovakia, Chile, Iran and Iceland, and achieved [final registration](#) of CytoSorb in Russia
- [Expanded direct sales territories to Belgium and Luxembourg](#) and established the CytoSorbents Switzerland subsidiary

- Entered into a [strategic partnership with Terumo Cardiovascular](#) as exclusive distributor of CytoSorb for cardiac surgery applications in France, Denmark, Norway, Finland, Sweden, and Iceland, and facilitated [market launch in December](#) with availability of the cardiac surgery cardiopulmonary bypass (CPB) pack
- Worked closely with Fresenius Medical Care to assist the [market launch of CytoSorb in May 2016](#) in six countries
- Attained a [permanent dedicated reimbursement code for CytoSorb](#) in Germany
- CytoSorb selected as an innovative therapy with [U.K. NICE MedTech Innovation Briefing](#)
- Announced [CytoSorb-XL](#), in advanced development and patent pending as the future successor to CytoSorb
- Secured a [\\$10 million debt facility with Bridge Bank](#), of which \$5 million remains available
- Announced multiple SBIR and STTR research contract awards of up to \$950K for the development of novel [potassium binding sorbents](#) to treat severe hyperkalemia, [fungal mycotoxin](#) countermeasures, and technologies to enable [universal plasma](#)
- Recently [received \\$319K](#) through the monetization of New Jersey net operating losses

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, “We recorded our strongest financial performance ever in 2016, led by record sales in Germany – the largest medical device market in Europe and the 3rd largest in the world - where we first began commercialization of CytoSorb®. Reorders from a broad base of existing direct customers continue to drive this growth, with many reference accounts becoming significant and one exceeding 10% of 2016 product sales. These large accounts validate our assertion that a single hospital can approach or exceed \$1M in sales. Also, we are now seeing many other countries, managed by distributors or partners, begin to follow a similar sales trajectory as Germany, albeit time-shifted depending on when the therapy first became available there.”

“In 2017, we expect to build upon this sales momentum with several important recent catalysts. In particular, we believe our direct sales are primed to benefit from the recent [achievement of a dedicated reimbursement code for CytoSorb in Germany](#), which was obtained with the initiation and support of major national medical societies. In this estimated \$1.0-1.5 billion total addressable market for CytoSorb, this enhanced reimbursement is expected to drive sustainable long-term sales growth in Germany, leveraging our critical mass of usage amongst most major university and many public hospitals, strong key opinion leader support in both critical care and cardiac surgery, our outstanding direct sales team, and a broad clinical program to support usage.”

“On the international sales side, the recently announced [co-marketing program](#) with Fresenius Medical Care, the initiation of sales by Terumo Cardiovascular, the establishment of a dedicated CytoSorb division by Biocon, and the growing pull-through that we are seeing from independent distributor accounts, are all expected to accelerate indirect sales in 2017.”

“Based on our expectations of growth, our goal is to drive to operating profitability within the next 1-2 years, at product sales of approximately \$20 million and rising gross margins, at which

point we expect approximately 40-50 cents on every dollar in sales will drop to the bottom line. Concurrently, we plan to pursue U.S. approval of CytoSorb. Pending near-term discussions with the FDA, we plan to begin a pivotal registration REFRESH 2 trial later this year, focused on demonstrating the clinical benefit of intra-operative use of CytoSorb during complex open heart surgery to reduce serious post-operative complications.”

“We believe this dual focus on 1) Rapid growth and near-term operating profitability with expected significant positive cash flow coupled with 2) The initiation of a U.S. pivotal trial designed to seek U.S. regulatory approval and open up the U.S. market for CytoSorb, is compelling and has attracted a broader audience. We look forward to spreading our unique story at leading investor conferences such as the Cowen Healthcare Conference, where we were invited to present next week.”

“Please join us on our previously announced earnings call today at 11:00AM EST where we will cover our progress. 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: Friday, March 3, 2017

Time: 11:00 AM Eastern

Participant Dial-In: 1-719-325-2149

Live Presentation Webcast: <http://public.viavid.com/index.php?id=123053>

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=123053>

An archived recording and written transcript 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/>

***Fiscal Year 2016 Financial Results:***

***Revenues:***

For the year ended December 31, 2016, we generated total revenue, which includes product revenue and grant income, of approximately \$9,528,000 as compared to revenues of approximately \$4,792,000 for the year ended December 31, 2015, an increase of approximately \$4,736,000, or 99%. Revenue from product sales was approximately \$8,206,000 for the year ended December 31, 2016, as compared to approximately \$4,044,000 in the year ended December 31, 2015, an increase of approximately \$4,162,000 or 103%. 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 increased by approximately \$586,000 to approximately \$1,322,000 in 2016 from \$736,000 in 2015 as a result of revenue received from existing grants as well as revenue received from several new grants awarded during 2016.

***Cost of Revenue:***

For the years ended December 31, 2016 and 2015, cost of revenue was approximately \$3,954,000 and \$2,213,000, respectively, an increase of approximately \$1,741,000, or 79%. This increase is related to an increase in product cost of revenue of approximately \$1,198,000 attributable to increased sales in 2016. Product gross margins were approximately 67% for the year ended December 31, 2016, as compared to approximately 62% for the year ended December 31, 2015 due to a favorable mix of sales prices and, to a lesser extent, a reduction in our product costs. Grant income related expenses increased by approximately \$544,000 during the year ended December 31, 2016 as compared to the year ended December 31, 2015 due to progress made in meeting grant milestones on both existing and new grants.

***Research and Development Expenses:***

Our research and development costs were approximately \$4,783,000 and \$3,871,000 for the years ended December 31, 2016 and 2015, respectively, an increase of approximately \$912,000, or 24%. This increase in research and development expenditures is related to an increase in costs related to our various clinical studies and trials of approximately \$833,000, an increase in stock-based compensation of approximately \$584,000 due to milestone options awarded to the Company's research and development employees during the year ended December 31, 2016, an increase in salaries related to non-clinical research and development activities of approximately \$14,000 and an increase in supplies and other research and development expenses of approximately \$25,000. These increases were offset by an increase in direct labor and other costs being deployed toward grant-funded activities of approximately \$544,000, which had the effect of decreasing the amount of our non-reimbursable research and development costs.

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

Our legal, financial and other consulting costs were approximately \$1,185,000 and \$1,089,000 for the years ended December 31, 2016 and 2015, respectively, an increase of approximately \$96,000, or 9%. The increase of approximately \$51,000 was due to an increase in accounting and auditing fees of approximately \$65,000 due to fees incurred which were related to the audit of our internal controls as required by The Sarbanes-Oxley Act of 2002 and increases in consulting fees of approximately \$151,000. These increases were offset by a decrease in employment agency fees of approximately \$81,000 related to fees incurred in 2015 related to the hiring of senior level personnel that did not recur in 2016 and a reduction in legal

fees of approximately \$40,000 as a result of fees related to certain corporate initiatives in 2015 that did not recur in 2016.

***Selling, General and Administrative Expenses:***

Our selling, general and administrative expenses were approximately \$11,098,000 and \$6,923,000 for the years ended December 31, 2016 and 2015, respectively, an increase of approximately \$4,175,000, or 60%. The increase in selling, general, and administrative expenses was due to an increase in salaries, commissions and related costs of approximately \$1,468,000 due to headcount additions and personnel related costs, an increase in royalty expenses of approximately \$291,000 due to the increase in product sales, additional sales and marketing costs, which include advertising, and conferences of approximately \$114,000, an increase in travel and entertainment and other costs of approximately \$71,000 due to the increased headcount, an increase in stock-based compensation of approximately \$2,096,000 due to milestone options awarded to the Company's employees and restricted stock units awarded to the Company's executive staff during the year ended December 31, 2016, an increase in rent expense of approximately \$17,000 related to the new expanded office facility in Germany, an increase in bad debt expense of approximately \$65,000, an increase in sales consulting fees of approximately \$33,000 and an increase in postage and delivery costs and other general and administrative costs of approximately \$62,000. These increases were offset by a decrease in public relations fees of approximately \$42,000.

***Interest Income (Expense):***

For the year ended December 31, 2016, interest expense was approximately \$232,000, as compared to interest income of approximately \$9,000 for the year ended December 31, 2015. This increase in interest expense of approximately \$241,000 is directly related to interest expense incurred and amortization of loan acquisition costs related to the Company's financing facility with Bridge Bank on which \$5,000,000 was drawn on June 30, 2016.

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

For the year ended December 31, 2016, the loss on foreign currency transactions was approximately \$358,000, as compared to \$507,000 for the year ended December 31, 2015, a decrease of approximately \$129,000. This decrease is attributable to the rate of the decline in the exchange rate of the Euro for the year ended December 31, 2016 as compared to the year ended December 31, 2015. During the year ended December 31, 2016, the exchange rate of the Euro declined from \$1.09 at the beginning of the year to \$1.05 at December 31, 2016. During the year ended December 31, 2015, the exchange rate of the Euro declined from \$1.22 at the beginning of the year to \$1.09 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 expense of approximately \$175,000 for the year ended December 31, 2016 and other income of approximately \$1,345,000 for the year ended December 31, 2015. The change in warrant liability was as a result of the change in the fair value of the warrant liability from January 1, 2016 to December 31, 2016 and from January 1, 2015 to December 31, 2015. See the consolidated financial statements for details related to the calculation of the fair value of the warrant liability.

### ***Benefit from Income Taxes:***

Our benefit from income taxes was approximately \$319,000 and \$325,000 for the years ended December 31, 2016 and 2015, respectively. These benefits were realized by utilizing the New Jersey Technology Business Tax Certificate Transfer Program whereby the State of New Jersey allows us to sell our net operating losses to a third party.

### ***Liquidity and Capital Resources***

Since inception, our operations have been primarily financed through the private and public placement of our debt and equity securities. At December 31, 2016, we had current assets of approximately \$7,828,000 including cash on hand of approximately \$5,245,000 and had current liabilities of approximately \$6,090,000. In December 2016, we received approximately \$319,000 in cash from the sale of our net operating losses to the State of New Jersey.

We believe that we have sufficient cash to fund our operations through the first half of 2017; however, we will need to raise additional capital to support our ongoing operations in the future. In addition, we will need to raise additional funds to support clinical trials in the U.S. and in Europe. We will be better able to assess this need once the specific protocols of these trials are finalized.

### ***2017 First 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 first quarter 2017 product sales to exceed sales reported in the first quarter of 2016.

For additional information please see the Company's Annual Report on Form 10-K for the year ended December 31, 2016 filed on March 3, 2017 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 42 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. CytoSorbents has completed its REFRESH (REduction in FREe Hemoglobin) 1 trial - a multi-center, randomized controlled study that has demonstrated the safety of intra-operative CytoSorb® use in a heart-lung machine during complex cardiac surgery. In 2017, the company plans to initiate a pivotal REFRESH 2 trial intended to support U.S. FDA approval. CytoSorb® has been used safely in more than 20,000 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 in excess of \$18 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 32 issued U.S. patents and multiple applications pending, including CytoSorb-XL, HemoDefend™, VetResQ™, ContrastSorb, DrugSorb, and others. For more information, please visit the Company's websites at [www.cytosorbents.com](http://www.cytosorbents.com) and [www.cytosorb.com](http://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 3, 2017, 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)



	Year ended December 31,		
	2016	2015	2014
Revenue:			
Sales	\$ 8,206	\$ 4,044	\$ 3,135
Grant income	1,322	736	979
Other revenue	--	12	9
Total revenue	<u>9,528</u>	<u>4,792</u>	<u>4,123</u>
Cost of revenue	<u>3,954</u>	<u>2,213</u>	<u>2,134</u>
Gross profit	5,574	2,579	1,989
Expenses:			
Research and development	4,783	3,871	2,432
Legal, financial and other consulting	1,185	1,089	897
Selling, general and administrative	11,098	6,923	5,553
Total operating expenses	<u>17,066</u>	<u>11,883</u>	<u>8,882</u>
Loss from operations	(11,492)	(9,304)	(6,893)
Other income(expense), net	<u>(766)</u>	<u>847</u>	<u>(2,814)</u>
Loss before benefit from income taxes	(12,258)	(8,457)	(9,707)
Benefit from income taxes	<u>319</u>	<u>325</u>	<u>386</u>
Net loss	(11,939)	(8,132)	(9,321)
Preferred stock dividends	--	--	(9,267)
Net loss available to common shareholders	<u>\$ (11,939)</u>	<u>\$ (8,132)</u>	<u>\$ (18,588)</u>
Earnings per share:			
Basic and diluted earnings per share	<u>\$ (0.47)</u>	<u>\$ (0.33)</u>	<u>\$ (1.29)</u>
Basic and diluted weighted average shares outstanding	<u>25,433,719</u>	<u>24,885,809</u>	<u>14,382,813</u>

CYTOSORBENTS CORPORATION  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(amounts in thousands)

	December 31, 2016	December 31, 2015
<b>ASSETS:</b>		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 5,245	\$ 5,316
Short-term investments	--	2,192
Grants and accounts receivable, net	1,433	649
Inventories	834	1,191
Prepaid expenses and other current assets	316	512
Total current assets	<u>7,828</u>	<u>9,860</u>
Property and equipment, net	569	557
Other assets	1,297	837
<b>TOTAL ASSETS</b>	<u>\$ 9,694</u>	<u>\$ 11,254</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT):</b>		
<i>Current Liabilities:</i>		
Accounts payable	\$ 1,330	\$ 685
Accrued expenses and other current liabilities	2,115	723
Current Maturities of long-term debt, net of debt issuance costs	833	--
Warrant liability	1,812	1,636
Total current liabilities	<u>6,090</u>	<u>3,044</u>
Long-term debt, net of current maturities	4,078	--
<b>TOTAL LIABILITIES</b>	<u>10,168</u>	<u>3,044</u>
Total stockholders' equity/(deficit)	<u>(474)</u>	<u>8,210</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)</b>	<u>\$ 9,694</u>	<u>\$ 11,254</u>

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