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 September 30, 2022

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.)**
305 College Road East Princeton, New Jersey (Address of principal executive offices)	**08540 (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 November 2, 2022, there were 43,635,715 shares of the issuer's common stock outstanding.

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This Quarterly Report on Form 10-Q includes our trademarks and trade names, such as "CytoSorb," "CytoSorb XL," "ECOS-300CY," "BetaSorb," "ContrastSorb," "DrugSorb," "DrugSorb-ATR," "HemoDefend-RBC," "HemoDefend-BGA," "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 SM 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

	September 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 22,552,239	$ 52,137,707
Grants and accounts receivable, net of allowance for doubtful accounts of $66,634 as of September 30, 2022 and $60,539 at December 31, 2021	4,961,245	4,523,430
Inventories	3,541,596	4,766,098
Prepaid expenses and other current assets	1,325,724	2,871,655
Total current assets	32,380,804	64,298,890
Property and equipment, net	10,711,690	5,150,886
Restricted cash	1,687,459	1,687,459
Right-of-use assets	12,794,340	13,423,472
Other assets	4,695,265	4,958,575
Total Assets	$ 62,269,558	$ 89,519,282
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,347,823	$ 2,805,235
Lease liability – current portion	376,529	570,566
Accrued expenses and other current liabilities	7,394,293	10,314,341
Total current liabilities	10,118,645	13,690,142
Lease liability, net of current portion	13,009,413	13,250,943
Total Liabilities	23,128,058	26,941,085
Commitments and Contingencies (Note 6)		
Stockholders' Equity:		
Preferred Stock, Par Value $0.001, 5,000,000 shares authorized; -0- shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common Stock, Par Value $0.001, 100,000,000 shares authorized; 43,634,845 and 43,478,487 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	43,634	43,478
Additional paid-in capital	286,129,098	283,194,429
Accumulated other comprehensive income	6,200,520	525,585
Accumulated deficit	(253,231,752)	(221,185,295)
Total Stockholders' Equity	39,141,500	62,578,197
Total Liabilities and Stockholders' Equity	$ 62,269,558	$ 89,519,282

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three months ended September 30, 2022 (Unaudited)	2021 (Unaudited)	Nine months ended September 30, 2022 (Unaudited)	2021 (Unaudited)
Revenue:				
CytoSorb sales	$ 6,271,228	$ 8,901,089	$ 21,176,194	$ 30,405,114
Other sales	191,468	797	541,694	5,578
Total product sales	6,462,696	8,901,886	21,717,888	30,410,692
Grant income	1,648,657	858,530	3,580,447	1,972,640
Total revenue	8,111,353	9,760,416	25,298,335	32,383,332
Cost of revenue	4,493,976	2,462,946	10,322,315	7,924,608
Gross margin	3,617,377	7,297,470	14,976,020	24,458,724
Other expenses:				
Research and development	3,290,149	4,262,206	11,716,976	10,243,572
Legal, financial and other consulting	609,518	664,689	2,089,330	2,090,310
Selling, general and administrative	8,735,048	7,776,575	26,335,238	25,307,766
Total expenses	12,634,715	12,703,470	40,141,544	37,641,648
Loss from operations	(9,017,338)	(5,406,000)	(25,165,524)	(13,182,924)
Other income/(expense):				
Interest income (expense), net	46,845	12,766	78,849	15,713
Loss on foreign currency transactions	(3,230,315)	(1,013,051)	(6,966,613)	(2,084,425)
Miscellaneous income (expense)	(29)	—	6,831	—
Total other expense	(3,183,499)	(1,000,285)	(6,880,933)	(2,068,712)
Loss before benefit from income taxes	(12,200,837)	(6,406,285)	(32,046,457)	(15,251,636)
Benefit from income taxes	—	—	—	—
Net loss attributable to common shareholders	$ (12,200,837)	$ (6,406,285)	$ (32,046,457)	$ (15,251,636)
Basic and diluted net loss per common share	$ (0.28)	$ (0.15)	$ (0.74)	$ (0.35)
Weighted average number of shares of common stock outstanding	43,606,980	43,396,464	43,552,238	43,319,507
Net loss	$ (12,200,837)	$ (6,406,285)	$ (32,046,457)	$ (15,251,636)
Other comprehensive income (loss):				
Currency translation adjustment	2,658,809	807,965	5,674,935	1,701,202
Total Comprehensive loss	$ (9,542,028)	$ (5,598,320)	$ (26,371,522)	$ (13,550,434)

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
For the three and nine months ended September 30, 2022 and 2021 (Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Stockholders' Equity
	Shares	Par value				
Balance at June 30, 2022	43,574,619	$ 43,575	$ 285,005,396	$ 3,541,711	$ (241,030,915)	$ 47,559,767
Stock-based compensation - employees, consultants and directors	—	—	1,005,403	—	—	1,005,403
Other comprehensive loss: foreign translation adjustment	—	—	—	2,658,809	—	2,658,809
Stock issued to vendor in lieu of cash payment	—	—	—	—	—	—
Issuance of restricted stock units	60,226	59	118,299	—	—	118,358
Net loss	—	—	—	—	(12,200,837)	(12,200,837)
Balance at September 30, 2022	43,634,845	$ 43,634	$ 286,129,098	$ 6,200,520	$ (253,231,752)	$ 39,141,500
Balance at December 31, 2021	43,478,487	$ 43,478	$ 283,194,429	$ 525,585	$ (221,185,295)	$ 62,578,197
Stock-based compensation - employees, consultants and directors	—	—	2,554,092	—	—	2,554,092
Other comprehensive income: foreign translation adjustment	—	—	—	5,674,935	—	5,674,935
Stock issued to vendor in lieu of cash payment	12,500	12	42,487	—	—	42,499
Issuance of restricted stock units	143,858	144	378,449	—	—	378,593
Legal/audit fees related to ATM offering	—	—	(40,359)	—	—	(40,359)
Net loss	—	—	—	—	(32,046,457)	(32,046,457)
Balance at September 30, 2022	43,634,845	$ 43,634	$ 286,129,098	$ 6,200,520	$ (253,231,752)	$ 39,141,500

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Stockholders' Equity
	Shares	Par value				
Balance at June 30, 2021	43,337,905	$ 43,338	$ 280,654,464	$ (840,841)	$ (205,471,998)	$ 74,384,963
Stock-based compensation - employees, consultants and directors	—	—	998,642	—	—	998,642
Other comprehensive loss: foreign translation adjustment	—	—	—	807,965	—	807,965
Proceeds from exercise of stock options	102,437	103	589,615	—	—	589,718
Cashless exercise of stock options	4,561	5	(5)	—	—	—
Issuance of restricted stock units	30,745	30	236,076	—	—	236,106
Net loss	—	—	—	—	(6,406,285)	(6,406,285)
Balance at September 30, 2021	43,475,648	$ 43,476	$ 282,478,792	$ (32,876)	$ (211,878,283)	$ 70,611,109
Balance at December 31, 2020	43,221,999	$ 43,222	$ 277,533,082	$ (1,734,078)	$ (196,626,647)	$ 79,215,579
Stock-based compensation - employees, consultants and directors	—	—	3,224,255	—	—	3,224,255
Other comprehensive income: foreign translation adjustment	—	—	—	1,701,202	—	1,701,202
Proceeds from exercise of stock options	137,102	137	795,986	—	—	796,123
Cashless exercise of stock options	9,885	10	(2,841)	—	—	(2,831)
Issuance of restricted stock units	106,662	107	928,310	—	—	928,417
Net loss	—	—	—	—	(15,251,636)	(15,251,636)
Balance at September 30, 2021	43,475,648	$ 43,476	$ 282,478,792	$ (32,876)	$ (211,878,283)	$ 70,611,109

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine months ended September 30, 2022 (Unaudited)	Nine months ended September 30, 2021 (Unaudited)
Cash flows from operating activities:		
Net loss	$ (32,046,457)	$ (15,251,636)
Adjustments to reconcile net loss to net cash used by operating activities:		
Non-cash restricted stock unit compensation	149,368	1,875,422
Depreciation and amortization	659,407	517,176
Amortization of right of use asset	193,567	—
Impairment of patents	431,426	—
Bad debt expense	10,369	6,137
Stock-based compensation	2,554,092	3,224,255
Foreign currency transaction loss	6,966,613	2,084,425
Changes in operating assets and liabilities:		
Grants and accounts receivable	(860,022)	(278,105)
Inventories	459,434	(2,099,051)
Prepaid expenses and other current assets	1,577,559	1,243,579
Other assets	53,226	(136,773)
Accounts payable and accrued expenses	(3,042,537)	300,571
Net cash used in operating activities	(22,893,955)	(8,514,000)
Cash flows from investing activities:		
Purchases of property and equipment	(5,873,928)	(2,108,821)
Payments for patent costs	(375,568)	(499,691)
Net cash used in investing activities	(6,249,496)	(2,608,512)
Cash flows from financing activities:		
Equity contributions - net of fees incurred	(40,359)	—
Proceeds from exercise of stock options	—	796,123
Net cash provided by (used in) financing activities	(40,359)	796,123
Effect of exchange rates on cash	(401,658)	(52,366)
Net change in cash, cash equivalents and restricted cash	(29,585,468)	(10,378,755)
Cash, cash equivalents and restricted cash - beginning of period	53,825,166	71,421,601
Cash, cash equivalents and restricted cash - end of period	$ 24,239,698	$ 61,042,846
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ —	$ —
Supplemental disclosure of non-cash financing activities:		
Issuance of common stock to vendor in lieu of cash payment	$ 42,499	$ —
Capital expenditures included in accounts payable	$ 280,729	$ —
Settlement of accrued bonuses with restricted stock units	$ 378,593	$ 928,417

See accompanying notes to consolidated financial statements.

CytoSorbents Corporation
Notes to Consolidated Financial Statements
(UNAUDITED)
September 30, 2022

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, 2021 included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (the "SEC") on March 10, 2022. The results for the three and nine months ended September 30, 2022 and 2021 are not necessarily indicative of the results to be expected for a full year, any other interim periods or any future year or period.

As of September 30, 2022, the Company's cash and cash equivalents balances were approximately $22.6 million, which the Company expects will fund the Company's operations beyond twelve months from the issuance of these consolidated financial statements. In addition, the Company has $15 million of debt availability and $25 million of availability under its ATM facility to provide additional liquidity, as needed. As a result, the Company has determined that the going concern risk has been substantially mitigated.

2. PRINCIPAL BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Business

The Company is a leader in the treatment of life-threatening conditions in intensive care and cardiac surgery using blood purification. 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 the Company's clinical trial activities in the United Kingdom. In March 2022, the Company formed CytoSorbents Medical UK Limited to provide marketing and direct sales services in the United Kingdom and the Republic of Ireland. CytoSorb, the Company's flagship product, was approved in the European Union ("EU") in March 2011 and is currently being marketed and distributed in more than 70 countries around the world, as an effective extracorporeal cytokine absorber, designed to reduce the "cytokine storm" or "cytokine release syndrome" seen in critical illnesses that may result in massive inflammation, organ failure, and patient death. 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 that can lead to post-operative complications, including multiple organ failure. In January 2020, CytoSorb received EU CE Mark label expansion to include the removal of ticagrelor during cardiopulmonary bypass in patients undergoing cardiothoracic surgery. In May 2020, CytoSorb also received EU CE Mark label expansion to include rivaroxaban removal for the same indication.

In April 2020, CytoSorb received United States Food and Drug Administration ("FDA") Emergency Use Authorization ("EUA") of CytoSorb for use in adult critically-ill COVID-19 patients with imminent or confirmed respiratory failure. The CytoSorb device has neither been cleared nor approved for the indication to treat patients with COVID-19 infection. The EUA is 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 for its DrugSorb-ATR Antithrombotic Removal System 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, the FDA intends to work with CytoSorbents to expedite the development, assessment, and regulatory review of CytoSorbents' technology 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. In July 2021, the Company received full approval of its Investigative Device Exemption ("IDE") to conduct the pivotal STAR-T (Safe and Timely Antithrombotic Removal – Ticagrelor) double-blind randomized control trial ("RCT") for up to 120 patients in the United States to support FDA marketing approval.

In August 2021, the Company announced that it was granted a second Breakthrough Device designation for its DrugSorb-ATR Antithrombotic Removal System by the FDA. This Breakthrough Device designation covers the removal of the Direct Oral Anticoagulants (DOACs) apixaban and rivaroxaban in a cardiopulmonary bypass circuit to reduce the likelihood of serious perioperative bleeding during urgent cardiothoracic surgery. In October 2021, the Company also received full FDA approval of an IDE application to conduct a double-blind, randomized, controlled clinical study for up to 120 patients entitled, "Safe and Timely Antithrombotic Removal – Direct Oral Anticoagulants (STAR-D)," in the United States to support FDA marketing approval.

If FDA marketing approval is obtained for either the removal of ticagrelor or direct oral anticoagulants indications, the device would be marketed as DrugSorb-ATR in the United States. The DrugSorb-ATR Antithrombotic Removal System is based on the same polymer technology as CytoSorb.

In May 2022, the Company announced that the Company entered into a 3-year preferred supplier agreement with Asklepios, making CytoSorb available without restrictions to all of the approximate 170 healthcare facilities across 14 states throughout Germany at which Asklepios operates. This includes Asklepios Klinik St. Georg in Hamburg, Germany, which pioneered the use of CytoSorb to remove antithrombotic drugs during cardiothoracic surgery, and is well-known for their seminal publication on CytoSorb use for this application during emergency cardiac surgery in patients at high risk of bleeding.

In June 2022, the Company announced that, following a successful pilot program in three countries, the Company signed an expanded non-exclusive agreement with Nikkiso Europe GmbH ("Nikkiso") to distribute Nikkiso's PureADJUST stand-alone hemoperfusion pump and accessories in a total of 14 countries. In addition to securing the rights to sell Nikkiso's stand-alone pump and accessories in Germany, Austria, and Luxembourg, the Company entered into an expanded multi-country reseller agreement with Nikkiso covering the following countries: Belgium, Bosnia and Herzegovina, Croatia, Finland, France, Iceland, Lichtenstein, Poland, Serbia, Slovenia and Switzerland. The Company will also be able to provide field support services in these countries.

In August 2022, the Company entered into a Marketing Agreement (the "Marketing Agreement") with Fresenius Medical Care Deutschland GmbH ("Fresenius"), which expands the Company's strategic partnership with Fresenius by establishing a multi-stage global collaboration to combat life-threatening diseases in critical care. The Marketing Agreement provides for the combined marketing and promotion of CytoSorb with Fresenius' critical care products by Fresenius' marketing organization worldwide, excluding the United States. The Marketing Agreement has an initial term of three years, with an automatic renewal for an additional two years at the end of such initial term, subject to earlier termination by either of the parties (the "Term"). Compared to the prior co-marketing agreement between the parties, the Marketing Agreement intends to increase the commitments from both parties and to ensure an ongoing and consistent level of marketing and promotional activity specifically focused around CytoSorb, where Fresenius will actively market and promote CytoSorb as the featured blood purification therapy for removal of cytokines, bilirubin, and myoglobin on its critical care platforms. Specifically, the Marketing Agreement provides that various Fresenius-led in-person, virtual, social media, and web-based marketing programs and events will feature the CytoSorb therapy and highlight the cooperation between the two companies in the field of critical care during the Term. In addition to strengthening and expanding the global marketing of CytoSorb, the Company and Fresenius also plan to work together to bring new innovative solutions to the market. The Marketing Agreement also includes the certification of compatibility of CytoSorb for usage on Fresenius' current critical care platforms.

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 21 issued U.S. patents and multiple international patents, with applications pending both in the U.S. and internationally, including HemoDefend, ContrastSorb, DrugSorb, DrugSorb-ATR and others.

These patents and patent applications are directed to various compositions and methods of use related to the Company's blood purification technologies and are expected to expire between 2022 and 2038, absent any patent term extensions. Management believes that any near-term expiring patents will not have a significant impact on the Company's 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, CytoSorbents Poland Sp. z.o.o. and CytoSorbents Medical UK Limited, wholly owned subsidiaries of CytoSorbents Europe GmbH, and CytoSorbents UK Limited, a wholly-owned subsidiary of CytoSorbents Medical, Inc. 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 the European subsidiary are included in operations. The Euro is the functional currency of CytoSorbents Europe GmbH. Foreign currency transaction loss included in net loss amounted to approximately $3,230,000 and $1,013,000 for the three months ended September 30, 2022 and 2021, respectively. Foreign currency transaction loss included in net loss amounted to approximately $6,967,000 and $2,084,000 for the nine months ended September 30, 2022 and 2021, respectively. The Company translates assets and liabilities of its foreign subsidiaries at the exchange rate in effect at the consolidated balance sheet date. The Company translates revenue and expenses at the daily average exchange rates during the period. The Company includes accumulated net translation adjustments in accumulated other comprehensive income as a component of stockholders' equity.

Cash, Cash Equivalents and Restricted Cash

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

The following table provides a reconciliation of cash and cash equivalents and restricted cash to amounts shown in the consolidated balance sheets:

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 22,552,239	$ 52,137,707
Restricted cash	1,687,459	1,687,459
Total cash, cash equivalents and restricted cash	$ 24,239,698	$ 53,825,166

Restricted Cash

The Company's total restricted cash in the amount of $1,687,459 consists of cash of $1,467,459 that the Company is obligated to maintain as collateral for the outstanding letter of credit with Bridge Bank that was provided to the landlord of the College Road facility as security and cash of $220,000 that the Company is obligated to maintain as collateral for the credit limit on the Company's credit card accounts.

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 amounted to approximately $67,000 and $61,000 at September 30, 2022 and December 31, 2021, respectively.

Inventories

Inventories are valued at the lower of cost or net realizable value under the first in, first out (FIFO) method. As of September 30, 2022 and December 31, 2021, the Company's inventory was comprised of finished goods, which amounted to $2,075,570 and $3,084,606, respectively; work in process which amounted to $818,909 and $1,322,736, respectively; and raw materials, which amounted to $647,117 and $358,756, 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. Donated devices are removed from inventory and charged to selling, general and administrative expenses.

In September 2022, the Company experienced an equipment failure of a refrigeration unit at its new College Road manufacturing facility. This equipment stored various items of work-in-process inventory. The Company determined all the items that were stored in this unit were required to be scrapped. The value of this inventory was approximately $599,000. Accordingly, this inventory was written-off and is included in cost of goods sold in the accompanying consolidated statements of operations and comprehensive loss in the three and nine months ended September 30, 2022. The Company has filed a claim with its insurance carrier related to this loss. The claim is currently under review by the insurance company. The claim has not yet been approved nor has a reimbursement amount been determined. Accordingly, in the third quarter of 2022, the Company has not recorded any provision for insurance reimbursement. The Company expects to record the insurance reimbursement at the time that the amount to be reimbursed is determined and approved by the insurance carrier.

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. There were no charges for impairments during the three months ended September 30, 2022. During the nine months ended September 30, 2022, the Company recorded an impairment charge of approximately $431,000 related to certain patent costs. There were no impairment charges during either of the three and nine months ended September 30, 2021. This charge is included in legal, financial and other consulting in the consolidated statements of operations and comprehensive loss.

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 Revenue: 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. Amounts invoiced in excess of costs actually incurred on fixed price contracts are classified as deferred revenue and are included in accrued expenses and other current liabilities in the consolidated balance sheet. Costs subject to reimbursement by these grants have been reflected as costs of revenue.

Research and Development and Clinical Trial Expenses

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

Advertising Expenses

Advertising expenses are included in selling, general, and administrative expenses on the consolidated statements of operations and comprehensive loss when incurred. Advertising expenses amounted to approximately $143,000 and $151,000 for the three months ended September 30, 2022 and 2021, respectively, and approximately $358,000 and $455,000 for the nine months ended September 30, 2022 and 2021, respectively.

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 September 30, 2022 or December 31, 2021. 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 carryforwards to an industrial company.

Each of CytoSorbents Europe GmbH, CytoSorbents Switzerland GmbH, CytoSorbents Poland Sp. Z.o.o. CytoSorbents Medical Limited and CytoSorbents UK Limited files 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 the Company's revenues are from product sales in Germany. Substantially all of the Company's grant income is from government agencies in the United States. (See Note 4 for further information relating to the Company's revenue.)

As of September 30, 2022, two distributors accounted for approximately 39% of outstanding grants and accounts receivable. As of December 31, 2021, one distributor accounted for approximately 12% of outstanding grants and accounts receivables. For the three

months ended September 30, 2022, one distributor accounted for approximately 16% of the Company's total revenue and for the nine months ended September 30, 2022, no distributor or direct customer accounted for more than 10% of total revenue. For the three and nine months ended September 30, 2021, no distributor or direct customer accounted for more than 10% of the Company's total revenue.

Financial Instruments

The carrying values of cash and cash equivalents, grants and accounts receivable, accounts payable and accrued expenses and other current liabilities approximate their fair values due to their short-term nature.

Net Loss Per Common Share

Basic loss per share is computed by dividing loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted loss per common share is computed using the treasury stock method utilizing 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 stock options and restricted shares. The computation of diluted loss 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 $79,000 and $56,000, respectively, for the three months ended September 30, 2022 and 2021, and $166,000 and $196,000, respectively, for the nine months ended September 30, 2022 and 2021.

Effect of Recent Accounting Pronouncements

In November 2021, the Financial Accounting Standards Board (the "FASB"), issued Accounting Standards Update ("ASU") 2021-10, "Government Assistance (Topic 832), Disclosures by Business Entities about Government Assistance". ASU 2021-10 will require enhanced disclosures related to the Company's contracts with the U.S. Government. ASU 2021-10 is effective for annual periods beginning after December 15, 2021. The Company intends to implement the provisions of ASU 2021-10 during 2022 and does not believe this ASU will have a material impact on the Company's financial statements.

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 14, 2021, the Company filed a registration statement on Form S-3 with the SEC, which was amended on July 20, 2021 and declared effective by the SEC on July 27, 2021 (as amended, the "2021 Shelf"). The 2021 Shelf 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.

Open Market Sale Agreement with Jefferies LLC

On December 30, 2021, the Company entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC (the "Agent"), 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 million through the Agent, as the Company's sales agent. All shares of the Company's common stock offered and sold, or to be offered and sold under the Sale Agreement will be issued and sold pursuant to the Company's 2021 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.

Subject to the terms of the Sales Agreement, the Agent is required to use its 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 Agent 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. There have been no sales under the Sale Agreement. In addition, during the year ended December 31, 2021 and during the nine months ended September 30, 2022, the Company paid approximately $90,000 and $40,000, respectively, in expenses related to the Sale Agreement.

Stock-Based Compensation

Total share-based employee, director, and consultant compensation amounted to approximately $1,005,000 and $2,554,000 for the three and nine months ended September 30, 2022, respectively, and $999,000 and $3,224,000 for the three and nine months ended September 30, 2021, respectively. These amounts are included in the consolidated statements of operations and comprehensive loss under selling, general and administrative expenses.

The summary of the stock option activity for the nine months ended September 30, 2022 is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (Years)
Outstanding, December 31, 2021	6,885,978	$ 7.09	7.15
Granted	2,674,055	$ 2.00	—
Forfeited	(1,221,475)	$ 8.77	—
Expired	(162,668)	$ 8.14	—
Exercised	—	$ —	—
Outstanding, September 30, 2022	8,175,890	$ 5.15	7.17

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 $1.39 to $3.91 per share) and expected life of the stock option (10 years), the current price of the underlying stock and its expected volatility (64.7%), expected dividends (0%) on the stock and the risk free interest rate (ranging from 1.52% to 3.91%) for the expected term of the stock option.

The intrinsic value is calculated as the difference between the market value of the shares as of September 30, 2022 of $1.36 and the exercise price of the shares.

Options Outstanding				
Range of Exercise Price	Number Outstanding at September 30, 2022	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
$1.39 - $13.20	8,175,890	$ 5.15	7.17	$ —

Options Exercisable		
Number Exercisable at September 30, 2022	Weighted Average Exercise Price	Aggregate Intrinsic Value
4,611,352	$ 6.36	$ —

The summary of the status of the Company's non-vested options for the nine months ended September 30, 2022 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, December 31, 2021	2,994,846	$ 4.68
Granted	2,674,055	$ 1.21
Forfeited	(1,221,475)	$ 8.77
Vested	(882,888)	$ 3.74
Non-vested, September 30, 2022	3,564,538	$ 2.13

As of September 30, 2022, the Company had approximately $5,471,000 of total unrecognized compensation cost related to stock options which will be amortized over approximately 46 months.

Awards of Stock Options:

On August 10, 2022, the Board of Directors granted options to purchase 1,163,800 shares of common stock to the Company's employees which will be awarded based upon each employee's 2022 individual performance evaluation. Once awarded, these options will vest one quarter on February 15, 2023, one quarter on February 15, 2024, one quarter on February 15, 2025 and one quarter on February 15, 2026. The grant date fair value of these unvested options amounted to approximately $1,381,000. During the three and nine months ended September 30, 2022, the Company recorded approximately $65,000 of stock option expense related to these options.

On August 10, 2022, the Board of Directors granted options to purchase 772,905 shares of common stock to the Company's employees. These options will vest one eighth on the six-month anniversary of the grant date, one eighth on the first anniversary of the grant date, one quarter on second anniversary of the grant date, one quarter on third anniversary of the grant date and one quarter on fourth anniversary of the grant date. The grant date fair value of these unvested options amounted to approximately $917,000. During the three and nine months ended September 30, 2022, the Company recorded approximately $32,000 of stock option expense related to these options.

On August 10, 2022, the Board of Directors granted options to purchase 113,850 shares of common stock to members of the Company's Board of Directors. These options will vest one quarter on the grant date, one quarter on September 30, 2022, one quarter on 12/31/2022, and one quarter on 3/31/2023. The grant date fair value of these unvested options amounted to approximately $135,000. During the three and nine months ended September 30, 2022, the Company recorded approximately $68,000 of stock option expense related to these options.

On August 10, 2022, the Board of Directors granted options to purchase 1,163,800 shares of common stock to certain senior managers of the Company. These options will vest one quarter on the grant date, one quarter on the first anniversary of the grant date, one quarter on second anniversary of the grant date, one quarter on third anniversary of the grant date. The grant date fair value of these unvested

options amounted to approximately $562,000. During the three and nine months ended September 30, 2022, the Company recorded approximately $132,000 of stock option expense related to these options.

On August 10, 2022, the Board of Directors granted options to purchase 1,365,000 shares of common stock to certain senior managers of the Company which will only vest upon the achievement of certain specific, predetermined milestones related to the Company's long-term performance goals. The grant date fair value of these unvested options amounted to approximately $1,620,000. As of September 30, 2022, none of these milestones has been met. Accordingly, no charge for these options has been recorded in the consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2022.

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 employees of the Company. These restricted stock units will only vest upon a Change in Control of the Company, as defined in the Amended and Restated CytoSorbents Corporation 2014 Long-Term Incentive Plan.

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

	Restricted Stock Units				
	Board of Directors	Executive Management	Other Employees	Total	Intrinsic Value
December 31, 2021	277,200	724,500	1,709,500	2,711,200	$ 11,359,928
Granted	69,300	55,000	339,250	463,550	
Forfeited	—	—	(235,750)	(235,750)	
September 30, 2022	346,500	779,500	1,813,000	2,939,000	$ 3,997,040

Due to the uncertainty over whether these restricted stock units will vest, which only happens 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 nine months ended September 30, 2022 and 2021.

Other Awards of Restricted Stock Units:

On March 4, 2019, certain named executive officers and senior managers were granted 22,220 restricted stock units. 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 vested 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 nine months ended September 30, 2022 and 2021, the Company recorded expense of approximately $0 and $0, and $0 and $12,000, respectively, related to these restricted stock unit awards.

On July 22, 2019, certain named executive officers and senior managers were granted 180,300 restricted stock units. 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 vested 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 nine months ended September 30, 2022 and 2021, the Company recorded expense of approximately $0 and $54,000, and $0 and $259,000, respectively, related to these restricted stock unit awards.

On February 28, 2020, certain named executive officers and senior managers were granted 168,100 restricted stock units. 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 vested 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 nine months ended September 30, 2022 and 2021, the Company recorded (income) expense of approximately $0 and $84,000, and $(65,000) and $443,000, related to these restricted stock unit awards, respectively.

On April 12, 2021, certain named executive officers and senior managers were granted 235,765 restricted stock units. These awards were valued at approximately $2,220,000 at the date of issuance, based upon the market price of the Company's common stock at the date of the grant, and vested (or will 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 nine months ended September 30, 2022 and 2021, the

Company recorded expense of approximately $177,000 and $177,000, and $50,000 and $1,030,000, respectively, related to these restricted stock unit awards.

On August 10, 2022, certain named executive officers and senior managers were granted 288,500 restricted stock units. These awards were valued at approximately $563,000 at the date of issuance, based upon the market price of the Company's common stock at the date of the grant, and vested (or will 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 nine months ended September 30, 2022 and 2021, the Company recorded expense of approximately $214,000 and $0, and $214,000 and $0, respectively, related to these restricted stock unit awards.

Additionally, in 2021 and 2020 certain employees were offered 91,750 restricted stock units as a condition of their employment. These awards were valued at approximately $713,868 at the date of issuance. 45,000 of the restricted stock units were forfeited in 2022. 16,750 of these restricted stock units vest upon the earlier of a Change in Control or one-third after the second anniversary of the award, one-third on the third anniversary of the award, and one-third on the fourth anniversary of the award. The other 30,000 of these restricted stock units vest upon the earlier of a Change in Control or four years from the date of the award. For the three and nine months ended September 30, 2022 and 2021, the Company recorded (income) expense of approximately $0 and $45,000, and $(34,000) and $131,000, respectively, related to these restricted stock unit awards.

The following table outlines the restricted stock unit activity for the nine months ended September 30, 2022:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, December 31, 2021	304,962	$ 8.08
Granted	288,500	$ 1.95
Vested	(235,120)	$ 5.38
Forfeited	(45,000)	$ 8.35
Non-vested, September 30, 2022	313,342	$ 4.42

4. REVENUE

The following table disaggregates the Company's revenue by customer type and geographic area for the three months ended September 30, 2022:

	Direct	Distributors/ Strategic Partners	United States Government Agencies	Total
Product sales:				
United States	$ 191,468	$ 9,000	$ —	$ 200,468
Germany	2,493,044	—	—	2,493,044
All other countries	978,805	2,790,379	—	3,769,184
Total product revenue	3,663,317	2,799,379	—	6,462,696
Grant and other income:				
United States	—	—	1,648,657	1,648,657
Total revenue	$ 3,663,317	$ 2,799,379	$ 1,648,657	$ 8,111,353

The following table disaggregates the Company's revenue by customer type and geographic area for the three months ended September 30, 2021:

	Direct	Distributors/ Strategic Partners	United States Government Agencies	Total
Product sales:				
United States	$ 9,197	$ 568,250	$ —	$ 577,447
Germany	3,662,409	—	—	3,662,409
All other countries	1,398,786	3,263,244	—	4,662,030
Total product revenue	5,070,392	3,831,494	—	8,901,886
Grant and other income:				
United States	—	—	858,530	858,530
Total revenue	$ 5,070,392	$ 3,831,494	$ 858,530	$ 9,760,416

The following table disaggregates the Company's revenue by customer type and geographic area for the nine months ended September 30, 2022:

	Direct	Distributors/ Strategic Partners	United States Government Agencies	Total
Product sales:				
United States	$ 541,695	$ 181,750	$ —	$ 723,445
Germany	9,259,338	—	—	9,259,338
All other countries	3,245,637	8,489,468	—	11,735,105
Total product revenue	13,046,670	8,671,218	—	21,717,888
Grant and other income:				
United States	—	—	3,580,447	3,580,447
Total revenue	$ 13,046,670	$ 8,671,218	$ 3,580,447	$ 25,298,335

The following table disaggregates the Company's revenue by customer type and geographic area for the nine months ended September 30, 2021:

	Direct	Distributors/ Strategic Partners	United States Government Agencies	Total
Product sales:				
United States	$ 39,678	$ 1,203,450	$ —	$ 1,243,128
Germany	15,678,750	—	—	15,678,750
All other countries	4,114,126	9,374,688	—	13,488,814
Total product revenue	19,832,554	10,578,138	—	30,410,692
Grant and other income:				
United States	—	—	1,972,640	1,972,640
Total revenue	$ 19,832,554	$ 10,578,138	$ 1,972,640	$ 32,383,332

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. The majority of sales of the device are outside the United States, as CytoSorb is not yet approved for commercial sale in the United States. However, in April 2020, the Company was granted U.S. FDA Emergency Use Authorization (EUA) of CytoSorb for use in critically-ill patients infected with COVID-19 with imminent or confirmed respiratory failure by FDA. Direct sales outside the United States relate to sales to hospitals located in Germany, Switzerland, Austria, Belgium, Luxembourg, Poland, the Netherlands, Sweden, Denmark, Norway and the United Kingdom. Direct sales are fulfilled from the Company's warehouse facility in Berlin, Germany. 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 versus 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. Certain distributors are eligible for volume discount pricing if their unit sales are in excess of the base amount in the contract.

Most distributor's/strategic partner's contracts have minimum annual purchase requirements in order to maintain exclusivity in their respective territories.

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. If billings on fixed price contracts exceed the costs incurred, revenue will be deferred to the extent of the excess billings.

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 upon 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:

	September 30, 2022	December 31, 2021
Receivables, which are included in grants and accounts receivable	$ 4,217,149	$ 3,000,708
Contract liabilities, which are included in accrued expenses and other current liabilities	$ 1,722,546	$ 2,251,177

Contract receivables represent balances due from sales to distributors and amounts invoiced on grant contracts.

Contract liabilities represent the value of free of charge goods and credit rebates earned in accordance with the terms of certain direct customer agreements, which amounted to $78,466 and $303,824 as of September 30, 2022 and December 31, 2021, respectively, and deferred grant revenue related to the billing on fixed price contracts in excess of costs incurred , which amounted to $1,644,080 and $1,947,353 at September 30, 2022 and December 31, 2021, respectively.

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 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 may be 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 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 million 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. On December 4, 2020 (the "Third Amendment Closing Date"), the Company closed on the Third Amendment (the "Third Amendment") of its Amended Loan and Security Agreement with Bridge Bank. Under the terms of the Amendment, the Company repaid the outstanding principal balance of its existing $15 million term loans and simultaneously received a commitment from Bridge Bank to provide a new term loan of $15 million, if needed. On January 19, 2022 (the "Fourth Amendment Closing Date"), the Company closed on the Fourth Amendment (the "Fourth Amendment") of its Amended Loan and Security Agreement with Bridge Bank. Under the terms of the Amendment, the Company received a commitment from Bridge Bank to provide a new term loan of up to $15 million, if needed and entered into the Fourth Amendment Success Fee Letter (the "2022 Success Fee Letter").

The Fourth Amendment provides a tranche of term loans (the "Term C Loans") in the aggregate amount of $15 million, which are available for the Company to draw down at its sole discretion in three tranches of $5 million each at any time during the period commencing on the Fourth Amendment Date and ending on the earlier of (i) December 31, 2022 and (ii) the occurrence of an Event of Default (as defined in the Amended Loan and Security Agreement). The Term C Loans, if taken, shall bear interest at the Index Rate (defined in the Amendment as the greater of 3.25% or the Prime Rate as published by the Wall Street Journal on the last business date of the month immediately preceding the month in which the interest will accrue) plus 1.25%. Pursuant to the Fourth Amendment, interest on the Term C Loans is subject to an interest rate cap of 8.00%. The Fourth Amendment, together with the Amended Loan and Security Agreement, provides for a period of interest only payments on the Term C Loans until the amortization date, which is January 1, 2024. The interest-only period may be further extended through July 2024 if the Company maintains compliance with certain conditions as outlined in the Fourth Amendment. Following the interest-only period, the Company will be required to make equal monthly payments of principal and interest until maturity of the Term C Loans. The maturity date of the Term C Loans is December 1, 2025.

On the Fourth Amendment Closing Date, the Company was required to pay a non-refundable closing fee of approximately $18,750, which will amortized as a monthly charge to interest expense. On the Third Amendment Closing Date, the Company paid a non-refundable closing fee of $75,000, which was amortized and written off as a charge to interest expense. 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 the Term Loan funded upon the earlier of the (i) the maturity date or (ii) termination of the Term Loans via acceleration or prepayment.

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. This obligation shall terminate on the fifth anniversary of the funding of the Term B Loan and shall survive the termination of the loan agreement and the prepayment of the Term B Loan.

2022 Success Fee Letter:

Pursuant to the 2022 Success Fee Letter, the Borrower will pay to the Bank a success fee equal to (i) 1% of $5 million if the Company draws down the first tranche of the Term C Loan and is payable only if the Company's stock price equals or exceeds $8 for five consecutive trading days; (ii) 1.5% of $5 million if the Company draws down the second tranche of the Term C Loan and is payable only if the Company's stock price equals or exceeds $10 for five consecutive trading days; and (iii) 2% of $5,000,000 if the Company draws down the third tranche of the Term C Loan and is payable only if the Company's stock price equals or exceeds $12 for five consecutive trading days (together, the "Success Fee"). Borrower may pay the Success Fee in cash or in shares of common stock, at Borrower's sole discretion. The right of Bank to receive the success fees and the obligation of the Borrower to pay the success fees hereunder shall terminate on the date that is fifth anniversary of the funding date of the last Term C Loans made but shall survive the termination of the Loan Agreement and any prepayment of the Term C Loans.

6. COMMITMENTS AND CONTINGENCIES

Payroll Tax Examination

In December 2021, the Company was notified that its European subsidiary, CytoSorbents Europe GmbH, would be subject to an audit of their payroll tax and social cost filings for the four-year period from 2018 through 2021. The Company has determined that payroll taxes and social costs were not paid on certain employee expense reimbursements as is required by German tax rules. Accordingly, the Company has accrued approximately $598,000 as an estimate of this liability. This liability is included in accrued expenses and other current liabilities in the consolidated balance sheets as of December 31, 2021 and September 30, 2022. Approximately $154,000 of this liability relates to 2021, approximately $131,000 relates to 2020, approximately $175,000 relates to 2019 and approximately $138,000 relates to 2018. The audit is on-going and is expected to be completed in 2022, subject to the availability of the German tax authorities.

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 expired 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. In January 2022, these employment agreements automatically renewed for an additional 1 year. 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.

On September 30, 2022, Ms. Bloch notified the Company of her intention to retire effective March 31, 2023. A search has been initiated for Ms. Bloch's replacement. Ms. Bloch and the Company expect to enter into a consulting arrangement under which Ms. Bloch will continue to provide services to the Company in a limited capacity following the effective date of her retirement.

Litigation

The Company is, from time to time, subject to claims and litigation arising in 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 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 perpetual royalty of 3% on all gross revenues received by the Company from the sale of its CytoSorb device which such rights were assigned to an existing investor in 2017. For the three months ended September 30, 2022 and 2021, the Company recorded royalty expenses of approximately $187,000 and $265,000, respectively. For the nine months ended September 30, 2022 and 2021, the Company recorded royalty expenses of approximately $627,000 and $904,000, respectively. These expenses are included in selling, general and administrative expenses in the consolidated statements of operations and comprehensive loss.

On August 1, 2022, the Company entered into the Marketing Agreement with Fresenius, which expands the Company's strategic partnership with Fresenius by establishing a multi-stage global collaboration to combat life-threatening diseases in critical care. The Marketing Agreement has an initial term of three years, with an automatic renewal for an additional two years at the end of such initial term, subject to earlier termination by either of the parties (the "Term") To help support the increased marketing and promotional efforts of the expanded collaboration, the Company has agreed to subsidize a portion of the marketing costs through royalty payments to Fresenius. Initially, the Marketing Agreement provides for royalty payments equal to 0.9% of the Company's net sales of CytoSorb products made during the Term (excluding net sales in the United States). This initial royalty rate was determined based on certain assumptions regarding the percentage of the Company's sale of CytoSorb products that are used with the Fresenius critical care platforms in the intensive care unit outside of the United States but is subject to adjustment if the Company determines that the underlying assumptions have changed significantly. For the three and nine months ended September 30, 2022, the Company recorded royalty expenses of approximately $48,000. This expense is included in selling, general and administrative expenses in the consolidated statements of operations and comprehensive loss.

License Agreement

In an agreement dated September 1, 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 license fees 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 September 30, 2022 and 2021 pursuant to the terms of the license agreement, the Company recorded licensing expenses of

approximately $312,000 and $441,000, respectively. For the nine months ended September 30, 2022 and 2021, pursuant to the terms of the license agreement, the Company recorded licensing expenses of approximately $1,046,000 and $1,507,000, respectively. These expenses are included in selling, general and administrative expenses in the consolidated statements of operations and comprehensive loss.

7. LEASES

The Company leases its operating facilities in both the United States and Germany under operating lease agreements. In March 2021, CytoSorbents Medical Inc. entered into a lease agreement for a new operating facility at 305 College Road East, Princeton, New Jersey, which contains office, laboratory, manufacturing and warehouse space. The lease commenced on June 1, 2021. The Early Term commenced on June 1, 2021 and lasted until September 30, 2021. The lease also contains two five-year renewal options; however, the Company has determined that it is not likely that they will exercise these options. Commencing on September 30, 2021, the remaining lease term will last for 15.5 years. The lease requires monthly rental payments of $25,208 for the Initial Early Term, $88,254 for the Early Term and initial monthly payments of approximately $111,171 in the first year of the remaining term. Following the first year of the remaining term, the annual base rent will increase by approximately 2.75% annually over the remaining term. The lease also contains six months of rent abatement (months 1, 2, 3, 25, 26 and 27 of the remaining lease term). In addition to the base rent, payments of operating expenses and real estate taxes will be required. These payments are to be based on actual amounts incurred during 2021 multiplied by the Company's share of the total building space (92.3%). The landlord will also provide an allowance of approximately $1,455,000 related to certain building improvements as outlined in the lease. In April 2021, the Company provided the landlord with a letter of credit in the amount of approximately $1,334,000 as security. The Company has determined that this lease should be treated as an operating lease in accordance with the provisions of Accounting Standards Codification ("ASC") 842. On April 1, 2021, the Company recorded a Right of Use asset and related lease liability of approximately $11.6 million, which represents the estimated present value of the lease payments at the commencement date discounted at the Company's incremental borrowing rate of 9.8%. In addition, due to the six months of rent abatement and annual base rent escalations during the remaining lease term that commenced on September 30, 2021, the Company will recognize rent expense on this lease on a straight-line basis over the remaining term of the lease for the difference between the rent expense recognized and the required payments under the lease.

In April 2021, the Company entered into a Twentieth Amendment to Lease with the landlord at the existing Monmouth Junction facility which became effective May 31, 2021. This amendment extends the term of the lease for the Company's existing facility to May 31, 2022. The Company's base rent is approximately $35,000 per month. In addition, the Company is obligated to pay monthly operating expenses of approximately $30,000 per month. Under the terms of this amendment, the Company vacated a portion of the space as of May 31, 2022. The Company will continue to lease the remaining space until December 31, 2022, at which time the Company will vacate the remaining space and the lease will terminate. The Company's base rent for the remaining space will be approximately $20,000 per month. Monthly operating expenses will be approximately $11,000 per month. In addition, the Company agreed to increase its security deposit by approximately $54,000 to a total of $150,000. At the end of the lease term, the entire security deposit will be paid to the landlord for the purpose of making any needed repairs to the vacated premises, and the Company will have no further obligation to pay for repairs to the vacated premises. Effective April 1, 2021, the Company adjusted its incremental borrowing rate to the incremental borrowing rate used in the College Road lease and recalculated the right of use asset and lease liability under the amended terms of this lease. In addition, the Company also adjusted the incremental borrowing rate and related right of use asset and lease liability on the existing Germany office lease effective April 1, 2021.

In September 2021, the Company extended its two operating leases for its office facility in Germany. These leases require combined base rent payments amounting to approximately $12,100 per month. The initial lease term of both leases ends August 31, 2026. In addition, the Company is obligated to monthly operating expenses of approximately $3,000 per month. Both leases have a five-year option to renew that would extend the lease term to August 31, 2031. 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.

In January 2021, CytoSorbents Europe GmbH entered into a lease for 1,068 square meters of additional warehouse space. The lease commenced on April 1, 2021 and requires monthly payments of base rent of $7,784 and other costs of approximately $239 per month and has a term of five years. The lease also has an option to extend the lease term for an additional five-year period through March 31, 2031. The Company has determined that this lease should be treated as an operating lease in accordance with the provisions of ASC 842. On April 1, 2021, the Company recorded a Right of Use asset and related lease liability at the estimated present value of the lease payments at the commencement date of approximately $594,000.

Right-Of-Use Asset and Lease Liability:

The Company's consolidated balance sheets reflect 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 9.8%, 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:

	September 30, 2022	December 31, 2021
Right-of-use asset	$ 12,794,340	$ 13,423,472
Total lease liability	$ 13,385,942	$ 13,821,509
Less current portion	(376,529)	(570,566)
Lease liability, net of current portion	$ 13,009,413	$ 13,250,943

The maturities of the lease liabilities are as follows during the years ended September 30th:

2022	$ 1,668,230
2023	1,294,887
2024	1,685,727
2025	1,725,524
2026	1,766,416
Thereafter	17,684,408
Total lease payments	25,825,192
Present value discount	(12,439,250)
Total	$ 13,385,942

For the three months ended September 30, 2022 and 2021, operating cash flows paid in connection with operating leases amounted to approximately $659,000 and $593,000, and $2,057,000 and $1,248,000 for the nine months ended September 30, 2022 and 2021, respectively.

As of September 30, 2022 and December 31, 2021, the weighted average remaining lease term was 12.8 years and 14.3 years, respectively.

8. NET LOSS PER SHARE

Basic loss per share and diluted loss per share for the three months ended September 30, 2022 and 2021 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 options and restricted stock awards representing approximately 11,428,000 and 9,891,000 incremental shares at September 30, 2022 and 2021, respectively, have been excluded from the computation of diluted loss per share as they are anti-dilutive.

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 our expectations of the effects of the COVID-19 pandemic 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 any risks reported in our Quarterly Reports on Form 10-Q 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 consolidated financial statements, including the notes contained elsewhere in this Quarterly Report on Form 10-Q, and the consolidated financial statements, including the notes thereto, contained in our Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on March 10, 2022.

We are a leader in the treatment of life-threatening conditions in the intensive care ("ICU") and cardiac surgery using blood purification via our proprietary polymer adsorption technology. We have a number of products commercialized and in development based on this technology platform. Our flagship product, CytoSorb®, is already commercialized, and is being used to reduce deadly uncontrolled inflammation and dangerous substances in hospitalized patients around the world, with the goal of preventing or treating multiple organ failure, bleeding, and other potentially fatal complications. Organ failure is the cause of nearly half of all deaths in the ICU, with little to improve clinical outcome. CytoSorb, is approved in the European Union ("EU") as an effective extracorporeal cytokine absorber, designed to reduce the "cytokine storm" or "cytokine release syndrome" that could otherwise cause massive inflammation, organ failure and death in common critical illnesses such as sepsis, burn injury, trauma, lung injury, liver failure, cytokine release syndrome due to cancer immunotherapy, and pancreatitis. These are conditions where the mortality is extremely high, yet few to 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. In January 2020, we received CE-Mark label expansion for CytoSorb covering the use of the device for the removal of the anti-platelet agent, ticagrelor, in patients undergoing surgery requiring cardiopulmonary bypass. In April 2020, the United States Food and Drug Administration (the "FDA") granted CytoSorbents' technology Breakthrough Device Designation for the removal of ticagrelor in a cardiopulmonary bypass circuit during emergent and urgent cardiothoracic surgery. If FDA marketing approval for this indication is obtained, the device would be marketed as DrugSorb-ATR in the United States. The DrugSorb-ATR Antithrombotic Removal System is based on the same polymer technology as CytoSorb. In April 2020, we announced that the U.S. FDA has granted U.S. Emergency Use Authorization ("EUA") of CytoSorb for use in critically ill patients with COVID-19 infection and respiratory failure. In May 2020, we received a CE-Mark label expansion for CytoSorb for the removal of rivaroxaban during cardiothoracic surgery requiring cardiopulmonary bypass. In August 2021, the Company announced that it was granted a second Breakthrough Device Designation for its DrugSorb-ATR Antithrombotic Removal System by the FDA to remove the direct oral anticoagulants, rivaroxaban and apixaban. The Company has initiated two U.S. clinical trials evaluating the use of DrugSorb-ATR during cardiothoracic surgery to remove ticagrelor, apixaban and rivaroxaban to prevent or reduce perioperative bleeding complications in pursuit of U.S. FDA marketing approval. In October 2022, we announced the release of new cardiac surgery data at the European Association for Cardio-Thoracic Surgery (EACTS) highlighting the benefit of CytoSorb when used intraoperatively during cardiothoracic surgery in Staphylococcus aureus infective endocarditis, heart transplantation, and to remove antithrombotic agents.

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, and shock. 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 186,000 human treatments to date in critical illnesses and in cardiac surgery. CytoSorb has received CE-Mark label expansions for the removal of bilirubin (liver disease), myoglobin (trauma) and both ticagrelor and rivaroxaban during cardiothoracic surgery. CytoSorb has also received FDA Emergency Use Authorization in the United States for use in critically ill COVID-19 patients with imminent or confirmed respiratory failure, in defined circumstances. The EUA will be effective until a declaration is made that the circumstances justifying the EUA have terminated or until revoked by the FDA. CytoSorb has been used globally in more than 7,650 human treatments to date in COVID-19 patients.

We are focusing on four key objectives that we believe are the key to driving sustainable, long-term growth:

- Open the U.S. market by obtaining FDA Marketing approval for DrugSorb™-ATR to remove blood thinning drugs during cardiothoracic surgery (see clinical studies update)
- Grow core CytoSorb sales to profitability, driven by numerous internal initiatives (see sales and marketing update)
- Transition CytoSorb production to our new manufacturing facility and headquarters in Princeton, New Jersey this year
- Forge and expand new and existing strategic partnerships to maximize the synergy between our technology and those of our partners, while creating new global opportunities for growth

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 21 issued U.S. patents and multiple international patents, with applications pending both in the U.S. and internationally. We have numerous other product candidates under development based upon this unique blood purification technology, including CytoSorb XL, K^+ontrol, HemoDefend-RBC, HemoDefend-BGA, ContrastSorb, DrugSorb, DrugSorb-ATR and others.

Our proprietary polymer technologies form the basis of a broad technology portfolio. Some of our products and product candidates 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.
- DrugSorb-ATR — an investigational extracorporeal antithrombotic removal system based on the same polymer technology as CytoSorb that is being evaluated in the U.S. STAR-T and STAR-D pivotal randomized, controlled trials to reduce the level of antithrombotic drugs, ticagrelor, apixaban and rivaroxaban to reduce bleeding complications in patients undergoing cardiothoracic surgery while on these drugs.
- ECOS-300CY — an adsorption cartridge approved in the E.U. for use with *ex vivo* organ perfusion systems to remove cytokines and other inflammatory mediators in the organ perfusate, with the goal of maintaining or improving solid organ function. prior to transplant. In 2021, commercialization of PerSorb™ and Aferetica's PerLife™ *ex vivo* organ perfusion system commenced in Italy.
- 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 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.

- HemoDefend-BGA—a development-stage purification technology that can remove anti-A and anti-B antibodies from plasma and whole blood, to enable "universal plasma," and safer whole blood transfusions, respectively.

- 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 radiological imaging with contrast, or interventional radiology procedures such as cardiac catheterization and angioplasty. 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.

Clinical Studies Update

For a complete discussion regarding our clinical study history, please refer to the section entitled Clinical Studies included in Item 1 of the Company's Annual Report on Form 10-K for the year ended December 31, 2021 as filed with the SEC on March 10, 2022. The following includes certain updates regarding these clinical studies subsequent to the filing of the Company's Annual Report on Form 10-K:

In July 2021, we received full FDA approval of an Investigational Device Exemption (IDE) application to conduct a double-blind, randomized, controlled clinical study for up to 120 patients entitled, "**S**afe and **T**imely **A**ntithrombotic **R**emoval – **T**icagrelor (**STAR-T**)," in the United States to support FDA marketing approval. This was done under the previously announced FDA Breakthrough Device Designation granted for the removal of ticagrelor in a cardiopulmonary bypass circuit to reduce the likelihood of serious perioperative bleeding during urgent cardiac surgery. In October 2021, the first patient was enrolled, and the STAR-T study is now actively recruiting at multiple sites. Pending continuing uncertainty from the ongoing COVID-19 pandemic and widespread staffing shortages at participating institutions, the speed of enrollment remains uncertain, however, we anticipate that the study to reach its first scheduled milestone of 33% patient enrollment that will trigger the first Data Safety Monitoring Board (DSMB) meeting in the 4th quarter of 2022. We have also recently received FDA approval to expand the study to Canada and believe that this will further accelerate enrollment based on the very frequent use of ticagrelor there and the excellent track record of Canadian sites as top enrollers in cardiac surgery trials. Accordingly, we will be prioritizing our clinical resources to STAR-T with the intent of further accelerating trial enrollment to achieve a potential completion of enrollment of all 120 patients by Summer 2023.

In October 2021, we also received full FDA approval of an Investigational Device Exemption (IDE) application to conduct a double-blind, randomized, controlled clinical study for up to 120 patients entitled, "**S**afe and **T**imely **A**ntithrombotic **R**emoval – **D**irect Oral Anticoagulants (**STAR-D**)," in the United States to support FDA marketing approval. This was done under the previously announced 2nd FDA Breakthrough Device Designation granted for our DrugSorb-ATR Antithrombotic Removal System. This Breakthrough Device designation covers the removal of the Direct Oral Anticoagulants (DOACs) apixaban and rivaroxaban in a cardiopulmonary bypass circuit to reduce the likelihood of serious perioperative bleeding during urgent cardiac surgery. The first patient was enrolled in April 2022 and currently we have the majority of sites activated and recruiting. However, based on the prioritization of our resources to accelerate STAR-T enrollment, we are pausing the STAR-D study with the intent of resuming the study, either when STAR-T nears, or is at, completion or when we have the financial resources to do so. This will save an estimated $4 million in expenses in 2023.

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. The international **S**afe and **T**imely **A**ntithrombotic **R**emoval (**STAR**) **Registry** is designed to capture real world clinical and health economic outcomes with intraoperative antithrombotic drug removal. The Registry is actively enrolling patients in the U.K., Germany and Austria and has reached 100 patients enrolled to date. The Registry is planned to expand to additional EU countries with the intent of reporting results at international conferences and also submitting these results for publication on a rolling basis with initial data readouts starting in 2023.

In April 2020, we received U.S. FDA Emergency Use Authorization for the treatment of adult critically ill COVID-19 patients with confirmed or imminent respiratory failure. The **C**ytoSorb **T**herapy in **C**OVID-19 (**CTC**) **Registry** was launched to capture outcomes and device utilization patterns from multiple U.S. participating centers. Initial results on critically ill COVID-19 patients on extracorporeal membrane oxygenation (ECMO) treated with CytoSorb at participating U.S. centers showed high survival rates compared with the international benchmark Extracorporeal Life Support Organization (ELSO) Registry. The initial CTC results were presented at the International Symposium of Intensive Care Medicine conference in August 2021 in Brussels, Belgium, and published in the peer reviewed journal *Frontiers in Medicine*. The CTC has completed enrollment at 100 critically ill COVID-19 patients on ECMO and CytoSorb, and the final results have been presented at the European Society of Intensive Care Medicine conference in October 2022 confirming high survival and have also been submitted for publication.

The German **PROCYSS** multicenter, randomized controlled trial evaluating the ability of CytoSorb to restore hemodynamic stability in patients with refractory septic shock is now actively enrolling at multiple sites.

The German **Hep-On-Fire** study experienced significant operational delays and was stopped. We continue to assess options for a pilot study evaluating CytoSorb in patients suffering from acute liver failure due to alcoholic hepatitis and we will be providing further updates in the course of 2023. The international **COSMOS Registry** was designed to capture real world outcomes and device utilization patterns across multiple critical care indications including but not limited to sepsis, acute respiratory failure, postoperative vasoplegia, acute liver failure, and acute pancreatitis. The Registry has now begun patient enrollment at several centers in two countries, with the goal of being active at many more centers in 2023. The intent of the Registry is to report outcomes at international conferences and submit the results for publication on a rolling basis as enrollment progresses.

Sales and Marketing Update

The following are the key initiatives that we have been executing upon to drive product sales growth in the future.

Near-term growth drivers

- *Focus on STAR-T*: We are focusing our internal resources on our lead program, the STAR-T clinical trial. We expect to have 40 patients enrolled in November 2022. Should the pace of the study continue, we expect to achieve the second millstone of 80 patients enrolled this spring 2023, which would trigger a formal interim analysis, and if needed, expected potential completion of enrollment of all 120 patients by Summer 2023.

- *Resume In-person Sales from a Strong Customer Base:* Our core customer base accounts for the majority of our direct sales grew from the start of the pandemic. We are in close contact with all of these accounts and have confirmed that COVID-19 related issues, including its effect on staffing and numbers of ICU patients, are the primary issue for volatility in ordering. We believe a return to in-person selling will reinvigorate growth.

- *New Therapy Divisions:* We have established three distinct therapy divisions within our commercial operations including Critical Care, Cardiovascular, and Liver/Kidney/other to develop these markets internationally with the focus of leaders with area-specific medical and commercial expertise, who will work closely with our sales teams and best serve the needs and interests of our customers. We have already seen our efforts bear fruit with now more than 150 cardiac surgery centers internationally who have begun to use CytoSorb to remove antithrombotic drugs during urgent cardiac surgery, for example. We believe this infrastructure will yield many more similar successes across a broad array of applications.

- *New Exclusive Private Hospital Chain Partnerships:* In May 2022, we entered into a 3-year preferred supplier agreement with Asklepios, making CytoSorb available without restrictions to all of the approximate 170 healthcare facilities across 14 states throughout Germany that Asklepios operates. This includes Asklepios Klinik St. Georg in Hamburg, Germany, which pioneered the use of CytoSorb to remove antithrombotic drugs during cardiothoracic surgery, and is well-known for their seminal publication on CytoSorb use for this application during emergency cardiac surgery in patients at high risk of bleeding.

- *Expand Existing Strategic Partnerships:* In August 2022, the Company entered into a Marketing Agreement (the "Marketing Agreement") with Fresenius Medical Care Deutschland GmbH ("Fresenius"), which expands the Company's strategic partnership with Fresenius by establishing a multi-stage global collaboration to combat life-threatening diseases in critical care. The Marketing Agreement provides for the combined marketing and promotion of CytoSorb with Fresenius' critical care products by Fresenius' marketing organization worldwide, excluding the United States. Specifically, the Marketing Agreement provides that various Fresenius-led in-person, virtual, social media, and web-based marketing programs and events will feature the CytoSorb therapy and highlight the cooperation between the two companies in the field of critical care during the Term. In addition to strengthening and expanding the global marketing of CytoSorb, the Company and Fresenius also plan to work together to bring new innovative solutions to the market. The Marketing Agreement also includes the certification of compatibility between CytoSorb and Fresenius' current critical care platforms.

- *Rise of Existing and New Applications:* Among the many applications, we highlight:

    - *Shock:* Many studies have highlighted the ability of CytoSorb to remove inflammatory mediators and help to stabilize shock, a potentially fatal drop in blood pressure, in a wide range of patients. A 2019 meta-analysis, found that approximately 10% of ICU patients have septic shock at admission and 8% of patients admitted to the ICU have septic shock at some point in their hospital stay, with a high mortality of 38%. CytoSorb is being used around the world as a treatment of shock and we are conducting the PROCYSS RCT to formally evaluate CytoSorb as a treatment of this common and major unmet medical need.

    - *Liver disease:* In the treatment of acute liver disease, CytoSorb outperforms the market leading MARS® platform (Baxter) in the *in vitro* removal of many liver toxins, but has the added benefit of removing cytokines and inflammatory mediators, while being much easier to use. In real-world practice, CytoSorb has replaced MARS at many accounts.

    - *Lung Injury:* Our U.S. CTC registry highlights the high survival of critically ill COVID-19 patients with acute respiratory distress syndrome (ARDS) treated with CytoSorb and ECMO under FDA Emergency Use Authorization. We believe these data demonstrate a therapeutic strategy of "enhanced lung rest" using the combined therapies that can be extrapolated to the treatment of ARDS in non-COVID patients, a very large market.

Longer-term growth drivers

- *Stand-alone blood pump strategy:* There are many applications where a simple, low-cost stand-alone hemoperfusion pump is sufficient to implement our CytoSorb blood purification technology. By making available such a pump to our customers, we believe it will expand the numbers of patients where CytoSorb is used, while making it easier to initiate CytoSorb therapy earlier in the course of the disease. Early intervention with CytoSorb, particularly before renal failure has developed, has been cited as a key predictor of treatment success in a number of published studies. In the future, we also believe that the availability of an easy-to-use stand-alone pump will enable "hospital-wide" applications of CytoSorb, such as in the emergency room, surgery suites, and elsewhere. In June 2022, we announced that, following a successful pilot program in three countries, we have signed an expanded non-exclusive agreement with Nikkiso Europe GmbH (Nikkiso) to distribute their PureADJUST stand-alone hemoperfusion pump and accessories in a total of 14 countries. In addition to securing the rights to sell Nikkiso's stand-alone pump and accessories, we will also be able to provide field support services in these countries.

- *Expansion of direct sales territories:* Although opening new countries with a direct sales force requires time, cost, and effort, it also allows us to directly lead the effort, drive results, and benefit from more profitable sales. With the announcement of expansion of direct sales into the U.K. and Ireland, we now sell direct in two of the E.U.'s Big 5 Economies - Germany and the U.K. – and a total of 15 countries direct overall, while working with distributors or partners in the other three Big 5 Economies: France, Italy, and Spain.

COVID-19 Business Update

COVID-19 patients develop life-threatening complications such as acute respiratory distress syndrome (ARDS), shock (i.e., a potentially fatal drop in blood pressure), kidney failure, acute cardiac injury, thromboses and emboli, and secondary bacterial infections. The underlying cause for these complications is often 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. Hypercoagulability, thought triggered by inflammation, and resulting thromboembolic events such as pulmonary emboli and thrombotic microangiopathy, play another critical role in the pathophysiology of COVID-19 infection and severity of illness.

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 to treat dangerous inflammation and related life-threatening complications in more than 7,650 COVID-19 patients in more than 30 countries as of September 30, 2022. Based upon initial data and 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, decannulation from extracorporeal membrane oxygenation (ECMO), 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 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 January 2021, Health Canada granted Medical Device Authorization for the importation, sale, and emergency use of CytoSorb in hospitalized COVID-19 patients.

The use of CytoSorb has not been approved in the U.S. by the 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 U.S. Emergency Use Authorization (EUA) of CytoSorb for use in adult critically ill COVID-19 patients. 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 and 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. 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.

The CTC (CytoSorb Therapy in COVID-19) Registry was launched to capture outcomes and device utilization patterns from multiple U.S. participating centers. Primary results on observed ICU mortality of COVID-19 patients with acute respiratory distress syndrome (ARDS) requiring extracorporeal membrane oxygenation (ECMO) and treated with CytoSorb according to FDA EUA criteria were presented at the International Symposium of Intensive Care Medicine conference in September 2021 in Brussels, Belgium. In December 2021, we announced the publication of these results in the peer-reviewed journal *Frontiers in Medicine*. As of September 2022, the CTC Registry has completed enrollment and the final results were presented at the European Society of Intensive Care Medicine conference in October 2022 and also have been submitted for publication.

Government Research Grants:

We have historically 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 U.S. Army, U.S. Special Operations Command ("USSOCOM"), the U.S. Air Force, Air Force Material Command ("USAF/AFMC") and others. Currently, we have ongoing projects funded, in part, by the U.S. Army Medical Research Acquisition Activity ("USAMRAA"), the NHLBI, and the USAF/AFMC. For a complete discussion of the various research grants we have obtained, please refer to the section entitled Government Research Grants included in Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on March 10, 2022. The following additional research grant has been awarded subsequent to the filing of our Annual Report on Form 10-K:

On May 9, 2022, the Company received a U.S. Army Medical Research Acquisition Activity Award (the "USAMRAAA") entitled "Demonstration of the Safety and Efficacy of Field-Ready Blood Group Antibody (BGA) Adsorber in the Porcine Universal Transfusion

Model." The Department of Defense (DoD) Defense Medical Research and Development Program (DMRDP) Joint Program Committee 6 (JPC-6) Combat Casualty Care Research Program (CCCRP) Battlefield Resuscitation for the Immediate Stabilization of Combat Casualties Award, for up to $1,977,024, was granted to the Company to validate the safety and efficacy of the BGA device in a preclinical study in pigs. This award is being funded by the USAMRAAA under Contract No. W81XWH-22-1-0235. The contract effective date was August 1, 2022.

On August 22, 2022, the Company received a U.S. Army Medical Research Acquisition Activity Award (the "USAMRAAA") entitled "Integrating Isoagglutinin Reduction for a Universal Dried Plasma Product for Battlefield and First Responder Use." This three-year Phase III contract, which is valued at $4,292,641, is to be used to customize the design of the HemoDefend-BGA™ filter for sterile integration into collections systems for freeze-dried plasma processing to generate freeze-dried universal plasma. Without the need for blood typing, widespread availability of universal plasma could help save lives via faster emergency treatment in both civilian and military settings. This award is being funded by the USAMRAAA under Contract No. W81XWH-22-C0046. The contract effective date was August 22, 2022.

On August 29. 2022, the Company was granted a Phase I Small Business Innovation Research (SBIR) award entitled "Novel Extracorporeal Therapy for the Reversal of Septic Shock and Restoring Hemodynamic Stability" by the National Institute of General Medical Sciences (NIGMS), a division of the U.S. National Institutes of Health. This eight-month award, which is valued at $281,835, will allow CytoSorbents to test the ability of its novel and existing polymers to remove cytokines and lipopolysaccharide (LPS) endotoxin, a well-known potent and deadly trigger of sepsis and septic shock, from septic porcine plasma. The contract effective date was September 1, 2022.

Manufacturing Update

We are continuing the transition of our manufacturing operations from the Deer Park Road location to our new facility at 305 College Road in Princeton, New Jersey. The build out of the manufacturing and laboratory areas are substantially complete. The administrative offices are substantially complete as well. The remaining costs to complete the current build out are estimated to be approximately $400,000. We are currently in the process of transferring the polymer manufacturing activities to the new facility, which will be completed before the end of the year. All other manufacturing processes have already been relocated to the new facility. In September 2022, we announced that we have received ISO 13485 Certification of our new manufacturing facility from our European Union (E.U.) notified body, clearing the way for full manufacturing of CytoSorb®, DrugSorb®-ATR, and ECOS-300CY® from the new manufacturing site. We also have capacity to add additional product lines as they are developed. Once complete, this facility will have the capacity to support approximately $400 million in total product sales.

Research and Development Update

Our research and development efforts have experienced challenges due to the COVID-19 pandemic over the last 2 years. As the COVID-19 pandemic transitions from a pandemic to an endemic, we have started to advance our research programs forward. We have been able to hire much needed technical staff and we are restructuring our research team to focus greater efforts on our grant related projects to reduce the current backlog of work. During this past quarter, the number of billable hours worked on our grant related projects increased by approximately 29%. Prior issues related to blood availability for research has significantly decreased. As of September 30, 2022, the revenue remaining to be earned on open grant contracts is $13.2 million. Overall, grant funded programs, HemoDefend-BGA™ (Universal Plasma), HemoDefend-RBC™ and K^{+}ontrol™, continue to progress and we have been the beneficiary of approximately $15.8 million, $4.7 million and $7.7 million in total funding, respectively, awarded to date.

Impact of Inflation and Other Issues:

During 2022, the current high inflationary environment has impacted us in various ways. Due to the current competitive labor market and rising inflation, our labor costs have risen significantly in order to attract and retain qualified employees throughout our organization. In addition, we have experienced raw material price increases primarily related to the oil-based chemicals used in the polymer manufacturing process as well additional requests for higher fuel surcharges from most suppliers. Rising energy costs, including electricity and fossil fuels, have also made it more expensive to support our operations, manufacturing, and commercial activities. We have also experienced increases in our transportation costs; however, we have been able to substantially mitigate these cost increases by implementing bulk shipping methods. In addition, we have been able to mitigate most supply chain issues that existed during the COVID-19 pandemic by ordering larger quantities of inventory as they were available. Inflationary pressures may continue to impact our product gross margins in the future.

Comparison for the three months ended September 30, 2022 and 2021:

Revenues:

Revenue from product sales was approximately $6,463,000 in the three months ended September 30, 2022, as compared to approximately $8,902,000 in the three months ended September 30, 2021, a decrease of approximately $2,439,000 or 27%. The decrease in the average exchange rate of the Euro to the U.S. dollar negatively impacted 2022 product sales by approximately $771,000. For the three months ended September 30, 2022, the average exchange rate of the Euro to the U.S. dollar was $1.01 as compared to an average exchange rate of $1.18 for the three months ended September 30, 2021. We estimate that demand for CytoSorb to treat COVID-19 patients was de minimis in the third quarter of 2022 as compared to approximately $1.1 million in the third quarter of 2021. This decrease is partly attributed to high rates of vaccinations that are associated with reduced severity of illness, reduced need for hospitalization, and reduced risk of death. Overall direct sales declined by approximately $1,407,000 resulting primarily from lower sales in Germany due to COVID-19 pandemic-driven market conditions, and unfavorable currency conversions. Although improved, continued staffing shortages, reduction in ICU bed capacity, decreased elective surgical procedures, hospital budgets, and hospital restrictions which at some hospitals continue to limit our access to hospital personnel, continue to impact the hospital market.

Grant income was approximately $1,649,000 for the three months ended September 30, 2022 as compared to approximately $859,000 for the three months ended September 30, 2021, an increase of approximately $790,000, or 92%. During the three months ended September 30, 2021, our research and development employees were either deployed to work-from-home status or reassigned to assist in activities related to increasing the production of CytoSorb. In 2022, research and development employees were assigned exclusively to grant and other research and development activities.

Total revenues were approximately $8,111,000 for the three months ended September 30, 2022, as compared to total revenues of approximately $9,760,000 for the three months ended September 30, 2021, a decrease of approximately $1,649,000, or 17%.

Cost of Revenues:

For the three months ended September 30, 2022 and 2021, cost of revenue was approximately $4,494,000 and $2,463,000, respectively, an increase of approximately $2,031,000. This increase was due to an increase in grant cost of revenue due to the increase billable hours charged our grant related projects of approximately $757,000, an equipment failure of a refrigeration unit at our new manufacturing facility that caused a write-off of approximately $599,000 of work-in-process inventory (see Note 2) and to inefficiencies associated with lower production due to a decrease in sales and the process of relocating our production activities to the new facility. Product cost of revenue was approximately $2,916,000 and $1,642,000, respectively, for the three months ended September 30, 2022 and 2021, an increase of approximately $1,274,000. This increase was due to the equipment failure of a refrigeration unit and to inefficiencies associated with the relocation of our production activities as discussed above. Product gross margins were approximately 55% for the three months ended September 30, 2022 as compared to approximately 82% for the three months ended September 30, 2021. The decrease in the gross margin percentage in 2022 was due to the factors mentioned above. Excluding the write-off of inventory related to the equipment failure, product gross margin would have been 64%.

***Research and Development Expenses**:*

For the three months ended September 30, 2022, research and development expenses were approximately $3,290,000, as compared to research and development expenses of approximately $4,262,000 for the three months ended September 30, 2021, a decrease of approximately $972,000. This decrease was due to a decrease in our clinical trial spend of approximately $666,000, and a decrease in our non-grant labor and other costs of approximately $306,000 as we prioritized our grant related projects.

Legal, Financial and Other Consulting Expenses:

Legal, financial and other consulting expenses were approximately $610,000 for the three months ended September 30, 2022, as compared to approximately $665,000 for the three months ended September 30, 2021. The decrease of approximately $55,000, was due to a decrease in employment agency fees of approximately $37,000 and a decrease in consulting fees of approximately $88,000. These decreases were offset by an increase in legal fees of approximately $63,000 and an increase in accounting fees of approximately $7,000.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were approximately $8,735,000 for the three months ended September 30, 2022, as compared to approximately $7,777,000 for the three months ended September 30, 2021, an increase of $958,000. This increase was due to an increase sales and marketing costs, which include advertising and conference attendance of approximately $417,000, an increase in salaries, severence, commissions and related costs of approximately $116,000, an increase in travel and entertainment costs of approximately $44,000, an increase in occupancy costs of approximately $387,000 related to the rent expense on our new manufacturing facilityand an increase in other general and administrative expenses of approximately $153,000. These increases were offset by a decrease in royalty expenses of approximately $159,000 due to the decrease in product sales.

Loss on Foreign Currency Transactions:

For the three months ended September 30, 2022, the loss on foreign currency transactions was approximately $3,230,000 as compared to a loss of approximately $1,013,000 for the three months ended September 30, 2021. The 2022 loss was directly related to the decrease in the spot exchange rate of the Euro to the U.S. dollar at September 30, 2022 as compared to June 30, 2022. The spot exchange rate of the Euro to the U.S. dollar was $0.98 per Euro at September 30, 2022, as compared to $1.05 per Euro at June 30, 2022. The 2021 loss was directly related to the decrease in the spot exchange rate of the Euro at September 30, 2021 as compared to June 30, 2021. The spot exchange rate of the Euro to the U.S. dollar was $1.16 per Euro at September 30, 2021, as compared to $1.19 per Euro at June 30, 2021.

Comparison for the nine months ended September 30, 2022 and 2021:

Revenues:

Revenue from product sales was approximately $21,718,000 in the nine months ended September 30, 2022, as compared to approximately $30,411,000 in the nine months ended September 30, 2021, a decrease of approximately $8,693,000, or 29%. The decrease in the average exchange rate of the Euro to the U.S. dollar negatively impacted 2022 product sales by approximately $2,252,000. For the nine months ended September 30, 2022, the average exchange rate of the Euro to the U.S. dollar was $1.06 as compared to an average exchange rate of $1.20 for the nine months ended September 30, 2021. Though difficult to quantify, we estimate that approximately $300,000 of total product sales in the nine months ended September 30, 2022 was due to the demand for CytoSorb to treat COVID-19 patients as compared to $4.6 million in the nine months ended September 30, 2021. This decrease is partly attributed to high rates of vaccinations that are associated with reduced severity of illness, reduced need for hospitalization, and reduced risk of death. Overall direct sales declined by of approximately $6,786,000 resulting primarily from lower sales in Germany due to COVID-19 pandemic-driven market conditions and unfavorable currency exchange conversions. Although improved, continued staffing shortages, reduction in ICU bed capacity, decreased elective surgical procedures, hospital budgets, and hospital restrictions which at some hospitals continue to limit our access to hospital personnel, continue to impact the hospital market.

Grant income was approximately $3,580,000 for the nine months ended September 30, 2022 as compared to approximately $1,973,000 for the nine months ended September 30, 2021, an increase of approximately $1,607,000 or 81%. During the nine months ended September 30, 2021, our research and development employees were either deployed to work-from-home status or reassigned to assist in activities related to increasing the production of CytoSorb. In 2022, research and development employees were assigned exclusively to grant and other research and development activities.

Total revenues were approximately $25,298,000 for the nine months ended September 30, 2022, as compared to total revenues of approximately $32,383,000 for the nine months ended September 30, 2021, a decrease of approximately $7,085,000, or 22%.

Cost of Revenues:

For the nine months ended September 30, 2022 and 2021, cost of revenue was approximately $10,322,000 and $7,925,000, respectively, an increase of approximately $2,397,000. This increase was due to an increase in grant cost of revenue due to the increase billable hours charged our grant related projects of approximately $1,451,000, an equipment failure of a refrigeration unit at our new manufacturing facility that caused a write-off of approximately $599,000 of work-in-process inventory (see Note 2) and to inefficiencies associated with lower production due to a decrease in sales and the process of relocating our production activities to the new facility, including a scheduled four-week production hiatus in Q2 2022. Product gross margins were approximately 68% for the nine months ended September 30, 2022 and approximately 80% for the nine months ended September 30, 2021. The decrease in the gross margin percentage in 2022 was due to the factors mentioned above. Excluding the write-off of inventory related to the equipment failure, 2022 product gross margin would have been 71%.

Research and Development Expenses:

For the nine months ended September 30, 2022, research and development expenses were approximately $11,717,000 as compared to research and development expenses of approximately $10,244,000 for the nine months ended September 30, 2021, an increase of approximately $1,473,000. This increase was due to an increase in costs associated with our clinical trial activities of approximately $1,498,000 primarily related to our STAR-T and STAR-D trials in the United States and an increase in non-grant related research and development labor of approximately $350,000 due to the hiring of additional technical staff. These increases were offset by a decrease in non-grant related research and development costs of approximately $374,000 as we prioritized our grant related projects.

Legal, Financial and Other Consulting Expenses:

Legal, financial and other consulting expenses were approximately $2,089,000 for the nine months ended September 30, 2022, as compared to approximately $2,090,000 for the nine months ended September 30, 2021. The decrease of approximately $1,000 was due to an increase in legal fees of approximately $368,000 due to the abandonment of certain patent applications and an increase in accounting fees of approximately $129,000. These increases were offset by decreases in hiring fees of approximately $302,000 and consulting fees of approximately $196,000.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were approximately $26,335,000 for the nine months ended September 30, 2022, as compared to $25,308,000 for the nine months ended September 30, 2021, an increase of $1,027,000. This increase is related to an increase in salaries, severence, commissions and related costs of approximately $1,326,000, an increase in sales and marketing costs, which include advertising and conference attendance of approximately $1,098,000, an increase in travel and entertainment costs of approximately $513,000, an increase in occupancy costs of approximately $1,110,000 related to the rent expense on our new manufacturing facility and an increase in other general and administrative expenses of approximately $53,000. These increases were offset by a decrease in royalty expenses of approximately $691,000, a decrease in non-cash restricted stock expense of approximately $1,711,000 related to restricted stock units granted to the Company's executive officers and a decrease in non-cash stock compensation expense of approximately $671,000.

Loss on Foreign Currency Transactions:

For the nine months ended September 30, 2022, the loss on foreign currency transactions was approximately $6,967,000 as compared to a loss of approximately $2,084,000 for the nine months ended September 30, 2021. The 2022 loss was directly related to the decrease in the spot exchange rate of the Euro to the U.S. dollar as of September 30, 2022 as compared to December 31, 2021. The spot exchange rate of the Euro to the U.S. dollar was $0.98 per Euro as of September 30, 2022, as compared to $1.14 per Euro at December 31, 2021. The 2021 loss of approximately $2,084,000 was directly related to the decrease in the spot exchange rate of the Euro as of September 30, 2021 as compared to December 31, 2020. The spot exchange rate of the Euro to the U.S. dollar was $1.16 per Euro at September 30, 2021, as compared to $1.22 per Euro at December 31, 2020.

History of Operating Losses:

We have experienced substantial operating losses since inception. As of September 30, 2022, we had an accumulated deficit of approximately $253,232,000, which included losses of approximately $32,046,000 and $15,252,000 for the nine-month periods ended September 30, 2022 and 2021, 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. As of September 30, 2022, we had current assets of approximately $32,381,000 including unrestricted cash on hand of approximately $22,552,000 and current liabilities of approximately $10,119,000. As of September 30, 2022, $25 million of our total shelf amount was allocated to our ATM facility, all of which remains available. In addition, we have $15 million of debt availability, providing financial flexibility, if needed. In April of 2022, we received approximately $740,000 in cash from the approved sale of our net operating losses and research and development credits from the State of New Jersey.

As of September 30, 2022, cash and cash equivalents were $22.6 million compared to $30.2 million as of June 30, 2022. The change in cash, or our third quarter 2022 cash burn, was approximately $7.7 million. This cash burn was due to lower-than-expected sales volumes, product gross margins that were lower due to decreased production volumes, and other factors (e.g. a delay in realizing savings from cost cutting due to notice periods and labor laws in Europe). A reduction in product gross margins from 80% in Q1 2022 to 64% (excluding the previously mentioned inventory write-off) in Q3 2022, unfavorably impacted our cash burn by approximately $1.9 million. We expect product gross margins to return to previous levels as we transition production fully to the new facility by the end of this year, end the lease at our Deer Park Drive facility, and begin to capture manufacturing efficiencies driven by expected improvement in market conditions and increased product demand.

We are also managing our resources proactively, continuing to invest in key areas such as our U.S. clinical program. while driving cost-cutting throughout our Company. At the beginning of Q2 2022, we began instituting tighter cost controls and have reduced our headcount (including full and part-time employees and consultants) internationally by 10%, with the goal of reducing our cash burn. In addition, we have shifted our R&D headcount to funded grant programs, where we have an extensive $13.2 million backlog as of September 30, 2022. Some of our costs savings of our headcount reduction are not yet visible in our results due to notice periods and labor laws in Europe, but will be reflected in our 2023 operating budget. We are continuing to identify areas for additional potential cost savings to reduce our future cash burn. Meanwhile, we are working diligently to prioritize activities that we believe have a near-term return on

investment and advance our strategic priorities, which cutting non-core or non-essential activities and spend. Our goal is, through a combination of driving an increase in sales and gross margin, and cutting costs, to significantly reduce our cash burn and to extend our operating runway with the resources we have.

Including cash related to the use of a portion of our available debt facility, we believe that we have sufficient cash to fund the Company's operations beyond twelve months from the issuance of these consolidated financial statements.

COVID-19 Impact on Financial Results

For the first year and a half of the coronavirus pandemic, COVID-19 was generally a positive driver for CytoSorb sales and highlighted the use of CytoSorb to treat cytokine storm and hyperinflammation. Hyperinflammation is associated with the most severe COVID-19 illness and is correlated to the development of respiratory failure and the need for mechanical ventilation and ECMO. Because of this, the pandemic was a catalyst for CytoSorb orders from existing customers and also from new hospitals in countries where CytoSorb was not previously sold. We believe this awareness of CytoSorb increased overall usage during the COVID-19 pandemic and may help to drive further CytoSorb sales in the future.

However, starting in Q3 2021, the protracted COVID-19 pandemic began to have a negative impact on our business, due to pandemic-driven adverse market conditions worldwide, especially in Germany which is our largest market. This was exacerbated by multiple waves of new COVID-19 cases in Germany and Austria this year, with the largest surge since the pandemic began occurring in Q1 2022, driven by the Omicron variant. The excessive workload in hospitals due to COVID has led to an exodus of healthcare workers from acute care worldwide, leaving hospitals short-staffed, particularly nursing. This in turn has forced the reduction in ICU beds and allowable patient censuses, and reduced the scheduling of revenue generating surgical procedures, resulting in decreased revenue and economic weakness at hospitals. Meanwhile, the rates of severe COVID-19 illness requiring ICU care, and COVID-related death have been disproportionately very low. This is mainly attributed to high rates of vaccinations, natural immunity, and the availability of anti-viral drugs that are associated with reduced severity of illness, reduced need for hospitalization, and risk of death. These factors, in turn, have decreased the numbers of patients treatable with CytoSorb.

The pandemic also directly disrupted our normal sales processes. These disruptions have been amplified in Germany and Austria due to multiple waves of new COVID-19 cases this year. For example, we have experienced decreased access of our sales representatives to hospitals and fewer sales meetings with physicians due to visitor restrictions, COVID infections in the majority of our sales force and many hospital workers resulting in sick leave and in a slowdown of business, = decreased effectiveness of virtual medical conferences, and limits on our ability to market new indications, such as ticagrelor and rivaroxaban removal. Additionally, COVID slowed our ability to generate clinical data to support our sales and marketing efforts. These factors negatively impacted our critical care and cardiac surgery markets in Germany, contributing to lower-than-expected sales of CytoSorb for the nine months ended September 30, 2022. We would expect over time to regain unrestricted access to hospitals and physicians which should positively impact our product sales in the future.

The above factors have had a negative impact on our product sales, where CytoSorb is used primarily on critically ill patients in the ICU, including COVID-19 patients in respiratory distress or failure, or in cardiac surgery. Our product revenues decreased by 29% during the nine months ended September 30, 2022 to approximately $21.7 million from approximately $30.4 million in the nine months ended September 30, 2021. Though difficult to quantify, we estimate that approximately $300,000 of our product revenues were directly or indirectly related to COVID-19 during the nine-month period ended September 30, 2022 as compared to $4.6 million during the nine months ended September 30, 2021.

With the pandemic in flux, it is difficult to predict what the near-term impact of COVID-19 will have on overall ongoing product sales. We expect that COVID-19 revenues will continue to decline in future periods, as increasing vaccinations globally result in fewer new cases, hospitalizations, and deaths from COVID-19. However, we also expect an eventual recovery in the hospital markets, with a positive impact on our core, non-COVID related sales. These assumptions are dependent on the course 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 $182,000 for the nine months ended September 30, 2022. Given the significant decrease in COVID-19 cases in the U.S. at this time, we do not believe that U.S. sales under FDA EUA will have a significant impact on our overall product sales during the remainder of 2022.

The COVID-19 pandemic did not impact grant income during the nine months ended September 30, 2022 but did negatively impact first half 2021 results, when our research and development employees were either deployed to work-from-home or reassigned to assist in production activities to increase production of CytoSorb. Currently, the team is executing upon our grant contracts. Our grant income increased by 81% during the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021. However, this may change depending on whether there is a resurgence of COVID-19, which may result in a reduction of grant income until such time as the pandemic is over, however, this reduction is not expected to have a material impact on our financial results because of the low gross margins associated with grant activities.

During the pandemic, there was a worldwide slowdown in clinical trial activities as medical providers focused on COVID-19 patients, exacerbated by widespread staffing shortages. This resulted in temporary pauses and delays in a number of our company-sponsored clinical trials, which resulted in lower-than-expected costs and expenses associated with clinical trial activity. For example, because of COVID-19-related delays in the U.K., we elected to stop our TISORB single arm trial in April 2021, in favor of dedicating those resources to the U.S. STAR-T randomized controlled trial in the United States which is currently enrolling. Currently, the direct impact of COVID infections on clinical studies has abated both in the U.S. and Europe, though we continue to observe the aftermath of COVID in the staffing shortages and resource constraints at clinical sites, the financial pressures that hospitals face, the interest of patients to participate in clinical trials, and on the overall execution of our international clinical programs. We believe the clinical trial environment will improve over time, but the timing is uncertain.

As the pandemic fades and business returns to pre-pandemic levels, we expect certain of our selling, general, and administrative expenses, such as travel and conference expenses that have been curtailed by COVID, to increase.

Contractual Obligations

In March 2021, the Company entered into a lease agreement for a new operating facility at 305 College Road East, Princeton, New Jersey, which contains office, laboratory, manufacturing and warehouse space. The commencement date of the lease was April 1, 2021. The Initial Early Term began on the commencement date (April 1, 2021) and lasted two months. The Early Term commenced on June 1, 2021 and lasted until September 30, 2021. The lease also contains two five-year renewal options. Commencing on September 30, 2021, the remaining lease term will last for 15.5 years. The lease requires monthly rental payments of $25,208 for the Initial Early Term, $88,254 for the Early Term and initial monthly payments of approximately $111,171 in the first year of the remaining term. Following the first year of the remaining term, the annual base rent will increase by approximately 2.75% annually over the remaining term. The lease also contains nine months of rent abatement. In addition to the base rent, payments of operating expenses and real estate taxes will be required. These payments are to be based on actual amounts incurred during 2021, multiplied by the Company's share of the total building space (92.3%). The landlord will also provide an allowance of approximately $1,455,000 related to certain building improvements as outlined in the lease. In April 2021, the Company provided the landlord with a letter of credit in the amount of approximately $1,334,000 as security.

In April 2021, the Company entered into a Twentieth Amendment to Lease with the landlord at our existing Monmouth Junction facility which became effective May 31, 2021. This amendment extends the term of the lease for the Company's existing facility to May 31, 2022. The Company's base rent is approximately $35,000 per month. In addition, the Company is obligated to pay monthly operating expenses of approximately $30,000 per month. Under the terms of this amendment, the Company vacated a portion of the space as of May 31, 2022. The Company will continue to lease the remaining space until December 31, 2022, at which time the Company will vacate the remaining space and the lease will terminate. The Company's base rent for the remaining space will be approximately $20,000 per month. Monthly operating expenses will be approximately $11,000 per month. In addition, the Company agreed to increase its security deposit by approximately $54,000 to a total of $150,000. At the end of the lease term, the entire security deposit will be paid to the landlord for the purpose of making any needed repairs to the vacated premises, and the Company will have no further obligation to pay for repairs to the vacated premises.

In January 2021, CytoSorbents Europe GmbH entered into a lease for 1,068 square meters of additional warehouse space. The lease commenced on April 1, 2021, requires monthly payments of base rent of $7,784 and other costs of approximately $239 and has a term of five years. The lease also has an option to extend the lease term for an additional five-year period through March 31, 2031.

In September 2021, the Company extended its two operating leases for its office facility in Germany. These leases require combined base rent payments amounting to approximately $12,100 per month. The initial lease term of both leases ends August 31, 2026. In

addition, the Company is obligated to monthly operating expenses of approximately $3,000 per month. Both leases have a five-year option to renew that would extend the lease term to August 31, 2031.

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 $53.8 million. As of September 30, 2022, the Company's cash and cash equivalents (excluding restricted cash) were approximately $22.6 million, which the Company expects will fund the Company's operations beyond twelve months from the issuance of these consolidated financial statements. In addition, the Company has $15 million of debt availability and $25 million of availability under its ATM facility to provide additional liquidity, as needed. As a result, the Company has determined that the going concern risk has been substantially mitigated.

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, international conflicts and trade wars, 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 consolidated 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 September 30, 2022 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.

For a discussion of risks that affect the Company's business, please refer to Part I, Item IA, "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on March 10, 2022.

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.

Number	Description
10.1	Marketing Agreement, by and between the Company and Fresenius Medical Care Deutschland GmbH, dated as of August 1, 2022.*
31.1	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.
31.2	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.
32.1	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.**
32.2	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.**
101	The following materials from CytoSorbents Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at September 30, 2022 and December 31, 2021, (ii) Consolidated Statements of Operations for the three and nine months ended September 30, 2022 and 2021, (iii) Consolidated Statement of Changes in Stockholders' Equity for the three and nine months ended September 30, 2022 and 2021, (iv) Consolidated Statements of Cash Flows for the nine months ended September 30, 2022 and 2021 and (v) Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Portions of this exhibit are redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K and the schedules to this exhibit are omitted pursuant to Item 601(a)(5) of Regulation S-K.

** 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: November 3, 2022

By: /s/ Phillip P. Chan
Name: Phillip P. Chan
Title: Chief Executive Officer
(Principal Executive Officer)

Dated: November 3, 2022

By: /s/ Kathleen P. Bloch
Name: Kathleen P. Bloch, CPA
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Certain confidential information contained in this document has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Execution Version

MARKETING AGREEMENT

This Marketing Agreement (this "Agreement"), effective as of August 1, 2022 (the "Effective Date"), is by and between CytoSorbents Corporation, a corporation existing under the laws of Delaware, with offices at 305 College Road East, Princeton, New Jersey 08540, United States ("CytoSorbents") and Fresenius Medical Care Deutschland GmbH, a corporation existing under the laws of Germany, with offices located at Else-Kroener-Strasse 1, 61352 Bad Homburg vor der Hoehe, Germany ("FMC", together with CytoSorbents, the "Parties" and each, a "Party").

WHEREAS, in accordance with the terms of this Agreement, FMC and CytoSorbents desire to work together to create broad market awareness of the compatibility between the FMC Platform and the CytoSorb Products and advance ICU access to the CytoSorb Products for use with the FMC Platform.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

1. **DEFINITIONS**. For purposes of this Agreement, the following terms have the following meanings:

1.1 "Additional FMC Platform" means Xenios AG's extracorporeal membrane oxygenation (ECMO) system (and associated tubing lines and disposables/kits).

1.2 "Affiliates" means, with respect to a Party, any entity or person which directly or indirectly, through one or more intermediaries, controls, or is controlled by, or is under the common control with another entity or person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with", means the beneficial ownership of more than 50% of the issued share capital of a company or the legal power to direct or cause the direction of the general management of the company.

1.3 "Applicable Law" means any national, supranational, multinational, provincial, federal, state or local law (in each case, whether statutory, common or otherwise), constitution, treaty, convention, ordinance, code, rule, statute, regulation or other similar requirement enacted, issued, adopted, promulgated, entered into or applied by a governmental, federal, or regulatory authority that may be in effect during the Term and applicable to a particular activity or country or other jurisdiction hereunder.

1.4 "Claims" has the meaning set forth in Section 11.1.

1.5 "Commercially Reasonable Efforts" means, in respect of a Party, that level of effort and resources to accomplish such objective or activity as such Party would normally use to accomplish a similar objective or activity under similar circumstances, it being understood and agreed that, in the case of FMC with respect to the promotion and marketing of the CytoSorb Products, such efforts and resources shall be consistent with those efforts and resources commonly used by FMC for the promotion and marketing of its own products under similar circumstances at a similar stage in their development or product life and of similar market potential based on conditions then prevailing.

1.6 "Confidential Information" means any information that is treated as confidential by a Party, or its Affiliates or Representatives, whether in oral, written, electronic or other form or media, whether or not such information is marked, designated or otherwise identified as "confidential," and includes any information that due to the nature of its subject matter or circumstances surrounding its disclosure, would reasonably be understood to be non-public, confidential or proprietary. Confidential Information does not include information to the extent the Receiving Party can demonstrate by competent documentary evidence that such information:
(a) was already known by or in the possession of the Receiving Party or its Affiliates or their Representatives without restriction on use or disclosure before the receipt of such information directly or indirectly from or on behalf of the Disclosing Party; (b) was or is independently developed by the Receiving Party, without reference to or use of any of the Disclosing Party's Confidential Information; (c) was or becomes generally known by the public other than as a result of any breach of this Agreement, or other wrongful act, of the Receiving Party or its Affiliates, or their Representatives; or (d) was or becomes available to the Receiving Party, or its Affiliates, or their Representatives received by the Receiving Party from a third party who was not, at the time, under an obligation to the Disclosing Party or its Affiliates or their Representatives or any other person or entity to maintain the confidentiality of such information.

1.7 "CytoSorb Products" means CytoSorbents' CytoSorb adsorber products set forth on Schedule 1.7.

1.8 "CytoSorbents" has the meaning set forth in the preamble to this Agreement.

1.9 "CytoSorbents Marks" means the trademarks listed on Schedule 1.9, and any other trademarks as CytoSorbents may stipulate in writing.

1.10 "Disclosing Party" has the meaning set forth in Section 9.1.

1.11 "FMC Platform" means mftPRO and multiFiltrate classic and any future acute dialysis platforms. When FMC certifies the technical compatibility between the CytoSorb Products and any of the Additional FMC Platform, the FMC Platform shall include such Additional FMC Platform.

1.12 "ICU" means Intensive Care Unit.

1.13 "Indemnified Party" has the meaning set forth in Section 11.1.

1.14 "Indemnifying Party" has the meaning set forth in Section 11.1.

1.15 "Initial Term" has the meaning set forth in Section 12.1.

1.16 "Net Sales" means, with respect to a CytoSorb Product for any period, the total amount invoiced on sales of such CytoSorb Product during such period by CytoSorbents and its Affiliates in the Territory to Third Parties less the following deductions: [***]. In addition, if an invoice remains unpaid for [***] after issuance, CytoSorbents will deduct [***]. Net Sales shall not include [***]. Net Sales shall not include [***].

1.17 "Receiving Party" has the meaning set forth in Section 9.1.

1.18 "Events" has the meaning set forth in Section 4.1(a).

1.19 "Renewal Term" has the meaning set forth in Section 12.1.

1.20 "Representative" means a Party's and its Affiliates' employees, officers, directors, consultants and legal, technical and business advisors.

1.21 "Term" has the meaning set forth in Section 12.1.

1.22 "Territory" means the entire world except for the United States of America (including its territories and possessions, any state of the United States of America and the District of Columbia).

1.23 "Third Party" means any person or entity other than FMC, CytoSorbents and their respective Affiliates.

1.24 "USD" means United States Dollars.

2. REGULATORY ACTIVITIES AND COMPATIBILITY.

2.1 CytoSorb Products. As between the Parties, CytoSorbents shall have the sole right to conduct all regulatory activities with respect to the CytoSorb Products and shall use Commercially Reasonable Efforts to establish, maintain, and extend application possibilities of the CytoSorb Products in the ICU environment.

2.2 FMC Platform. As between the Parties, FMC shall have the sole right to conduct all regulatory activities with respect to the FMC Platform and shall use Commercially Reasonable Efforts to maintain technical compatibility of the FMC Platform with the CytoSorb Products.

2.3 Additional FMC Platform. The Parties will explore in good faith the possibility of FMC confirming the technical compatibility of the CytoSorb Products with the Additional FMC Platform.

2.4 Changes. Promptly after (a) CytoSorbents becomes aware of a change to a CytoSorb Product or (b) FMC becomes aware that a change to the FMC Platform, in either case (a) or (b), that is required or will otherwise be made that would cause it to become incompatible with the other Party's product (and in all cases at least [***] prior to making such change), such Party shall provide written notice to the other Party. Upon receipt of such notice, the Parties shall discuss such issue in good faith. Notwithstanding anything to the contrary, if at any time, any of the CytoSorb Products and any of the FMC Platform are determined not to be compatible due to product changes or otherwise, the Parties shall cease marketing and promoting such non- compatible use.

3. PRODUCT SUPPLY.

3.1 CytoSorb Products. As between the Parties, CytoSorbents shall have the sole right (in its sole discretion) (a) to supply CytoSorb Products to the market at prices solely determined by CytoSorbents and (b) to provide technical expertise on the proper use of CytoSorb Products,

and (c) to sell and fulfill orders for the CytoSorb Products. If customers direct orders for the CytoSorb Products to FMC as a result of the activities under this Agreement, FMC will promptly forward those orders to CytoSorbents. FMC shall have no right to enter into any agreements or other arrangements binding CytoSorbents (or its Affiliates) to supply any CytoSorb Products.

3.2 FMC Platform. As between the Parties, FMC shall have the sole right (in its sole discretion) (a) to supply the FMC Platform to the market at prices solely determined by FMC, (b) to provide technical expertise on the proper use of the FMC Platform, and (c) to sell and fulfill orders for the FMC Platform. CytoSorbents shall have no right to enter into any agreements or other arrangements binding FMC (or its Affiliates) to supply the FMC Platform.

4. MARKETING ACTIVITIES.

4.1 Marketing Events.

(a) The Parties shall agree upon the events to be attended [***] by FMC for marketing the CytoSorb Products for use with the FMC Platform (the "Events"). The agreed [***] Events are listed in Schedule 4.1 attached hereto. FMC will be under the obligation to promote the CytoSorb product at these Events only if FMC also attends these Events with its own booth.

(b) FMC shall have the right to subcontract its obligations under this Agreement to its Affiliates or other Third Parties for purposes of the Events; provided that (i) such subcontracting shall not relieve FMC of its obligations hereunder and (ii) FMC shall be responsible and liable for any actions or inactions of such subcontractor as if it were its own.

(c) FMC will showcase CytoSorb Products at the FMC booth at each Event, using materials and messaging approved by CytoSorbents. To facilitate the marketing of the CytoSorb Products with FMC Platform, CytoSorbents shall provide FMC with dedicated marketing materials for the CytoSorb Products for use with the FMC Platform. CytoSorbents shall be responsible for the compliance of such marketing materials with Applicable Laws in the countries in the Territory for which their use is authorized by CytoSorbents, in particular but not limited to, applicable legal provisions on the advertising of medicinal products in such countries in the Territory.

4.2 Subject to mutual agreement of the Parties, Events will also take place at medical conferences or at Party-sponsored medical symposia For Party-sponsored medical symposia, the Parties shall work in good faith to:

(a) develop an agenda to showcase the proper tools, training, and market awareness to encourage mutual use of the CytoSorb Products and the FMC Platform together;

(b) secure meeting space and arrange logistics for the event;

(c) identify and recruit potential speakers;

(d) identify and recruit customer attendees, including marketing the event; and

(e) carry out Party-sponsored medical symposia.

For the avoidance of doubt, there shall be no obligation for FMC under this Agreement to carry out any such Party-sponsored medical symposia. Such Party-sponsored medical symposia shall only take place if there is mutual fit and prior agreement between the Parties, with such agreement to include the allocation of costs associated with such symposia (which shall be negotiated in good faith).

4.3 General Marketing Efforts.

(a) CytoSorbents will provide FMC personnel with training on the CytoSorb Products for the purposes of FMC's promotion and marketing activities under this Agreement and FMC shall ensure that such personnel receive such training before commencing such activities. For clarity, FMC staff shall not provide training on the CytoSorb Products to customers.

(b) FMC shall use Commercially Reasonable Efforts to promote and market the CytoSorb Products for use with the FMC Platform in the Territory. In addition, within [***] after the Effective Date, FMC will promote and market the use of the CytoSorb Products with the FMC Platform in the Acute Care Product section on the FMC website in a manner no less favorable to the CytoSorb Products than the manner in which FMC promotes and markets its own products. Such promotion and marketing activities shall include marketing messages in accordance with sub-section (c) below. When the CytoSorb Products are referenced on FMC's website, FMC shall include the CytoSorbents Marks and a link to the CytoSorb website in a manner approved by CytoSorbents.

(c) During its promotion and marketing activities, FMC will use marketing messages provided to FMC by CytoSorbents ("CytoSorbents Marketing Messages") stating, among other things, that (i) the CytoSorb Products are a featured blood purification therapy on FMC critical care platforms, including for cytokine, bilirubin, and myoglobin reduction; (ii) the CytoSorb Products and [***] are complementary and not competing products; and (iii) the CytoSorb Products are compatible for use with the FMC Platform. FMC shall use CytoSorbents Marketing Messages in compliance with Applicable Laws, in particular but not limited to, applicable legal provisions on the advertising of medicinal products in the Territory.

(d) FMC will integrate technical information in its sale support materials for the FMC Platform describing the combination with the CytoSorb Products in a manner approved by CytoSorbents.

4.4 Exclusion of Markets. This Agreement is not intended to cover, and FMC shall not conduct activities under or in relation to this Agreement outside the Territory.

4.5 Virtual Events. The Parties may, as mutually agreed, conduct or attend any of the Events under this Agreement virtually or in-person.

5. FUTURE COLLABORATIONS.

5.1 Within [***] after the Effective Date, the Parties shall establish a working group to identify and discuss new collaboration opportunities (e.g., [***], or [***]). For clarity, neither Party shall be required to enter into such new collaborations.

6. LIMITATIONS.

6.1 Marketing Materials. Any reference to CytoSorb Products in FMC's marketing materials must receive CytoSorbents' prior written approval.

6.2 Compliance.

(a) As stated in the FRESENIUS MEDICAL CARE Code of Ethics and Business Conduct, FMC upholds the values of integrity and lawful conduct, especially with regard to anti-bribery and anti-corruption. FRESENIUS MEDICAL CARE upholds these values in its own operations, as well as in its relationships with business partners. FMC's continued success and reputation depends on a common commitment to act accordingly. FMC and CytoSorbents commit to uphold these fundamental values by adherence to Applicable Laws.

(b) CytoSorbents represents that it has read the FRESENIUS MEDICAL CARE Code of Ethics and Business Conduct (Code of Conduct) and the Business Partner Compliance Brochure (Business Partner Compliance Brochure) available on the FRESENIUS MEDICAL CARE website at https://www.freseniusmedicalcare.com/ en/about-us/compliance/our-code-of-ethics-and-business-conduct and https://www. freseniusmedicalcare.com/fileadmin/data/masterContent/pdf/About_us/Business_Partner _Trainings/Business_Partner_Compliance_Brochure/4_Business_Partner_Compliance_B rochure_EN.pdf. FMC and CytoSorbents agrees to adhere to the principles contained therein.

(c) In addition to the forgoing commitment, each Party confirms that it will inform the other Party immediately of any circumstances of which it becomes aware or should reasonably be aware which could amount to any bribery, corruption or undue influence-related conflict of interest between CytoSorbents and FMC and/or their respective employees by virtue of its actions or those of its employees.

(d) The Parties shall conduct all activities under this Agreement in compliance with all Applicable Law. If any antitrust, competition, or other law precludes any of the activities contemplated in this agreement for a given country or region in the Territory, the Parties shall not conduct such activity.

(e) FMC and its Affiliates shall conduct their business with the highest ethical standards, in compliance with all applicable rules and regulations.

6.3 Third Party Agreements. FMC acknowledges that CytoSorbents may have agreements with third parties that preclude certain marketing and promotion activities with respect to the CytoSorb Products in certain countries in the Territory and, upon written notice from

CytoSorbents, FMC shall not conduct such marketing and promotion activities under this Agreement.

7. **LICENSES.**

7.1 Trademark Licenses.

(a) Subject to compliance with Applicable Law and subject to, and in accordance with, the terms and conditions of this Agreement, CytoSorbents hereby grants to FMC a limited, terminable, non-exclusive, royalty-free, non-transferable, non- sublicensable license to use the CytoSorbents Marks in the performance of its obligations under this Agreement. CytoSorbents shall provide FMC with copies of the CytoSorbents Marks in an appropriate form for the uses mutually agreed to by the Parties under this Agreement in connection with the marketing and promotion of the CytoSorb Products for use with the FMC Platform. CytoSorbents shall have the right to approve the appearance, placement and manner of use of the CytoSorbents Marks in advance of their use. FMC agrees to use the CytoSorbents Marks solely in the form provided or approved in writing by CytoSorbents and to comply with any standards or guidelines regarding the usage or presentation of the CytoSorbents Marks which CytoSorbents may communicate from time to time, with any revisions to be effective upon written notice to FMC. FMC acknowledges that CytoSorbents or its Affiliate is the sole and exclusive owner of all right, title and interest in and the CytoSorbents Marks. CytoSorbents or its Affiliate shall retain all right, title, and interest in and to the CytoSorbents Marks, and any and all goodwill derived from the use of the CytoSorbents Marks shall inure solely to the benefit of CytoSorbents or its Affiliate. To the extent FMC acquires any trademark or trade dress rights on the basis of using the CytoSorbents Marks in commerce with the consequence that the marks have attained market recognition, FMC is obliged to transfer such trademark rights acquired by use to CytoSorbents or its Affiliate upon expiration or termination of this Agreement. FMC agrees that neither it nor its agents shall, during or after the Term, anywhere in the world, take any action that in CytoSorbents' sole and absolute discretion impairs or contests or tends to impair or contest the validity of CytoSorbents' or its Affiliates' right, title and interest in and to the CytoSorbents Marks, including using, or filing an application to register, any word, mark, domain name, user name, hashtag, symbol or device, or any combination thereof, that is confusingly similar to or dilutes the distinctiveness of any of the CytoSorbents Marks.

(b) Except as expressly permitted pursuant to subsection (a) above, Section 4 or Section 9.5, FMC shall refrain from any use of CytoSorbents name, trade names, trademarks, service marks, designs or logos, including the CytoSorbents Marks, in any publication, press release, marketing or promotional materials, domain name, username, hashtag, web site or otherwise without the prior written approval of CytoSorbents, which may be granted or withheld at CytoSorbents' sole discretion. FMC shall refrain from any use of the CytoSorbents Marks in a manner that threatens to damage the goodwill associated with the CytoSorbents Marks or which threatens to tarnish the reputation or otherwise unfavorably reflect upon CytoSorbents. FMC shall advise CytoSorbents of any instances of possible infringement or other violation of CytoSorbents' rights in the CytoSorbents Marks that come to its attention during the Tenn. FMC agrees to fully

cooperate with CytoSorbents regarding any action CytoSorbents may take with respect to such infringement or violation. CytoSorbents shall have the exclusive right, exercisable in its sole and unlimited discretion, to institute in its own name and to control or settle actions against Third Parties relating to CytoSorbents' rights, [***]. CytoSorbents shall be entitled to receive and retain [***] or [***].

(c) Except for the limited right to use the CytoSorbents Marks granted to FMC as set forth herein, no right, license or other interest with respect to any CytoSorbents Marks is granted under this Agreement.

(d) The Parties agree to cooperate in recording the trademark licenses with the local trademark authority and in providing notice to the local trademark authority about the expiration or termination of this Agreement, to the extent such recordation is required under local laws. FMC shall take any action to record these trademark licenses without the written consent of CytoSorbents.

7.2 No other License. Subject to Section 7.1:

(a) CytoSorbents retains all rights in and to the CytoSorb Products and its Confidential Information. This Agreement grants FMC no right or license under or to the CytoSorb Products or CytoSorbents' Confidential Information except for use in connection with the marketing activities as expressly set forth in this Agreement.

(b) FMC retains all rights in and to the FMC Platform and its Confidential Information. This Agreement grants CytoSorbents no right or license under or to the FMC Platform or FMC's Confidential Information.

8. PAYMENTS AND RECORDS.

8.1 Royalty. In accordance with this Section 8, CytoSorbents shall pay FMC 0.9% royalty on Net Sales of CytoSorb Products made during the Term in the Territory, which royalty rate is calculated based on a rate of 3% multiplied by 60% (based on the assumption that ICU sales make up 60% of CytoSorbents aggregate sales of CytoSorb Product in the Territory) multiplied by 50% (based on the assumption that 50% of CytoSorb Products are used with the FMC Platform in the ICU in the Territory). If the foregoing assumptions (or the assumptions used to calculate any amended royalty rate) change by more than [***], then the Parties will promptly, acting in good faith, amend the royalty rate in this Agreement to reflect such changed assumptions. For the purposes of the royalty calculation, all non-USD currency based sales will be converted to USD using CytoSorbents standard exchange rate methodology. CytoSorbents shall have no obligation to pay any amounts to FMC with respect to Net Sales of any CytoSorb Products (a) outside the Territory or (b) for any Net Sales prior to, or after the expiration of, the Term.

8.2 Payments and Reports. CytoSorbents shall calculate all amounts payable to FMC pursuant to this Section 8 at the end of each calendar [***]. CytoSorbents shall provide a statement of the amount of Net Sales of each CytoSorb Product in the Territory during the applicable calendar [***] and a calculation of the amount of payment due on such Net Sales pursuant to Section 8.1 for such calendar [***]. This information shall be emailed to [***] of FMC and the royalty payment shall be paid to FMC with respect to a given calendar [***] within [***] after the end of

such calendar [***]. As part of CytoSorbents' annual audit of its financial statements, its independent auditors (WithumSmith+Brown, PC as of the Effective Date) will provide FMC with a letter certifying their review of the CytoSorbents-prepared reconciliation of the CytoSorb Product sales per the financial statements to the Net Sales of CytoSorb Product per the royalty calculation. If CytoSorbents' independent auditors identify an underpayment of royalties to FMC in a particular period, CytoSorbents shall [***] If CytoSorbents' independent auditors identify an overpayment to FMC in a particular period, CytoSorbents shall [***] pursuant to this Agreement; provided that, upon expiration or termination of this Agreement, FMC shall promptly [***] that have [***].

8.3 Mode of Payment. All payments under this Agreement shall be made by a deposit of USD in the requisite amount to such bank account as FMC may from time to time designate by notice to CytoSorbents.

8.4 Withholding Taxes. Where any sum due to be paid to FMC hereunder is subject to any withholding or similar tax, the Parties shall use their commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax [***].

8.5 Expenses. [***].

9. CONFIDENTIALITY AND NON-DISCLOSURE.

9.1 Confidentiality Obligations. Each Party (the "Receiving Party") acknowledges that in connection with this Agreement it may gain access to Confidential Information of the other Party (the "Disclosing Party"). As a condition to being provided with Confidential Information, during the Term and for [***] thereafter, the Receiving Party shall:

(a) not use the Disclosing Party's Confidential Information other than as strictly necessary to exercise its rights and perform its obligations under this Agreement; and

(b) maintain the Disclosing Party's Confidential Information in strict confidence and, subject to Section 9.2, not disclose the Disclosing Party's Confidential Information without the Disclosing Party's prior written consent, provided, however, the Receiving Party may disclose the Confidential Information to its Representatives who (i) have a need to know the Confidential Information for purposes of the Receiving Party's performance, or exercise of its rights concerning the Confidential Information, under this Agreement, (ii) have been apprised of this restriction, (iii) are themselves bound by written nondisclosure agreements at least as restrictive as those set forth in Section 9.1 and (iv) are not employees or consultants of competitors of the Disclosing Party (i.e., companies with products competitive with the CytoSorb Products or FMC Platform, as applicable, with respect to CytoSorbents as the Disclosing Party, the companies listed on Schedule 9.1, which may be amended by written notice from CytoSorbents from time to time), provided further that the Receiving Party shall be responsible for ensuring its Representatives' compliance with, and shall be liable for any breach by its Representatives of, Section 9.1.

(c) safeguard the Disclosing Party's Confidential Information from use or disclosure other than as permitted hereby using measures at least as protective as the efforts it uses for its own Confidential Information (but in no case less than reasonable care).

9.2 Exceptions.

(a) If the Receiving Party becomes legally compelled to disclose any Confidential Information, the Receiving Party shall (i) provide prompt written notice to the Disclosing Party so that the Disclosing Party may seek a protective order or other appropriate remedy or waive its rights under Section 9 and (ii) disclose only the portion of Confidential Information that it is legally required to furnish. If a protective order or other remedy is not obtained, or the Disclosing Party waives compliance under Section 9, the Receiving Party shall, at the Disclosing Party's expense, use reasonable efforts to obtain assurance that confidential treatment will be afforded the Confidential Information.

(b) The Receiving Party may disclose Confidential Information of the Disclosing Party to a third party if prior written approval for such disclosure is received from the Disclosing Party.

9.3 Return of Confidential Information. Upon the effective date of the termination of this Agreement, and the Receiving Party shall, as soon as reasonably practicable, either (a) destroy all copies of such Confidential Information in its possession and confirm such destruction in writing to the Disclosing Party; or (b) deliver to the Disclosing Party, at the Disclosing Party's expense, all copies of such Confidential Information in the possession of the Receiving Party; provided, that the Receiving Party shall be permitted to retain one copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder, as required by applicable law, or for archival purposes. Notwithstanding the foregoing, the Receiving Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose.

9.4 Use of Name. Except as expressly provided herein or as mutually agreed by the Parties in writing in connection with marketing activities hereunder, neither Party shall mention or otherwise use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 9.4 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the Disclosing Party's counsel, is required by applicable law; provided, that such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably so as to provide a reasonable opportunity to comment thereon.

9.5 Public Announcements. The Parties shall issue a joint press release promptly after the Effective Date in the form attached hereto as Schedule 9.5. In addition, FMC shall cooperate with CytoSorbents with respect to other ongoing press releases and investor relations communications that may be issued by CytoSorbents. Except as provided in this Section 9.5,

neither Party shall issue any public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the Disclosing Party's counsel, required by applicable law or the rules of a stock exchange on which the securities of the Disclosing Party are listed (or to which an application for listing has been submitted). In the event a Party is, in the opinion of its counsel, required by applicable law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon.

10. **REPRESENTATIONS AND WARRANTIES.**

10.1 Mutual Representations and Warranties. Each Party represents and warrants, as of the Effective Date, and covenants to the other Party that:

(a) the execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary action on the part of such Party;

(b) this Agreement, when executed and delivered by such Party in accordance with the provisions hereof, will be a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, moratorium, reorganization or similar laws affecting the enforcement of creditors' rights generally and by general principles of equity;

(c) such Party's execution, delivery and performance of this Agreement shall not constitute a violation, breach or default under any contract, instrument, obligation or agreement to which it is a Party or by which it is bound, and will not conflict with or violate any applicable law of any governmental authority having jurisdiction over it or its assets or property; and

(d) it shall comply with all applicable laws in connection with its performance of its tasks and obligations under this Agreement.

10.2 Warranty Disclaimer. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE.

11. **INDEMNIFICATION AND LIMITATIONS OF LIABILITY.**

11.1 Indemnification. Each Party (the "Indemnifying Party") hereby agrees to indemnify, defend and hold harmless the other Party (the "Indemnified Party"), its Affiliates and Representatives from and against all third party liabilities, claims, damages, losses, costs,

expenses, demands, suits and actions (including [***]) (collectively, "Claims") arising out of or resulting from (a) the negligence or willful misconduct of the Indemnifying Party or its Affiliates, Representatives or subcontractors, (b) violation of Applicable Law by the Indemnifying Party or its Affiliates, Representatives or subcontractors in connection with its performance under this Agreement or (c) product liability arising from the Indemnifying Party's products; except, in each case, to the extent the Claims are due to (i) the negligence or willful misconduct of the Indemnified Party or its Affiliates, Representatives or subcontractors, (ii) violation of law by the Indemnified Party or its Affiliates, Representatives or subcontractors in connection with its performance under this Agreement or (d) product liability arising from the Indemnified Party's product.

11.2 Indemnification Procedures. The Indemnified Party shall promptly notify the Indemnifying Party in writing of any Claims covered by Section 11.1. Promptly after receipt of such notice, the Indemnifying Party shall assume the defense of such Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party, within a reasonable time after receipt of such notice, fails to assume the defense, then the Indemnified Party (or the indemnified persons or entities) shall have the right to undertake the defense, compromise and settlement of such Claim for the account and at the expense of the Indemnifying Party. The Indemnified Party shall provide reasonable assistance to the Indemnifying Party, [***], in connection with any Claim. The Indemnifying Party shall not (a) settle any Claim, (b) compromise any Claim, or (c) consent to the entry of any judgment, without the prior written consent of the Indemnified Party, not to be unreasonably withheld, conditioned or delayed.

11.3 Limitation of Liability. EXCEPT FOR (A) INDEMNIFICATION UNDER SECTION 11 AND (B) AS PROVIDED IN SECTION 13.9, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES HAVE ANY DAMAGES OR LIABILITY TO THE OTHER PARTY, ANY OF ITS AFFILIATES OR ANY THIRD PARTY ARISING OUT OF, RELATED TO OR IN CONNECTION WITH THIS AGREEMENT, REGARDLESS OF THE FORM OF THE ACTION, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, PRODUCT LIABILITY OR OTHERWISE AND REGARDLESS OF WHETHER IT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LIABILITY FOR INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES OR LIABILITIES OF ANY KIND OR FOR LOSS OF REVENUE OR PROFITS OR LOSS OF BUSINESS.

12. **TERM AND TERMINATION.**

12.1 Term. The initial term of this Agreement shall commence on the Effective Date and, unless earlier terminated pursuant to Sections 12.2 or 12.3, shall continue in full force and effect for three (3) years (the "Initial Term"). Unless this Agreement is earlier terminated pursuant to Sections 12.2 or 12.3, or a Party provides the other Party with notice of non-renewal at least [***] prior to the end of the Initial Term, this Agreement shall automatically extend for an additional period of two (2) years (the "Renewal Term", and together with the Initial Term, collectively the "Term").

12.2 Termination for Convenience. Each Party may terminate this agreement for any or no reason upon [***] advance written notice to the other Party.

12.3 Termination for Cause.

(a) Upon the occurrence of a material breach or default as to any obligation under this Agreement by either Party and the failure of the breaching Party to promptly cure (within [***] after receiving written notice thereof from the non-breaching Party) such material breach or default, this Agreement may be terminated by the non-breaching Party by giving written notice of termination to the breaching Party, such termination being immediately effective upon the giving of such notice of termination.

(b) Upon the filing of a petition in bankruptcy, insolvency or reorganization against or by either Party, or either Party becoming subject to a composition for creditors, whether by law or agreement, or either Party going into receivership or otherwise becoming insolvent, this Agreement may be terminated by the other Party by giving written notice of termination to the insolvent Party, such termination immediately effective upon the giving of such notice of termination.

12.4 Effect of Termination.

(a) Expiration or termination of this Agreement shall not relieve the Parties of any obligations accruing prior to the effective date of expiration or termination. Any expiration or termination of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have under this Agreement at law or in equity with respect to any breach of this Agreement.

(b) On any expiration or termination of this Agreement, each Party shall promptly return the other Party's Confidential Information in accordance with Section 9.3.

(c) On any expiration or termination of this Agreement, FMC shall cease all use of the CytoSorbents' marketing materials and of the CytoSorbents Marks.

12.5 Survival. The rights and obligations of the Parties set forth in the last four sentences of Section 7.1(a) and Sections 7.1(c), 9.1, 9.2, 9.3, 9.5, 10.2, 11, 12.4, 12.5, and 13, and any right, obligation or required performance of the Parties in this Agreement which, by its express terms or nature and context is intended to survive termination or expiration of this Agreement, shall survive any such termination or expiration.

13. **MISCELLANEOUS.**

13.1 Independent Contractors. The relationship between the Parties is that of independent contractors. Nothing contained in this Agreement shall be construed as creating any agency, partnership, joint venture or other form of joint enterprise, employment or fiduciary relationship between the Parties, and neither Party shall have authority to contract for or bind the other Party in any manner whatsoever.

13.2 Notices.

(a) All notices, requests, consents, claims, demands, waivers and other communications hereunder shall be in writing, shall be sent to the applicable address below

(or such other address as the applicable Party shall have last given by notice to the other Party), and shall be deemed to have been given in accordance with this Section:

If to CytoSorbents:	CytoSorbents Corporation 305 College Road East Princeton, NJ 08540 United States Attention: Chris Cramer, VP Business Development Email: [***]
Required copy to:	Phillip Chan, Chief Executive Officer Email: [***]
If to FMC:	Fresenius Medical Care Deutschland GmbH Else-Kpliner-Str 3 61352 Bad Homburg Germany Attention: Pete Newcomb, SVP Commercial Operations Critical Care Email: [***]
Required copy to:	Dr. Olaf Schermeier, Head of Critical Care and Ventures Email: [***]

(b) Notices sent in accordance with this Section shall be deemed effectively given: (i) when received, if delivered by hand (with written confirmation of receipt); (ii) when received, if sent by a nationally recognized overnight courier (receipt requested); (iii) on the date sent by e-mail (with confirmation of transmission), if sent during normal business hours of the recipient, and on the next business day if sent after normal business hours of the recipient; or (iv) on the fifteenth (15) business day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid.

13.3 Entire Agreement. This Agreement, together with all Schedules, constitutes the sole and entire agreement of the Parties to this Agreement with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings and agreements, both written and oral, with respect to such subject matter. In the event of an inconsistency between this Agreement and any agreed regional or country-specific activities, this Agreement shall control.

13.4 Assignment. Neither Party shall assign or otherwise transfer any of its rights, or delegate or otherwise transfer any of its obligations or performance, under this Agreement, in each case whether voluntarily, involuntarily, by operation of law or otherwise, without the other Party's prior written consent; provided that no such consent shall be required for assignment or transfer to
(a) [***] or (b) [***]. No delegation or other transfer will relieve the other Party of any of its obligations or performance under this Agreement. Any purported assignment, delegation or

transfer in violation of this Section 13.4 is void. This Agreement is binding upon and inures to the benefit of the Parties hereto and their respective permitted successors and assigns.

13.5 Amendment; Modification; Waiver. This Agreement may only be concluded, terminated or modified in writing. This writing requirement may also be effected by Portable Document Format (PDF) sent by electronic mail or by electronic signature, including but not limited to DocuSign/ AdobeSign/ CongaSign. No waiver by any Party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the waiving Party. Except as otherwise set forth in this Agreement, no failure to exercise, or delay in exercising, any rights, remedy, power or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

13.6 Force Majeure. Neither Party shall be held liable to the other Party nor be considered in breach of this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is results from causes beyond the reasonable control of the affected Party (such as embargoes, war, terrorism, insurrections, strikes, fire, floods, or other acts of God, or acts of any governmental authority). The affected Party shall notify the other Party of any such force majeure event as soon as reasonably practicable and shall promptly undertake all reasonable efforts to cure such force majeure events.

13.7 Severability. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon a determination that any term or other provision is invalid, illegal or unenforceable, the Parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

13.8 Governing Law.

(a) This Agreement and all rights and obligations thereunder shall be exclusively governed and exclusively construed in accordance with [***], under explicit exclusion of its provisions on conflict of laws [***].

(b) Any and all disputes, claims or litigation arising from or related in any way to this Agreement, including its formation, shall be exclusively submitted to and resolved by the courts sitting in [***].

13.9 Equitable Relief. Each Party acknowledges and agrees that the restrictions set forth in Sections 6 and 9 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Sections may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Sections, the non-breaching Party

shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, including specific performance, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other (a) post a bond or other security as a condition for obtaining any such relief, and (b) show irreparable harm, balancing of harms, consideration of the public interest, or inadequacy of monetary damages as a remedy.

13.10 Nonexclusive Remedies. Except if expressly set forth in this Agreement, all rights and remedies of the Parties provided under this Agreement are not exclusive and are in addition to any rights and remedies provided by law or in equity.

13.11 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, e-mail or other means of electronic transmission (to which a PDF copy is attached) shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

{SIGNATURE PAGE FOLLOWS}

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement effective as of the Effective Date.

FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH

By /s/ Pete Newcomb 29.07.2022
Name: Pete Newcomb
Title: SVP ComOp Critical Care

By /s/ Dr. Olaf Schermeier 29.07.2022
Name: Dr. Olaf Schermeier
Title: Head of Critical Care and Ventures

CYTOSORBENTS CORPORATION

By /s/ Dr. Phillip Chan
Name: Dr. Phillip Chan
Title: Chief Executive Officer
July 31, 2022

Exhibit 31.1

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: November 3, 2022
/s/ Phillip P. Chan
Phillip P. Chan Principal Executive Officer

Exhibit 31.2

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 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: November 3, 2022
/s/ Kathleen P. Bloch
Kathleen P. Bloch Principal Financial Officer

Exhibit 32.1

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 ended September 30, 2022 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 ended September 30, 2022, fairly presents, in all material respects, the financial condition and results of operations of CytoSorbents Corporation.

Date: November 3, 2022

CYTOSORBENTS CORPORATION

By: */s/ Phillip P. Chan*
Phillip Chan
Chief Executive Officer

Exhibit 32.2

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 ended September 30, 2022, 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 ended September 30, 2022, fairly presents, in all material respects, the financial condition and results of operations of CytoSorbents Corporation.

Date: November 3, 2022

CYTOSORBENTS CORPORATION

By: */s/ Kathleen P. Bloch*
Kathleen P. Bloch
Chief Financial Officer