



# CytoSorbents

Working to Save Lives Through Blood Purification

## CytoSorbents Achieves Record Revenue and Product Sales Growth in 2018

*2018 Total Revenue was \$22.5 million, with 2018 Product Sales surpassing \$20M for the first time, representing 51% growth over 2017*

MONMOUTH JUNCTION, N.J., March 7, 2019 — [CytoSorbents Corporation](#) (NASDAQ: CTSO) a critical care immunotherapy leader commercializing its [CytoSorb](#)<sup>®</sup> blood purification technology to treat deadly inflammation in critically-ill and cardiac surgery patients around the world, achieves record total revenue, CytoSorb<sup>®</sup> sales, and product gross margins in 2018.

### **2018 Financial Highlights:**

- Full year 2018 total revenue was \$22.5 million, including both product sales and grant income, a 49% increase from \$15.2M in 2017
- 2018 product sales increased 51% to \$20.3 million, compared to \$13.4 million in 2017
- Q4 2018 product sales were \$5.5M, the highest in our history
- 2018 product gross margins expanded 300 basis points to 74%, compared to 71% for 2017
- Solid end-of-year cash balance of \$22.4 million

### **2018 and Recent Operational Highlights:**

- Exceeded 56,000 cumulative CytoSorb treatments delivered in 2018, from 35,000 in 2017
- Launched [new manufacturing facility](#) in June 2018 that quadrupled production capacity and helped propel the highest quarterly blended gross margin of 75% in Q4 2018
- Expanded into major clinical applications with the [CytoSorb E.U. label addition of bilirubin and myoglobin removal](#), to treat acute liver disease and severe trauma, respectively
- Broadened distribution of CytoSorb to an aggregate of 55 countries, including Malaysia, Hong Kong, Lebanon, Bosnia, Herzegovina, Croatia, Estonia, Latvia, Lithuania, Moldova, Montenegro, Serbia, and the recent expansion to Mexico and South Korea with our Fresenius Medical Care partnership
- Was assigned a [dedicated procedure code for CytoSorb in Switzerland](#), that is now pending reimbursement value assignment
- Began enrollment of the REFRESH 2 – AKI pivotal trial in earnest in October following an FDA protocol amendment approval, now at 56 patients enrolled with 21 initiated sites, with an additional 8 sites undergoing approvals, contracting and/or site-initiation.

- Passed the midway point of the German government-funded REMOVE endocarditis trial with 130 patients enrolled at 13 sites, following an [interim analysis of the first 50 patients](#) and a recommendation to continue the study by the independent scientific advisory board and data safety monitoring board (DSMB)
- Cited by the [Deloitte 2018 Fast 500](#) as one of the fastest growing companies in North American for the second year in a row
- [Added to the Russell 2000 Small Cap and the Russell 3000 indexes](#)

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, “As highlighted in our January 7, 2019 stockholder letter, we had an outstanding 2018, with record total revenue and product gross margins, and surpassed \$20M in annual sales of CytoSorb for the first time. Although our progress has been exciting, we believe there is a significant multi-year global growth story ahead of us, targeting the overall opportunity in critical care and cardiac surgery. We see this daily, with so many new and different successful applications where CytoSorb has been credited with helping to improve clinical outcomes in patients with major illnesses such as sepsis, shock, trauma, lung injury, pancreatitis, endocarditis, and post-operative inflammation, with important new applications in the near future such as acute liver disease, cytokine release syndrome in cancer immunotherapy, and many others.”

Dr. Chan continued, “We believe we have achieved a critical mass of revenue and gross margins, where faster top-line growth is expected to eventually generate free cash flow, enabling further investments to accelerate even faster growth and driving greater value. Because of this, we are making very calculated investments in our infrastructure and in clinical studies, with the goal of driving sales growth and GAAP (generally accepted accounting principles) profitability. One of these investments was the [expansion of our direct sales efforts to 5 additional countries, including Poland, Sweden, Denmark, Norway, and the Netherlands](#). We are fully staffed in these countries, with the exception of Poland, which will start with a full sales team in April of this year. We believe these are countries that collectively serve a population similar in size to our major market Germany, ones that we can easily support due to their geographic proximity to our direct sales territories, while leveraging our expertise in selling direct and benefitting from significantly higher direct sale gross margins. We are very excited about the opportunities in front of us, as we believe we are in the right place, with the right product, at the right time.”

“We invite you to join us on our earnings conference call, details below.”

***Conference Call Details:***

Date: Thursday, March 7, 2019

Time: 4:45 PM Eastern Time

Participant Dial-In: 1-201-389-0879

Conference ID: 13687658

Live Presentation Webcast: <http://public.viavid.com/index.php?id=133295>

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=133295>

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 2018 Financial Results:**

### ***Revenues:***

For the year ended December 31, 2018, we generated total revenue, which includes product revenue and grant income, of approximately \$22,504,000 as compared to revenues of approximately \$15,151,000 for the year ended December 31, 2017, an increase of approximately \$7,353,000, or 49%. Revenue from product sales was approximately \$20,252,000 for the year ended December 31, 2018, as compared to approximately \$13,382,000 in the year ended December 31, 2017, an increase of approximately \$6,870,000 or 51%. This increase was primarily driven by increases in both direct and distributor sales from both new customers and repeat orders from existing customers. In addition, approximately \$792,000 of this increase was due to the increase in the average Euro to U.S. dollar exchange rate for the year ended December 31, 2018 as compared to the year ended December 31, 2017.

Grant income increased by approximately \$483,000, or 27%, to approximately \$2,251,000 in 2018 from \$1,768,000 in 2017 as a result of increased revenue received from existing grants and revenue received from a new grant awarded in 2018.

### ***Cost of Revenue:***

For the years ended December 31, 2018 and 2017, cost of revenue was approximately \$7,489,000 and \$5,518,000, respectively, an increase of approximately \$1,971,000, or 36%. This increase is related to an increase in product cost of revenue of approximately \$1,482,000 attributable to increased sales in 2018. Product gross margins were approximately 74% for the year ended December 31, 2018, as compared to approximately 71% for the year ended December 31, 2017, due to a reduction in the cost of devices manufactured as a result of production efficiencies achieved and, to a lesser extent, the impact of the increase in the exchange rate of the Euro. Grant income related expenses increased by approximately \$489,000 during the year ended December 31, 2018 as compared to the year ended December 31, 2017 due to an increase in direct labor and other costs being deployed toward grant-funded activities during the year ended December 31, 2018 as compared to the year ended December 31, 2017.

### ***Gross Profit:***

Gross profit was approximately \$15,015,000 for the year ended December 31, 2018, an increase of approximately \$5,383,000 or 56%, over gross profit of \$9,632,000 in 2017. This increase is primarily attributed to an increase in CytoSorb product sales during 2018, and, to a lesser extent, a result of the increase in product gross margins.

***Research and Development Expenses:***

Our research and development costs were approximately \$7,723,000 and \$3,221,000 for the years ended December 31, 2018 and 2017, respectively, an increase of approximately \$4,502,000, or 140%. This increase in research and development expenditures was due to an increase in our clinical trial costs of approximately \$4,179,000, which is primarily related to our REFRESH 2-AKI trial, an increase in non-clinical research and development salary related costs of approximately \$329,000 and an increase in new product development costs of approximately \$164,000 and increases in other non-grant related research and development costs of approximately \$319,000. These increases were offset by an increase in direct labor and other costs being deployed toward grant-funded activities of approximately \$489,000, 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 \$2,002,000 and \$1,339,000 for the years ended December 31, 2018 and 2017, respectively, an increase of approximately \$663,000, or 50%. This increase was due to an increase in employment agency fees of approximately \$271,000 related to the recruitment of senior level personnel, an increase in legal fees of approximately \$254,000 related to certain corporate initiatives, an increase in accounting fees of approximately \$39,000 related to fees in Germany and an increase in other professional fees of approximately \$99,000.

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

Our selling, general and administrative expenses were approximately \$20,874,000 and \$14,914,000 for the years ended December 31, 2018 and 2017, respectively, an increase of approximately \$5,960,000, or 40%. The increase in selling, general, and administrative expenses was due to an increase in non-cash stock compensation expense of approximately \$1,379,000 primarily based upon achievement of the 2018 operating milestones, increases in salaries, commissions and related costs of approximately \$2,831,000 due to headcount additions, an increase in royalty expenses of approximately \$555,000 due to the increase in product sales, additional sales and marketing costs, which include advertising and conferences of approximately \$343,000, an increase in travel and entertainment costs and other expenses of approximately \$453,000, an increase in occupancy cost of approximately \$237,000 related to our manufacturing facility expansion, an increase in public relations expense of approximately \$98,000 and an increase in other G&A expenses of approximately \$64,000.

***Interest Expense, Net:***

For the year ended December 31, 2018, interest expense, net was approximately \$1,461,000, as compared to interest expense, net of approximately \$749,000 for the year ended December 31, 2017. This increase in net interest expense of approximately \$712,000 is directly related to 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 the additional interest related to the drawdown of the Term B Loan (as defined in the Loan and Security Agreement dated June 30, 2016 with Bridge Bank) on June 30, 2017 in the amount of \$5,000,000.

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

For the year ended December 31, 2018, the loss on foreign currency transactions was approximately \$785,000, as compared to a gain on foreign currency transactions of approximately \$1,454,000 for the year ended December 31, 2017. The 2018 loss is directly related to the decrease in the exchange rate of the Euro at December 31, 2018, as compared to December 31, 2017. The exchange rate of the Euro to the U.S. dollar was \$1.15 per Euro at December 31, 2018 as compared to \$1.20 per Euro at December 31, 2017. The 2017 income is directly related to the increase in the exchange rate of the Euro at December 31, 2017, as compared to December 31, 2016. The exchange rate of the Euro to the U.S. dollar was \$1.20 per Euro at December 31, 2017 as compared to \$1.05 per Euro at December 31, 2016.

***Benefit from Income Taxes:***

Our benefit from income taxes was approximately \$620,000 and \$677,000 for the years ended December 31, 2018 and 2017, 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 a portion of our state 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, 2018, we had current assets of approximately \$28,264,000 including cash on hand of approximately \$22,369,000 and had current liabilities of approximately \$6,538,000. In January 2019, we received approximately \$620,000 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 into 2020.

**2019 First Quarter Revenue Guidance**

CytoSorbents has not historically given specific financial guidance on quarterly results until the quarter has been completed. However, we expect our first quarter 2019 product sales will exceed sales reported in the first quarter of 2018.

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 56,000 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<sup>+</sup>ontrol™, 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 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)

	Year ended December 31,		
	<u>2018</u>	<u>2017</u>	<u>2016</u>
Revenue:			
Product sales	\$ 20,252	\$ 13,382	\$ 8,206
Grant income	2,252	1,769	1,322
Total revenue	<u>22,504</u>	<u>15,151</u>	<u>9,528</u>
Cost of revenue	<u>7,489</u>	<u>5,519</u>	<u>3,954</u>
Gross profit	<u>15,015</u>	<u>9,632</u>	<u>5,574</u>
Expenses:			
Research and development	7,723	3,221	4,073
Legal, financial and other consulting	2,002	1,340	1,185
Selling, general and administrative	20,874	14,914	11,808
Total operating expenses	<u>30,599</u>	<u>19,475</u>	<u>17,066</u>
Loss from operations	(15,584)	(9,843)	(11,492)
Other income(expense), net	<u>(2,247)</u>	<u>705</u>	<u>(590)</u>
Loss before benefit from income taxes	(17,831)	(9,138)	(12,082)
Benefit from income taxes	<u>620</u>	<u>677</u>	<u>319</u>
Net loss	(17,211)	(8,461)	(11,763)
Dividend, warrant exercise price adjustment	--	336	--
Net loss available to common shareholders	\$ <u><u>(17,211)</u></u>	\$ <u><u>(8,797)</u></u>	\$ <u><u>(11,763)</u></u>
Earnings per share:			
Basic and diluted loss per share	\$ <u><u>(0.56)</u></u>	\$ <u><u>(0.32)</u></u>	\$ <u><u>(0.46)</u></u>
Weighted average shares outstanding	<u>30,719,176</u>	<u>27,613,911</u>	<u>25,433,719</u>



CYTOSORBENTS CORPORATION  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(amounts in thousands)

	December 31, 2018	December 31, 2017
<b>ASSETS:</b>		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 22,369	\$ 17,322
Grants and accounts receivable, net	3,943	2,206
Inventories	833	795
Prepaid expenses and other current assets	1,119	416
Total current assets	28,264	20,739
Property and equipment, net	1,730	1,403
Other assets	2,753	1,961
TOTAL ASSETS	\$ 32,747	\$ 24,103
 <b>LIABILITIES AND STOCKHOLDERS' EQUITY:</b>		
<i>Current Liabilities:</i>		
Accounts payable	\$ 1,486	\$ 1,244
Accrued expenses and other current liabilities	4,385	2,604
Current Maturities of long-term debt, net of debt issuance costs	667	4,000
Total current liabilities	6,538	7,848
Long-term debt, net of current maturities	9,274	5,992
TOTAL LIABILITIES	15,812	13,840
Total stockholders' equity	16,935	10,263
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 32,747	\$ 24,103

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