

---

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2020

Or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-36792

**CYTOSORBENTS CORPORATION**

(Exact name of registrant as specified in its charter)

Delaware

98-0373793

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer Identification No.)

7 Deer Park Drive, Suite K  
Monmouth Junction, New Jersey  
(Address of principal executive offices)

08852  
(Zip Code)

(732) 329-8885

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	CTSO	Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

As of July 31, 2020 there were 43,157,879 shares of the issuer's common stock outstanding.

---

---

**CytoSorbents Corporation**  
**FORM 10-Q**  
**TABLE OF CONTENTS**

	Page
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<b><u>Item 1. Financial Statements</u></b>	3
<u>Consolidated Balance Sheets as of June 30, 2020 (unaudited) and December 31, 2019</u>	3
<u>Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2020 and 2019 (unaudited)</u>	4
<u>Consolidated Statements of Changes in Stockholders' Equity for the Three and Six Months Ended June 30, 2020 and 2019 (unaudited)</u>	5
<u>Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2020 and 2019 (unaudited)</u>	6
<u>Notes to Consolidated Financial Statements (unaudited)</u>	7
<b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	23
<b><u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u></b>	39
<b><u>Item 4. Controls and Procedures</u></b>	39
<b><u>PART II. OTHER INFORMATION</u></b>	
<b><u>Item 1. Legal Proceedings</u></b>	39
<b><u>Item 1A. Risk Factors</u></b>	40
<b><u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	53
<b><u>Item 3. Defaults Upon Senior Securities</u></b>	53
<b><u>Item 4. Mine Safety Disclosures</u></b>	53
<b><u>Item 5. Other Information</u></b>	53
<b><u>Item 6. Exhibits</u></b>	53

This Quarterly Report on Form 10-Q includes our trademarks and trade names, such as “CytoSorb”, “CytoSorb XL”, “BetaSorb”, “ContrastSorb”, “DrugSorb”, “HemoDefend”, “K+ontrol” and “VetResQ”, which are protected under applicable intellectual property laws and are the property of CytoSorbents Corporation and our subsidiaries. This Quarterly Report on Form 10-Q also contains the trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this Quarterly Report on Form 10-Q may appear without the ™, ®, or <sup>SM</sup> symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

## PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements.

CYTOSORBENTS CORPORATION  
CONSOLIDATED BALANCE SHEETS

	June 30, 2020 (Unaudited)	December 31, 2019
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 35,113,888	\$ 12,232,418
Grants and accounts receivable, net of allowance for doubtful accounts of \$70,746 at June 30, 2020 and \$145,313 at December 31, 2019	3,890,392	4,467,087
Inventories	1,986,970	2,113,897
Prepaid expenses and other current assets	956,709	2,088,127
<b>Total current assets</b>	<u>41,947,959</u>	<u>20,901,529</u>
Property and equipment, net	1,952,347	1,925,325
Right of use asset	1,232,388	1,070,762
Other assets	4,126,077	3,484,894
<b>Total Assets</b>	<u>\$ 49,258,771</u>	<u>\$ 27,382,510</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 2,726,614	\$ 2,039,222
Current maturities of long-term debt	6,666,667	1,666,666
Lease liability – current portion	417,699	428,083
Accrued expenses and other current liabilities	5,853,355	5,802,296
<b>Total current liabilities</b>	<u>15,664,335</u>	<u>9,936,267</u>
Long term debt, net of current maturities and debt issuance costs	8,457,257	13,385,522
Lease liability, net of current portion	814,689	642,679
<b>Total Liabilities</b>	<u>24,936,281</u>	<u>23,964,468</u>
Commitments and Contingencies (Note 6)		
<b>Stockholders' Equity:</b>		
Preferred Stock, Par Value \$0.001, 5,000,000 shares authorized; -0- shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common Stock, Par Value \$0.001, 100,000,000 shares authorized; 36,811,870 and 32,616,107 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	36,812	32,616
Additional paid-in capital	218,864,425	191,648,907
Accumulated other comprehensive income	530,447	525,978
Accumulated deficit	(195,109,194)	(188,789,459)
<b>Total Stockholders' Equity</b>	<u>24,322,490</u>	<u>3,418,042</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 49,258,771</u>	<u>\$ 27,382,510</u>

See accompanying notes to consolidated financial statements.

**CYTOSORBENTS CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

	Three months ended June 30,		Six months ended June 30,	
	2020 (Unaudited)	2019 (Unaudited)	2020 (Unaudited)	2019 (Unaudited)
<b>Revenue:</b>				
CytoSorb sales	\$ 9,451,328	\$ 5,850,417	\$ 17,607,297	\$ 10,360,196
Other sales	69,000	—	69,000	66,800
Total product sales	9,520,328	5,850,417	17,676,297	10,426,996
Grant income	274,575	382,109	825,915	997,159
Total revenue	9,794,903	6,232,526	18,502,212	11,424,155
Cost of revenue	3,249,767	1,834,366	5,634,609	3,572,955
Gross margin	6,545,136	4,398,160	12,867,603	7,851,200
<b>Other expenses:</b>				
Research and development	2,406,039	2,929,603	4,371,324	5,348,236
Legal, financial and other consulting	845,861	592,038	1,364,863	1,153,554
Selling, general and administrative	6,590,903	4,506,516	12,907,837	9,264,600
Total expenses	9,842,803	8,028,157	18,644,024	15,766,390
Loss from operations	(3,297,667)	(3,629,997)	(5,776,421)	(7,915,190)
<b>Other income/(expense):</b>				
Interest expense, net	(273,818)	(214,552)	(579,355)	(419,731)
Gain (loss) on foreign currency transactions	704,529	297,144	36,041	(96,311)
Total other income (expense), net	430,711	82,592	(543,314)	(516,042)
Loss before benefit from income taxes	(2,866,956)	(3,547,405)	(6,319,735)	(8,431,232)
Benefit from income taxes	—	—	—	—
Net loss attributable to common shareholders	<u>\$ (2,866,956)</u>	<u>\$ (3,547,405)</u>	<u>\$ (6,319,735)</u>	<u>\$ (8,431,232)</u>
Basic and diluted net loss per common share	<u>\$ (0.08)</u>	<u>\$ (0.11)</u>	<u>\$ (0.18)</u>	<u>\$ (0.26)</u>
Weighted average number of shares of common stock outstanding	<u>36,483,355</u>	<u>32,266,861</u>	<u>35,232,308</u>	<u>32,099,834</u>
Net loss	\$ (2,866,956)	\$ (3,547,405)	\$ (6,319,735)	\$ (8,431,232)
<b>Other comprehensive income (loss):</b>				
Currency translation adjustment	(605,359)	(249,807)	4,469	56,480
Comprehensive loss	<u>\$ (3,472,315)</u>	<u>\$ (3,797,212)</u>	<u>\$ (6,315,266)</u>	<u>\$ (8,374,752)</u>

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY  
For the three and six months ended June 30, 2020 (Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
	Shares	Par value				
<b>Balance at March 31, 2020</b>	36,130,355	\$ 36,130	\$ 212,383,812	\$ 1,135,806	\$ (192,242,238)	\$ 21,313,510
Stock based compensation - employees, consultants and directors	—	—	1,046,203	—	—	1,046,203
Issuance of common stock, net of fees	447,021	446	4,470,565	—	—	4,471,011
Other comprehensive (loss): foreign translation adjustment	—	—	—	(605,359)	—	(605,359)
Proceeds from exercise of stock options	223,975	225	963,856	—	—	964,081
Cashless exercise of stock options	10,519	11	(11)	—	—	—
Net loss	—	—	—	—	(2,866,956)	(2,866,956)
<b>Balance at June 30, 2020</b>	<u>36,811,870</u>	<u>\$ 36,812</u>	<u>\$ 218,864,425</u>	<u>\$ 530,447</u>	<u>\$ (195,109,194)</u>	<u>\$ 24,322,490</u>
<b>Balance at December 31, 2019</b>	32,616,107	\$ 32,616	\$ 191,648,907	\$ 525,978	\$ (188,789,459)	\$ 3,418,042
Stock based compensation - employees, consultants and directors	—	—	1,775,632	—	—	1,775,632
Issuance of common stock, net of fees	3,868,258	3,867	24,008,765	—	—	24,012,632
Other comprehensive income: foreign translation adjustment	—	—	—	4,469	—	4,469
Proceeds from exercise of stock options	262,252	263	1,102,248	—	—	1,102,511
Cashless exercise of stock options	10,519	11	(11)	—	—	—
Issuance of restricted stock units	54,734	55	328,884	—	—	328,939
Net loss	—	—	—	—	(6,319,735)	(6,319,735)
<b>Balance at June 30, 2020</b>	<u>36,811,870</u>	<u>\$ 36,812</u>	<u>\$ 218,864,425</u>	<u>\$ 530,447</u>	<u>\$ (195,109,194)</u>	<u>\$ 24,322,490</u>

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
	Shares	Par value				
<b>Balance at March 31, 2019</b>	32,243,044	32,243	188,795,855	594,462	(174,407,642)	15,014,918
Stock based compensation - employees, consultants and directors	—	—	144,763	—	—	144,763
Other comprehensive (loss): foreign translation adjustment	—	—	—	(249,807)	—	(249,807)
Proceeds from exercise of stock options	37,800	38	180,153	—	—	180,191
Cashless exercise of stock options	22,387	22	(22)	—	—	—
Net loss	—	—	—	—	(3,547,405)	(3,547,405)
<b>Balance at June 30, 2019</b>	<u>32,303,231</u>	<u>\$ 32,303</u>	<u>\$ 189,120,749</u>	<u>\$ 344,655</u>	<u>\$ (177,955,047)</u>	<u>\$ 11,542,660</u>
<b>Balance at December 31, 2018</b>	31,774,139	\$ 31,774	\$ 186,138,466	\$ 288,175	\$ (169,523,815)	\$ 16,934,600
Stock based compensation - employees, consultants and directors	—	—	372,421	—	—	372,421
Issuance of common stock, net of fees	—	—	—	—	—	—
Other comprehensive income: foreign translation adjustment	—	—	—	56,480	—	56,480
Proceeds from exercise of stock options	84,534	85	416,176	—	—	416,261
Cashless exercise of stock options	23,354	22	(22)	—	—	—
Cashless exercise of warrants	9,029	9	(9)	—	—	—
Issuance of restricted stock units	51,817	52	425,587	—	—	425,639
Proceeds from exercise of warrants	360,358	361	1,768,130	—	—	1,768,491
Net loss	—	—	—	—	(8,431,232)	(8,431,232)
<b>Balance at June 30, 2019</b>	<u>32,303,231</u>	<u>\$ 32,303</u>	<u>\$ 189,120,749</u>	<u>\$ 344,655</u>	<u>\$ (177,955,047)</u>	<u>\$ 11,542,660</u>

See accompanying notes to consolidated financial statements.

**CYTOSORBENTS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Six months ended June 30, 2020 (Unaudited)	Six months ended June 30, 2019 (Unaudited)
<b>Cash flows from operating activities:</b>		
Net loss	\$ (6,319,735)	\$ (8,431,232)
<b>Adjustments to reconcile net loss to net cash used by operating activities:</b>		
Non-cash compensation	667,267	372,302
Depreciation and amortization	339,862	275,370
Amortization of debt costs	71,735	47,508
Bad debt recoveries	(94,660)	(44,411)
Stock-based compensation	1,775,632	372,421
Foreign currency transaction loss	(36,041)	96,311
<b>Changes in operating assets and liabilities:</b>		
Grants and accounts receivable	659,987	526,547
Inventories	128,541	(671,490)
Prepaid expenses and other current assets	1,138,867	181,640
Other assets	—	4,067
Accounts payable and accrued expenses	397,381	(155,439)
<b>Net cash used by operating activities</b>	<b>(1,271,164)</b>	<b>(7,426,406)</b>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(316,511)	(431,042)
Payments for patent costs	(689,409)	(370,488)
<b>Net cash used by investing activities</b>	<b>(1,005,920)</b>	<b>(801,530)</b>
<b>Cash flows from financing activities:</b>		
Equity contributions - net of fees incurred	24,012,632	—
Proceeds from long-term debt	1,410,900	—
Repayment of long-term debt	(1,410,900)	—
Proceeds from exercise of stock options	1,102,511	416,261
Proceeds from exercise of warrants	—	1,768,491
<b>Net cash provided by financing activities</b>	<b>25,115,143</b>	<b>2,184,752</b>
Effect of exchange rates on cash	43,411	15,908
<b>Net change in cash and cash equivalents</b>	<b>22,881,470</b>	<b>(6,027,276)</b>
<b>Cash and cash equivalents - beginning of period</b>	<b>12,232,418</b>	<b>22,368,837</b>
<b>Cash and cash equivalents - end of period</b>	<b>\$ 35,113,888</b>	<b>\$ 16,341,561</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for interest	\$ 585,828	\$ 458,333
<b>Supplemental disclosure of non-cash financing activities</b>		
Settlement of accrued bonuses with restricted stock units	\$ 328,939	\$ 425,639

See accompanying notes to financial statements.

**CytoSorbents Corporation**  
**Notes to Consolidated Financial Statements**  
**(UNAUDITED)**  
**June 30, 2020**

**1. BASIS OF PRESENTATION**

The interim consolidated financial statements of CytoSorbents Corporation (the “Company”) have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”). In the opinion of management, the Company has made all necessary adjustments, which include normal recurring adjustments, for a fair statement of the Company’s consolidated financial position and results of operations for the interim periods presented. Certain information and disclosures normally included in the annual consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes for the year ended December 31, 2019 included in the Company’s Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (the “SEC”) on March 5, 2020. The results for the three and six months ended June 30, 2020 and 2019 are not necessarily indicative of the results to be expected for a full year, any other interim periods or any future year or period.

Prior to June 30, 2020, the Company’s consolidated financial statements were prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

On July 24, 2020, the Company closed an underwritten public offering of 6,052,631 shares of its common stock at a public offering price of \$9.50 per share (the “Offering”). Gross proceeds from the Offering amounted to approximately \$57.5 million and, after deducting the underwriting discounts and commissions and expenses related to the Offering, the Company received total net proceeds of approximately \$54.0 million. See Note 9. As a result of the Offering, the Company’s cash balance increased to approximately \$89.0 million, which the Company expects will fund the Company’s operations well beyond the next twelve months. As a result, the Company has determined that the going concern risk has been eliminated.

**2. PRINCIPAL BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Nature of Business**

The Company is a leader in critical care immunotherapy using blood purification technology to treat deadly inflammation in critically-ill and cardiac surgery patients around the world. The Company, through its subsidiary CytoSorbents Medical, Inc. (formerly known as CytoSorbents, Inc.), is engaged in the research, development and commercialization of medical devices with its blood purification technology platform which incorporates a proprietary adsorbent, porous polymer technology. The Company, through its wholly owned European subsidiary, CytoSorbents Europe GmbH, conducts sales and marketing related operations for the CytoSorb device. In March 2016, the Company formed CytoSorbents Switzerland GmbH, a wholly-owned subsidiary of CytoSorbents Europe GmbH. This subsidiary, which began operations during the second quarter of 2016, provides marketing and direct sales services in Switzerland. In November 2018, the Company formed CytoSorbents Poland Sp. z.o.o., a wholly-owned subsidiary of CytoSorbents Europe GmbH. This subsidiary, which began operations during the first quarter of 2019, provides marketing and direct sales services in Poland. In the third quarter of 2019, the Company formed CytoSorbents UK Limited, a wholly-owned subsidiary of CytoSorbents Medical, Inc. which is responsible for the management of our clinical trial activities in the United Kingdom. CytoSorb, the Company’s flagship product, was approved in the European Union (“EU”) in March 2011, and is currently being marketed and distributed in sixty-five countries around the world, as a safe and effective extracorporeal cytokine absorber, 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. In May 2018, the Company received a label extension for CytoSorb covering use of the device for the removal of bilirubin and myoglobin which allows for the use of the device in the treatment of liver failure and trauma, respectively. 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.

## [Table of Contents](#)

In April 2020, the Company announced that the United States Food and Drug Administration (the “FDA”) granted Emergency Use Authorization (“EUA”) of CytoSorb for use in critically-ill patients infected with COVID-19. Under the EUA, the Company can make CytoSorb available, through commercial sales, to all hospitals in the United States for use in patients, 18 years of age or older, with confirmed COVID-19 infection who are admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure who have early acute lung injury or acute respiratory distress syndrome (ARDS), severe disease, or life-threatening illness resulting in respiratory failure, septic shock, and/or multiple organ dysfunction or failure. The CytoSorb device has neither been cleared nor approved for the indication to treat patients with COVID-19 infection. The EUA will be effective until a declaration is made that the circumstances justifying the EUA have terminated or until revoked by the FDA.

In April 2020, the Company also announced that the FDA had granted Breakthrough Designation to CytoSorb for the removal of ticagrelor in a cardiopulmonary bypass circuit during emergent and urgent cardiothoracic surgery. The Breakthrough Devices Program provides for more effective treatment of life-threatening or irreversibly debilitating disease or conditions, in this case the need to reverse the effects of ticagrelor in emergent or urgent cardiac surgery that can otherwise cause a high risk of serious or life-threatening bleeding. Through Breakthrough Designation, FDA intends to work with CytoSorbents to expedite the development, assessment, and regulatory review of CytoSorb for the removal of ticagrelor, while maintaining statutory standards of regulatory approval (e.g., 510(k), *de novo* 510(k) or premarket approval ) consistent with the FDA’s mission to protect and promote public health.

The technology is based upon biocompatible, highly porous polymer sorbent 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, which is protected by 19 issued U.S. patents and multiple international patents, with applications pending both in the U.S. and internationally, including HemoDefend, ContrastSorb, DrugSorb, and others. These patents and patent applications are directed to various compositions and methods of use related to our blood purification technologies and are expected to expire between 2020 and 2035, absent any patent term extensions. Management believes that any near term expiring patents will not have a significant impact on our ongoing business.

### **Stock Market Listing**

On December 17, 2014 the Company’s common stock, par value \$0.001 per share, was approved for listing on the Nasdaq Capital Market (“Nasdaq”), and it began trading on Nasdaq on December 23, 2014 under the symbol “CTSO.” Previously, the Company’s common stock traded in the over-the-counter-market on the OTC Bulletin Board.

### **Basis of Consolidation and Foreign Currency Translation**

The consolidated financial statements include the accounts of CytoSorbents Corporation and its wholly-owned subsidiaries, CytoSorbents Medical, Inc. and CytoSorbents Europe GmbH. In addition, the consolidated financial statements include CytoSorbents Switzerland GmbH and CytoSorbents Poland Sp. z.o.o., wholly owned subsidiaries of CytoSorbents Europe GmbH. All significant intercompany transactions and balances have been eliminated in consolidation.

Translation gains and losses resulting from the process of remeasuring into the United States Dollar, the foreign currency financial statements of CytoSorbents Europe GmbH, for which the Euro is the functional currency, are included in operations. Foreign currency transaction gain included in net loss amounted to approximately \$705,000 and \$297,000 for the three months ended June 30, 2020 and 2019, respectively. Foreign currency transaction gains (loss) included in net loss amounted to approximately \$36,000 and \$(96,000) for the six months ended June 30, 2020 and 2019, respectively. The Company translates assets and liabilities of CytoSorbents Europe GmbH at the exchange rate in effect at the consolidated balance sheet date. The Company translates revenue and expenses at the daily average exchange rates. The Company includes accumulated net translation adjustments in accumulated other comprehensive income (loss) as a component of stockholders’ equity.

### **Cash and Cash Equivalents**

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

### **Grants and Accounts Receivable**

Grants receivable represent amounts due from U.S. government agencies and are included in Grants and Accounts Receivable.



Accounts receivable are unsecured, non-interest bearing customer obligations due under normal trade terms. The Company sells its devices to various hospitals and distributors. The Company performs ongoing credit evaluations of its customers' financial conditions. Management reviews accounts receivable periodically to determine collectability. Balances that are determined to be uncollectible are written off to the allowance for doubtful accounts. The allowance for doubtful accounts contains a general accrual for estimated bad debts and amounted to approximately \$71,000 and \$145,000 at June 30, 2020 and December 31, 2019, respectively.

### **Inventories**

Inventories are valued at the lower of cost or net realizable value under the first in, first out (FIFO) method. At June 30, 2020 and December 31, 2019, the Company's inventory was comprised of finished goods, which amounted to \$471,177 and \$305,452, respectively; work in process which amounted to \$1,260,310 and \$1,523,923, respectively; and raw materials, which amounted to \$255,483 and \$284,522, respectively. Devices used in clinical trials or for research and development purposes are removed from inventory and charged to research and development expenses at the time of their use.

### **Property and Equipment**

Property and equipment are recorded at cost less accumulated depreciation. Depreciation of property and equipment is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the lesser of their economic useful lives or the term of the related leases. Gains and losses on depreciable assets retired or sold are recognized in the consolidated statements of operations and comprehensive loss in the year of disposal. Repairs and maintenance expenditures are expensed as incurred.

### **Patents**

Legal costs incurred to establish and successfully defend patents are capitalized. When patents are issued, capitalized costs are amortized on the straight-line method over the related patent term. In the event a patent is abandoned, the net book value of the patent is written off.

### **Impairment or Disposal of Long-Lived Assets**

The Company assesses the impairment of patents and other long-lived assets under accounting standards for the impairment or disposal of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. For long-lived assets to be held and used, the Company recognizes an impairment loss only if its carrying amount is not recoverable through its undiscounted cash flows and measures the impairment loss based on the difference between the carrying amount and fair value.

### **Revenue Recognition**

*Product Sales:* Revenues from sales of products to both direct and distributor/strategic partner customers are recognized at the time when control passes to the customer, in accordance with the terms of their respective contracts. Recognition of revenue occurs as each performance obligation is completed.

*Grant Income:* Revenue from grant income is based on contractual agreements. Certain agreements provide for reimbursement of costs; other agreements provide for reimbursement of costs and an overhead margin and certain agreements are performance based, where revenue is earned based upon the achievement of milestones outlined in the contract. Revenues are recognized when the associated performance obligation is fulfilled. Costs are recorded as incurred. Costs subject to reimbursement by these grants have been reflected as costs of revenue.

### **Research and Development**

All research and development costs, payments to laboratories and research consultants are expensed when incurred.

## **Advertising Expenses**

Advertising expenses are charged to activities when incurred. Advertising expenses amounted to approximately \$55,000 and \$93,000 for the three months ended June 30, 2020 and 2019, respectively, and approximately \$86,000 and \$145,000 for the six months ended June 30, 2020 and 2019, respectively, and are included in selling, general, and administrative expenses on the consolidated statement of operations.

## **Income Taxes**

Income taxes are accounted for under the asset and liability method prescribed by accounting standards for accounting for income taxes. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax asset will not be realized. The Company has provided a valuation allowance against all deferred tax assets. Under Section 382 of the Internal Revenue Code, the net operating losses generated prior to the previously completed reverse merger may be limited due to the change in ownership. Additionally, net operating losses generated subsequent to the reverse merger may be limited in the event of changes in ownership.

The Company follows accounting standards associated with uncertain tax positions. The Company had no unrecognized tax benefits at June 30, 2020 or December 31, 2019. The Company files tax returns in the U.S. federal and state jurisdictions.

The Company utilizes the Technology Business Tax Certificate Transfer Program to sell a portion of its New Jersey Net Operating Loss carry forwards to an industrial company.

Each of CytoSorbents Europe GmbH, CytoSorbents Switzerland GmbH, CytoSorbents Poland Sp. Z.o.o. and CytoSorbents UK Limited file an annual corporate tax return, VAT return and a trade tax return in Germany, Switzerland, Poland and the United Kingdom, respectively.

## **Use of Estimates**

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities. Actual results could differ from these estimates. The valuation of options granted is a significant estimate in these consolidated financial statements.

## **Concentration of Credit Risk**

The Company maintains cash balances, at times, with financial institutions in excess of amounts insured by the Federal Deposit Insurance Corporation. Management monitors the soundness of these institutions in an effort to minimize its collection risk of these balances.

A significant portion of our revenues are from product sales in Germany. Substantially all of our grant and other income are from grant agencies in the United States. (See Note 4 for further information relating to the Company's revenue.)

As of June 30, 2020, one distributor accounted for approximately 21% of outstanding grants and accounts receivable. As of December 31, 2019, no agency, distributor/strategic partners or direct customer represented more than 10% of outstanding grants and accounts receivables. For the three and six months ended June 30, 2020, no agency, distributor, or direct customer represented more than 10% of the Company's total revenue. For the three and six months ended June 30, 2019, no agency, distributor, or direct customer represented more than 10% of the Company's total revenue.

## **Financial Instruments**

The carrying values of cash and cash equivalents, short-term investments, accounts payable, notes payable, and other debt obligations approximate their fair values due to their short-term nature.

### **Net Loss Per Common Share**

Basic earnings per share is computed by dividing loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per common share is computed using the treasury stock method on the basis of the weighted-average number of shares of common stock plus the dilutive effect of potential common shares outstanding during the period. Dilutive potential common shares include outstanding warrants, stock options and restricted shares. The computation of diluted earnings per share does not assume conversion, exercise or contingent exercise of securities that would have an anti-dilutive effect on earnings (See Note 8).

### **Stock-Based Compensation**

The Company accounts for its stock-based compensation under the recognition requirements of accounting standards for accounting for stock-based compensation, for employees and directors whereby each option granted is valued at fair market value on the date of grant. Under these accounting standards, the fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model.

The Company also follows the guidance of accounting standards for accounting for equity instruments that are issued to other than employees for acquiring, or in conjunction with selling, goods or services for equity instruments issued to consultants.

### **Shipping and Handling Costs**

The cost of shipping product to customers and distributors is typically borne by the customer or distributor. The Company records other shipping and handling costs in cost of revenue. Total freight costs amounted to approximately \$149,000 and \$212,000, respectively, for the three months ended June 30, 2020 and 2019, and \$282,000 and \$358,000, respectively, for the six months ended June 30, 2020 and 2019.

## **3. STOCKHOLDERS' EQUITY**

### **Preferred Stock**

In June 2019, the Company amended and restated its certificate of incorporation. The amended and restated certificate of incorporation authorizes the issuance of up to 5,000,000 shares of "blank check" preferred stock, with such designation rights and preferences as may be determined from time to time by the Board of Directors.

### **Common Stock**

In June 2019, the Company amended and restated its certificate of incorporation. The amended and restated certificate of incorporation increased the number of shares of common stock authorized for issuance from 50,000,000 shares to 100,000,000 shares.

### Shelf Registration

On July 26, 2018, the Company filed a registration statement on Form S-3 with the SEC (as amended, the "2018 Shelf"). The 2018 Shelf, which was declared effective on August 7, 2018, enables the Company to offer and sell, in one or more offerings, any combination of common stock, preferred stock, senior or subordinated debt securities, warrants and units, up to a total dollar amount of \$150 million.

### Termination of Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co.

On May 31, 2019, the Company delivered to Cantor Fitzgerald & Co. ("Cantor") written notice of termination (the "Termination Notice") of the Controlled Equity Offering Sales Agreement, dated November 4, 2015, by and between the Company and Cantor, as amended by Amendment No. 1 to Sales Agreement, dated July 26, 2018 (collectively, the "Sales Agreement"). In accordance with Section 13(b) thereof, the Sales Agreement terminated on June 10, 2019, ten (10) days after the delivery of the Termination Notice. As provided in the Sales Agreement, the Sales Agreement terminated without liability of any party to any other party, except that certain provisions of the Sales Agreement identified therein shall remain in full force and effect notwithstanding the termination.

Pursuant to the Sales Agreement, the Company offered and sold, from time to time through Cantor, shares of the Company's common stock. In the aggregate, the Company sold 2,094,140 shares pursuant to the Sales Agreement, at an average selling price of \$8.72 per share, generating net proceeds of approximately \$17,718,000 from November 4, 2015 through December 31, 2018. There were no sales during the year ended December 31, 2019.

Open Market Sale Agreement with Jefferies LLC and B. Riley FBR, Inc.

On July 9, 2019, the Company entered into an Open Market Sale Agreement (the "New Sale Agreement") with Jefferies LLC and B. Riley FBR, Inc. (each an "Agent" and, together, the "Agents"), pursuant to which the Company may sell, from time to time, at its option, shares of the Company's common stock having an aggregate offering price of up to \$25,000,000 through the Agents, as the Company's sales agents. All shares of the Company's common stock offered and sold, or to be offered and sold under the New Sale Agreement were or will be issued and sold pursuant to the Company's 2018 Shelf by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, in block transactions or if specified by the Company, in privately negotiated transactions.

On April 20, 2020, the Company and the Agents entered into an amendment to the New Sale Agreement (the "Amendment") to provide for an increase in the aggregate offering amount under the New Sales Agreement, such that as of April 20, 2020, the Company may offer and sell Shares having an additional aggregate offering price of up to \$50 million under the New Sale Agreement, as amended by the Amendment (the "Amended Sale Agreement").

Subject to the terms of the Amended Sales Agreement, the Agents are required to use their commercially reasonable efforts consistent with their normal sales and trading practices to sell the shares of the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company is required to pay the Agents a commission of up to 3.0% of the gross proceeds from the sale of the shares of the Company's common stock sold thereunder, if any. The Company has also agreed to provide the Agents with customary indemnification rights. The offering of the shares of the Company's common stock under the Amended Sales Agreement will terminate upon the earliest of (a) the sale of the maximum number or amount of the shares of the Company's stock permitted to be sold under the Amended Sale Agreement and (b) the termination of the Amended Sale Agreement by the parties thereto. During the year ended December 31, 2019, the Company sold 191,244 shares pursuant to the Amended Sale Agreement, at an average selling price of \$4.11 per share, generating net proceeds of approximately \$762,000. During the six months ended June 30, 2020, the Company sold 3,868,258 shares pursuant to the Amended Sale Agreement, at an average selling price of \$6.41 per share, generating net proceeds of approximately \$24,062,000. During the period from July 1, 2020 through July 31, 2020, the Company sold 242,367 shares pursuant to the Amended Sale Agreement, at an average selling price of \$10.27 per share, generating net proceeds of approximately \$2,414,000. In the aggregate, the Company has sold 4,301,869 shares pursuant to the Amended Sale Agreement, at an average selling price of \$6.53 per share, generating net proceeds of approximately \$27,238,000. In addition, during the three and six months ended June 30, 2020, the Company paid approximately \$49,000 in expenses related to the Amended Sale Agreement.

**Stock-Based Compensation**

Total share-based employee, director, and consultant compensation amounted to approximately \$1,046,000 and \$1,776,000 for the three and six months ended June 30, 2020, and \$145,000 and \$372,000 for the three and six months ended June 30, 2019, respectively. These amounts are included in the consolidated statements of operations and comprehensive loss under selling, general and administrative expenses.

[Table of Contents](#)

The summary of the stock option activity for the six months ended June 30, 2020 is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (Years)
Outstanding, December 31, 2019	4,218,189	\$ 6.16	7.0
Granted	1,553,825	\$ 6.12	9.5
Forfeited	(14,174)	\$ 6.68	—
Expired	(223,960)	\$ 5.57	—
Exercised	(285,552)	\$ 4.27	—
Outstanding, June 30, 2020	<u>5,248,328</u>	\$ 6.27	7.7

The fair value of each stock option was estimated using the Black Scholes pricing model which takes into account as of the grant date the exercise price (ranging from \$5.68 to \$10.58 per share) and expected life of the stock option (10 years), the current price of the underlying stock and its expected volatility (ranging from 66.3 percent to 69.8 percent), expected dividends (-0- percent) on the stock and the risk free interest rate (ranging from 0.37 to 0.96 percent) for the term of the stock option.

The intrinsic value is calculated at the difference between the market value as of June 30, 2020 of \$9.90 and the exercise price of the shares.

Options Outstanding				
Range of Exercise Price	Number Outstanding at June 30, 2020	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
\$2.25 - \$14.50	5,248,328	\$ 6.27	7.7	\$ 19,191,721

Options Exercisable				
Number Exercisable at June 30, 2020	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value	
3,076,521	\$ 6.51		\$ 11,881,967	

The summary of the status of the Company's non-vested options for the six months ended June 30, 2020 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, December 31, 2019	1,183,790	\$ 4.49
Granted	1,553,825	\$ 3.73
Forfeited	(12,173)	\$ 4.19
Vested	(553,635)	\$ 4.17
Non-vested, June 30, 2020	<u>2,171,807</u>	\$ 4.03

As of June 30, 2020, the Company had approximately \$3,764,000 of total unrecognized compensation cost related to stock options which will be amortized over 33 months.

On February 28, 2020, the Board of Directors allotted a pool of options to purchase 1,041,325 shares of common stock to the Company's employees which will be awarded based upon the achievement of certain specific, predetermined milestones related to the Company's 2020 operations. Once awarded, these options will vest in four equal tranches, the first tranche vesting on the date of the award. The grant date fair value of these unvested options amounted to approximately \$6,279,000. Based upon an assessment by management, which was reviewed with the Board of Directors, as of June 30, 2020, the Company met approximately 20% of these milestones, and accordingly, we have recorded \$197,000 in stock option expense related to these options in each of the three and six month periods ended June 30, 2020, respectively.

*Change in Control-Based Awards of Restricted Stock Units:*

The Board of Directors has granted restricted stock units to members of the Board of Directors, to the Company's executive officers, and to certain employees of the Company. These specific restricted stock units will only vest upon a Change in Control of the Company, as defined in the Company's 2014 Long-Term Incentive Plan.

The following table is a summary of these restricted stock units:

	Restricted Stock Units			Total	Intrinsic Value
	Board of Directors	Executive Management	Other Employees		
December 31, 2019	277,200	604,500	1,205,050	2,086,750	\$ 8,033,988
Granted	—	120,000	158,700	278,700	
Forfeited	—	—	(16,000)	(16,000)	
June 30, 2020	<u>277,200</u>	<u>724,500</u>	<u>1,347,750</u>	<u>2,349,450</u>	<u>\$ 23,259,555</u>

Due to the uncertainty over whether these restricted stock units will vest, which will only happen upon a Change in Control, no charge for these restricted stock units has been recorded in the consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2020 and 2019.

*Performance-Based Awards of Restricted Stock Units:*

Pursuant to a review of the compensation of the senior management of the Company and managements' performance in 2017, on February 28, 2018, the Board of Directors granted 146,200 restricted stock units to certain senior managers of the Company in order to settle bonuses accrued as of December 31, 2017. These awards were valued at approximately \$1,148,000 at the date of issuance, based upon the market price of the Company's common stock at the date of the grant, and vest one third on the date of the grant one third on the first anniversary of the date of the grant, and one third on the second anniversary of the date of the grant. For the three months and six months ended June 30, 2020 and 2019, the Company recorded a charge of approximately \$0 and \$0, and \$96,000 and \$96,000, related to these restricted stock unit awards , respectively.

Pursuant to a review of the compensation of the senior management of the Company and managements' performance in 2018, on March 4, 2019 the Board of Directors granted 22,220 restricted stock units to certain senior managers of the Company in order to settle bonuses accrued as of December 31, 2018. These awards were valued at approximately \$179,000 at the date of issuance, based upon the market price of the Company's common stock at the date of the grant, and vest one third on the date of the grant, one third on the first anniversary of the date of the grant, and one third on the second anniversary of the date of the grant. For the three and six months ended June 30, 2020 and 2019, the Company recorded a charge of approximately \$12,000 and \$21,000 , and \$14,000 and \$19,000, related to these restricted stock unit awards , respectively.

Pursuant to a review of the compensation of the senior management of the Company and managements' performance in 2019, on July 22, 2019 the Board of Directors granted 180,300 restricted stock units to certain senior managers of the Company in order to settle bonuses accrued as of December 31, 2019. These awards were valued at approximately \$1,300,000 at the date of issuance, based upon the market price of the Company's common stock at the date of the grant, and vest one third on the date of the grant, one third on the first anniversary of the date of the grant, and one third on the second anniversary of the date of the grant. For the three and six months ended June 30, 2020 and 2019, the Company recorded a charge of approximately \$93,000 and \$196,000 and \$0 and \$0, related to these restricted stock unit awards , respectively.

Pursuant to a review of the compensation of the senior management of the Company and managements' performance in 2019, on February 28, 2020, the Board of Directors granted 168,100 restricted stock units to certain senior managers of the Company in order to settle bonuses accrued as of December 31, 2020. These awards were valued at approximately \$1,014,000 at the date of issuance, based upon the market price of the Company's common stock at the date of the grant, and vest one third on the date of the grant one third on the first anniversary of the date of the grant, and one third on the second anniversary of the date of the grant. For the three and six months ended June 30, 2020 and 2019, the Company recorded a charge of approximately \$84,000 and \$451,000 and \$0 and \$0, related to these restricted stock unit awards , respectively.

The following table outlines the restricted stock unit activity for the six months ended June 30, 2020:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2020	167,872	\$ 7.52
Granted	168,100	\$ 6.03
Vested	(105,968)	\$ 6.90
Non-vested, June 30, 2020	<u>230,004</u>	\$ 6.71

*Warrants:*

As of June 30, 2020, the Company had no warrants outstanding.

**4. REVENUE**

The following table disaggregates the Company's revenue by customer type and geographic area for the three months ended June 30, 2020:

	Direct	Distributors/ Strategic Partners	United States Government Agencies	Total
<b>Product sales:</b>				
United States	\$ 735,500	\$ —	\$ —	\$ 735,500
Germany	4,539,621	—	—	4,539,621
All other countries	977,886	3,267,321	—	4,245,207
Total product revenue	<u>6,253,007</u>	<u>3,267,321</u>	<u>—</u>	<u>9,520,328</u>
<b>Grant and other income:</b>				
United States	—	—	274,575	274,575
<b>Total revenue</b>	<u>\$ 6,253,007</u>	<u>\$ 3,267,321</u>	<u>\$ 274,575</u>	<u>\$ 9,794,903</u>

The following table disaggregates the Company's revenue by customer type and geographic area for the three months ended June 30, 2019:

	Direct	Distributors/ Strategic Partners	United States Government Agencies	Total
<b>Product sales:</b>				
United States	\$ —	\$ —	\$ —	\$ —
Germany	3,693,035	—	—	3,693,035
All other countries	844,703	1,312,679	—	2,157,382
Total product revenue	<u>4,537,738</u>	<u>1,312,679</u>	<u>—</u>	<u>5,850,417</u>
<b>Grant and other income:</b>				
United States	—	—	382,109	382,109
<b>Total revenue</b>	<u>\$ 4,537,738</u>	<u>\$ 1,312,679</u>	<u>\$ 382,109</u>	<u>\$ 6,232,526</u>

[Table of Contents](#)

The following table disaggregates the Company's revenue by customer type and geographic area for the six months ended June 30, 2020:

	Direct	Distributors/ Strategic Partners	United States Government Agencies	Total
<b>Product sales:</b>				
United States	\$ 735,500	\$ —	\$ —	\$ 735,500
Germany	9,453,209	—	—	9,453,209
All other countries	2,473,692	5,013,896	—	7,487,588
Total product revenue	12,662,401	5,013,896	—	17,676,297
<b>Grant and other income:</b>				
United States	—	—	825,915	825,915
Total revenue	<u>\$ 12,662,401</u>	<u>\$ 5,013,896</u>	<u>\$ 825,915</u>	<u>\$ 18,502,212</u>

The following table disaggregates the Company's revenue by customer type and geographic area for the six months ended June 30, 2019:

	Direct	Distributors/ Strategic Partners	United States Government Agencies	Total
<b>Product sales:</b>				
United States	\$ 66,800	\$ —	\$ —	\$ 66,800
Germany	6,791,211	—	—	6,791,211
All other countries	1,660,932	1,908,053	—	3,568,985
Total product revenue	8,518,943	1,908,053	—	10,426,996
<b>Grant and other income:</b>				
United States	—	—	997,159	997,159
Total revenue	<u>\$ 8,518,943</u>	<u>\$ 1,908,053</u>	<u>\$ 997,159</u>	<u>\$ 11,424,155</u>

The Company has two primary revenue streams: (1) sales of the CytoSorb device and related device accessories and (2) grant income from contracts with various agencies of the United States government. The following is a brief description of each revenue stream.

#### *CytoSorb Sales*

The Company sells its CytoSorb device using both its own sales force (direct sales) and through the use of distributors and/or strategic partners. All sales of the device are outside the United States, as CytoSorb is not yet approved in the United States, other than in respect of the EUA. Direct sales are fulfilled from the Company's office in Berlin, Germany. Direct sales relate to sales to hospitals located in Germany, Switzerland, Austria, Belgium, Luxembourg, Poland, the Netherlands, Sweden, Denmark and Norway. There are no formal sales contracts with any direct customers relating to product price or minimum purchase requirements. However, there are agreements in place with certain direct customers that provide for either free of charge product or rebate credits based upon achieving minimum purchase levels. The Company records the value of these items earned as a reduction of revenue. These customers submit purchase orders and the order is fulfilled and shipped directly to the customer. Prices to all direct customers are based on a standard price list based on the packaged quantity (6 packs vs 12 packs).

Distributor and strategic partner sales make up the remaining product sales. These distributors are located in various countries throughout the world. The Company has a formal written contract with each distributor/strategic partner. These contracts have terms ranging from 1-5 years in length, with three years being the typical term. In addition, certain distributors are eligible for volume discount pricing if their unit sales are in excess of the base requirement per the contract.

Each distributor's/strategic partner's contract has minimum annual purchase requirements in order to maintain exclusivity in their respective territories.



[Table of Contents](#)

There is no additional consideration or monetary penalty that would be required to be paid to the Company if a distributor does not meet the minimum purchase commitments included in the contract, however, at the discretion of the Company, the distributor may lose its exclusive rights in the territory if such commitments are not met.

*Government Grants*

The Company has been the recipient of various grant contracts from various agencies of the United States government, primarily the Department of Defense, to perform various research and development activities. These contracts fall into one of the following categories:

1. Fixed price – the Company invoices the contract amount in equal installments over the term of the contract without regard to the timing of the costs incurred related to this contract.
2. Cost reimbursement – the Company submits monthly invoices during the term of the contract for the amount of direct costs incurred during that month plus an agreed percentage that relates to allowable overhead and general and administrative expenses. Cumulative amounts invoiced may not exceed the maximum amount of funding stipulated in the contract.
3. Cost plus – this type of contract is similar to a cost reimbursement contract but this type also allows for the Company to additionally invoice for a fee amount that is included in the contract.
4. Performance based – the Company submits invoices only upon the achievement of the milestones listed in the contract. The amount to be invoiced for each milestone is documented in the contract.

In summary, the contracts the Company has with customers are the distributor/strategic partner contracts related to CytoSorb product sales, agreements with direct customers related to free-of-charge product and credit rebates based upon achieving minimum purchase levels, and contracts with various government agencies related to the Company's grants. The Company does not currently incur any outside/third party incremental costs to obtain any of these contracts. The Company does incur internal costs, primarily salary related costs, to obtain the contracts related to the grants. Company employees spend time reviewing the program requirements and developing the budget and related proposal to submit to the grantor agency. There may additionally be travel expenditures involved with meeting with government agency officials during the negotiation of the contract. These internal costs are expensed as incurred.

The following table provides information about receivables and contract liabilities from contracts with customers:

	June 30, 2020	December 31, 2019
Receivables, which are included in grants and accounts receivable	\$ 2,195,606	\$ 2,246,821
Contract liabilities	\$ 121,922	\$ 171,842

Contract liabilities represent the value of free of charge goods and credit rebates earned in accordance with the terms of certain direct customer agreements during the periods ended June 30, 2020 and December 31, 2019, and deferred revenue on distributor/strategic partner contracts. Deferred revenue is the difference between the average selling price anticipated for the year ended 2020 and the actual price invoiced during the six months ended June 30, 2020. There was no deferred revenue liability as of December 31, 2019.

## 5. LONG-TERM DEBT, NET

On June 30, 2016, the Company and its wholly-owned subsidiary, CytoSorbents Medical, Inc. (together, the “Borrower”), entered into a Loan and Security Agreement with Bridge Bank, a division of Western Alliance Bank, (the “Bank”), pursuant to which the Company borrowed \$10 million in two equal tranches of \$5 million (the “Original Term Loans”). On March 29, 2018 (the “Closing Date”), the Original Term Loans were refinanced with the Bank pursuant to an Amended and Restated Loan and Security Agreement by and between the Bank and the Borrower (the “Amended and Restated Loan and Security Agreement”), under which the Bank agreed to loan the Borrower up to an aggregate of \$15 million to be disbursed in two tranches (1) one tranche of \$10 million (the “Term A Loan”), which was funded on the Closing Date and used to refinance the Original Term Loans, and (2) a second tranche of \$5 million which could have been disbursed at the Borrower’s sole request prior to March 31, 2019 provided certain conditions are met (the “Term B Loan” and together with the Term A Loan, the “Term Loans”). On July 31, 2019 (the “Settlement Date”), the Borrower entered into the First Amendment to the Amended and Restated Loan and Security Agreement (the “First Amendment”) with the Bank, which amended certain provisions of the Amended and Restated Loan and Security Agreement and the 2018 Success Fee Letter (the “2018 Letter”). In connection with the execution of the First Amendment, the draw period for the Term B Loan was extended to August 15, 2019 and the Company drew down the full \$5.0 million Term B Loan on the Settlement Date, bringing the total outstanding debt to \$15,000,000 at July 31, 2019. The proceeds of Term Loans were used for general business requirements in accordance with the Amended and Restated Loan and Security Agreement. The outstanding balances on Term Loans bear interest at the prime rate reported in the Wall Street Journal plus 3.66%. This rate was 6.91% at June 30, 2019.

On the Closing Date, the Company was required to pay a non-refundable closing fee of \$25,000, expenses incurred by the Bank related to the Amended and Restated Loan and Security Agreement of \$11,000 and a portion of the final fee for the period the Original Term Loans was outstanding of \$85,938. In addition, the Company incurred legal expenses related to the Amended and Restated Loan and Security Agreement of \$20,050. As of the Closing Date, the total unamortized loan costs related to the Term Loans amounted to \$130,060. These costs have been presented as a direct deduction from the proceeds of the loan on the consolidated balance sheet in accordance with the provisions of ASC 850. These costs are being amortized over the loan period as a charge to interest expense. For the three and six months ended June 30, 2020, the Company recorded interest expense amounting to \$8,524 and \$17,048, and for both the three and six months ended June 30, 2019 the Company recorded interest expense amounting to \$8,129, respectively, related to these costs. Under the terms of the First Amendment, commencing on the first calendar day of the calendar month after the Term B Loan was made, the Company is required to make monthly payments of interest-only through April 2020. The interest-only period will be further extended through November 2020 provided the Borrower has been compliant with its obligations under the financial covenant revenue test set forth in the Amended and Restated Loan and Security Agreement for all months from the month immediately after the month in which the Term B Loan is funded through March 2020. Since the Company has complied with its obligations under the financial covenant revenue test through March 2020, commencing on November 1, 2020, the Company shall make equal monthly payments of principal of \$833,333, together with accrued and unpaid interest. All unpaid principal and accrued and unpaid interest shall be due and payable in full on April 1, 2022. In addition, the Amended and Restated Loan and Security Agreement requires the Company to pay a non-refundable final fee equal to 2.5% of the principal amount of each Term Loan funded upon the earlier of the (i) April 1, 2022 maturity date or (ii) termination of the Term Loan via acceleration or prepayment. This final fee is being accrued and charged to interest expense over the term of the loan. For the three and six months ended June 30, 2020 and 2019, the Company recorded interest expense of \$27,344 and \$15,625, respectively, and \$54,687 and \$31,250, respectively, related to the final fee. The Term Loans are evidenced by secured promissory notes issued to the Bank by the Company. If the Company elects to prepay the Term Loans pursuant to the terms of the Amended and Restated Loan and Security Agreement, it will owe a prepayment fee to the Bank, as follows: (1) for a prepayment made on or after the funding date of a Term Loan through and including the first anniversary of such funding date, an amount equal to 2.0% of the principal amount of such Term Loan prepaid; (2) for a prepayment made after the first anniversary of the funding date of a Term Loan through and including the second anniversary of such funding date, an amount equal to 1.5% of the principal amount of such Term Loan prepaid; and (3) for a prepayment made after the second anniversary of the funding date of a Term Loan through April 1, 2022, an amount equal to 1.0% of the principal amount of such Term Loan prepaid.

Events of default which may cause repayment of the Term Loans to be accelerated include, among other customary events of default, (1) non-payment of any obligation when due, (2) the failure to perform any obligation required under the Amended and Restated Loan and Security Agreement and to cure such default within a reasonable time frame, (3) the occurrence of a Material Adverse Event (as defined in the Amended and Restated Loan and Security Agreement), (4) the attachment or seizure of a material portion of the Borrower's assets if such attachment or seizure is not released, discharged or rescinded within 10 days, and (5) if the Borrower becomes insolvent or starts an insolvency proceeding or if an insolvency proceeding is brought by a third party against the Borrower and such proceeding is not dismissed or stayed within 30 days. The Amended and Restated Loan and Security Agreement includes customary loan conditions, Borrower representations and warranties, Borrower affirmative covenants and Borrower negative covenants for secured transactions of this type. The Company is in substantial compliance with these covenants.

The Company's and CytoSorbents Medical, Inc.'s obligations under the Amended and Restated Loan and Security Agreement are joint and severable and are secured by a first priority security interest in favor of the Bank with respect to the Company's Shares (as defined in the Amended and Restated Loan and Security Agreement) and the Borrower's Collateral (as defined in the Amended and Restated Loan and Security Agreement, which definition excludes the Borrower's intellectual property and other customary exceptions).

**2018 Success Fee Letter:**

Pursuant to the amended 2018 Letter, the Borrower shall pay to the Bank a success fee in the amount equal to 6.37% of the funded amount of the Term B Loan (as defined in the Restated Loan and Security Agreement) (the "Success Fee") upon the first occurrence of any of the following events: (a) a sale or other disposition by the Borrower of all or substantially all of its assets; (b) a merger or consolidation of the Borrower into or with another person or entity, where the holders of the Borrower's outstanding voting equity securities as of immediately prior to such merger or consolidation hold less than a majority of the issued and outstanding voting equity securities of the successor or surviving person or entity as of immediately following the consummation of such merger or consolidation; (c) a transaction or a series of related transactions in which any "person" or "group" (within the meaning of Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of a sufficient number of shares of all classes of stock then outstanding of the Borrower ordinarily entitled to vote in the election of directors, empowering such "person" or "group" to elect a majority of the Board of Directors of the Borrower, who did not have such power before such transaction; or (d) the closing price per share for the Company's common stock on the Nasdaq Capital Market being the greater of (i) 70% or more over \$7.05, the closing price of the Company's common stock on March 29, 2018 (after giving effect to any stock splits or consolidations effected after the date thereof) for five successive business days, or (ii) at least 26.13% more than the average price of Company's common stock for the 365 day period ending on the date of the funding of the Term B Loan.

Long-term debt consists of the following at June 30, 2020:

Principal amount	\$ 15,000,000
Less unamortized debt acquisition costs	(59,670)
Plus accrued final fee	183,594
Subtotal	15,123,924
Less Current maturities	(6,666,667)
Long-term debt net of current maturities	<u>\$ 8,457,257</u>

Principal payments of long-term debt are due as follows during the year ended June 30<sup>th</sup>:

2021	\$ 6,666,667
2022	8,333,333
Total	<u>\$ 15,000,000</u>

**Payroll Protection Program:**

On April 13, 2020, the Company received approximately \$1,411,000 in loan proceeds from the Payroll Protection Program (the "PPP") administered by the Small Business Administration (the "SBA") of the United States government. This program was established under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). On April 29, 2020, following a reassessment of the Company's financial and operating position, including cash on hand and access to public capital markets, the Company repaid the PPP loan.

**6. COMMITMENTS AND CONTINGENCIES**

**Employment Agreements**

On July 30, 2019, CytoSorbents Corporation entered into amended and restated executive employment agreements with its principal executives, Dr. Phillip P. Chan, Chief Executive Officer, Vincent Capponi, President and Chief Operating Officer, and Kathleen P. Bloch, Chief Financial Officer. Each of the agreements has an initial term of three years, and was retroactively effective as of January 1, 2019. On April 12, 2020, CytoSorbents Corporation entered into an executive employment agreement with Dr. Efthymios Deliargyris, who began employment as Chief Medical Officer on May 1, 2020, with an initial term that expires on December 31, 2021. After the expiration of the initial terms, the employment agreements will automatically renew for additional terms of one year unless either party provides written notice of non-renewal at least 60 days prior to a renewal.

The foregoing employment agreements each provide for base salary and other customary benefits which include participation in group insurance plans, paid time off and reimbursement of certain business related expenses, including travel and continuing educational expenses, as well as bonus and/or equity awards at the discretion of the Board of Directors. In addition, the agreements provide for certain termination benefits in the event of termination without "Cause" or voluntary termination of employment for "Good Reason", as defined in each agreement. The agreements also provide for certain benefits in the event of a "Change of Control" of the Company, as defined in each agreement.

**Litigation**

The Company is from time to time subject to claims and litigation arising out of the ordinary course of business. The Company intends to defend vigorously against any future claims and litigation. The Company is not currently a party to any significant legal proceedings.

**Royalty Agreements**

Pursuant to an agreement dated August 11, 2003, an existing investor agreed to make a \$4 million equity investment in the Company. These amounts were received by the Company in 2003. In connection with this agreement, the Company granted the investor a future royalty of 3% on all gross revenues received by the Company from the sale of its CytoSorb device. For the three months ended June 30, 2020 and 2019, the Company has recorded royalty costs of approximately \$281,000 and \$175,000, respectively. For the six months ended June 30, 2020 and 2019, the Company has recorded royalty costs of approximately \$523,000 and \$309,000, respectively.

**License Agreements**

In March 2006, the Company entered into a license agreement which provides the Company the exclusive right to use its patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the agreement, the Company has agreed to pay royalties of 2.5% to 5% on the sale of certain of its products if and when those products are sold commercially for a term not greater than 18 years commencing with the first sale of such product. For the three months ended June 30, 2020 and 2019, per the terms of the license agreement, the Company has recorded royalty costs of approximately \$467,000 and \$292,000, respectively. For the six months ended June 30, 2020 and 2019, the Company recorded royalty costs of approximately \$871,000 and \$515,000, respectively.

## 7. LEASES

Effective January 1, 2019, the Company adopted the provisions of Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842). The provisions of this ASU require the Company to record a right-of-use asset and related lease liability related to their leases. Accordingly, the Company has adjusted its December 31, 2018 consolidated balance sheet to properly reflect the provisions of this ASU as discussed below.

The Company leases its operating facilities in both the United States and Germany under operating lease agreements. In the United States, in May 2020, the Company entered into a Nineteenth Amendment to Lease with the landlord which became effective May 1, 2020. This amendment expands the Company's space to 20,821 square feet and extends the term of the lease to May 31, 2021. The Company's base rent is approximately \$34,000 per month. In addition, the Company is obligated to pay monthly operating expenses of approximately \$30,000 per month. The amendment also includes a one year renewal option. The base rent for the renewal term will increase by the greater of five percent or the increase in the Consumer Price Index. There were no lease incentives and no initial direct costs were incurred related to this lease amendment.

In Germany, the Company leases its operating facility under two operating lease agreements. These leases require combined base rent payments amounting to approximately \$8,800 per month. The initial lease term of both leases ends August 31, 2021. In addition, the Company is obligated to monthly operating expenses of approximately \$2,900 per month. Both leases have a five year option to renew that would extend the lease term to August 31, 2026. There are no provisions in the leases to increase the base rent during the renewal period. There were no lease incentives and no initial direct costs were incurred related to these leases.

### Initial Measurement of Right-Of-Use Asset and Lease Liability:

The Company's consolidated balance sheets reflects the value of the right-of-use asset and related lease liability. This value was calculated based on the present value of the remaining base rent lease payments. The remaining lease payments include the renewal periods for both facilities as the Company has determined that it is probable that the renewal options will be exercised under each of the lease agreements. The discount rate used was the Company's incremental borrowing rate, which is 9.16%, as the Company could not determine the rate implicit in the lease. As a result, the value of the right-of- use asset and related lease liability is as follows:

	June 30, 2020	December 31, 2019
Right-of-use asset	\$ 1,232,388	\$ 1,070,762
Total lease liability	\$ 1,232,388	\$ 1,070,762
Less current portion	(417,699)	(428,083)
Lease liability, net of current portion	\$ 814,689	\$ 642,679

The maturities of the lease liabilities are as follows as of June 30, 2020:

2021	\$ 417,699
2022	441,657
2023	77,046
2024	84,407
2025	92,471
Thereafter	119,108
Total	\$ 1,232,388

For the three months ended June 30, 2020 and 2019, operating cash flows paid in connection with operating leases amounted to approximately \$213,000 and \$230,000, and \$447,000 and \$440,000 for the six months ended June 30, 2020 and 2019, respectively.

As of June 30, 2020 and December 31, 2019, the weighted average remaining lease term was 4.30 years and 4.01 years, respectively.

## **8. NET LOSS PER SHARE**

Basic loss per share and diluted loss per share for the three months ended June 30, 2020 and 2019 have been computed by dividing the net loss for each respective period by the weighted average number of shares outstanding during that period.

All outstanding warrants and options and restricted stock awards representing approximately 7,828,000 and 5,664,000 incremental shares at June 30, 2020 and 2019, respectively, have been excluded from the computation of diluted loss per share as they are anti-dilutive.

## **9. SUBSEQUENT EVENTS**

During the period from July 1, 2020 through July 31, 2020, the Company sold 242,367 shares of its common stock pursuant to the Amended Sale Agreement, at an average selling price of \$10.27 per share, generating net proceeds of approximately \$2,414,000 (see Note 3).

On July 21, 2020, the Company received notification that it received a U.S. Army Medical Research Acquisition Activity Award (the "USAMRAAA") for its HemoDefend™ platform, a development-stage technology designed to be a practical, low cost, and effective way to safeguard the quality and safety of the blood supply. The USAMRAAA award, for up to \$4,421,487, was granted to the Company in order to develop a highly efficient adsorber to remove anti-A and Anti-B antibodies from blood and plasma for transfusion. This Award is supported by the U.S. Department of Defense Peer Reviewed Medical Research Program (PRMRP)/Congressionally Directed Medical Research Program (CDMRP) under Contract No. W81XWH2010712.

On July 24, 2020, the Company completed the Offering pursuant to the terms of an Underwriting Agreement, dated as of July 21, 2020, by and among the Company and Cowen and Company, LLC and SVB Leerink LLC, as representatives of the several underwriters named therein. The Company issued and sold an aggregate of 6,052,631 shares of common stock in the Offering and received gross proceeds of approximately \$57.5 million, before deducting the underwriting discounts and commissions and fees and expenses payable by the Company in connection with the offering.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

### Cautionary Notes Regarding Forward Looking Statements

*This Quarterly report on Form 10-Q includes "forward-looking statements" within the meaning of the safe harbor provisions of 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 included herein 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, as updated by the risks reported in our Quarterly Reports on Form 10-Q, in any prospectus or prospectus supplement filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, and in the press releases and other communications to stockholders issued by us from time to time which attempt to advise interested parties of the risks and factors which may affect our business. 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.*

### Overview

This discussion of our financial condition and the results of operations should be read together with the financial statements, including the notes contained elsewhere in this Quarterly Report on Form 10-Q, and the financial statements, including the notes thereto, contained in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on March 5, 2020.

We are a leader in critical care immunotherapy, investigating and commercializing our CytoSorb blood purification technology to reduce deadly uncontrolled inflammation in hospitalized patients around the world, with the goal of preventing or treating multiple organ failure in life-threatening illnesses and cardiac surgery. Organ failure is the cause of nearly half of all deaths in the intensive care unit ("ICU"), with little to improve clinical outcome. CytoSorb, our flagship product, is approved in the European Union ("EU") as a safe and effective extracorporeal cytokine filter and is 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 mortality is extremely high, yet no effective treatments exist. In May 2018, we received a label expansion for CytoSorb covering use of the device for the removal of bilirubin and myoglobin in the treatment of liver disease and trauma, respectively, and in January 2020, we received a further label expansion for CytoSorb covering the use of the device for the removal of the anti-platelet agent, ticagrelor, in patients undergoing cardiothoracic surgery requiring cardiopulmonary bypass. In May 2020, we received a label expansion for CytoSorb for the removal of rivaroxaban during cardiothoracic surgery requiring cardiopulmonary bypass. In April 2020, the United States Food and Drug Administration (the "FDA") granted Breakthrough Designation to CytoSorb for the removal of ticagrelor in a cardiopulmonary bypass circuit during emergent and urgent cardiothoracic surgery.

CytoSorb is used during and after cardiac surgery to remove inflammatory mediators, such as cytokines, activated complement and free hemoglobin that can lead to post-operative complications, such as acute kidney injury, lung injury, shock, and stroke. We believe CytoSorb has the potential to be used in many other inflammatory conditions, including the treatment of autoimmune disease flares, cytokine release syndrome in cancer immunotherapy, and other applications in cancer, such as cancer cachexia. CytoSorb has been used globally in more than 100,000 human treatments to date in critical illnesses and in cardiac surgery. Our 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 technology is protected by 19 issued U.S. patents and multiple international patents, with applications pending both in the U.S. and internationally. We have numerous product candidates under development based upon this unique blood purification technology, including HemoDefend, ContrastSorb, DrugSorb, and others.



In March 2011, CytoSorb was “CE Marked” in the EU as an extracorporeal cytokine filter indicated for use in clinical situations where cytokines are elevated, allowing for commercial marketing. The CE Mark demonstrates that a conformity assessment has been carried out and the product complies with the Medical Devices Directive. The goal of CytoSorb is to prevent or treat organ failure by reducing cytokine storm and the potentially deadly systemic inflammatory response syndrome (“SIRS”) in diseases such as sepsis, trauma, burn injury, acute respiratory distress syndrome, pancreatitis, liver failure, and many others. Organ failure is the leading cause of death in the ICU, and remains a major unmet medical need, with little more than supportive care therapy (e.g., mechanical ventilation, dialysis, vasopressors, fluid support, etc.) as treatment options. By potentially preventing or treating organ failure, CytoSorb may improve clinical outcome, including survival, while reducing the need for costly ICU treatment, thereby potentially saving significant healthcare costs.

Our CE Mark enables CytoSorb to be sold throughout the European Union and member states of the European Economic Area. In addition, many countries outside the EU accept the CE Mark for medical devices, but may also require registration with or without additional clinical studies. The broad indication for which CytoSorb is CE Marked allows it to be used “on-label” in diseases where cytokines are elevated including, but not limited to, critical illnesses such as those mentioned above, autoimmune disease flares, cancer cachexia, and many other conditions where cytokine-induced inflammation plays a detrimental role.

As part of the CE Mark approval process, we completed our randomized, controlled, European Sepsis Trial amongst 14 trial sites in Germany in 2011, with enrollment of 100 patients with sepsis and respiratory failure. The trial established that CytoSorb was sufficiently safe in this critically-ill population, and that it was able to broadly reduce key cytokines in the blood of these patients. In this first study, CytoSorb was used intermittently, 6 hours a day. CytoSorb is currently used to treat patients continuously, which is deemed to be more effective. We plan to conduct larger, prospective studies in septic patients in the future to confirm the European Sepsis Trial findings.

In addition to CE Marking, we also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the EU. We manufacture CytoSorb at our manufacturing facilities in New Jersey for commercial sales abroad and for additional clinical studies, the expansion of which we officially completed in June 2018. Upon expanding our facility we quadrupled our manufacturing capacity and completed an audit upgrade from an ISO 13485:2003 certification to an ISO 13485:2016 certification.

In late June 2012, following the establishment of our European subsidiary, CytoSorbents Europe GmbH, a wholly-owned operating subsidiary of CytoSorbents Corporation, we began the commercial launch of CytoSorb in Germany with the hiring of Dr. Christian Steiner as Vice President of Sales and Marketing and three additional sales representatives who joined us and completed their sales training during the third quarter of 2012. The fourth quarter of 2012 represented the first quarter of direct sales with the full sales team in place. During this period, we expanded our direct sales efforts to include both Austria and Switzerland.

Fiscal year 2013 represented the first full year of CytoSorb commercialization. We focused our direct sales efforts in Germany, Austria and Switzerland with four sales representatives. The focus of the team was to encourage acceptance and usage by key opinion leaders (“KOLs”) throughout these countries. We believe our relationships with KOLs are essential to drive adoption and recurrent usage of CytoSorb, facilitate purchases by hospital administration, arrange reimbursement, and generate data for papers and presentations. As of the end of 2019, we had hundreds of KOLs in our commercialized territories worldwide in critical care, cardiac surgery, and blood purification, who were either using CytoSorb or supporting its use in clinical practice or clinical trials.

In March 2016, we established CytoSorbents Switzerland GmbH, a wholly-owned subsidiary of CytoSorbents Europe GmbH, to conduct marketing and direct sales in Switzerland. This subsidiary began operations during the second quarter of 2016. In 2017, we further expanded our direct sales efforts into Belgium and Luxembourg.

In May 2018, the approved uses of CytoSorb in the EU were expanded to include the removal of bilirubin in liver disease, and the removal of myoglobin in trauma.

On March 5, 2019, we announced the expansion of direct sales of CytoSorb for all applications to Poland and the Netherlands, and critical care applications to Sweden, Denmark and Norway. As part of this effort we established CytoSorbents Poland Sp. z o.o., a wholly-owned subsidiary of CytoSorbents Europe GmbH.

In the third quarter of 2019, we established CytoSorbents UK Limited, a wholly-owned subsidiary of CytoSorbents Medical, Inc., to manage our clinical trial activities in the United Kingdom.

In August 2019, we announced that CytoSorb had received renewal of its European Union CE Mark through May 2024 and ISO 13485:2016 Full Quality Assurance System certification of its manufacturing facility through September 2022.



In addition, we now have more than 60 investigator-initiated studies and additional Company sponsored trials that are currently planned, enrolling or completed in Europe and elsewhere outside of the United States. We believe that these trials, which are conducted and supported by what we believe to be well-known university hospitals and KOLs, are the equivalent of Phase 3 and Phase 4 clinical studies. We believe they will provide invaluable information regarding the success of the device in the treatment of sepsis, cardiopulmonary bypass surgery, trauma, and many other indications, and if successful, may be integral in helping to drive additional usage and adoption of CytoSorb.

In January 2020, we received CE-Mark label expansion approving the use of CytoSorb to remove the anti-platelet agent, ticagrelor, in cardiac patients during surgery requiring cardiopulmonary bypass.

In April 2020, we announced that the FDA has granted Emergency Use Authorization ("EUA") of CytoSorb for use in patients with COVID-19 infection. Under the EUA, we can make CytoSorb available, through commercial sales, to all hospitals in the United States for use in patients, 18 years of age or older, with confirmed COVID-19 infection who are admitted to the ICU with confirmed or imminent respiratory failure who have early acute lung injury or acute respiratory distress syndrome ("ARDS"), severe disease, or life-threatening illness resulting in respiratory failure, septic shock, and/or multiple organ dysfunction or failure, as described in FDA's authorization. Under the EUA, we plan to ramp up the availability of CytoSorb in a controlled manner, to clinical centers that will work with us to generate data and leverage our knowledge of how to use the device most effectively. The CytoSorb device has been authorized by FDA under an EUA. It has neither been cleared nor approved for the indication to treat patients with COVID-19 infection. The EUA will be effective until a declaration is made that the circumstances justifying the EUA have terminated or until revoked by the FDA.

In April 2020, we announced that the FDA has granted Breakthrough Designation to CytoSorb for the removal of ticagrelor in a cardiopulmonary bypass circuit during emergent and urgent cardiothoracic surgery. The Breakthrough Devices Program provides for more effective treatment of life-threatening or irreversibly debilitating disease or conditions, in this case the need to reverse the effects of ticagrelor in emergent or urgent cardiac surgery that can otherwise cause a high risk of serious or life-threatening bleeding. Through Breakthrough Designation, FDA will work with CytoSorbents to expedite the development, assessment, and regulatory review of CytoSorb for the removal of ticagrelor, while maintaining statutory standards of regulatory approval (e.g., 510(k), *de novo* 510(k) or premarket approval (PMA)) consistent with the FDA's mission to protect and promote public health.

In May 2020, we received CE-Mark label expansion approving the use of CytoSorb for the removal of rivaroxaban, a widely-used Factor Xa inhibitor and novel oral anticoagulant, during cardiothoracic surgery requiring cardiopulmonary bypass. With this announcement, and the E.U. approval earlier this year to remove ticagrelor, for the same indication, CytoSorb is providing cardiac surgeons and perfusionists an easy-to-use and rapid new treatment option to help reduce the risk of serious and potentially fatal perioperative bleeding complications caused by these two drugs, in separate categories of blood thinners.

As of August 1, 2020, our European commercialization team included 84 people.

Overall, we have established either direct sales or distribution (via distributors or strategic partners) of CytoSorb in 65 countries worldwide. Registration of CytoSorb is typically required in each of these countries prior to active commercialization. With CE Mark approval, this can be typically achieved within several months in EU countries. Outside of the EU, the process is more variable and can take several months to more than a year due to different requirements for documentation and clinical data. Variability in the timing of registration affects the initiation of active commercialization in these countries, which affects the timing of expected CytoSorb sales. We actively support all of our distributors and strategic partners in the product registration process. We cannot generally predict the timing of these registrations, and there can be no guarantee that we will ultimately achieve registration in countries where we have established distribution. For example, in August 2014 we announced exclusive distribution of CytoSorb in Taiwan with Hemoscien Corporation. However, in March 2015, due to the complexity we encountered with Taiwanese product registration, we elected to terminate our agreement with Hemoscien. Outside of the EU, CytoSorb has distribution in Turkey, India, Sri Lanka, Australia, New Zealand, Russia, Serbia, Norway, Vietnam, Malaysia, Hong Kong, Chile, Panama, Costa Rica, Colombia, Brazil, Mexico, Argentina, Perú, Guatemala, Ecuador, Bolivia, the Dominican Republic, El Salvador, Iceland, Israel, UAE, Iran, Saudi Arabia and other Middle Eastern countries, and South Korea. We cannot guarantee that we will generate meaningful sales in the countries where we have established registration, due to other factors such as market adoption and reimbursement. For example, in December 2019, we discontinued our distributor relationship with Dr. Reddy's in South Africa. We continuously evaluate other potential distributor and strategic partner networks in other countries that accept CE Mark approval.

In February 2020, we announced an agreement with China Medical System Holdings Limited ("CMS"), a well-established, innovation-driven specialty pharma with a focus on sales and marketing in China and Asia, to bring CytoSorb to mainland China to treat critically-ill patients with COVID-19 coronavirus infection. Under the terms of the agreement, CytoSorbents and CMS partnered together to earn regulatory clearance to import CytoSorb into China under the "fast-track" review process established by the National Medical Products Administration of the People's Republic of China (NMPA) to respond to the COVID-19 pandemic. CytoSorbents donated the initial CytoSorb devices and provided product, training, and support to CMS to introduce CytoSorb initially into four hospitals in the Wuhan, China area. The therapy was evaluated in 17 severe COVID-19 coronavirus patients with a systemic inflammatory response who were treated with either continuous renal replacement therapy ("CRRT") or extracorporeal membrane oxygenation ("ECMO"). During the initial term of the agreement, CytoSorbents and CMS will explore the possibility for future commercial collaboration in China. The use of CytoSorb for the treatment of patients with severe COVID-19 coronavirus infection is considered exploratory in nature, and is currently not yet approved for commercial purposes in mainland China.

We have been working to expand the number and scope of our strategic partnerships. In September 2013, we entered into a distribution agreement with Biocon Ltd. ("Biocon"), India's largest biopharmaceuticals company, under which Biocon was granted exclusive commercialization rights to the CytoSorb therapy in India and select emerging markets, initially focused on sepsis. Biocon committed to annual minimum purchases to maintain exclusivity. In October 2014, the Biocon partnership was expanded to include all critical care applications and cardiac surgery. In addition, Biocon committed to higher annual minimum purchases of CytoSorb to maintain distribution exclusivity and committed to conduct and publish results from multiple investigator-initiated studies and patient case studies. Under the terms of the expanded partnership, the term of the distribution agreement was extended to December 2022. Biocon recently announced that CytoSorb has now received approval from the Drugs Controller General of India to treat COVID-19 patients in certain instances.

In December 2014, we entered into a multi-country strategic partnership with Fresenius Medical Care AG & Co KGaA (together with its affiliates, as appropriate, "Fresenius") to commercialize the CytoSorb therapy. Under the agreement reflecting the terms of the partnership, Fresenius was granted exclusive rights to distribute CytoSorb for critical care applications in France, Poland, Sweden, Denmark, Norway, and Finland. The partnership allows Fresenius to offer an innovative and easy way to use blood purification therapy for removing cytokines in patients that are treated in the ICU. To promote the success of CytoSorb, Fresenius agreed to also engage in the ongoing clinical development of the product. This includes the support and publication of a number of small case series and patient case reports as well as the potential for future larger, clinical collaborations. In May 2016, Fresenius launched the product in the six countries for which it was granted exclusive distribution rights. In January 2017, the Fresenius partnership was expanded pursuant to a revised three-year agreement. The terms of the revised agreement extended Fresenius' exclusive distributorship of CytoSorb for all critical care applications in their existing territories through 2019 and include guaranteed minimum quarterly orders and payments, evaluable every one and a half years.

At the same time, we entered into a comprehensive co-marketing agreement with Fresenius. Under the terms of the co-marketing agreement, CytoSorbents and Fresenius agreed to jointly market CytoSorb to Fresenius' critical care customer base in all countries where CytoSorb is being actively commercialized. CytoSorb continues to be sold by our direct sales force or through our international network of distributors and partners, while Fresenius sells all ancillary products to their customers. Fresenius further provides written endorsements of CytoSorb for use with their multiFiltrate and multiFiltratePRO acute care dialysis machines that can be used by us and our distribution partners to promote CytoSorb worldwide. Training and preparation for this co-marketing program began in five initial countries in 2017 and is continuing, with implementation of the co-marketing program in additional countries planned for the future.

In December 2018, the Fresenius agreement signed in December 2014 was amended, to grant Fresenius exclusive distribution rights for the Czech Republic and Finland and all critical care medicine and ICU applications on dialysis or ECMO machines for France. In addition, in 2019, Poland, Sweden, Denmark, and Norway were transitioned into the co-marketing program. Finally, the guaranteed minimum quarterly purchases and payments requirements were removed for 2019.

In addition, also in December 2018, we entered into agreements to expand the partnership with Fresenius into South Korea and Mexico. Under the terms of these agreements, Fresenius has exclusive rights to distribute CytoSorb for acute care and other hospital applications in Korea and Mexico. In March 2020, we announced that CytoSorb has been approved to be marketed and sold in Mexico the Federal Committee for Protection from Sanitary Risks or Comisión Federal para la Protección contra Riesgos Sanitarios, the country's health authority. With this approval, commercial promotional activities and sales of CytoSorb may now officially commence in Mexico. Commercial sales of CytoSorb are expected to commence in South Korea after securing market registration clearance from the country's health authorities. These multi-year agreements include an initial stocking order and are subject to annual minimum purchases of CytoSorb to maintain exclusivity. These agreements, which commenced on January 1, 2019, have an initial term of three years and will automatically renew for an additional two years unless terminated by either party.

In 2015, we entered into a distribution agreement with Aferetica s.r.l., a distributor based in Bologna, Italy that specializes in the sale of certain medical products and devices, specifically extracorporeal therapies, in the critical care, cardiac surgery and liver disease markets ("Aferetica"). Under the terms of the agreement, we granted Aferetica the exclusive right to distribute CytoSorb in Italy, San Marino and the Vatican for application in CRRT (Continuous Renal Replacement Therapies), dialysis and hemoperfusion machine run treatments, as described in the agreement. In connection with the grant of distribution rights, Aferetica agreed to certain minimum purchase and inventory requirements. Aferetica further agreed not to market or sell products competitive with CytoSorb in Italy, San Marino and the Vatican. The agreement expired by its terms on December 31, 2019. In January 2020, the agreement was amended extending the term to December 2023 and will automatically renew for an additional two years unless terminated by either party.

In addition, in September 2017, we announced a partnership with Aferetica to provide dedicated, branded sorbent cartridges for use with Aferetica's proprietary PerLife™ ex-vivo organ perfusion system, with the goal of rehabilitating or preserving the function solid organs destined for eventual transplant. In July 2018, Aferetica and CytoSorbents debuted the PerLife™ system for organ preservation at the 27<sup>th</sup> International Congress of the Transplantation Society. In July 2020, Aferetica received CE Mark registration of the system.

In September 2016, we entered into a multi-country strategic partnership with Terumo Cardiovascular Group ("Terumo") to commercialize CytoSorb for cardiac surgery applications. Under the terms of the agreement, Terumo has exclusive rights to distribute the CytoSorb cardiopulmonary bypass ("CPB") procedure pack for intra-operative use during cardiac surgery in France, Sweden, Denmark, Norway, Finland and Iceland. Terumo launched the product in these six countries in December 2016.

We continuously evaluate other potential distributor and strategic partner networks in other countries where we are approved to market the device.

Concurrent with our commercialization plans, we intend to conduct or support additional clinical studies in sepsis, cardiac surgery, and other critical care diseases to generate additional clinical data to expand the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. In 2014, we completed a single arm, dose ranging trial in Germany amongst several clinical trial sites to evaluate the safety and efficacy of CytoSorb when used 24 hours per day for seven days, each day with a new device, and are conducting final statistical analysis of the data. Patients were stratified for age, cytokine levels, and co-morbid illnesses in this matched pairs analysis.

In addition to the dosing study, we plan to use data generated and published in the more than 50 investigator-initiated studies and additional Company sponsored trials that are currently planned, enrolling or completed in Europe and elsewhere. We believe that these trials, which are conducted and supported by what we believe to be well-known university hospitals and KOLs, are the equivalent of Phase 3 and Phase 4 clinical studies. They will provide invaluable information regarding the success of the device in the treatment of sepsis, cardio-pulmonary bypass surgery, trauma, and many other indications, and if successful, may be integral in helping to drive additional usage and adoption of CytoSorb.

In addition to sepsis and other critical care applications, cardiac surgery is an important application for CytoSorb. There are approximately one million cardiac surgery procedures performed annually in the U.S. and EU combined including, for example, coronary artery bypass graft surgery, valve replacement surgery, heart and lung transplant, congenital heart defect repair, aortic reconstruction, and left ventricular assist device (“LVAD”) implantation. Cardiac surgery can result in inflammation and the production of high levels of inflammatory cytokines, an activation of complement, and hemolysis, leading to the release of toxic plasma free hemoglobin. These can lead to post-operative complications such as respiratory failure, circulatory failure, and acute kidney injury. CytoSorb has a unique competitive advantage as a cytokine and free hemoglobin removal technology that can be used during the operative procedure and can be easily installed in a bypass circuit in a heart-lung machine without the need for an additional pump. Direct cytokine and hemoglobin removal with CytoSorb enables it to replace the existing market for leukoreduction filters in cardiac surgery that attempt to indirectly reduce cytokines by capturing cytokine-producing leukocytes – an inefficient and suboptimal approach.

In February 2015, the FDA approved our Investigational Device Exemption (“IDE”) application to commence a planned U.S. cardiac surgery feasibility study called REFRESH I (REduction of FREe Hemoglobin) amongst 20 patients and three U.S. clinical sites. The FDA subsequently approved an amendment to the protocol, expanding the study to a 40-patient randomized controlled study (20 treatment, 20 control) in eight clinical centers. REFRESH I represented the first part of a larger clinical trial strategy intended to support the approval of CytoSorb in the U.S. for intra-operative use during cardiac surgery.

The REFRESH I study was designed to evaluate the safety and feasibility of CytoSorb when used intra-operatively with a heart-lung machine to reduce plasma free hemoglobin (pfHb) and cytokines in patients undergoing complex cardiac surgery. The study was not powered to measure effect on clinical outcomes. The length, complexity and invasiveness of these procedures cause hemolysis and inflammation, leading to high levels of plasma free hemoglobin, cytokines, activated complement, and other substances. These inflammatory mediators are correlated with the incidence of serious post-operative complications such as kidney injury, renal failure and other organ dysfunction. The goal of CytoSorb is to actively remove these inflammatory and toxic substances as they are being generated during the surgery and reduce complications. Enrollment was completed with 46 patients. A total of 38 patients were evaluable for pfHb and completed all aspects of the study.

The primary safety and efficacy endpoints of the study were the assessment of serious device related adverse events and the change in plasma free hemoglobin levels, respectively. On October 5, 2016, we announced positive top-line safety data. In addition, following a detailed review of all reported adverse events in a total of 46 enrolled patients, the independent Data Safety Monitoring Board (“DSMB”) found no serious device related adverse events with the CytoSorb device, achieving the primary safety endpoint of the study. In addition, the therapy was well-tolerated and technically feasible, implementing easily into the cardiopulmonary bypass circuit without the need for an additional external blood pump. The REFRESH I study represented the first randomized controlled study demonstrating the safety of intra-operative CytoSorb use in patients undergoing high risk cardiac operations.

Investigators of the REFRESH I study submitted an abstract with data, including free hemoglobin data, from the REFRESH I study which was selected for a podium presentation at the American Association of Thoracic Surgery conference on May 1, 2017. On May 5, 2017, we announced additional REFRESH I data, including data from the study on the reduction of pfHb and activated complement, and in May 2019, the manuscript of the REFRESH I study was electronically published in the journal, *Seminars in Thoracic and Cardiovascular Surgery*.

In December 2017, the FDA approved our IDE application for our REFRESH 2-AKI study, permitting us to conduct this pivotal study designed to provide the key safety and efficacy data needed to support United States regulatory approval for CytoSorb in cardiac surgery, which we plan to pursue via the PMA pathway. The REFRESH 2-AKI study is a randomized, controlled, multi-center, clinical study designed to evaluate intraoperative CytoSorb use as a therapy to reduce the incidence and severity of AKI, as measured by Kidney Disease Improving Global Outcomes (KDIGO) criteria, following complex cardiac surgery. Postoperative AKI following cardiac surgery is common and is associated with 1-5 year mortality, and is a risk factor for developing chronic kidney disease requiring hemodialysis in the future. The study will enroll up to 400 patients at increased risk of cardiovascular surgery-associated AKI, undergoing elective, non-emergent open-heart surgery for either valve replacement, or aortic reconstruction with hypothermic cardiac arrest. In April 2018, we announced the first patient enrollment into the pivotal U.S. REFRESH 2-AKI study. Based on the recommendations of key clinical advisors, a protocol amendment was submitted to the FDA on July 19, 2018 to improve operational aspects of the patient screening process and expand the inclusion criteria. It was the preference of clinical trial sites to defer enrollment until the amendment was approved by the FDA, announced in September 2018. On November 25, 2019 the Company announced a pause in enrollment for the REFRESH 2-AKI study. The study's Data Monitoring Committee (the "DMC") recommended this pause following a blinded, interim, milestone review of clinical study data. The DMC requested that additional clinical data and data analysis, not pre-specified in the current version of the protocol, be provided by the Company. In addition, the Company appointed NAMSA as the new contract research organization ("CRO") for the study to improve the monitoring of patient safety endpoints. As of November 25, 2019, the study had enrolled 153 patients at 25 initiated sites. Since then, the Company and its new CRO have completed a comprehensive program to re-monitor existing data, collect new data, and analyze the safety data from the 153 patients included in the trial to date. These data were reviewed by the DMC resulting in a favorable opinion on safety, dated July 24, 2020, and the recommendation to resume the trial with only minor modifications. Based on multiple reports, we believe that clinical trial activity in the U.S. and in many countries abroad, with the exception of studies related to COVID-19, has slowed significantly due to the COVID-19 pandemic. Because of this, we currently do not have good visibility on when the REFRESH 2-AKI trial will resume, if at all. As an example, assuming a timely restart of the study in mid-year 2020 at the majority of our REFRESH 2-AKI trial sites, we believe we can reach a pre-specified interim analysis at 200 patients enrolled, where the DMC will evaluate the trial for safety and futility, by Q4 2020-Q1 2021. Assuming steady enrollment at our trial sites, we may be able to complete enrollment of the targeted 400 patients in the REFRESH 2-AKI study by the end of 2021. However, there can be no assurance the study will be restarted or will enroll patients in a timely manner. This may trigger business and/or clinical decisions on the trial based on factors such as the cost, timing, probability of success of the study, and other factors. Because of this, there can be no assurances that trial will continue or have a positive outcome. However, if the study is successful, we plan to submit a PMA application to the FDA in 2022 for U.S. regulatory approval.

The German government, via the German Federal Ministry of Education and Research, is funding a 250 patient, multi-center randomized, controlled study ("REMOVE") using CytoSorb during valve replacement open heart surgery in patients with infective endocarditis. The study enrolled its first patient in January 2018. An interim analysis of the first 50 patients has been completed. On February 4, 2019, Prof. Dr. med. Frank Brunkhorst, Director of the Center for Clinical Studies at Jena University Hospital, who is providing management and oversight to the REMOVE study, and Prof. Dr. med. Torsten Doenst, Director of the Clinic for Cardiac and Thoracic Surgery at the University of Jena, provided the following joint statement, "The Scientific Advisory Board (SAB) of the Center of Sepsis Control and Care (CSCC) and the Data Safety Monitoring Board (DSMB) of the REMOVE study recommended continuation of the study, based upon results of a pre-specified interim analysis that analyzed cytokine and vasoactive mediator levels as an indicator of the mechanistic mode of action of the device in 28 CytoSorb-treated patients and 22 control patients. There were no device-associated adverse events in the CytoSorb group." As of March 31, 2020, the study has completed enrollment with 288 patients enrolled. The current plan for analysis of the study data and issuance of topline data is expected for Q3 2020, with a full analysis of data expected to be reported in the second half of 2020.

In September 2019, we announced that Hannover Medical School in Germany will begin the first clinical study, called CYTORELEASE, evaluating the use of CytoSorb in treating cytokine release syndrome (CRS) and inflammation of the brain called CAR-related Encephalopathy Syndrome ("CRES"), following CAR-T cell immunotherapy. The CYTORELEASE trial, entitled "Effectivity of Extracorporeal Cytokine Adsorption (CytoSorb) as Additive Treatment of CAR-T Cell Associated Cytokine Release Syndrome ("CRS") and Encephalopathy Syndrome ("CRES")," is a randomized, controlled pilot study in 34 cancer patients who have received CAR-T cell immunotherapy and who have developed either severe CRS or CRES for a duration less than 6 hours. Patients will receive either standard of care therapy versus standard of care therapy plus CytoSorb hemoadsorption. The primary endpoint of the study is a plasma reduction of the pro-inflammatory cytokine interleukin-6 (IL-6). Secondary and exploratory endpoints will examine other potential clinical benefits such as improvements in CRES, shock, and other organ injury. The trial has been approved by the Hannover Medical School ethics committee and has been screening patients for enrollment.

In September 2019, a new publication entitled, "Hemoadsorption with CytoSorb showed a decreased observed versus expected 28-day all-cause mortality in ICU patients with septic shock: a propensity-score-weighted retrospective study," in the journal Critical Care. In this study, clinical researchers at Maasstad Hospital and at Erasmus University Medical Center in Rotterdam, Netherlands conducted a retrospective evaluation of 116 patients with septic shock, who required vasopressors to increase their blood pressure, and renal replacement therapy (RRT) due to kidney failure. Of these, 49 patients received standard of care therapy, and 67 were treated with standard of care plus CytoSorb. Both groups were compared by stabilized Inverse Probability of Treatment Weights (sIPTW) to overcome baseline differences in the type of sepsis, age, comorbidities, surgery vs no surgery, Sequential Organ Failure Assessment (SOFA) score, use of the vasopressor noradrenaline, and lactate levels. Patients treated with standard of care and CytoSorb had a statistically significant reduction in 28-day all-cause mortality compared to standard of care alone (53% vs 72% control,  $p < 0.04$ ), based on the sIPTW analysis. In addition, observed 28-day all-cause mortality in the CytoSorb treatment group was significantly lower than the predicted mortality (48% observed vs 75% predicted,  $p < 0.001$ ), based on SOFA score.

In October 2019, CytoSorbents initiated TISORB (Ticagrelor CytoSorb Hemoadsorption), a Company-sponsored, multicenter study in the United Kingdom to prospectively evaluate the removal of ticagrelor during cardiopulmonary bypass in patients on ticagrelor undergoing emergent cardiothoracic surgery. Ticagrelor (Brilinta®, Astra Zeneca) is a potent platelet inhibitor and antithrombotic therapy and recognized as a standard of care to reduce the risk of heart attacks and strokes in patients with acute coronary syndromes. Unfortunately, given the absence of an approved treatment to reverse the antithrombotic effects of ticagrelor, treated patients who require urgent or emergent cardiothoracic surgery may either proceed at high risk for severe perioperative bleeding (as high as 65% higher risk due to ticagrelor) or stay waiting for days in the hospital until the ticagrelor antithrombotic effect washes out. Neither option is optimal since patients proceeding to surgery are at great risk for serious or even fatal bleeding and patients waiting for washout are at risk of a thrombotic complications such as a stroke or heart attack, while delaying surgery and increasing hospitalization costs. The benefits of CytoSorb in this setting are both clinical and economic. In the publication in 2019 by Hassan et al, outcomes of 55 patients requiring emergent cardiac surgery while on ticagrelor or rivaroxaban therapy were evaluated according to the use of CytoSorb. Antithrombotic (either ticagrelor or rivaroxaban) removal with CytoSorb was associated with significant reductions in operation time (-23%), red cell transfusions (-59%), platelet transfusions (-67%), need for re-operations to control bleeding (-100%) and shorter length of ICU stay (-41%). Importantly, these significant clinical benefits are expected to also result in substantial economic benefits. This was demonstrated in the publication by Javanbakht et al. in 2019, that projected an average cost savings of £3,982 per patient (approximately \$5,000 USD per patient), including the cost of the CytoSorb adsorber. The primary endpoint of the TISORB study is the change in platelet reactivity and ticagrelor blood concentration before and after cardiopulmonary bypass for patients undergoing CytoSorb hemoadsorption removal of ticagrelor from their blood. A protocol amendment was submitted to expand the population of eligible patients to now include patients requiring urgent cardiac surgery. These changes were approved by the UK Medicines and Healthcare products Regulatory Agency (MHRA) at the end of February 2020. We intend to enroll thirty patients who received ticagrelor within 48 hours of undergoing emergent or urgent cardiothoracic surgery on cardiopulmonary bypass. As of May 1, 2020, we have initiated eight sites and one patient has been enrolled. However, due the COVID-19 pandemic, the trial has paused and not enrolled additional patients, and we cannot predict when the trial will resume. In January 2020, CytoSorb received European Union CE Mark label expansion to include the removal of ticagrelor during cardiopulmonary bypass in patients undergoing cardiothoracic surgery. In May 2020, CytoSorb also received European Union CE Mark label expansion to include rivaroxaban removal for the same indication. We have recently announced the plans to launch the Safe and Timely Antithrombotic Removal (STAR) Registry to capture real world use of CytoSorb for this indication. With the caveat of a potential second wave of COVID-19 this fall in mind, our intent is to launch the registry before the end of 2020. The registry will initially launch in Europe with the intent of expanding to the United States and rest of the territories where CytoSorb is available in the future.

The market focus for CytoSorb is the prevention or treatment of organ failure in life-threatening conditions, including commonly seen illnesses in the ICU such as infection and sepsis, trauma, burn injury, liver failure, pancreatitis, lung injury, ARDS, and others. Severe sepsis and septic shock, a potentially life-threatening systemic inflammatory response to a serious infection, accounts for approximately 10% to 20% of all ICU admissions and is one of the largest target markets for CytoSorb. Sepsis is a major unmet medical need with no approved products in the U.S. or Europe to treat it. As with other critical care illnesses, multiple organ failure is the primary cause of death in sepsis. When used with standard of care therapy, that includes antibiotics, the goal of CytoSorb in sepsis is to reduce excessive levels of cytokines and other inflammatory toxins, to help reduce the SIRS response and either prevent or treat organ failure.



In addition to the sepsis indication, we intend to conduct or support additional clinical studies in sepsis, cardiac surgery, and other critical care diseases where CytoSorb could be used, such as ARDS, trauma, severe burn injury, acute pancreatitis, and in other acute conditions that may benefit by the reduction of cytokines in the bloodstream. Some examples include the prevention of post-operative complications of cardiac surgery (cardiopulmonary bypass surgery) and damage to organs donated for transplant prior to organ harvest. We intend to generate additional clinical data to expand the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications.

Our proprietary hemocompatible porous polymer bead technology forms the basis of a broad technology portfolio. Some of our products include:

- CytoSorb – an extracorporeal hemoperfusion cartridge approved in the EU for cytokine removal, with the goal of reducing SIRS and sepsis and preventing or treating organ failure.
- CytoSorb XL – an intended next generation successor to CytoSorb currently in advanced pre-clinical testing designed to reduce a broad range of cytokines and inflammatory mediators, including lipopolysaccharide (LPS) endotoxin, from blood.
- VetResQ – a broad spectrum blood purification adsorber designed to help treat deadly inflammation and toxic injury in animals with critical illnesses such as septic shock, toxic shock syndrome, severe systemic inflammation, toxin-mediated diseases, pancreatitis, trauma, liver failure, and drug intoxication. VetResQ is being commercialized in the United States.
- HemoDefend-RBC – a development-stage blood purification technology designed to remove non-infectious contaminants in blood transfusion products, with the goal of reducing transfusion reactions and improving the quality and safety of blood. With the support of NHLBI, we plan to initiate a U.S. pivotal trial designed to support U.S. FDA approval, expected to begin by the end of 2020.
- HemoDefend-BGA – a development-stage adsorber designed to enable “universal plasma”, or plasma that can be administered to anyone regardless of blood type, and to improve the safety of whole blood transfusions, by the rapid and efficient removal of anti-A and anti-B antibodies from these two blood products.
- K+ontrol – a development-stage blood purification technology designed to reduce excessive levels of potassium in the blood that can be fatal in severe hyperkalemia.
- ContrastSorb – a development-stage extracorporeal hemoperfusion cartridge designed to remove IV contrast from the blood of high risk patients undergoing CT imaging with contrast, or interventional radiology procedures such as cardiac catheterization. The goal of ContrastSorb is to prevent contrast-induced nephropathy.
- DrugSorb – a development-stage extracorporeal hemoperfusion cartridge designed to remove toxic chemicals from the blood (e.g., drug overdose, high dose regional chemotherapy).
- BetaSorb – a development-stage extracorporeal hemoperfusion cartridge designed to remove mid-molecular weight toxins, such as b2-microglobulin, that standard high-flux dialysis cannot remove effectively. The goal of BetaSorb is to improve the efficacy of dialysis or hemofiltration.

### **COVID-19 Business Update**

A significant problem relating to the COVID-19 pandemic is that an increasing number of COVID-19 patients are developing life-threatening complications, such as ARDS, shock (i.e. a potentially fatal drop in blood pressure), kidney failure, acute cardiac injury and secondary bacterial infections. The underlying cause for these complications is often a cytokine storm that results in a massive, systemic inflammatory response, leading to the damage of vital organs such as the lungs, heart, and kidneys, and ultimately multiple organ failure and death in many cases. CytoSorb, has been used in more than 100,000 treatments as an approved treatment of cytokine storm in the European Union and is distributed in 65 countries around the world, where it has helped physicians control severe inflammation while helping to reverse shock and improve respiratory and other organ function.

The use of CytoSorb in patients infected with COVID-19 in Italy, China, Germany and France began in March 2020. CytoSorb has now been used in approximately 1,200 COVID-19 patients to help treat cytokine storm and the related life-threatening complications in more than 30 countries. Based upon initial data and preliminary reports from physicians treating these complications, CytoSorb use has generally been associated with a marked reduction in cytokine storm and inflammation, improved lung function, weaning from mechanical ventilation, and a reversal of shock. CytoSorb has been specifically recommended in the Italy Brescia Renal COVID Task Force Guidelines to treat patients with severe COVID-19 infection and Stage 3 renal failure on continuous renal replacement therapy. CytoSorb has also been recommended in the National Treatment Guidelines from Panama for Adult COVID-19 Patients if patients have either refractory shock, or have severe or refractory respiratory failure requiring either high ventilator support or extracorporeal membrane oxygenation. CytoSorb has now received approval from the Drugs Controller General of India to treat COVID-19 patients in certain instances. CytoSorb has also received approval to treat patients with COVID-19 from the Israel Ministry of Health (AMAR). In addition, CytoSorb is directly or indirectly recommended and/or approved in China (Handbook of COVID-19 Prevention and Treatment), Columbia (Expert consensus – Colombian Journal of Nephrology), Great Britain (Medtech Innovation Briefing published by NICE) and Germany (Treatment of severe COVID-19 courses in ICU medicine).

The use of CytoSorb has not been approved in the U.S. by FDA. However, under certain circumstances, investigational medical devices that have not yet been FDA-approved may be made available for emergency use in the U.S. under the FDA's Expanded Access Program ("EAP"). On April 13, 2020, we announced that the FDA, in a different program than the EAP, granted Emergency Use Authorization ("EUA") of CytoSorb for use in U.S. patients infected with COVID-19. Under the EUA, CytoSorbents can make CytoSorb available, through commercial sales, to all hospitals in the U.S. for use in patients, 18 years of age or older, with confirmed COVID-19 infection who are admitted to the intensive care unit with confirmed or imminent respiratory failure who have early acute lung injury or ARDS, severe disease, or life-threatening illness resulting in respiratory failure, septic shock, and/or multiple organ dysfunction or failure. Before and after the announcement of the EUA, we had been contacted by many U.S. hospitals concerning the potential use of CytoSorb for patients infected with COVID-19. The CytoSorb device has been authorized by FDA under an EUA. It has neither been cleared nor approved for the indication to treat patients with COVID-19 Infection. The EUA will be effective until a declaration is made that the circumstances justifying the EUA have terminated or until revoked by the FDA.

To meet the growing demand for CytoSorb worldwide, our manufacturing facility is currently running 24 hours a day, seven days a week and is contemplating adding additional teams per shift to reach full capacity.

### **Government Grants**

We have been successful in obtaining technology development contracts from governmental agencies such as the National Institutes of Health and the U.S. Department of Defense, including the Defense Advanced Research Projects Agency ("DARPA"), the Defense Health Agency, the U.S. Army, U.S. Special Operations Command ("USSOCOM"), the U.S. Air Force, Air Force Material Command ("USAF/AFMC"), and others.

In August 2012, we were awarded a \$3.8 million, five-year contract by DARPA for our "Dialysis-Like Therapeutics" ("DLT") program to treat sepsis. DARPA has been instrumental in funding many of the major technological and medical advances since its inception in 1958, including development of the Internet, development of GPS, and robotic surgery. The DLT program in sepsis sought to develop a therapeutic blood purification device that was capable of identifying the cause of sepsis (e.g., cytokines, toxins, pathogens, activated cells) and remove these substances in an intelligent, automated, and efficient manner. Our contract was for advanced technology development of our hemocompatible porous polymer technologies to remove cytokines and a number of pathogen and biowarfare toxins from blood. We have completed our work under the contract with DARPA and SSC Pacific under Contract No. N66001-12-C-4199, which provided for maximum funding of approximately \$3,825,000. We received approximately \$3,825,000 in funding under this contract and no funding remains. Our performance under this contract has been completed.

In September 2012, we were awarded a Phase II SBIR contract by the U.S. Army Medical Research and Material Command to evaluate our technology for the treatment of trauma and burn injury in large animal models. In 2013, we finalized the Phase II SBIR contract which provided for a maximum funding of approximately \$803,000 with the granting agency. This work is supported by the U.S. Army Medical Research and Material Command under an amendment to Contract W81XWH-12-C-0038. In June 2016, this contract was further amended to increase the maximum funding by \$443,000 to approximately \$1,246,000. We received approximately \$1,246,000 in funding under this contract and no funding remains. Our performance under this contract has been completed.



In September 2013, the National Heart Lung and Blood Institute (“NHLBI”) awarded us a Phase I Small Business Innovation Research (“SBIR”) contract, (number HHSN-268201-300044C), valued at \$203,351, to further advance our HemoDefend blood purification technology for pRBC transfusions. The University of Dartmouth collaborated with us as a subcontractor on the project, entitled “Elimination of blood contaminants from pRBCs using HemoDefend hemocompatible porous polymer beads.” The overall goal of this program was to reduce the risk of potential side effects of blood transfusions, and help to extend the useful life of pRBCs. Our performance under this contract has been completed.

In October 2015, we were awarded a Phase II SBIR contract by the NHLBI and USSOCOM to help advance our HemoDefend blood purification technology towards commercialization for the purification of pRBC transfusions. The contract, entitled “pRBCs Contaminant Removal with Porous Polymer Beads”, (contract number HHSN-268201-600006C), provided for maximum funding of approximately \$1,524,000 over a two-year period. We received approximately \$1,524,000 under this contract and no funding remains. Our performance under this contract has been completed.

In March 2016, we were awarded a Phase I SBIR contract for a development program entitled “Mycotoxin Adsorption with Hemocompatible Porous Polymer Beads.” The purpose of this contract was to develop effective blood purification countermeasures for weaponized mycotoxins that can be easily disseminated in water, food and air. This work was funded by the U.S. Joint Program Executive Office for Chemical and Biological Defense, or JPEO-CBD, under contract number W911QY-16-P-0048 and provided for maximum funding of \$150,000. We received approximately \$150,000 and no funding remains under this contract. Our performance under this contract has been completed.

In June 2016, we were awarded a Phase I Small Business Technology Transfer (“STTR”) contract for its development program entitled “Use of Highly Porous Polymer Beads to Remove Anti-A and Anti-B antibodies from Plasma for Transfusion”. The purpose of this contract was to develop our HemoDefend blood purification technology to potentially enable universal plasma. This work was funded by the USAMRAA under contract W81XWH-16-C-0025 and provided for maximum funding of \$150,000. We received approximately \$150,000 and no funding remains under this contract. Our performance under this contract has been completed.

In July 2016, we were awarded a Phase I SBIR contract for its development program entitled “Investigation of a sorbent-based potassium adsorber for the treatment of hyperkalemia induced by traumatic injury and acute kidney injury in austere conditions”. The objective of this Phase I project was to develop two novel and distinct treatment options for life-threatening hyperkalemia. This work was funded by the U.S. Army Medical Research Acquisition Activity (“USAMRAA”) under contract W81XWH-16-C-0080 and provided for maximum funding of approximately \$150,000. We received approximately \$150,000 and no funding remains under this contract. Our performance under this contract has been completed.

In January 2017, we were awarded a Phase II SBIR contract to continue development of CytoSorb for fungal mycotoxin blood purification. This program focused on demonstrating the ability of CytoSorb to adsorb mycotoxins *in vivo* and improve survival in animals. This contract, W911QY-17-C-0007, provided for maximum funding of \$999,996 over two years. This program was funded by the Joint Program Executive Office - Chemical and Biological Defense (“CBD”) SBIR program. We received approximately \$999,996 in funding under this contract and no further funding remains under this contract. Our performance under this contract has been completed.

In May 2017, we were awarded a Phase II STTR contract entitled “Use of Highly Porous Polymer Beads to Remove Anti-A and Anti-B Antibiotics from Plasma Transfusion”. The purpose of this contract is to continue development of our HemoDefend blood purification technology to potentially enable universal plasma. We collaborate with researchers at Penn State University on this project. This contract provides for maximum funding of \$999,070 over two years. This work is being funded by the USAMRAA under contract number W81XWH-17-C-0053. We received approximately \$999,070 and no further funding remains under this contract. Our performance under this contract has been completed.

In May 2017, the Company was awarded a Congressionally Directed Medical Research Program (“CDMRP”) Phase I contract to improve delayed evacuation and prolonged field care for severe burn injury via novel hemoadsorptive and hydration therapies. This work is being funded by the USAMRAA under contract number W81XWH-17-2-0013. This contract provides for maximum funding of \$719,000 over four years. As of June 30, 2020, we received approximately \$640,000 and have approximately \$79,000 remaining under this contract.

In September 2017, the Company was awarded a Phase II SBIR contract for its development program entitled “Investigation of a sorbent-based potassium adsorber for the treatment of hyperkalemia induced by traumatic injury and acute kidney injury”. The purpose of this contract is to continue development of two novel and distinct treatment options for life-threatening hyperkalemia. This work is being funded by the USAMRAA under contract W81XWH-17-C-0142 and provides for maximum funding of approximately \$999,871. As of June 30, 2020, we received approximately \$999,871 and no further funding remains under this contract. Our performance under this contract has been completed.

In August 2018, the Company was awarded a Phase IIB Bridge SBIR contract by the NHLBI to facilitate and accelerate the commercialization of our HemoDefend blood purification technology for the purification of pRBC transfusions. The contract, entitled “pRBCs Contaminant Removal with Hemocompatible Porous Polymer Beads” (award number 2R44HL141928-03), provides for maximum funding of approximately \$2,971,000 over a three-year period. As of June 30, 2020 we received approximately \$1,475,000 in funding under this contract and have approximately \$1,496,000 remaining under this contract. Under the terms of this contract, we must make a matching contribution equal to the funds awarded thereunder.

In September 2019, the Company was awarded a Rapid Innovation Fund contract by the USAF/AFMC to develop a simple, easy-to-use renal support system to treat severe hyperkalemia. The contract, entitled “K+ontrol Renal Support System for Reduction of Hyperkalemia” (award number FA8650-19-C-6065), provides for maximum funding of approximately \$2,960,000 over a two-year period. As of June 30, 2020 we received approximately \$486,000 in funding and have approximately \$2,474,000 remaining under this contract.

In June 2020, the Company was awarded a Defense Health Agency Small Business Technology Transfer (STTR) Phase III contract, to advance its HemoDefend-BGA plasma and whole blood adsorber to human clinical trials. The program, entitled “Development of a Highly Efficient Adsorber to Remove Anti-A and Anti-B Antibodies from Blood and Plasma for Transfusion,” is being funded by the U.S. Army Medical Research and Development Command (USAMRDC) office of the Congressionally Directed Medical Research Programs (CDMRP) (award number W81XWH20C0050) provides for maximum funding of approximately \$2,897,000 over a two-year period. As of June 30, 2020 we received no funding and have approximately \$2,897,000 remaining under this contract.

In July 2020, the Company received notification that it received a U.S. Army Medical Research Acquisition Activity Award (the “USAMRAAA”) for its HemoDefend™ platform, a development-stage technology designed to be a practical, low cost, and effective way to safeguard the quality and safety of the blood supply. The USAMRAAA award, for up to approximately \$4,421,000, was granted to the Company in order to develop a highly efficient adsorber to remove anti-A and Anti-B antibodies from blood and plasma for transfusion. This Award is supported by the U.S. Department of Defense Peer Reviewed Medical Research Program (PRMRP)/Congressionally Directed Medical Research Program (CDMRP) under Contract No. W81XWH2010712.

***Comparison for the three months ended June 30, 2020 and 2019:***

***Revenues:***

Revenue from product sales was approximately \$9,520,000 in the three months ended June 30, 2020, as compared to approximately \$5,850,000 in the three months ended June 30, 2019, an increase of approximately \$3,670,000, or 63%. This increase was driven by an increase in direct sales of approximately \$1,715,000 resulting from sales to both new customers and repeat orders from existing customers and an increase in distributor sales of approximately \$1,955,000. Sales to hospitals in the United States under the EUA granted by the FDA amounted to approximately \$667,000 for the three months ended June 30, 2020. Though difficult to quantitate, we estimate that approximately \$2.4 to \$2.6 million of total product sales in the second quarter of 2020 was due to the demand for CytoSorb to treat COVID-19 patients. In addition, sales were negatively impacted by approximately \$156,000 as a result of the decrease in the average exchange rate of the Euro to the U.S. dollar. For the three months ended June 30, 2020, the average exchange rate of the Euro to the U.S. dollar was \$1.10 as compared to an average exchange rate of \$1.12 for the three months ended June 30, 2019.

Grant income was approximately \$275,000 for the three months ended June 30, 2020 as compared to approximately \$382,000 for the three months ended June 30, 2019, a decrease of approximately \$107,000 or 28%. This decrease was a result of delays in grant related

work caused by the COVID-19 pandemic as our research and development employees have either been deployed to work-from-home status or reassigned to assist in activities related to increasing the production of CytoSorb.

Total revenues were approximately \$9,795,000 for the three months ended June 30, 2020, as compared to total revenues of approximately \$6,233,000 for the three months ended June 30, 2019, an increase of approximately \$3,562,000, or 57%.

***Cost of Revenues:***

For the three months ended June 30, 2020 and 2019, cost of revenue was approximately \$3,250,000 and \$1,834,000, respectively, an increase of approximately \$1,416,000. Product cost of revenues increased approximately \$1,490,000 during the three months ended June 30, 2020 as compared to the three months ended June 30, 2019 primarily as a result of increased sales. Product gross margins were approximately 70% for the three months ended June 30, 2020 and approximately 76% for the three months ended June 30, 2019. The decrease in gross margin was due to an increase in percent contribution of lower margin distributor sales and certain costs associated with the rapid ramp-up of production during the three months ended June 30, 2020.

***Research and Development Expenses:***

For the three months ended June 30, 2020, research and development expenses were approximately \$2,406,000 as compared to research and development expenses of approximately \$2,930,000 for the three months ended June 30, 2019. The decrease of approximately \$524,000 was due to a decrease in our clinical trial costs of approximately \$602,000, which is due primarily to the pause in our Company-sponsored clinical trials as a result of hospital restrictions due to the COVID-19 pandemic and a decrease in non-grant related research and development costs of approximately \$40,000. These decreases were offset by a decrease in direct labor and other costs being deployed toward grant-funded activities of approximately \$74,000, which had the effect of increasing the amount of our non-reimbursable research and development costs, and an increase in non-clinical research and development salary related costs of approximately \$44,000.

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

Legal, financial and other consulting expenses were approximately \$846,000 for the three months ended June 30, 2020, as compared to approximately \$592,000 for the three months ended June 30, 2019. The increase of approximately \$254,000 was due to an increase in employment agency fees of approximately \$71,000 related to the hiring of senior level personnel, an increase in legal fees of approximately \$177,000 related certain corporate initiatives and an increase in accounting fees of approximately \$25,000. These increases were offset by a decrease in consulting fees of approximately \$19,000.

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

Selling, general and administrative expenses were approximately \$6,591,000 for the three months ended June 30, 2020, as compared to approximately \$4,507,000 for the three months ending June 30, 2019, an increase of \$2,084,000. This increase is related to an increase in salaries, commissions and related costs of approximately \$1,872,000, an increase in royalty expenses of approximately \$281,000 due to the increase in product sales, and an increase in non-cash restricted stock expense of approximately \$79,000 related to restricted stock units granted to the Company's executive officers, an increase in non-cash stock compensation expense of approximately \$901,000. These increases were offset by a decrease in travel and entertainment expenses of approximately \$78,000, a decrease in sales and marketing expenses, which include advertising and conference attendance of approximately \$483,000 and a decrease in office supplies and other general and administrative costs of approximately \$488,000.

***Interest Expense, net:***

For the three months ended June 30, 2020, interest expense was approximately \$274,000, as compared to interest expense of approximately \$215,000 for the three months ended June 30, 2019. This increase in interest expense of approximately \$59,000 was primarily a result of the additional interest incurred related to the drawdown of the \$5,000,000 Term B Loan with Bridge Bank on July 31, 2019.

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

For the three months ended June 30, 2020, the gain on foreign currency transactions was approximately \$705,000 as compared to a gain of approximately \$297,000 for the three months ended June 30, 2019. The 2020 gain was directly related to the increase in the spot exchange rate of the Euro to the U.S. dollar at June 30, 2020 as compared to March 31, 2020. The spot exchange rate of the Euro to the U.S. dollar was \$1.12 per Euro at June 30, 2020, as compared to \$1.10 per Euro at March 31, 2020. The 2019 gain was directly related to the increase in the spot exchange rate of the Euro at June 30, 2019 as compared to March 31, 2019. The spot exchange rate of the Euro to the U.S. dollar was \$1.14 per Euro at June 30, 2019, as compared to \$1.12 per Euro at March 31, 2019.

***Comparison for the six months ended June 30, 2020 and 2019:***

***Revenues:***

Revenue from product sales was approximately \$17,676,000 in the six months ended June 30, 2020, as compared to approximately \$10,427,000 in the six months ended June 30, 2019, an increase of approximately \$7,249,000, or 70%. This increase was driven by an increase in direct sales of approximately \$4,143,000 resulting from sales to both new customers and repeat orders from existing customers and an increase in distributor sales of approximately \$3,106,000. Sales to hospitals in the United States under the EUA granted by the FDA amounted to approximately \$667,000 for the six months ended June 30, 2020. Though difficult to quantitate, we estimate that approximately \$3.9 to \$4.3 million of total product sales in the six months ended June 30, 2020 was due to the demand for CytoSorb to treat COVID-19 patients. In addition, sales were negatively impacted by approximately \$393,000 as a result of the decrease in the average exchange rate of the Euro to the U.S. dollar. For the six months ended June 30, 2020, the average exchange rate of the Euro to the U.S. dollar was \$1.10 as compared to an average exchange rate of \$1.13 for the six months ended June 30, 2019.

Grant income was approximately \$826,000 for the six months ended June 30, 2020 as compared to approximately \$997,000 for the six months ended June 30, 2019, a decrease of approximately \$171,000 or 17%. This decrease was a result of delays in grant related work caused by the COVID-19 pandemic as our research and development employees have either been deployed to work-from-home status or reassigned to assist in activities related to increasing production of CytoSorb.

Total revenues were approximately \$18,502,000 for the six months ended June 30, 2020, as compared to total revenues of approximately \$11,424,000 for the six months ended June 30, 2019, an increase of approximately \$7,078,000, or 62%.

***Cost of Revenues:***

For the six months ended June 30, 2020 and 2019, cost of revenue was approximately \$5,635,000 and \$3,573,000, respectively, an increase of approximately \$2,062,000, primarily due to increased sales. Product gross margins were approximately 72% for the six months ended June 30, 2020 and approximately 75% for the six months ended June 30, 2019. The decrease in gross margin was due to an increase in percent contribution of lower margin distributor sales and certain costs associated with the rapid ramp-up of production during the six months ended June 30, 2020.

***Research and Development Expenses:***

For the six months ended June 30, 2020, research and development expenses were approximately \$4,371,000 as compared to research and development expenses of approximately \$5,348,000 for the six months ended June 30, 2019. The decrease of approximately \$977,000 was due to a decrease in our clinical trial costs of approximately \$1,361,000, which was due primarily to the pause in our Company-sponsored clinical trials as a result of hospital restrictions due to the COVID-19 pandemic and a decrease in non-grant related research and development costs of approximately \$31,000. These decreases were offset by a decrease in direct labor and other costs being deployed toward grant-funded activities of approximately \$213,000, which had the effect of increasing the amount of our non-reimbursable research and development costs, an increase in new product development costs of approximately \$87,000, and an increase in non-clinical research and development salary related costs of approximately \$115,000.

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

Legal, financial and other consulting expenses were approximately \$1,365,000 for the six months ended June 30, 2020, as compared to approximately \$1,154,000 for the six months ending June 30, 2019. The increase of approximately \$211,000 was due to an increase in

employment agency fees of approximately \$102,000 related to the hiring of senior level personnel, an increase in legal fees of approximately \$80,000 related certain corporate initiatives and an increase in accounting fees of approximately \$57,000. These increases were offset by a decrease in consulting fees of approximately \$28,000.

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

Selling, general and administrative expenses were approximately \$12,908,000 for the six months ended June 30, 2020, as compared to \$9,265,000 for the six months ended June 30, 2019, an increase of \$3,643,000. This increase is related to an increase in salaries, commissions and related costs of approximately \$2,373,000, an increase in royalty expenses of approximately \$569,000 due to the increase in product sales, and an increase in non-cash restricted stock expense of approximately \$295,000 related to restricted stock units granted to the Company's executive officers, an increase in non-cash stock compensation expense of approximately \$1,403,000. These increases were offset by a decrease in travel and entertainment expenses of approximately \$238,000, a decrease in sales and marketing expenses, which include advertising and conference attendance of approximately \$437,000 and a decrease in office supplies and other general and administrative costs of approximately \$322,000.

***Interest Expense, net:***

For the six months ended June 30, 2020, interest expense was approximately \$579,000, as compared to interest expense of approximately \$420,000 for the six months ended June 30, 2019. This increase in interest expense of approximately \$159,000 was primarily a result of the additional interest incurred related to the draw down of the \$5,000,000 Term B Loan with Bridge Bank on July 31, 2019.

***History of Operating Losses:***

We have experienced substantial operating losses since inception. As of June 30, 2020, we had an accumulated deficit of approximately \$195,109,000, which included losses of approximately \$6,320,000 and \$8,431,000 for the six-month periods ended June 30, 2020 and 2019, respectively. Historically, losses have resulted principally from costs incurred in the research and development of our polymer technology, clinical studies, and general and administrative expenses.

***Liquidity and Capital Resources***

Since inception, our operations have been primarily financed through the issuance of debt and equity securities. At June 30, 2020, we had current assets of approximately \$41,948,000 including cash on hand of approximately \$35,114,000 and current liabilities of approximately \$15,664,000. On July 24, 2020, the Company closed the sale of approximately 6,052,631 shares of its Common Stock and received gross proceeds of approximately \$57.5 million and, after deducting the underwriting discounts and commissions and expenses related to the offering, received total net proceeds of approximately \$54,000,000. In early July 2020, the Company received approximately \$2,414,000 in proceeds related to the sale of shares pursuant to the Open Market Sale Agreement with Jefferies LLC and B. Riley FBR, Inc.

On July 31, 2019, the Company executed an Amendment to its Loan Agreement with Bridge Bank and, simultaneous with this Amendment, received \$5 million in proceeds from an additional term loan. In addition, the Amendment extended the interest-only period of the loan through October 2020. Monthly principal payments of approximately \$833,000 commence in November 2020.

We believe that we have sufficient cash to fund our operations well into the future.

***COVID-19 Impact on Financial Results***

First half 2020 product revenues were positively impacted by underlying strength in our critical care and cardiac surgery business, and the use of CytoSorb to treat critically-ill COVID-19 patients in the ICU. Though difficult to quantitate, we estimate that approximately \$2.4 million to \$2.6 million of our second quarter 2020 revenues and \$3.9 million to \$4.3 million of our year-to-date revenues were related to COVID-19. Given the order patterns we are currently experiencing, we expect that the COVID-19 pandemic will continue to have a positive impact on product revenues in the third quarter of 2020. This may change with containment of the pandemic.

In addition, as a result of the EUA granted by the FDA on April 11, 2020, we began shipping CytoSorb to hospitals in the United States. Sales to hospitals in the United States under the EUA amounted to approximately \$667,000 for the three months ended June 30, 2020.

We are continuing to receive inquiries and orders for CytoSorb. However, at this time, we cannot predict the overall impact this will have on our product sales during the remainder of 2020.

As the impact of the COVID-19 pandemic eases, we may experience a decrease in revenue in the second half of 2020 as compared to the first half of 2020 as the impact of this catalyst for revenue growth is reduced.

Grant revenues have been negatively impacted by the COVID-19 pandemic. Our research and development employees have either been deployed to work-from-home status or reassigned to assist production activities to increase production of CytoSorb. This may reduce grant revenue until such time as the pandemic is over; however, this is not expected to have a material impact on our financial results because of the low gross margins associated with grant activities.

There has been a worldwide slowdown in clinical trial activities as medical providers focus on COVID-19 patients and this has resulted in the temporary pause in enrollment of our TISORB study in the United Kingdom and other clinical trials in Europe. Together with the previously disclosed pause in enrollment of our REFRESH 2 trial, this has resulted in an approximately \$525,000 reduction in our second quarter and a \$1,500,000 reduction in our year to date clinical trial expenses which has a corresponding reduction in our reported operating loss and quarterly cash burn. These clinical trial activities are expected to resume to normal levels as the impact of the COVID-19 pandemic eases.

There has been an approximately \$400,000 reduction in our second quarter and a \$650,000 reduction in our year to date 2020 selling, general, and administrative expenses due to the restrictions on travel and the cancelling of medical and investor conferences during the pandemic. This is also a temporary situation.

There has been no adverse impact on our ability to access capital. Subject to contractual lock-ups, we have the ability to access capital through our ATM facility and through the equity markets, if needed. There has also been no adverse impact on our ability to comply with the covenants associated with our debt facility with Bridge Bank. We do not expect that this will change materially in the near future.

#### **Contractual Obligations**

In May 2020, the Company entered into a Nineteenth Amendment to Lease with the landlord which became effective May 1, 2020. This amendment expands the Company's space to 20,821 square feet and extends the term of the lease to May 31, 2021. The Company's base rent is approximately \$34,000 per month. In addition, the Company is obligated to pay monthly operating expenses of approximately \$30,000 per month. The amendment also includes a one year renewal option. The base rent for the renewal term will increase by the greater of five percent or the increase in the Consumer Price Index.

In September 2016, the Company's wholly-owned subsidiary, CytoSorbents Europe GmbH, entered into a five year lease agreement with Klimik GmbH for 760 square meters of office and warehouse space. In May 2018, CytoSorbents Europe GmbH entered into an additional lease agreement with Klimik GmbH which expanded its office and warehouse space to 960 square meters. The leases have a total rent obligation of \$8,827 per month. Both leases expire on August 31, 2021. The leases also provide the Company with an option to extend the terms for an additional five year period through August 31, 2026.

#### **Off-balance Sheet Arrangements**

We have no off-balance sheet arrangements.



## **Going Concern**

Prior to June 30, 2020, the Company's consolidated financial statements were prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. On July 24, 2020, the Company closed an underwritten public offering of 6,052,631 shares of its common stock at a public offering price of \$9.50 per share (the "Offering").

Gross proceeds from the Offering amounted to approximately \$57.5 million and, after deducting the underwriting discounts and commissions and expenses related to the Offering, the Company received total net proceeds of approximately \$54.0 million. As a result of the Offering, the Company's cash balance increased to approximately \$89.0 million, which the Company expects will fund the Company's operations well beyond the next twelve months. As a result, the Company has determined that the going concern risk has been eliminated.

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

We are exposed to certain market risks in the ordinary course of business. These risks result primarily from changes in foreign currency exchange rates and interest rates. In addition, international operations are subject to risks related to differing economic conditions, changes in political climate, differing tax structures and other regulations and restrictions.

To date we have not utilized derivative financial instruments or derivative commodity instruments. We do not expect to employ these or other strategies to hedge market risk in the foreseeable future. Cash is held in checking, savings, and money market funds, which are subject to minimal credit and market risk. We generate sales in both dollars and Euros most significantly, the majority of our sales are in Euros and changes in the exchange rate of the Euro to the U.S. dollar may positively or negatively impact our revenue. On the other hand, should sales decline due to a devaluation of the Euro relative to the U.S. dollar, expenses related to CytoSorbents Europe GmbH would also decline. This produces a natural currency hedge. We believe that the market risks associated with these financial instruments are currently immaterial, although there can be no guarantee that these market risks will be immaterial to us in the future.

## **Item 4. Controls and Procedures.**

We maintain disclosure controls and procedures designed to ensure information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding disclosures. A controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

No change in our internal control over financial reporting occurred during the three months ended June 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

We are from time to time subject to claims and litigation arising in the ordinary course of business. We intend to defend vigorously against any future claims and litigation. We are not currently a party to any legal proceedings.

## Item 1A. Risk Factors.

### Risks Related to our Business and our Industry

#### *We may require additional capital in the future to fund our operations.*

As of June 30, 2020, we had current assets of approximately \$41,948,000, including cash on hand of approximately \$35,114,000 and current liabilities of approximately \$15,664,000. For six months ended June 30, 2020, our cash burn was approximately \$2,273,000. Our current and historical cash burn is not necessarily indicative of our future use of cash and cash equivalents.

We may require additional financing in the future in order to complete additional clinical studies and to support the commercialization of our proposed products. There can be no assurance that we will be successful in our capital raising efforts. The amount of long-term capital needed is expected to depend on many factors, including:

- rate of sales growth and adoption of our products in the marketplace;
- product gross margin;
- continued progress and cost of our research and development programs;
- progress and costs associated with pre-clinical studies and clinical studies;
- the time and costs involved in obtaining regulatory clearance in other countries and/or for other indications;
- costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- costs related to business development activities;
- costs of developing sales, marketing and distribution channels;
- market acceptance and reimbursement of our products; and
- cost for training physicians and other health care personnel.

We have an effective shelf registration statement dated July 26, 2018 with the SEC which enables us to raise up to \$150 million in one or more offerings, through the issuance and sale of any combination of equity securities, debt securities, warrants and units. As of July 31, 2020, \$50 million of the total shelf amount was allocated to our ATM facility, of which approximately \$22 million remains available. In addition, as a result of our \$57.5 million July 24, 2000 equity raise, the amount remaining on the existing shelf registration statement is approximately \$42.5 million.

On July 24, 2020, the Company closed an underwritten public offering of 6,052,631 shares of its common stock at a public offering price of \$9.50 per share (the "Offering"). Gross proceeds from the Offering amounted to approximately \$57.5 million and, after deducting the underwriting discounts and commissions and expenses related to the Offering, the Company received total net proceeds of approximately \$54.0 million

On July 9, 2019 we entered into an Open Market Sale Agreement with Jefferies LLC and B. Riley FBR, Inc., which we amended in April 2020 (as amended the "Sale Agreement"). Pursuant to the Sale Agreement we may offer to sell, from time to time shares of our common stock, up to a maximum of \$50,000,000. During the year ended December 31, 2019, the Company sold 191,244 shares pursuant to the Sale Agreement, at an average selling price of \$4.11 per share, generating net proceeds of approximately \$762,000. During the six months ended June 30, 2020, the Company sold 3,868,258 shares pursuant to the Sale Agreement, at an average selling price of \$6.41 per share, generating net proceeds of approximately \$24,062,000. During the period from July 1, 2020 through July 31, 2020, the Company sold 242,367 shares pursuant to the Sale Agreement, at an average selling price of \$10.27 per share, generating net proceeds of approximately \$2,414,000. In the aggregate, the Company has sold 4,301,869 shares pursuant to the Sale Agreement, at an average selling price of \$6.53 per share, generating net proceeds of approximately \$27,238,000.

On July 31, 2019 (the "Settlement Date") we entered into the First Amendment to the Amended and Restated Loan and Security Agreement (the "First Amendment") with Bridge Bank, which amended certain provisions of the Amended and Restated Loan and Security Agreement (the "Restated Loan and Security Agreement") and the 2018 Success Fee Letter, each previously entered into by and among us and Bridge Bank on March 28, 2018. In connection with the execution of the First Amendment, the draw period for the Term B Loan (as defined therein) was extended to August 15, 2019 and we drew down the full \$5.0 million Term B Loan on the Settlement Date, bringing the total outstanding debt to \$15,000,000 at July 31, 2019.



Despite the foregoing, we may require additional financing in the future. Should the financing we require be unavailable to us, or on terms unacceptable to us when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other non-dilutive sources, we may have to relinquish economic and/or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourselves. Such events may have a material adverse effect on our business, operating results, financial condition and prospects.

***A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and operations.***

The outbreak of COVID-19 originated in Wuhan, China in December 2019 and has since spread around the globe. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID-19 pandemic is affecting the United States and global economies has affected and is likely to continue to affect our operations and those of third parties on which we rely, including by causing disruptions in our raw material supply, the manufacturing of our lead product, CytoSorb, the commercialization of CytoSorb and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic has affected and is likely to continue to affect the operations of the U.S. Food and Drug Administration and other health authorities, which could result in delays of reviews and approvals, including with respect to CytoSorb and our product candidates. The evolving COVID-19 pandemic has impacted and is likely to continue to directly or indirectly impact our clinical trials, including but not limited to, the anticipated completion date of these trials and the pace of enrollment in our clinical trials for at least the next several months and possibly longer as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff can no longer get to the clinic. Such facilities and offices have and may continue to be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, and may not be available, in whole or in part, for clinical trial services. In particular, due to delays resulting from impacts of the COVID-19 pandemic, analysis of the study data and issuance of the study report for the 250 patient, multi-center randomized, controlled study ("REMOVE") using CytoSorb during valve replacement open heart surgery in patients with infective endocarditis is now anticipated to be completed in the second half of 2020 (rather than by mid-2020 that we initially anticipated), with top-line data potentially this quarter, and there may be further delays in patient enrollment in the REFRESH 2, TISORB, and CYTATION clinical trials. In addition, employee disruptions and remote working environments related to the COVID-19 pandemic and the federal, state and local responses to such virus, could materially impact the efficiency and pace with which we work and develop our product candidates and the manufacturing of CytoSorb. As of the date of this filing, our manufacturing facilities remain operational and we have resumed certain research and development activities that were temporarily suspended as a result of the COVID-19 pandemic. Further, while the potential economic impact brought on by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. Additionally, the stock market has been unusually volatile during the COVID-19 outbreak and such volatility may continue. To date, during certain periods of the COVID-19 pandemic, our stock price fluctuated significantly, and such fluctuation will likely continue to occur. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

***Although historically we have been a research and development company, we are in the process of commercializing our products. There can be no assurance that we will be successful in developing and expanding commercial operations or balancing our research and development activities with our commercialization activities.***

We have historically been engaged primarily in research and development activities and have generated limited revenues to date. With the launch of our CytoSorb product in the EU and elsewhere, there can be no assurance that we will be able to successfully manage the balance of our research and development operations with our planned commercial enterprise. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by an enterprise in balancing development, which include unanticipated problems relating to testing, product registration, regulatory compliance and manufacturing, with commercialization, which includes problems with market adoption, reimbursement, marketing problems and additional costs. Our products and product candidates will require significant additional research and testing, and we will need to overcome significant regulatory burdens prior to commercialization in other countries, such as the U.S., and for ongoing compliance for our CE Mark. Although we believe we are currently well-capitalized, we may need to raise additional funds to complete additional clinical studies and obtain regulatory approvals

in other countries before we can begin selling our products in markets not covered by our CE Mark. In addition, we may be required to spend significant funds on building out our commercial operations. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any products, generate any significant revenues or ever achieve and maintain a substantial level of sales of our products.

***If users of our products are unable to obtain adequate reimbursement from third-party payers, or if reimbursement is not available in specific countries, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues.***

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, the future revenues and profitability of our potential customers, suppliers and collaborative partners, and the availability of capital. For example, in certain foreign markets, pricing or profitability of medical devices is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of medical devices and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of these proposals could materially harm our business, financial condition and results of operations.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations (“HMOs”). Third-party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and medical devices, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for our products. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets often have a combination of government-managed and privately-managed healthcare systems that govern reimbursement for medical devices and related procedures. Socialized medicine is common in the EU, and reimbursement and the pricing of medical devices is generally subject to governmental control. Application for reimbursement, subsequent approvals, if any, and pricing negotiations with governmental authorities can take considerable time after a device has been CE marked. Private insurance has similar challenges. CytoSorb is currently reimbursed in Germany under government-funded insurance, and in other countries may be covered under the diagnosis-related group (“DRG”), or “lump sum payment” reimbursement, or other generalized reimbursement for acute care medical products. We are continuously working to obtain or improve upon the type and amount of reimbursement available to us in countries where CytoSorb is available, and as we attempt to move from an existing reimbursement platform to a new reimbursement platform, we may experience interruptions and/or reductions in the amount available for reimbursement. Because of this, there can be no assurance that new reimbursement will be obtained or that existing reimbursement will continue or that such reimbursement will be sufficient to adequately cover the cost of the device or treatment. As a result, our future revenues, profitability and access to capital may be negatively affected by any interruption or reduction in amounts of reimbursement. We plan to seek reimbursement for our product in other EU and non-EU countries to help further adoption. There can be no assurance when, or if, this additional reimbursement might be approved.

***We depend upon key personnel who may terminate their employment with us at any time.***

As of August 1, 2020, we had 156 full-time and part-time employees as well as several consultants and temporary employees. Our success will depend to a significant degree upon the continued services of our key management team and advisors, including, Dr. Phillip Chan, our Chief Executive Officer; Kathleen P. Bloch, our Chief Financial Officer; Vincent Capponi, our President and Chief Operating Officer and Dr. Efthymios Deliargyris, our Chief Medical Officer. On July 30, 2019, we entered into amended and restated employment agreements with Dr. Chan, Mr. Capponi, and Ms. Bloch that expire on December 31, 2021, and provide thereafter for annual renewals of the contract, unless either party provides written notice of non-renewal at least 60 days prior to renewal. On April 12, 2020, we entered into an employment agreement with Dr. Deliargyris, that expires on December 31, 2021. There can be no assurance that key management personnel or other members of our management team and advisors will continue to provide services to us. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Management and other employees may voluntarily terminate their employment with us at any time. The loss of

services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources.

***Acceptance of our medical devices in the marketplace is uncertain, and failure to achieve market acceptance will prevent or delay our ability to generate revenues.***

Our future financial performance will depend, at least in part, upon the introduction and customer acceptance of our products. Even with CE mark approval for our CytoSorb device as a cytokine filter, our products and product candidates may not achieve market acceptance in the countries that recognize and accept the CE mark. Additional approvals from other regulatory authorities (such as the FDA) will be required before we can market our device in countries not covered by the CE mark. There is no guarantee that we will be able to achieve additional regulatory approvals, and even if we do, our products may not achieve market acceptance in the countries covered by such approvals. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration of the advantages, safety and efficacy of our polymer technology;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- the development by our competitors of products or product candidates that are similar or identical to ours;
- our ability to attract corporate partners, including medical device companies, to assist in commercializing our products; and
- our ability to effectively market our products.

Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our products. Approval of our CytoSorb device as a cytokine filter as well as the data we have gathered in our clinical studies to support device usage in this indication may not be sufficient for market acceptance in the medical community. We may also need to conduct additional clinical studies to gather additional data for marketing purposes. If we are unable to obtain regulatory approval or commercialize and market our products when planned, we may not achieve any market acceptance or generate revenue.

***If we are unable to obtain and maintain patent protection for our products and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and product candidates similar or identical to ours, and our ability to successfully commercialize our products and product candidates may be adversely affected.***

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our products and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our products and product candidates that are important to our business. We cannot be certain that patents will be issued or granted with respect to applications that are currently pending or that we apply for in the future with respect to one or more of our products and product candidates, or that issued or granted patents will not later be found to be invalid and/or unenforceable.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, distribution partners, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued, and even if issued, the patents may not meaningfully protect our products or product candidates, effectively prevent competitors and third parties from commercializing competitive products or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

Changes in the patent laws, implementing regulations or interpretation of the patent laws in the United States and other countries may also diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions.

We cannot be certain that our patents and patent rights will be effective in protecting our products, product candidates and technologies. In addition, our existing patents are scheduled to expire between 2020 and 2035. Failure to protect such assets may have a material adverse effect on our business, operations, financial condition and prospects.

***We may face litigation from third parties claiming that our products infringe on their intellectual property rights, or seek to challenge the validity of our patents.***

Our future success is also dependent in part on the strength of our intellectual property, trade secrets and know-how, which have been developed from years of research and development. In addition to the previously settled “Purolite” litigation discussed below, we may be exposed to additional future litigation by third parties seeking to challenge the validity of our rights based on claims that our technologies, products or activities infringe the intellectual property rights of others or are invalid, or that we have misappropriated the trade secrets of others.

Since our inception, we have sought to contract with large, established manufacturers to supply commercial quantities of our adsorbent polymers. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers. We believe that these disclosures, while necessary for our business, have resulted in the attempt by potential suppliers to improperly assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing rights.

We previously engaged in discussions with the Brotech Corporation and its affiliate, Purolite International, Inc. (collectively referred to as “Purolite”), which had demonstrated a strong interest in being our polymer manufacturer. For a period of time beginning in December 1998, Purolite engaged in efforts to develop and optimize the manufacturing process needed to produce our polymer products on a commercial scale. However, the parties eventually decided not to proceed. In 2003, Purolite filed a lawsuit against us asserting, among other things, co-ownership and co-inventorship of certain of our patents. On September 1, 2006, the United States District Court for the Eastern District of Pennsylvania approved a Stipulated Order and Settlement Agreement under which we and Purolite agreed to the settlement of the action. The Settlement Agreement provides us with the exclusive right to use our patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the Settlement Agreement, we have agreed to pay Purolite royalties of 2.5% to 5% on the sale of certain of our products through 2024, after which time no royalties will be due under this settlement agreement.

***The expiration or loss of patent protection may adversely affect our future revenues and operating earnings.***

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing, and sale of our products and product candidates. In particular, patent protection is important in the development and eventual commercialization of our products and product candidates. Patents covering our products and product candidates normally provide market exclusivity, which is important in order for our products and product candidates to become profitable.

Our existing patents are scheduled to expire between 2020 and 2035. While we are seeking additional patent coverage which may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products and product candidates, we may be open to competition from generic versions of such methods and devices.

***We have commenced the process of seeking regulatory approvals of our products and product candidates, but the approval process involves lengthy and costly clinical studies and is, in large part, not in our control. The failure to obtain government approvals, internationally or domestically, for our products and product candidates, or to comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of our products and result in the failure to achieve revenues or maintain our operations.***

CytoSorb has already achieved marketing authorization in the EU under the CE marking process and the Medical Devices Directive. It is manufactured at our manufacturing facility in New Jersey under ISO 13485 Full Quality Systems certification. The manufacturing and marketing of our products will be subject to extensive and rigorous government regulation in the EU, as well as in the U.S. and in other countries. In the U.S. and other countries, the process of obtaining and maintaining required regulatory approvals is lengthy, expensive, and uncertain. There can be no assurance that we will ever obtain the necessary additional approvals to sell our products in the United States or other non-EU countries. Even if we do ultimately receive FDA approval or clearance for any of our products, we will be subject to extensive ongoing regulation. While we have received approval from our notified body to apply the CE mark to our CytoSorb device, we will be subject to extensive ongoing regulation and auditing requirements to maintain the CE mark.

Our products will be subject to international regulation as medical devices under the Medical Devices Directive. In Europe, which we expect to provide the initial market for our products, the notified body and Competent Authority govern, where applicable, development, clinical studies, labeling, manufacturing, registration, notification, clearance or approval, marketing, distribution, record keeping, and reporting requirements for medical devices. Different regulatory requirements may apply to our products depending on how they are categorized by the notified body under these laws. Current international regulations classify our CytoSorb device as a Class IIb device. Even though we have received CE mark certification of the CytoSorb device, there can be no assurance that we will be able to continue to comply with the required annual auditing requirements or other international regulatory requirements that may be applicable. In addition, there can be no assurance that government regulations applicable to our products or the interpretation of those regulations will not change. The extent of potentially adverse government regulation that might arise from future legislation or administrative action cannot be predicted. There can be no assurances that reimbursement will be granted or that additional clinical data will be required to establish reimbursement.

***If we fail to maintain the CE Mark in the European Union, we will not be able to commercially sell and market CytoSorb.***

In March 2011, CytoSorb, was “CE marked” in the EU as an extracorporeal cytokine filter indicated for use in clinical situations where cytokines are elevated, allowing for commercial marketing. The CE Mark demonstrates that a conformity assessment has been carried out and the product complies with the Medical Devices Directive. A re-certification audit was conducted in April 2019. The successful completion of this audit CE-certifies CytoSorb under the current Medical Device Directive (93/42/EEC) until May 2024. Prior to the expiration of such certificate, we will apply for certification under the new Medical Devices Regulation (MDR). Failure to certify CytoSorb under the Medical Devices Regulation will prevent us from using the CE mark for commercial distribution of CytoSorb in the European Union. Any new product that we submit for the CE Mark after August 2019 must be approved under the new Medical Devices Regulation.

Furthermore, if:

- we are not able to obtain re-certification for CytoSorb’s current use;
- we are not able to do so in time before the existing certificate expires;
- CytoSorb does not meet the new (and more stringent) requirements under the Medical Devices Regulation; or
- any variation in the uses for which the CE Mark has been affixed CytoSorb requires us to perform further research or to modify the technical documentation required to affix the CE Mark, our revenues and operating results could be adversely affected and our reputation could be harmed.

***We may pursue various indications for our product candidates, and they may be subject to different FDA regulatory pathways for marketing authorization, and under the jurisdiction of different FDA review divisions within the FDA's Office of Device Evaluation.***

As we seek to determine commercially viable indications for our product candidates, we may consider pursuing a variety of indications that may be approved through one of several different FDA regulatory clearance or approval pathways, and under the jurisdiction of different FDA review divisions within the FDA's Office of Device Evaluation. We expect the pathways available to us will be impacted by the FDA regulatory history of the category of "sorberent hemoperfusion systems" and our options may also be impacted by the FDA's interpretations and application of these and other regulatory standards to our product candidates. The regulatory pathways available to us may impact the level and type of data necessary to support our applications, and the post-marketing requirements to which we and our products will be subject.

***Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, affect whether government agencies promptly pay amounts awarded under grants from such agencies, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new drugs and medical devices can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and medical devices to be reviewed and/or approved by necessary government agencies as well as affect whether we receive timely payment of amounts awarded to us under grants and contracts with government agencies, including DARPA, which would adversely affect our business. For example, over the last several years, including from December 22, 2018 until January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***We have conducted limited clinical studies of our CytoSorb device. Clinical and pre-clinical data is susceptible to varying interpretations, which could delay, limit or prevent additional regulatory clearances.***

To date, we have conducted limited clinical studies on our CytoSorb product. There can be no assurance that we will successfully complete additional clinical studies necessary to receive additional regulatory approvals in markets not covered by the CE Mark. While studies conducted by us and others have produced results we believe to be encouraging and indicative of the potential efficacy of our products and technology, data already obtained, or in the future obtained, from pre-clinical studies and clinical studies do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical studies. Moreover, pre-clinical and clinical data are susceptible to varying interpretations, which could delay, limit or prevent additional regulatory approvals. A number of companies in the medical device and pharmaceutical industries have suffered significant setbacks in advanced clinical studies, even after promising results in earlier studies. The failure to adequately demonstrate the safety and effectiveness of an intended product under development could delay or prevent regulatory clearance of the device, resulting in delays to commercialization, and could materially harm our business. Even though we have received approval to apply the CE Mark to our CytoSorb device as a cytokine adsorber, there can be no assurance that we will be able to receive approval under the MDR for other potential applications of CytoSorb, or that we will receive regulatory clearance from other targeted regions or countries.



***We rely extensively on research and testing facilities at various universities and institutions, which could adversely affect us should we lose access to those facilities. At the same time, relationships with these individuals and entities are the subject of heightened scrutiny and may present the potential for future healthcare enforcement risk.***

Although we have our own research laboratories and clinical facilities, we collaborate with numerous institutions, universities and commercial entities to conduct research and studies of our products. We currently maintain a good working relationship with these parties. However, should the situation change, the cost and time to establish or locate alternative research and development facilities could be substantial and delay gaining CE Mark for other potential applications of our products, our other product candidates or technologies, and/or FDA approval and commercializing our products. In addition, our interactions, communications, and financial relationships with these individuals and entities present future healthcare enforcement risks.

***We are and will be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon us should we be sued.***

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of medical devices. We cannot be sure that claims will not be asserted against us. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We cannot give assurances that we will be able to continue to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against potential liabilities. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition and results of operations.

***Certain university and other relationships are important to our business and may potentially result in conflicts of interests.***

Dr. John Kellum and others are critical care advisors and consultants of ours and are associated with institutions such as the University of Pittsburgh Medical Center. Their association with these institutions may currently or in the future involve conflicting interests in the event they or these institutions enter into consulting or other arrangements with competitors of ours.

***We have limited manufacturing experience, and once our products are approved, we may not be able to manufacture sufficient quantities at an acceptable cost or quality, or without shut-downs or delays.***

In March 2011, we received approval from our notified body to apply the CE Mark to our CytoSorb device for commercial sale as a cytokine filter. We also achieved ISO 13485:2003 Full Quality Systems certification, and have since upgraded to ISO 13485:2016 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the EU. We manufacture CytoSorb at our manufacturing facilities in New Jersey for sale in the EU and for additional clinical studies. Manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices ("cGMP") for medical devices, as set forth in the QSR. As such, we are subject to continual review and periodic inspections to assess compliance with cGMP/QSR requirements as required by our International notified body and those FDA regulations governing companies that export medical products for sale outside the United States. Accordingly, we must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we or the third-party manufacturers of our products fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products.

In the second quarter of 2018 we quadrupled our manufacturing capabilities upon the official completion of the expansion of our CytoSorb manufacturing facility in New Jersey. In connection with the increased demand for the CytoSorb device to treat COVID-19 patients, our commercial distributions of CytoSorb has been, and may continue to be, delayed. In an attempt to reduce such delays, we have scaled, and will likely need to continue to scale up and increase our manufacturing capabilities in the future. In the event of any unforeseen additional increase in short- or long-term demand for CytoSorb or any of our other products, our commercial distributions could be further delayed significantly as we establish alternative supply sources within our budget. No assurance can be given that we will be able to successfully scale up our manufacturing capabilities, do so at an acceptable cost or quality, or that we will have sufficient financial or technical resources to do so on a timely basis or at all.

***Due to our limited marketing, sales and distribution experience, we may be unsuccessful in our efforts to sell our products.***

We expect to enter into agreements with third parties for the commercial marketing, and distribution of our products. There can be no assurance that parties we may engage to market and distribute our products will:

- satisfy their financial or contractual obligations to us;
- adequately market our products; or
- not offer, design, manufacture or promote competing products.

If for any reason any party we engage is unable or chooses not to perform its obligations under our marketing and distribution agreement, we would experience delays in product sales and incur increased costs, which would harm our business and financial results.

***Our results of operations can be significantly affected by foreign currency fluctuations and regulations.***

A significant portion of our revenues is currently derived in the local currencies of the foreign jurisdictions in which our products are sold. Accordingly, we are subject to risks relating to fluctuations in currency exchange rates. In the future, and especially as we further expand our sales efforts in international markets, our customers will increasingly make payments in non-U.S. currencies. Fluctuations in foreign currency exchange rates could affect our revenues, operating costs and operating margins. In addition, currency devaluation can result in a loss to us if we hold deposits of that currency or if it reduces the cost-competitiveness of our products. We cannot predict the effect of future exchange rate fluctuations on our operating results.

***If we are unable to convince physicians and other health care providers as to the benefits of our products, we may incur delays or additional expense in our attempt to establish market acceptance.***

Broad use of our products may require physicians and other health care providers to be informed about our products and their intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully carry out this education process may adversely affect market acceptance of our products. We may be unable to educate physicians regarding our products in sufficient numbers or in a timely manner to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our products. In addition, we may expend significant funds towards physician education before any acceptance or demand for our products is created, if at all.

***The market for our products is rapidly changing and competitive, and new devices and drugs, which may be developed by others, could impair our ability to maintain and grow our business and remain competitive.***

The medical device and pharmaceutical industries are subject to rapid and substantial technological change. Developments by others may render our technologies and products noncompetitive or obsolete. We also may be unable to keep pace with technological developments and other market factors. Technological competition from medical device, pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us.



***Our business could be harmed by adverse economic conditions in Germany, our primary geographical market, or by economic and/or political instability in the EU or elsewhere caused by Brexit, trade conflicts, or other factors.***

For the year ended December 31, 2019, we derived a majority of our net product sales from sales in Germany. Despite modest European and global growth, there are many economic and political issues that could negatively impact the health of Germany's economy, the broader EU economy, and the world economy overall. Examples include the uncertainty over the implications of the United Kingdom's exit from the EU, also known as "Brexit," economic instability in a number of EU member countries, and changes in the political leadership in the EU and United States. Germany and other European countries face additional risks to their local economies, some of which include the impact of foreign exchange fluctuations, unemployment, tightening of monetary policy, the economic burden of immigration, diminished liquidity and reliance on debt, the rising cost of healthcare, and other factors. In addition, the German government, insurance companies, health maintenance organizations and other payers of healthcare costs continue to focus on healthcare reform and containment of healthcare costs. We cannot predict whether Germany's economy will continue to grow or decline consistent with the overall global economy, which decline would negatively impact the demand for medical devices and healthcare technologies generally and lead to reduced spending on the products we provide. In addition, continued healthcare cost containment efforts may result in lower prices and a reduction or elimination of reimbursement for our products. Due to the concentration of our product sales in this country, any of the foregoing may have a negative impact on our revenues, business operations and financial condition.

***Significant economic downturns or international trade disruptions or disputes could adversely affect our business and operating results.***

Significant portions of our business are conducted in Europe, including the U.K.; Asia; and other international geographies. Interruptions in international relationships such as the recent exit by the U.K. from the EU, and trade disputes such as the current trade negotiations between the U.S. and China, could result in changes to regulations governing our products and our intellectual property, or otherwise affect our ability to do business. Additionally, global events such as the current COVID-19 coronavirus pandemic, that slow worldwide economies, disrupt travel and trade, and destabilize financial markets, may interfere with our ability to raise capital, sell and market our products, obtain reimbursement and payment of our products, or reduce the ability of our customers to pay for our product. Although these global problems transcend our company and afflict companies across industries and borders, these and similar events could adversely affect us, or our business partners or customers.

***Our business may be negatively affected if the United States and/or the countries in which we sell our products participate in wars, military actions or are otherwise the target of international terrorism.***

Involvement in a war or other military action or international acts of terrorism may cause significant disruption to commerce throughout the world. To the extent that such disruptions result in (i) delays or cancellations of customer orders, (ii) a general decrease in consumer spending on healthcare technology, (iii) our inability to effectively market and distribute our products globally or (iv) our inability to access capital markets, our business and results of operations could be materially and adversely affected. We are unable to predict whether acts of international terrorism or the involvement in a war or other military actions by the United States and/or the countries in which we sell our products will result in any long-term commercial disruptions or if such involvement or responses will have any long-term material adverse effect on our business, results of operations, or financial condition.

***We could be adversely affected by violations of the Foreign Corrupt Practices Act and similar worldwide anti-bribery laws.***

We are subject to the Foreign Corrupt Practices Act (the "FCPA"), which generally prohibits companies and their intermediaries from making payments to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are also subject to anti-bribery laws in the jurisdictions in which we operate. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with the FCPA and other anti-bribery laws, there is no assurance that such policies or procedures will protect us against liability under the FCPA or other laws for actions taken by our agents, employees and intermediaries with respect to our business or any businesses that we acquire. We do business in a number of countries in which FCPA violations by other companies have recently been enforced. Failure to comply with the FCPA, other anti-bribery laws or other laws governing the conduct of business with foreign government entities, including local laws, could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the federal government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

***We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws.***

Our products are subject to export control and import laws, tariffs, and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Exports of our products must be made in compliance with these laws, tariffs, and regulations. If we fail to comply with these laws, tariffs, and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in our products or changes in applicable export or import laws, tariffs, and regulations may create delays in the introduction and sale of our products in international markets or, in some cases, prevent the export or import of our products to certain countries, governments or persons altogether. Any change in export or import laws and regulations, shift in the enforcement or scope of existing laws, tariffs, and regulations, or change in the countries, governments, persons, products, or technologies targeted by such laws, tariffs, and regulations, could also result in decreased use of our products, or in our decreased ability to export or sell our products to existing or potential customers. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business, financial condition and results of operations.

***Cyberattacks and other security breaches could compromise our proprietary and confidential information which could harm our business and reputation.***

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information, as well as employee personal data. The secure storage, maintenance, and transmission of and access to this information is important to our operations our day-to-day business and our reputation. Security breaches have become more common across industries. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e-mails and other electronic communications, as well as our intellectual property and business data. In addition, an employee, contractor, or other third-party with whom we do business may attempt to obtain such information, and may purposefully or inadvertently cause a breach involving such information. Further, while many of our employees and certain suppliers with whom we do business operate in a remote working environment during the COVID-19 pandemic, the risk of cybersecurity attacks, particularly through phishing, are increased. We have recently experienced multiple attempts by third parties to penetrate our computer systems. While we have certain safeguards in place to reduce the risk of and detect cyber-attacks, as well as limit the potential exposure of proprietary and confidential information, including multi-layer security protections, our information technology networks and infrastructure may be vulnerable to unpermitted access by hackers or other breaches powered by new and sophisticated technologies, or employee error or malfeasance. Further, we may not be immediately aware of any unpermitted access by hacker or other breaches and we may be unable to quickly and effectively remediate any such breaches. Any such compromise of our data security and access to, or public disclosure or loss of, confidential business or proprietary information could disrupt our operations, damage our reputation, provide our competitors with valuable information, and subject us to additional costs which could adversely affect our business.

***Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.***

European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the European Union, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

In the U.S., even for companies that are not “covered entities” or business associates” under HIPAA, the U.S. Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC’s guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA Security Rule. Some state privacy and security laws apply more broadly than HIPAA and associated regulations. For example, California recently enacted legislation – the California Consumer Privacy Act, or CCPA – which goes into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Legislators have stated that they intend to propose amendments to the CCPA before it goes into effect, and the California Attorney General will issue clarifying regulations. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted.

### **Risks Connected to Our Securities**

***The price of our common stock has been highly volatile due to factors that will continue to affect the price of our stock.***

Our common stock closed as high as \$10.59 and as low as \$3.77 per share between January 1, 2020 and June 30, 2020 on Nasdaq. On July 31, 2020, the closing price of our common stock, as reported on Nasdaq, was \$9.57. Historically, medical device company securities such as our common stock have experienced extreme price fluctuations. Some of the factors leading to this volatility include, but are not limited to:

- fluctuations in our operating results;
- announcements of product releases by us or our competitors;
- announcements of acquisitions and/or partnerships by us and our competitors; and
- general market conditions.

There is no assurance that the price of our common stock will not continue to be volatile.

***Directors, executive officers and principal stockholders own a significant percentage of the shares of common stock, which will limit your ability to influence corporate matters.***

Our directors, executive officers and principal stockholders together beneficially own a significant percentage of the voting control of the common stock on a fully diluted basis. Accordingly, these stockholders could have a significant influence over the outcome of any corporate transaction or other matter submitted to stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets and also could prevent or cause a change in control. The interests of these stockholders may differ from the interests of our other stockholders. Third parties may be discouraged from making a tender offer or bid to acquire us because of this concentration of ownership. As of June 30, 2020, two shareholders hold 11.7% of our shares and our directors and officers hold 4.9% of our shares on a fully diluted basis.

***Our Board of Directors may, without stockholder approval, issue and fix the terms of shares of preferred stock and issue additional shares of common stock adversely affecting the rights of holders of our common stock.***

On December 3, 2014, we effected a twenty-five-for-one (25:1) reverse split of our common stock. Immediately after the reverse stock split, we changed our state of incorporation from the State of Nevada to the State of Delaware pursuant to an Agreement and Plan of Merger, dated December 3, 2014, whereby we merged with and into our recently formed, wholly-owned Delaware subsidiary. Pursuant to the Agreement and Plan of Merger effecting the merger, we adopted the certificate of incorporation, as amended and restated, and bylaws of our Delaware subsidiary as our certificate of incorporation and bylaws at effective time of the merger. As a result, our certificate of incorporation, as amended and restated, authorizes the issuance of up to 5,000,000 shares of “blank check” preferred stock, with such designation rights and preferences as may be determined from time to time by the Board of Directors. Currently, our certificate of incorporation, as amended and restated, which was effective June 12, 2019, authorizes the issuance of up to 100,000,000 shares of common stock, of which approximately 63,188,000 shares remain available for issuance as of June 30, 2020 and may be issued by us without stockholder approval.

***Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that our stockholders may favor and may prevent stockholders from changing the direction of our business or our management.***

After giving effect to our merger into our wholly-owned Delaware subsidiary, provisions of our certificate of incorporation, as amended and restated, and bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares, and may also frustrate or prevent any attempt by stockholders to change the direction or management of us. For example, these provisions:

- authorize the issuance of “blank check” preferred stock without any need for action by stockholders;
- eliminate the ability of stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent; and
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

***Compliance with changing corporate governance and public disclosure regulations may result in additional expense.***

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations will require an increased amount of management attention and external resources. In addition, prior to the merger, our current management team was not subject to these laws and regulations, as we were a private corporation. We intend to continue to invest all reasonably necessary resources to comply with evolving standards, which may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to compliance activities.

***Our common stock is thinly traded on The Nasdaq Capital Market exchange and no assurances can be made about stock performance, liquidity, or maintenance of our Nasdaq listing.***

Prior to December 23, 2014, our common stock was quoted on the OTCQB, which provided significantly less liquidity than a securities exchange (such as the New York Stock Exchange or the Nasdaq Stock Market). On December 17, 2014, our common stock was approved for trading on Nasdaq. Beginning on December 23, 2014, our common stock began trading on Nasdaq under the symbol “CTSO.” Although currently listed on Nasdaq, there can be no assurance that we will continue to meet Nasdaq’s minimum listing requirements or that of any other national exchange. In addition, there can be no assurances that a liquid market will be created for our common stock. If we are unable to maintain listing on Nasdaq or if a liquid market for our common stock does not develop, our common stock may remain thinly traded.

***Future sales of our common stock may cause our share price to fall.***

We are party to a Controlled Equity Offering Sales Agreement with Jefferies LLC and B. Riley FBR, who serve as agents, pursuant to which we may offer shares of our common stock from time to time through “at-the-market” offerings. We are not obligated to make or continue to make any sale of shares of our common stock under the “at-the-market” offerings. Although any sale of securities pursuant to the “at-the-market” offerings will result in a concomitant increase in cash for each share sold, it may result in shareholder dilution and may cause our share price to fall.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

<u>Number</u>	<u>Description</u>
10.1	<a href="#">Nineteenth Amendment to Lease Agreement by and between the Registrant and Princeton Corporate Plaza, LLC, dated April 16, 2020.</a>
10.2	<a href="#">Employment Agreement by and between the Registrant and Efthymios Deligiorgis, M.D., dated April 12, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K filed on April 27, 2020).</a>
31.1	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.</a>
31.2	<a href="#">Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.</a>
32.1	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes Oxley Act of 2002.*</a>
32.2	<a href="#">Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes Oxley Act of 2002.*</a>
101	The following materials from CytoSorbents Corporation’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at June 30, 2020 and December 31, 2019, (ii) Consolidated Statements of Operations for the three and six months ended June 30, 2020 and 2019, (iii) Consolidated Statement of Changes in Stockholders’ Equity for the three and six months ended June 30, 2020 and 2019, (iv) Consolidated Statements of Cash Flows for the six months ended June 30, 2020 and 2019 and (v) Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

\*In accordance with SEC Release 33-8238, Exhibits 32.1 and 32.2 are being furnished and not filed.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**CYTOSORBENTS CORPORATION**

Dated: August 4, 2020

By: /s/ Phillip P. Chan

Name: Phillip P. Chan

Title: Chief Executive Officer

(Principal Executive Officer)

Dated: August 4, 2020

By: /s/ Kathleen P. Bloch

Name: Kathleen P. Bloch, CPA

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

## NINETEENTH AMENDMENT TO LEASE

**Amendment** made this 16<sup>th</sup> day of April 2020, amending the Lease dated March 9, 2000 and amended on October 26, 2000, March 12, 2001, April 22, 2002, March 8, 2005, April 5, 2006, January 31, 2007, October 1, 2008, February 19, 2010, March 7, 2011, March 3, 2012, April 16, 2013, May 5, 2014, December 12, 2014, January 5, 2016, June 27, 2016, April 3, 2017, September 6, 2017, July 17, 2018 and January 4, 2019 (collectively, the “**Lease**”)

**Between** Princeton Corporate Plaza, LLC (“**Landlord**”)

**And** Cytosorbents, Inc., f/k/a Medasorb Corporation (“**Tenant**”)

**Witnesseth** that in consideration of the mutual understanding between them, Landlord and Tenant hereby agree to amend the Lease as follows:

Landlord does hereby lease to Tenant and Tenant does hereby rent from Landlord the following described premises: approximately 901 square feet in Landlord’s Building at 11 Deer Park Drive, Suite 113 (the “**Twelfth Expansion Space**”) in the Township of South Brunswick in the County of Middlesex and State of New Jersey, which space is further described on the Floor Plan marked **Exhibit A-38** attached hereto and made a part hereof,

**Upon the following Conditions and Covenants:**

1. **Demised Premises.** Effective on May 1, 2020 (the “**Twelfth Expansion Commencement Date**”), the Twelfth Expansion Space shall be included in the Demised Premises at both 7 Deer Park Drive Suite K and 11 Deer Park Drive Suite 125 and the total area of the Demised Premises at both 7 Deer Park Drive Suite K and 11 Deer Park Drive Suite 125 shall be approximately 20,821 square feet.
2. **Use.** The Demised Premises shall be used and occupied only and for no other purpose than laboratories and office (the “**Use**”), provided, however, that said Use in the laboratories shall be strictly limited and subject to the activities set forth in Tenant’s Application for Nonresidential Use Performance Standards and Tenancy Review submitted to and approved by the Township of South Brunswick regardless of whether said approval has been received as of the date of execution of this Lease (the “**Tenancy Review**”).
3. **Term.** The Term of the Lease is hereby extended to May 31, 2021 (the “**Expiration Date**”).
4. **Base Rent.** Effective on the Twelfth Expansion Commencement Date, Tenant’s monthly Base Rent for the remainder of the Term shall be \$33,641.00.
5. **Security.** Tenant has previously deposited with Landlord the sum of \$96,370.00 as security pursuant to Section 4 of the Lease.
6. **Tenant’s Proportionate Share.** Effective on the Twelfth Expansion Commencement Date, Tenant’s Proportionate Share for the remainder of the Term shall be a blended rate of 18.26%.



7. **Estimated Operating Expense.** Effective on the Twelfth Expansion Commencement Date, Tenant's estimated monthly Operating Expense shall be \$13,400.00 and Tenant's monthly HVAC maintenance charge shall be \$440.00. Excess water usage will be billed at \$3,500.00 per month, adjusted quarterly if required.
8. **Electric and Gas.** Effective on the Twelfth Expansion Commencement Date, Tenant shall pay as Additional Rent for estimated usage the amounts of \$10,497.00 per month for electricity and \$1,854.00 per month for gas.
9. **Acceptance and Workletter.** Tenant acknowledges that it has inspected and examined the Demised Premises and has entered into this Lease without any representations on the part of Landlord, its agents or representatives as to the condition thereof is leasing and accepting the Demised Premises "as-is" and "where-is". No representations or promises, except as specified herein, have been made by or on behalf of Landlord, its agents, employees or representatives, or by any real estate broker, prior to or at the execution of this Lease, and Landlord is not bound by, and Tenant will make no claim on account of, any representation, promise or assurance, expressed or implied, with respect to conditions, repairs, improvements, services, accommodations, concessions or any other matter, other than as contained herein.
10. **Renewal Option.**
  - a. Tenant has the option to renew for one (1) successive one (1) year term upon six (6) months written notice to Landlord prior to the expiration of the term of this Lease, time being of the essence; provided, however, that Tenant is not in default under any of the terms and conditions of this Lease and no event has occurred which with the giving of notice, passage of time, or both, would constitute an event of default on the date (i) this option is exercised and (ii) the renewal term commences. Base Rent for the renewal term shall be increased by the greater of five percent (5%) or the increases (if any) in the Consumer Price Index as published by the U.S. Department of Labor ("**CPI**"). Base Rent for the renewal term shall be determined (and shall be effective for the entire then operative lease years in the renewal term) by multiplying the annualized Base Rent in the last month of the prior term by the greater of a) five percent (5%) or b) a fraction, the numerator of which fraction shall be the CPI figure for the month which is two (2) months prior to the month in which the Commencement Date occurred (the "**CPI Month**") and the denominator of which fraction shall be the figure published for the corresponding month in the initial lease year for the first renewal and for subsequent renewals, the month used for the numerator in the preceding renewal period. The CPI used shall be the All Urban Consumers (CPI-U), U.S. City Average.
  - b. Should the CPI cease to be published, then the closest similar published index by an agency of the U.S. Government shall be substituted. Should there be no such substitute, the parties hereto shall, under the rules of the American Arbitration Association, agree to a substitute formula or source, designed to accomplish the same original purpose of this provision.
11. **Tenant's Statement of Estoppel in Favor of Landlord.** Tenant hereby confirms that to the best of its knowledge, after due inquiry and consideration:
  - a. Tenant does not have any pending or potential causes of action, suits, liabilities, debts, damages, controversies, agreements, trespasses, judgments, executions, demands and claims of any nature whatsoever, whether in law or in equity, against Landlord, its predecessors, successors and assigns, its parents, subsidiaries, officers, directors, shareholders, employees, agents and attorneys,



- any affiliated corporations, their officers, directors, shareholders and employees, by reason of any matter or cause whatsoever related to or arising from the Lease, or any other matter which has arisen prior to the date of execution of this Amendment.
- b. The Lease is in full force and effect and there are no defaults thereunder by Tenant (or to Tenant's knowledge, by Landlord), nor are there any conditions which with the passage of time or giving of notice or both would become a default under the Lease.
  - c. The Lease is the only agreement between Tenant and the Landlord affecting the Premises, and the Lease has not been assigned, amended, modified, changed, altered or supplemented, except as expressly specified herein. Tenant has no notice or knowledge of any person claiming rights as landlord or as tenant under the Lease other than Landlord and Tenant respectively.
  - d. Tenant is in full and complete possession of the Premises pursuant to the terms of the Lease. There are no options by Tenant or rights to extend or renew Tenant's leasehold or to expand the Premises provided for in the Lease, except as may be expressly provided in the Lease .
  - e. All duties of an inducement nature and all inducement clauses have been fulfilled by Landlord in all respects, including any allowance and rent and other financial concessions.
  - f. Tenant has not, at the Premises or within the building, generated, stored, handled or otherwise dealt with any hazardous or toxic waste or material, radioactive materials, or other contaminants, the removal of which is required or the maintenance of which is prohibited, regulated or penalized by any local, state or federal agency, authority or government unit except as expressly permitted in the Lease.
  - g. No petition, suit or proceeding involving Tenant's bankruptcy, insolvency, reorganization, receivership, or general assignment for the benefit of creditors is currently pending or contemplated.
12. **Release in Favor of Landlord.** Tenant hereby releases and forever discharges Landlord, its predecessors, successors and assigns, its parents, subsidiaries, officers, directors, shareholders, employees, agents and attorneys, any affiliated corporations, their officers, directors, shareholders and employees, from any and all causes of action, suits, liabilities, debts, damages, controversies, agreements, trespasses, judgments, executions, demands and claims of any nature whatsoever, whether in law or in equity, whether known or unknown, and any and all rights, duties, liabilities and obligations, whether presently enforceable or enforceable in the future, by reason of any matter or cause whatsoever from the beginning of time to the date of its execution of this Amendment, related to or arising from the Lease.
13. **Tenant's Representations.** Tenant represents and warrants that Tenant and the person(s) executing and delivering this Amendment on Tenant's behalf each represent and warrant that such person is duly authorized to so act; that Tenant is duly organized, is qualified to do business in the State of New Jersey, is in good standing under the laws of the state of its organization and the laws of the State of New Jersey, and has the power and authority to enter into this Lease; and that all action required to authorize Tenant and such person to enter into this Lease has been duly taken.
14. **Lease Amendment Submission.** Tenant has executed this Amendment upon the understanding that this Amendment shall not in any way bind Landlord until such time as the same has been approved and executed by Landlord and a counterpart delivered to or received by Tenant.

15. **Entire Lease.** This Amendment is made a part of the Lease and where a conflict exists between any provision in the Lease and the provisions of this Amendment, this Amendment shall govern. Except as specifically amended herein, all of the terms and conditions of the Lease shall continue with full force and effect.

**IN WITNESS WHEREOF**, the parties hereto have hereunto set their hands and seals, or caused these presents to be signed by their proper corporate officers or other duly authorized representatives and their proper corporate seal (if applicable) to be hereto affixed, as of the day and year first above written.

**WITNESS:**

**LANDLORD**

Princeton Corporate Plaza, L.L.C.  
By: Princeton Corporate Management Corp.,  
Managing Member

/s/ Jessie Kent

By: /s/ Harold Kent

Name: Harold Kent

5/29/20

Title: President

Date

**WITNESS:**

**TENANT**

Cytosorbents, Inc. f/k/a Medasorb Corporation

/s/ Vincent Capponi

By: /s/ Phillip Chan

Name: Phillip Chan

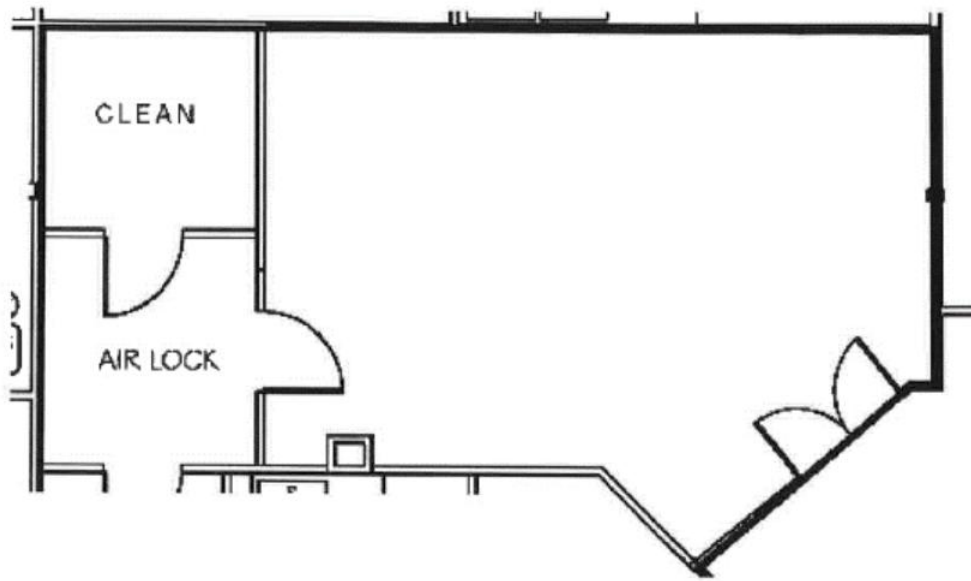
5/29/20

Title: CEO

Date

EXHIBIT A-38

Twelfth Expansion Space: 11 Deer Park Drive



**CERTIFICATION  
OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)  
AS ADOPTED PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Phillip Chan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CytoSorbents Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financing reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 4, 2020

*/s/ Phillip P. Chan*

\_\_\_\_\_  
Phillip P. Chan

Principal Executive Officer

---

**CERTIFICATION  
OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)  
AS ADOPTED PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Kathleen P. Bloch, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CytoSorbents Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 4, 2020

*/s/ Kathleen P. Bloch*

Kathleen P. Bloch

Principal Financial Officer

---

**CERTIFICATION OF  
PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT of 2002**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Phillip Chan, Chief Executive Officer of CytoSorbents Corporation, hereby certify, that, to my knowledge:

1. The Quarterly Report on Form 10-Q for the quarter ending June 30, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in such Quarterly Report on Form 10-Q for the quarter ending June 30, 2020, fairly presents, in all material respects, the financial condition and results of operations of CytoSorbents Corporation.

Date: August 4, 2020

**CYTOSORBENTS CORPORATION**

By: /s/ Phillip P. Chan

Phillip Chan

Chief Executive Officer

---

**CERTIFICATION OF  
PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT of 2002**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Kathleen P. Bloch, the Chief Financial Officer of CytoSorbents Corporation, hereby certify, that, to my knowledge:

1. The Quarterly Report on Form 10-Q for the quarter ending June 30, 2020, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in such Quarterly Report on Form 10-Q for the quarter ending June 30, 2020, fairly presents, in all material respects, the financial condition and results of operations of CytoSorbents Corporation.

Date: August 4, 2020

**CYTOSORBENTS CORPORATION**

By: /s/ Kathleen P. Bloch

Kathleen P. Bloch

Chief Financial Officer

---