



# CytoSorbents

Working to Save Lives Through Blood Purification

## CytoSorbents Announces 2019 Financial and Operational Results

*2019 Total Revenue was \$24.9 million, with 2019 Product Sales of \$22.8M, and blended product gross margins of 80% for Q4 2019*

MONMOUTH JUNCTION, N.J., March 5, 2020 — [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 2019.

### **2019 Financial Highlights:**

- Q4 2019 total revenue was approximately \$7.4 million compared to \$6.1 million a year ago
- Growth accelerated in Q4 2019, with quarterly product sales of approximately \$6.6 million, a 21% increase when compared to \$5.5 million of product sales a year ago, bolstered by a 30% increase in direct sales. On a constant currency/exchange rate basis, Q4 2019 product sales increased 24%
- 2019 total revenue was approximately \$24.9 million compared to \$22.5 million in 2018
- 2019 total product sales were approximately \$22.8 million compared to \$20.3 million in 2018
- On a constant currency/exchange rate basis, 2019 total revenue and product sales were \$26.1 million and \$24.0 million, representing 16% and 18% growth, respectively when compared to the prior year
- Achieved Q4 2019 blended product gross margins of 80%, mixing higher margin direct sales and lower margin distributor and partner sales

### **2019 and Recent Operational Highlights:**

- Exceeded 80,000 cumulative CytoSorb treatments delivered, up from 56,000 in 2018
- [Modified partnership with Fresenius Medical Care](#) to now include Mexico, Korea, France, the Czech Republic, and Finland
- Added 5 new direct sales countries including Poland, the Netherlands, Denmark, Norway and Sweden
- Strengthened our commercial capabilities and more than doubled the number of customer-facing sales reps and specialists in Germany, with a 50% expansion of our workforce

- [Expanded CytoSorb distribution in Latin and South America](#), including Brazil, Colombia, and Costa Rica
- [Renewed CytoSorb CE Mark through May 2024 and annual ISO 13485:2016 certification through September 2022](#)
- Approximately 25 published papers, and additional studies highlighting the clinical benefit and utility of CytoSorb therapy in a number of observational studies
  - [Significant reduction in bleeding complications in cardiac surgery patients on ticagrelor](#), resulting in [projected cost savings of \\$5,000 per patient](#)
  - [Improvements in hemodynamic stability during cardiac surgery](#)
  - [Reversal of septic shock when CytoSorb is started early](#)
  - [Improvements in microcirculation in septic shock](#)
  - [Decreased observed versus expected 28-day mortality in septic shock patients on continuous renal replacement therapy](#)
  - [Doubling of actual survival versus predicted survival in refractory cardiac arrest patients when CytoSorb was used with extracorporeal cardiopulmonary resuscitation \(eCPR\)](#)
  - [Third interim report of the International CytoSorb Registry confirming a marked reduction in IL-6 in critically-ill patients](#) with treatment
- CytoSorb was included in the [treatment guidelines on salvage treatment of relapsed and refractory hemophagocytic lymphohistiocytosis \(HLH\)](#), where infection often triggers a massive cytokine storm, similar to cytokine release syndrome (CRS) in CAR T-cell immunotherapy
- [Commencement of the first trial using CytoSorb to treat cytokine release syndrome \(CRS\) in CAR T-cell patients](#)
- [Award of a \\$3 million, 2-year contract from the U.S. Air Force Rapid Innovation Fund \(RIF\)](#) to advance development of the K<sup>+</sup>ontrol™ system to treat severe hyperkalemia
- Initiated the [company-sponsored TISORB trial in the United Kingdom](#) to further support use of CytoSorb to remove ticagrelor during cardiac surgery

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, “As discussed in our [January 14, 2020 stockholder letter](#), 2019 was a year of progress, though not without its fair share of growing pains. That said, we believe the significant investments and efforts made last year to strengthen our commercialization infrastructure have solidly positioned the company for future potential successes. I recommend that you read this letter if you have interest.”

Dr. Chan continued, “That said, 2020 has started with a burst of important achievements and new opportunity, but also a very deep sense of responsibility to investigate the use of CytoSorb as a possible adjunctive treatment in critically-ill patients infected with either COVID-19 coronavirus or influenza. In the U.S. alone, the Centers for Disease Control and Prevention (CDC) has estimated that influenza has infected 30 million people this season, killing 18,000. There have been more than 90,000 documented cases of COVID-19 coronavirus infection worldwide, with more than 3,000 deaths. In the U.S., there have been 162 cases across 18 states, and 11 deaths. We predict that as the coronavirus test becomes more available, and more people are

tested, the number of documented cases in the U.S. will increase dramatically. We want to be in a position to help as many people here in the U.S. and worldwide as possible.”

“As we have discussed in the past couple of weeks, our partnership with China Medical System Holding Ltd, a publicly-traded \$800+ million in revenue specialty pharma company in China, has led to the rapid introduction of donated CytoSorb devices into key hospitals in the Wuhan, China region, the epicenter of the COVID-19 pandemic, announced last Friday,” stated Dr. Chan.

“We have now learned that multiple COVID-19 infected patients at multiple hospitals have been undergoing CytoSorb treatment. Although too soon to report on clinical outcomes, we expect information to begin to be available in the near future. Physicians from hospitals in Beijing (Peking), Shanghai, and other cities throughout China, have generously come to Wuhan to assist in treating those infected with COVID-19. In particular, physicians working in Wuhan from [Peking Union Medical College Hospital](#), one of the most prestigious medical institutions in China, have registered a clinical study entitled, ‘Cytosorb adsorption therapy combined with standard therapy for new coronavirus pneumonia in adult severe patients’ in order to have a mechanism to collect ongoing safety and efficacy data from patients they are treating, and to publish these data.”

Dr. Chan continued, “We are also pleased that on March 3, 2020, the National Health Commission in China issued the official, updated [“Diagnosis and Treatment of New Coronavirus Pneumonia \(7<sup>th</sup> Version\)”](#) guidelines, which now includes the following translated statement as a treatment recommendation, “For severe and critically ill patients with cytokine storms, in order to remove inflammatory factors, block “cytokine storms” and increase “blood purification treatment”.

“Meanwhile, CytoSorb is already being sold in many countries around the world where COVID-19 cases have surged, including Italy, Iran, Germany, France, Spain, Hong Kong, and others. Meanwhile, here in the U.S., we have submitted our documentation to the multi-agency coronavirus task force, led by the Biomedical Advanced Research and Development Authority (BARDA), had a preliminary conversation with the agency, and await further feedback. There are many cases in the published literature where the use of CytoSorb, in conjunction with standard of care, has been successful in helping to treat the severe complications of influenza and coronavirus infection. These include the “cytokine storm” that triggers an overwhelming systemic inflammatory response syndrome that can then lead to acute respiratory distress syndrome (ARDS), shock, multiple organ failure, and sepsis from secondary bacterial pneumonia. If we observe the similar ability to treat these complications in patients afflicted with COVID-19, it would represent a major advance in the treatment of this deadly illness.”

“For further updates on our existing business, we invite you to join us on our earnings conference call, details below.”

***Conference Call Details:***

Date: Thursday, March 5, 2020

Time: 4:45 PM Eastern Time

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

Conference ID: 13699145

Live Presentation Webcast <http://public.viavid.com/index.php?id=138111>

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=138111>

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 2019 Financial Results:**

#### ***Revenues:***

For the year ended December 31, 2019, we generated total revenue, which includes product revenue and grant income, of approximately \$24,949,000 as compared to revenues of approximately \$22,504,000 for the year ended December 31, 2018, an increase of approximately \$2,445,000, or 11%. Revenue from product sales was approximately \$22,766,000 for the year ended December 31, 2019, as compared to approximately \$20,252,000 in the year ended December 31, 2018, an increase of approximately \$2,514,000 or 12%. This increase was primarily driven by an increase in direct sales of approximately \$3,194,000 resulting from both new customers and repeat orders from existing customers. This increase was offset by a decrease in distributor sales of approximately \$680,000. In addition, sales were negatively impacted by approximately \$1,201,000 as a result of the decrease in the average exchange rate of the Euro to the U.S. dollar. For the year ended December 31, 2019, the average exchange rate of the Euro to the U.S. dollar was \$1.12 as compared to an average exchange rate of \$1.18 for the year ended December 31, 2018.

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

For the years ended December 31, 2019 and 2018, cost of revenue was approximately \$7,364,000 and \$7,489,000, respectively, a decrease of approximately \$125,000. Product cost of revenues decreased approximately \$63,000 during the year ended December 31, 2019 as compared to the year ended December 31, 2018 as a result of achieved production efficiencies. Product gross margins were approximately 77% for the year ended December 31, 2019 and approximately 74% for the year ended December 31, 2018.

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

Gross profit was approximately \$17,586,000 for the year ended December 31, 2019, an increase of approximately \$2,571,000 or 17%, over gross profit of \$15,015,000 in 2018. This

increase is attributed to an increase in CytoSorb product sales during 2019 as well as achieved production efficiencies.

***Research and Development Expenses:***

Our research and development costs were approximately \$12,092,000 and \$7,723,000 for the years ended December 31, 2019 and 2018, respectively, an increase of approximately \$4,369,000, or 57%. This increase was due to an increase in clinical trial and related costs of approximately \$3,890,000, which include expenditures related to our REFRESH 2-AKI study and our TISORB study, an increase in non-clinical research and development salary related costs of approximately \$223,000, decreases in direct labor and other costs being deployed toward grant-funded activities of approximately \$62,000, which had the effect of increasing the amount of our non-reimbursable research and development costs and an increase in our non-grant related research and development costs of approximately \$194,000.

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

Our legal, financial and other consulting costs were approximately \$2,462,000 and \$2,002,000 for the years ended December 31, 2019 and 2018, respectively, an increase of approximately \$460,000, or 23%. This increase was due to an increase in legal fees of approximately \$334,000 related to patent matters and certain corporate initiatives, an increase in employment agency fees of approximately \$88,000 related to the hiring of senior level personnel, an increase in accounting and auditing fees of approximately \$24,000 and an increase in consulting fees of approximately \$14,000.

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

Our selling, general and administrative expenses were approximately \$22,006,000 and \$20,874,000 for the years ended December 31, 2019 and 2018, respectively, an increase of approximately \$1,132,000, or 5%. This increase was due to an increase in salaries, commissions and related costs of approximately \$2,323,000, additional sales and marketing costs, which include advertising and conference attendance of approximately \$863,000, an increase in royalty expenses of approximately \$198,000 due to the increase in product sales, and an increase in restricted stock expense of approximately \$226,000 related to restricted stock units granted to the Company's executive officers, an increase in public relations cost of approximately \$78,000 and increase in other general and administrative costs of approximately \$215,000. These increases were offset by a decrease in non-cash stock compensation expense of approximately \$2,771,000.

***Interest Expense, Net:***

For the year ended December 31, 2019, interest expense, net was approximately \$1,034,000, as compared to interest expense, net of approximately \$1,461,000 for the year ended December 31, 2018. This decrease in net interest expense of approximately \$427,000 is

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, offset by an increase in interest due to the draw down of the \$5,000,000 Term B Loan with Bridge Bank on July 31, 2019.

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

For the year ended December 31, 2019, the loss on foreign currency transactions was approximately \$350,000, as compared to a loss on foreign currency transactions of approximately \$785,000 for the year ended December 31, 2018. The 2019 loss is directly related to the decrease in the exchange rate of the Euro at December 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 December 31, 2019 as compared to \$1.15 per Euro at December 31, 2018. 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.

***Benefit from Income Taxes:***

Our benefit from income taxes was approximately \$1,092,000 and \$620,000 for the years ended December 31, 2019 and 2018, 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, 2019, we had current assets of approximately \$20,902,000 including cash on hand of approximately \$12,232,000 and had current liabilities of approximately \$9,936,000. During the period from January 1, 2020 through March 2, 2020, we raised approximately \$13,322,000 by utilizing our ATM facility with co-agents Jefferies LLC and B. Riley FBR. Also, we expect to receive approximately \$1,092,000 in cash from the approved sale of our net operating losses and research and development credits from the State of New Jersey in the first quarter of 2020. We believe that we have sufficient cash to fund our operations into 2021.

**2020 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 2020 product sales will exceed product sales reported in the first quarter of 2019.

For additional information, please see the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 5, 2020 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](#)<sup>®</sup> is approved in the European Union with distribution in 58 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<sup>®</sup> has been used in more than 80,000 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 \$29 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), the U.S. Army, U.S. Special Operations Command (USSOCOM), the U.S. Air Force, Air Force Material Command (USAF/AFMC) 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<sup>™</sup>, HemoDefend<sup>™</sup>, VetResQ<sup>™</sup>, K<sup>+</sup>ontrol<sup>™</sup>, 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 5, 2020, 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>2019</u>	<u>2018</u>	<u>2017</u>
Revenue:			
Product sales	\$ 22,766	\$ 20,252	\$ 13,382
Grant income	2,184	2,252	1,769
Total revenue	<u>24,950</u>	<u>22,504</u>	<u>15,151</u>
Cost of revenue	<u>7,364</u>	<u>7,489</u>	<u>5,519</u>
Gross profit	<u>17,586</u>	<u>15,015</u>	<u>9,632</u>
Expenses:			
Research and development	12,092	7,723	3,221
Legal, financial and other consulting	2,462	2,002	1,340
Selling, general and administrative	<u>22,006</u>	<u>20,874</u>	<u>14,914</u>
Total operating expenses	<u>36,560</u>	<u>30,599</u>	<u>19,475</u>
Loss from operations	(18,974)	(15,584)	(9,843)
Other income(expense), net	<u>(1,384)</u>	<u>(2,247)</u>	<u>705</u>
Loss before benefit from income taxes	(20,358)	(17,831)	(9,138)
Benefit from income taxes	<u>1,092</u>	<u>620</u>	<u>677</u>
Net loss	(19,266)	(17,211)	(8,461)
Dividend, warrant exercise price adjustment	--	--	336
Net loss available to common shareholders	\$ <u><u>(19,266)</u></u>	\$ <u><u>(17,211)</u></u>	\$ <u><u>(8,797)</u></u>
Earnings per share:			
Basic and diluted loss per share	\$ <u><u>(0.60)</u></u>	\$ <u><u>(0.56)</u></u>	\$ <u><u>(0.32)</u></u>
Weighted average shares outstanding	<u>32,255,253</u>	<u>30,719,176</u>	<u>27,613,911</u>

CYTOSORBENTS CORPORATION  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(amounts in thousands)

	<u>December 31, 2019</u>	<u>December 31, 2018</u>
<b>ASSETS:</b>		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 12,233	\$ 22,369
Grants and accounts receivable, net	4,467	3,943
Inventories	2,114	833
Prepaid expenses and other current assets	<u>2,088</u>	<u>1,119</u>
Total current assets	20,902	28,264
Property and equipment, net	1,925	1,730
Right of use asset	1,071	1,450
Other assets	<u>3,485</u>	<u>2,753</u>
TOTAL ASSETS	<u>\$ 27,383</u>	<u>\$ 34,197</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY:</b>		
<i>Current Liabilities:</i>		
Accounts payable	\$ 2,039	\$ 1,486
Accrued expenses and other current liabilities	5,802	4,385
Current Maturities of long-term debt, net of debt issuance costs	1,667	667
Lease liability-current portion	<u>428</u>	<u>379</u>
Total current liabilities	9,936	6,917
Lease liability, net of current portion	643	1,071
Long-term debt, net of current maturities	<u>13,386</u>	<u>9,274</u>
TOTAL LIABILITIES	23,965	17,262
Total stockholders' equity	<u>3,418</u>	<u>16,935</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 27,383</u>	<u>\$ 34,197</u>

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