

CytoSorbents Accelerates Growth in Q3 2015

MONMOUTH JUNCTION, NJ - November 13, 2015 - CytoSorbents Corporation (NASDAQ: CTSO), a leader in critical care immunotherapy commercializing its CytoSorb[®] blood purification technology to reduce deadly uncontrolled inflammation in hospitalized patients around the world, today reported financial and operating results for the three and nine months ended September 30, 2015.

CytoSorbents achieved strong product revenue of approximately \$1.1 million in Q3 2015, its best quarterly sales performance, and a 38% increase over Q2 2015

Recent Financial Highlights:

- Total sales for Q3 2015 were \$1.3M, which includes both product sales and grant income
- Q3 2015 product revenues were approximately \$1.1M, the Company's best quarterly sales performance, and a 38% increase over Q2 2015, driven by strength in reorders in both direct and distributor sales. Disregarding the decline in the Euro to U.S. Dollar exchange rate, product sales for Q3 2015 would have been approximately \$1.2M, a 19% increase compared to Q3 2014
- Product gross margins for Q3 2015 were approximately 63%
- Trailing 12-month CytoSorb[®] sales were \$3.4M at the end of Q3 2015, compared to \$2.6M for the same period a year ago, an increase of 31%
- Strong working capital position, with cash and short term investments totaling \$9.3M at the end of Q3 2015

Recent Operational Highlights:

- Submitted an <u>Expedited Access Pathway (EAP)</u> application to the FDA to request EAP Designation status for the treatment of sepsis with CytoSorb[®]. EAP Designation is equivalent to "Breakthrough" designation for drugs and biologics, but for medical devices that address major unmet medical needs
- One clinical site has begun screening patients for enrollment in the U.S. <u>REFRESH I</u> cardiac surgery trial, with 6 of 8 sites expected to be at this stage before the end of November. These are leading U.S. cardiac surgery centers including Baylor College of Medicine, Baystate Medical, Columbia University, Cooper University Hospital, University

of Kentucky, University of Maryland, University of Pennsylvania, and University of Pittsburgh Medical Center

- Were awarded a <u>\$1.5 million Phase II Small Business Innovation Research contract</u> from the National Heart, Lung, And Blood Institute (NHLBI), a division of the National Institutes of Health (NIH), to advance Hemodefend[™] toward commercialization to improve the quality and safety of the blood supply. The two-year project provides incremental, non-dilutive funding to the Company and begins immediately
- Conducted an extremely successful <u>2nd International CytoSorb Users Meeting</u> in Berlin, Germany in early October that brought together 110 clinicians, distributors and strategic partners from 18 countries. To date, CytoSorb[®] has been safely administered in more than 8,000 human treatments and is growing steadily in adoption and usage
- <u>Currently working with Fresenius</u> in the initial marketing to key opinion leaders in multiple countries with a formal launch expected in the next several months
- Supported global awareness of the dangers of sepsis through <u>sponsorship of numerous</u> <u>sepsis related initiatives</u> including the SepsisUpdate 2015 Congress, the Hugo Schottmüller Prize, and the Sepsis Alliance Sepsis Heroes Ceremony

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, "CytoSorbents achieved strong organic growth across the board in both direct and distributor/partner sales, delivering our best quarterly product sales to date. This speaks to the success of our recently expanded direct sales team and international distribution network, as well as to the increasing awareness and traction CytoSorb[®] is achieving in the marketplace."

"In early October we held the 2nd International CytoSorb Users Meeting in Berlin, which was one of the largest and most successful gatherings of worldwide CytoSorb[®] users, distributors and partners in the Company's history. We were excited to learn about the many treatment successes credited to CytoSorb[®], and were pleased that the quality of the data being reported from around the world continues to grow from case reports, to case series, and now to small completed randomized controlled studies. We hope to capture even more data from the more than 8,000 human treatments that have taken place to date, in our International CytoSorb[®] Registry, where more than 80 medical centers are registered and in the process of submitting treatment data."

"As we continue to expand our commercialization efforts, we remain on track in pursuing a dual path to potential U.S. approval for CytoSorb[®], including the use of CytoSorb[®] intra-operatively in a heart-lung machine during complex cardiac surgery in our REFRESH Trial, as well as for the treatment of sepsis, one of the top ten killers around the world for which there are no effective therapies. To that end, we have submitted an application with the FDA to request Expedited Access Pathway (EAP) designation for the treatment of sepsis and will have an update in the future as warranted."

"As we plan for a strong 2016, we are encouraged by the convergence of many key drivers of our business. These include the:

- Increasing momentum in clinical usage and data for CytoSorb®
- Growing number of CytoSorb[®] treatment successes in many different clinical applications
- Continued progress in geographic expansion with key countries turning on in 2016
- Expected contributions of major existing partners and distributors such as Fresenius and Biocon
- Keen interest from many industry players in different verticals
- Greater awareness of investors to our story
- Ability to fund more aggressive growth and attract non-dilutive grant funding

Together, with our dedicated team and network of thought leaders and users from around the world, we believe we have the formula to take our business to the next level."

Dr. Chan concluded, "Please join us on the earnings call today at 11:00AM EST where we will cover our progress in greater detail. In addition, we will address questions from analysts and investors during the live question and answer period. The investor presentation and a written transcript of the conference call will be available within a week of the webcast on our website."

Conference Call Details: Date: Friday, November 13, 2015 Time: 11:00 AM Eastern Participant Dial-In: 719-457-2731 Live Presentation Webcast: <u>http://public.viavid.com/index.php?id=116936</u> An archived recording of the conference call will be available under the Investor Relations section of the Company's website at <u>http://www.cytosorbents.com/invest.htm</u>

Financial Results for the Third Quarter Ended September 30, 2015

Revenues:

The Company generated total revenues of approximately \$1,343,000 and \$1,162,000 for the three months ending September 30, 2015 and September 30, 2014, respectively. Product revenues were approximately \$1,071,000 for the quarter ended September 30, 2015, as compared to product revenues of \$1,032,000 for the quarter ended September 30, 2014. Product sales were negatively impacted by the decline in the exchange rate of the Euro. The impact of the decline in the exchange rate of the Euro was approximately \$150,000, or 14% of sales, for the three months ended September 30, 2015. Additionally, grant revenue and other income was approximately \$272,000 and \$128,000 for the three month periods ended September 30, 2015 and 2014, respectively.

Cost of Revenues:

For the three months ended September 30, 2015 and 2014, cost of revenue was approximately \$639,000 and \$476,000, respectively. The increase in cost of revenues is directly related to an increase of direct labor and other costs being deployed toward grant-funded activities, which has the effect of increasing the amount of costs allocated to cost of revenue. Product gross margins were approximately 63% for each of the three month periods ended September 30, 2015 and 2014, respectively.

Research and Development Expenses:

For the three months ending September 30, 2015, research and development costs were approximately \$865,000, as compared to research and development costs of approximately \$880,000 for the three months ended September 30, 2014, a decrease of approximately \$14,000 or 2%. This decrease was primarily due to an increase of approximately \$234,000 of direct labor and other costs being deployed toward grant-funded activities in the three months ended September 30, 2015 as compared to the three months ended September 30, 2014, which had the effect of decreasing the amount of our non-reimbursable research and development costs. Also, materials and supplies related to our various research and development activities decreased approximately \$157,000 during the three months ended September 30, 2015 as compared to the three months ended September 30, 2014. These decreases were offset by increases in salaries and other costs related to our various clinical and investigator initiated studies of approximately \$295,000 and salaries related to non-clinical research and development activities increased approximately \$295,000 during the three months ended September 30, 2015 as compared to the three months ended September 30, 2014.

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting costs were approximately \$289,000 for the three months ending September 30, 2015, as compared to legal financial and other consulting costs of approximately \$49,000 for the three months ended September 30, 2014. This increase of approximately \$240,000 was primarily due to legal fees of approximately \$118,000 that were related to general corporate and governance matters and an increase in consulting fees of approximately \$93,000 primarily related to Sarbanes-Oxley compliance, marketing activities, and other matters.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately \$1,700,000 for the three months ended September 30, 2015, compared to approximately \$1,240,000 for the three months ended September 30, 2014, an increase of approximately \$460,000. This was primarily due to increases in payroll related costs of approximately \$336,000, increased royalties and license fees of approximately \$12,000 due to increases in product sales, additional sales and marketing costs, which include advertising and conferences of approximately \$166,000 and an increase in stock transfer, filing and stock exchange fees of approximately \$31,000 due to costs

associated with our listing on the NASDAQ Capital Market and our first annual meeting of stockholders in 2015, and an increase in travel-related expenses of approximately \$45,000. These increases were offset by a decrease in consulting expenses of approximately \$143,000.

Net Loss:

Our loss from operations for the three months ending September 30, 2015 was approximately \$2,150,000, as compared to a net loss from operations of approximately \$1,484,000 for the three months ended September 30, 2014.

Financial Results for the Nine Months Ended September 30, 2015

Revenues:

Revenue from product sales was approximately \$2,548,000 in the nine months ended September 30, 2015, as compared to approximately \$2,264,000 in the nine months ended September 30, 2014, an increase of approximately \$284,000, or 13%. This increase was driven by the continued growth in direct sales as well as the expansion of sales to our growing distributor network, which was offset by the negative impact of the decline in the exchange rate of the Euro relative to the U.S. dollar. The impact of the decline in the exchange rate of the Euro was approximately \$410,000, or 16% of sales, for the nine months ended September 30, 2015. Adjusted for the impact of the Euro, product sales for the nine months ended September 30, 2015 would have been approximately \$3.0 million.

Grant income was approximately \$471,000 for the nine months ended September 30, 2015 as compared to approximately \$978,000 for the nine months ended September 30, 2014 as a result of the conclusion during 2014 of several significant grants.

As a result of the decrease in grant income, for the nine months ended September 30, 2015, we generated total revenues of approximately \$3,031,000, as compared to total revenue of approximately \$3,249,000, for the nine months ended September 30, 2014, a decrease of approximately \$218,000, or 7%.

Cost of Revenues:

For the nine months ended September 30, 2015 and 2014, cost of revenue was approximately \$1,409,000 and \$1,805,000, respectively. The decrease is directly related to a decrease of approximately \$676,000 of direct labor and other costs being deployed toward grant-funded activities, which has the effect of decreasing the amount of costs allocated to cost of revenue. Product cost of revenues increased approximately \$139,000 during the nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014 due to increased sales. Product gross margins were approximately 62% for the nine months ended September 30, 2015, as compared to approximately 63% for the nine months ended September 30, 2014.

Research and Development Expenses:

For the nine months ended September 30, 2015, research and development expenses were approximately \$2,619,000 as compared to research and development expenses of approximately \$1,464,000 for the nine months ended September 30, 2014. The increase of approximately \$1,155,000 in research and development expenses was primarily due to a decrease of approximately \$451,000 of direct labor and other costs being deployed toward grant-funded activities, which had the effect of increasing the amount of our non-reimbursable research and development costs. In addition, salaries and other costs related to our various clinical and investigator-initiated studies increased approximately \$735,000 and salaries related to non-clinical research and development activities increased approximately \$128,000 during the nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014.

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting expenses were approximately \$802,000 for the nine months ended September 30, 2015, as compared to approximately \$452,000 for the nine months ended September 30, 2014. The increase of approximately \$350,000 was due to an increase in legal fees related to general corporate and governance matters of approximately \$182,000, an increase in employment agency fees of approximately \$68,000 related to the hiring of certain highly-qualified personnel and an increase in consulting fees of approximately \$80,000 related to marketing and compliance activities.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately \$4,842,000 for the nine months ended September 30, 2015, as compared to approximately \$3,518,000 for the nine months ending September 30, 2014. The increase of approximately \$1,324,000 in selling, general, and administrative expenses was due to increases in salaries, commissions and related costs of approximately \$659,000 due to the impact of headcount additions and an additional approximately \$110,000 of salary increases for named executive officers; additional sales and marketing costs; which include advertising and conferences of approximately \$302,000; an increase in stock transfer, filing and stock exchange fees of approximately \$131,000 due to costs associated with our listing on the NASDAQ Capital Market and our first annual meeting of stockholders in 2015; an increase in royalty and license expenses of approximately \$49,000 due to higher sales in 2015 and an increase in travel and entertainment costs of approximately \$73,000.

Net Loss:

Our net loss for the nine months ended September 30, 2015 was approximately \$6,130,000, as compared to a net loss of approximately \$4,327,000 for the nine months ended September 30, 2014.

Liquidity and Capital Resources:

Since inception, our operations have been primarily financed through the private placement of its debt and equity securities. At September 30, 2015, we had current assets of approximately \$11,591,000 including cash on hand and short-term investments of approximately \$9,329,000 and current liabilities of approximately \$3,447,000. We believe we have sufficient cash to fund our operations into 2016; however, we may need to raise additional capital to fully fund pivotal trials in the U.S. 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.

2015 Fourth Quarter Outlook

CytoSorbents has not historically given financial guidance on quarterly results until the quarter has been completed. However, we continue to expect our 2015 product sales to meet or exceed that achieved in 2014.

For additional information please see the Company's 10-Q report for the period ended September 30, 2015 filed on November 13, 2015 on <u>http://www.sec.gov</u>.

About CytoSorbents Corporation

CytoSorbents Corporation is a critical care focused immunotherapy company using blood purification to control severe inflammation -- with the goal of preventing or treating multiple organ failure in life-threatening illnesses. Organ failure is the cause of nearly half of all deaths in the intensive care unit, with little to improve clinical outcome. CytoSorb[®], the Company's flagship product, is approved in the European Union with distribution in 31 countries around the world, as a safe and effective extracorporeal cytokine adsorber, designed to reduce the "cytokine storm" that could otherwise cause massive inflammation, organ failure and death in common critical illnesses such as sepsis, burn injury, trauma, lung injury, and pancreatitis. 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' 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. CytoSorbents has numerous products under development based upon this unique blood purification technology, protected by 32 issued US patents and multiple applications pending, including HemoDefend[™], ContrastSorb, DrugSorb, and others.

Additional information is available for download on the Company's websites: <u>http://www.cytosorbents.com</u> and <u>http://www.cytosorb.com</u>

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 forwardlooking 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 forwardlooking 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 31, 2015, 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.

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CYTOSORBENTS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (amounts in thousands, except per share data)

	Nine months ended September 30,				Three months ended September 30,			
	2015		2014		2015		2014	
	(Unaudited)		(Unaudited)		(Unaudited)		(Unaudited)	
Revenues		<u> </u>		<u> </u>		<u> </u>		<u> </u>
Sales	\$	2,548	\$	2,264	\$	1,071	\$	1,032
Grant income		471		978		272		128
Other revenue		12		7				2
Total revenue		3,031		3,249		1,343		1,162
Cost of revenue		1,409		1,805		639		476
Gross profit		1,622		1,444		704		686
Expenses:								
Research and development		2,619		1,464		865		880
Legal, financial and other consulting		802		452		289		49
Selling, general and administrative		4,842		3,518		1,700		1,241
Total expenses		8,263		5,434		2,854		2,170
Loss from operations		(6,641)		(3,990)		(2,150)		(1,484)
Other income(expense), net		511		(337)		(697)		(14)
Income (loss) before benefit from								
income taxes		(6,130)		(4,327)		(2 <i>,</i> 847)		(1,498)
Benefit from income taxes								
Net income (loss)		(6,130)		(4,327)		(2 <i>,</i> 847)		(1,498)
Preferred stock dividend				3,770				1,281
Net income (loss) available to common								
shareholders	\$	(6,130)	\$	(8,097)	\$	(2,847)	\$	(2,779)
Basic and diluted net loss per								
common share	\$	(0.25)	\$	(0.69)	\$	(0.11)	\$	(0.22)
Weighted average number of shares of	Ŧ	(====)	Ŧ	(0000)	Ŧ	()	T	()
common stock outstanding	24	,812,707	11	,727,573	25	,037,538	12	,496,014
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Net income (loss)	\$	(6,130)	\$	(4,327)	\$	(2,847)	\$	(1,498)
Other comprehensive income (loss):	Ŧ	(-,,	Ŧ	('/= - ' /	Ŧ	(_,_ , , , , ,	Ŧ	(_,)
Currency translation adjustment		218		123		(50)		118
Comprehensive loss	\$	(5,912)	\$	(4,204)	\$	(2,897)	\$	(1,380)
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CYTOSORBENTS CORPORATION CONDENSED CONSOLIDATED BALANCE SHEETS (amounts in thousands)

	2	mber 30, 2015 audited)	December 31, 2014		
ASSETS:					
Cash and cash equivalents	\$	7,386	\$	3,605	
Short-term investments		1,943		1,945	
Grants and accounts receivable, net		553		819	
Inventories		1,337		538	
Prepaid expenses and other current assets		372	_	700	
Total current assets		11,591		7,607	
Property and equipment, net		480		246	
Other assets		731		616	
TOTAL ASSETS	\$	12,802	\$	8,469	
LIABILITIES AND STOCKHOLDERS' EQUITY	Å	527	ć	600	
Accounts payable	\$	527	\$	698	
Accrued expenses and other current liabilities		756		825	
Deferred revenue				1	
Warrant liability		2,164		2,982	
Total current liabilities		3,447		4,506	
TOTAL LIABILITIES		3,447		4,506	
Total stockholders' equity		9,355		3,963	
TOTAL LIABILITIES AND STOCKHOLDER'S EQUITY	\$	12,802	\$	8,469	