Table of Contents

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 March 31, 2023

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 May 1, 2023, there were 43,954,198 shares of the issuer's common stock outstanding.

CytoSorbents Corporation
FORM 10-Q
TABLE OF CONTENTS

	Page
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	3
Condensed Consolidated Balance Sheets as of March 31, 2023 (unaudited) and December 31, 2022	3
Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months ended March 31, 2023 and 2022 (unaudited)	4
Condensed Consolidated Statements of Changes in Stockholders' Equity for the Three Months ended March 31, 2023 and 2022 (unaudited)	5
Condensed Consolidated Statements of Cash Flows for the Three Months ended March 31, 2023 and 2022 (unaudited)	6
Notes to Condensed Consolidated Financial Statements (unaudited)	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	24
Item 3. Quantitative and Qualitative Disclosures about Market Risk	33
Item 4. Controls and Procedures	33
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	33
Item 1A. Risk Factors	33
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	33
Item 3. Defaults Upon Senior Securities	33
Item 4. Mine Safety Disclosures	33
Item 5. Other Information	33
Item 6. Exhibits	34

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

	March 31, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 19,048,410	$ 22,144,567
Grants and accounts receivable, net of allowance for doubtful accounts of $46,510 as of March 31, 2023 and $76,041 as of December 31, 2022	5,527,715	5,664,941
Inventories	1,725,673	3,461,586
Prepaid expenses and other current assets	1,863,193	2,488,597
Total current assets	28,164,991	33,759,691
Property and equipment, net	10,695,013	10,743,032
Restricted cash	1,687,459	1,687,459
Right of use assets	12,469,905	12,603,901
Other assets	4,445,467	4,437,447
Total Assets	$ 57,462,835	$ 63,231,530
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,994,903	$ 1,655,173
Lease liability – current portion	111,627	108,939
Accrued expenses and other current liabilities	7,329,386	7,950,440
Total current liabilities	10,435,916	9,714,552
Lease liability, net of current portion	13,060,760	13,142,005
Long-term debt	5,010,714	5,000,000
Total Liabilities	28,507,390	27,856,557
Commitments and Contingencies (Note 6)		
Stockholders' Equity:		
Preferred Stock, Par Value $0.001, 5,000,000 shares authorized; no shares issued and outstanding as of March 31, 2023 and December 31, 2022	—	—
Common Stock, Par Value $0.001, 100,000,000 shares authorized; 43,851,380 and 43,635,715 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	43,851	43,635
Additional paid-in capital	288,514,368	287,000,021
Accumulated other comprehensive income	1,720,987	2,329,195
Accumulated deficit	(261,323,761)	(253,997,878)
Total Stockholders' Equity	28,955,445	35,374,973
Total Liabilities and Stockholders' Equity	$ 57,462,835	$ 63,231,530

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Three Months Ended March 31, 2023 (Unaudited)	2022 (Unaudited)
Revenue:		
CytoSorb sales	$ 7,906,269	$ 7,866,865
Other product sales	3,770	57,592
Total product sales	7,910,039	7,924,457
Grant income	1,539,457	766,967
Total revenue	9,449,496	8,691,424
Cost of revenue	3,994,169	2,277,636
Gross margin	5,455,327	6,413,788
Other expenses:		
Research and development	4,214,415	4,243,365
Legal, financial and other consulting	669,233	800,735
Selling, general and administrative	8,463,275	9,160,823
Total expenses	13,346,923	14,204,923
Loss from operations	(7,891,596)	(7,791,135)
Other income (expense):		
Interest income (expense), net	(63,170)	8,027
Miscellaneous income/(expense)	(31,798)	30,000
Gain/(Loss) on foreign currency transactions	660,681	(1,213,290)
Total other expense, net	565,713	(1,175,263)
Loss before benefit from income taxes	(7,325,883)	(8,966,398)
Provision for income taxes	—	—
Net loss attributable to common stockholders	$ (7,325,883)	$ (8,966,398)
Basic and diluted net loss per common share	$ (0.17)	$ (0.21)
Weighted average number of shares of common stock outstanding	43,676,435	43,487,946
Net loss	$ (7,325,883)	$ (8,966,398)
Other comprehensive income/(loss):		
Foreign currency translation adjustment	(608,208)	962,911
Comprehensive loss	$ (7,934,091)	$ (8,003,487)

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
For the three months ended March 31, 2023 and 2022 (Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
	Shares	Par value				
Balance at December 31, 2022	43,635,715	$ 43,635	$ 287,000,021	$ 2,329,195	$ (253,997,878)	$ 35,374,973
Stock-based compensation - employees, consultants and directors	—	—	830,280	—	—	830,280
Issuance of common stock - offerings, net of fees incurred	197,665	198	698,237	—	—	698,435
Other comprehensive loss: foreign currency translation adjustment	—	—	—	(608,208)	—	(608,208)
Legal/audit fees related to ATM offering	—	—	(56,702)	—	—	(56,702)
Proceeds from the exercise of stock options for cash	18,000	18	42,532	—	—	42,550
Net loss	—	—	—	—	(7,325,883)	(7,325,883)
Balance at March 31, 2023	43,851,380	$ 43,851	$ 288,514,368	$ 1,720,987	$ (261,323,761)	$ 28,955,445
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	—	—	787,417	—	—	787,417
Other comprehensive income: foreign currency translation adjustment	—	—	—	962,911	—	962,911
Legal/audit fees related to ATM offering	—	—	(40,359)	—	—	(40,359)
Issuance of restricted stock units	27,461	27	106,242	—	—	106,269
Net loss	—	—	—	—	(8,966,398)	(8,966,398)
Balance at March 31, 2022	43,505,948	$ 43,505	$ 284,047,729	$ 1,488,496	$ (230,151,693)	$ 55,428,037

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the three months ended March 31, 2023 (Unaudited)	For the three months ended March 31, 2022 (Unaudited)
Cash flows from operating activities:		
Net loss	$ (7,325,883)	$ (8,966,398)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash restricted stock unit compensation	250,206	159,059
Depreciation and amortization	258,631	217,565
Bad debt expense	11,887	6,936
Amortization of right of use asset	55,439	64,523
Impairment of patents	111,224	305,505
Debt costs	10,714	—
Stock-based compensation	830,280	787,417
Foreign currency transaction (gain) loss	(660,681)	1,213,290
Changes in operating assets and liabilities:		
Grants and accounts receivable	177,170	(239,152)
Inventories	1,747,144	(827,351)
Prepaid expenses and other current assets	795,775	307,097
Other assets	—	56,100
Accounts payable and accrued expenses	629,883	(1,203,761)
Net cash used in operating activities	(3,108,211)	(8,119,170)
Cash flows from investing activities:		
Purchases of property and equipment	(509,669)	(710,239)
Payments for patent costs	(173,215)	(137,717)
Net cash used in investing activities	(682,884)	(847,956)
Cash flows from financing activities:		
Equity contributions - net of fees incurred	641,733	(40,359)
Proceeds from exercise of stock options	42,550	—
Net cash (used in) provided by financing activities	684,283	(40,359)
Effect of exchange rates on cash	10,655	(107,408)
Net change in cash, cash equivalents and restricted cash	(3,096,157)	(9,114,893)
Cash, cash equivalents and restricted cash - beginning of period	23,832,026	53,825,166
Cash, cash equivalents and restricted cash - end of period	$ 20,735,869	$ 44,710,273
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 71,112	$ —
Supplemental disclosure of non-cash financing activities:		
Settlement of accrued bonuses with restricted stock units	$ —	$ 106,269
Capital expenditures included in accounts payable	$ —	$ 2,135,537

See accompanying notes to consolidated financial statements.

CytoSorbents Corporation
Notes to Consolidated Financial Statements
(UNAUDITED)
March 31, 2023

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 presentation 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, 2022, included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (the "SEC") on March 9, 2023. The results for the three months ended March 31, 2023 and 2022, 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 March 31, 2023, the Company's cash, cash equivalents and restricted cash balances were approximately $20.7 million, which the Company expects will fund the Company's operations beyond twelve months from the issuance of these financial statements. 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. In October 2022, the Company formed CytoSorbents France SAS to provide marketing and direct sales services in France. 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 75 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 will be effective until a declaration is made that the circumstances justifying the EUA have terminated or until revoked by the FDA.

In April 2020, the Company also announced that the FDA had granted Breakthrough Designation 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. To help support the increased marketing and promotional efforts of the expanded collaboration, CytoSorbents has agreed to subsidize a portion of the marketing costs through a royalty payment to Fresenius Medical Care based on CytoSorb sales in the intensive care unit on Fresenius Medical Care platforms, excluding the United States. 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 launch of this program is expected to occur sometime in 2023.

The technology is based upon biocompatible, highly porous polymer sorbent beads that can actively remove toxic substances from blood and other bodily fluids by pore capture and surface adsorption. The Company has numerous products under development based upon this unique blood purification technology, which is protected by 19 issued U.S. patents and multiple international patents, with applications pending both in the U.S. and internationally, including HemoDefend, ContrastSorb, DrugSorb, 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 2023 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., CytoSorbents Medical UK Limited and CytoSorbents France SAS, 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 the European Subsidiary. Foreign currency transaction gain (loss) included in net loss amounted to approximately $661,000 and $(1,213,000) for the three months ended March 31, 2023 and 2022, respectively. The Company translates assets and liabilities of all 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. The Company includes accumulated net translation adjustments in accumulated other comprehensive income as a component of stockholders' equity.

Cash and Cash Equivalents

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

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

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 19,048,410	$ 22,144,567
Restricted cash	1,687,459	1,687,459
Total cash, cash equivalents and restricted cash	$ 20,735,869	$ 23,832,026

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 $47,000 and $76,000 at March 31, 2023 and December 31, 2022, respectively.

Inventories

Inventories are valued at the lower of cost or net realizable value under the first in, first out (FIFO) method. At March 31, 2023 and December 31, 2022, the Company's inventory was comprised of finished goods, which amounted to $839,033 and $1,567,871, respectively; work in process which amounted to $289,123 and $1,280,368, respectively; and raw materials, which amounted to $597,517 and $613,347, 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.

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 was no impairment recorded during the three months ended March 31, 2023. During the three months ended March 31, 2023 and 2022, the Company recorded an impairment charge of approximately $111,000 and $306,000, respectively, related to certain patent costs. 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

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

Advertising Expenses

Advertising expenses are charged to activities when incurred. Advertising expenses amounted to approximately $55,000 and $81,000 for the three months ended March 31, 2023 and 2022, respectively, and are included in selling, general, and administrative expenses on the consolidated statements of operations and comprehensive loss.

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 March 31, 2023 or December 31, 2022. 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.

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

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets, liabilities at the date of the balance sheet, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates. The valuation of options granted, allowance for doubtful accounts and recoverability of patents are significant estimates 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 (“FDIC”). Beginning in April of 2023, the Company joined the IntraFi network, and established an Insured Cash Sweep (“ICS”) account whereby all cash that was previously held in the Company’s money market account at Bridge Bank is swept daily in increments of less than $250,000 and deposited in a number of IntraFi’s 4,000 member banks. This arrangement provides FDIC insurance coverage for all of the cash balances previously held in the money market account, which represents all of the cash and cash equivalents held at Bridge Bank. This arrangement excludes the restricted cash balances. 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 and other income are from government agencies in the United States. (See Note 4 for further information relating to the Company’s revenue.)

As of March 31, 2023, two distributors accounted for approximately 30% of outstanding grants and accounts receivable. As of December 31, 2022, two distributors accounted for approximately 27% of outstanding grants and accounts receivable. For the three months ended March 31, 2023, one distributor accounted for approximately 11% of the Company's total revenue and for the three months ended March 31, 2022, no customer accounted for more than 10% of the Company's total revenue.

Financial Instruments

The carrying values of cash and cash equivalents, 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 on the basis of the weighted-average number of shares of common stock plus the dilutive effect of potential common shares outstanding during the period. Dilutive potential common shares include outstanding 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 $78,000 and $68,000, respectively, for the three months ended March 31, 2023 and 2022.

Effect of Recent Accounting Pronouncements

In June 2016, the FASB, issued ASU No. 2016-13 entitled, "Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments". This ASU provides guidance on the calculation of credit losses, which includes the allowance for doubtful accounts on trade accounts receivable. The updated guidance is effective for public entities for fiscal years beginning after December 15, 2022. The Company implemented the updated guidance during the three months ended March 31, 2023 and this did not have significant impact on its consolidated 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 could 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 would have been 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 their commercially reasonable efforts consistent with their normal sales and trading practices to sell the shares of the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company is required to pay the 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 were no sales pursuant to the Sale Agreement during the year ended December 31, 2022. During the three months ended March 31, 2023, the Company sold 197,665 shares of its common stock, generating net proceeds of approximately $698,000. In addition, during the year ended December 31, 2022 and during the three months ended March 31, 2023, the Company paid approximately $90,000 and $57,000, respectively, in expenses related to the Sale Agreement.

Stock-Based Compensation

Total share-based employee, director, and consultant compensation for the three months ended March 31, 2023 and 2022, amounted to approximately $830,000 and $787,000, 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 three months ended March 31, 2023, is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (Years)
Outstanding, December 31, 2022	8,109,824	$ 5.11	6.91
Granted	100,000	$ 2.65	—
Forfeited	(326,539)	$ 2.40	—
Expired	(186,309)	$ 4.75	—
Exercised	(18,000)	$ 2.36	—
Outstanding, March 31, 2023	7,678,976	$ 5.21	6.60

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 $1.55 to $3.50 per share) and expected life of the stock option (6 years), the current price of the underlying stock and its expected volatility (70.4%), expected dividends (-0- percent) on the stock and the risk free interest rate (ranging from 3.54 to 4.22%) 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 March 31, 2023, of $3.37 and the exercise price of the shares.

Options Outstanding				
Range of Exercise Price	Number Outstanding at March 31, 2023	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
$1.11 - $13.20	7,678,976	$ 5.21	6.60	$ 3,340,513

Options Exercisable		
Number Exercisable at March 31, 2023	Weighted Average Exercise Price	Aggregate Intrinsic Value
5,306,799	$ 6.03	$ 851,555

The summary of the status of the Company's non-vested options for the three months ended March 31, 2023, is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, December 31, 2022	3,486,739	$ 2.10
Granted	100,000	$ 1.73
Forfeited	(326,539)	$ 1.44
Vested	(888,023)	$ 2.55
Non-vested, March 31, 2023	2,372,177	$ 2.00

As of March 31, 2023, the Company had approximately $3,781,000 of total unrecognized compensation cost related to stock options which will be amortized over approximately 47 months.

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 March 31, 2023, 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 quarter ended March 31, 2023.

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, 2022	346,500	779,500	1,764,500	2,890,500	$ 4,480,275
Granted	—	—	58,000	58,000	
Forfeited	—	—	(114,250)	(114,250)	
March 31, 2023	346,500	779,500	1,708,250	2,834,250	$ 9,551,423

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 months ended March 31, 2023 and 2022.

Other Awards of Restricted Stock Units:

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 vest one third on the date of the grant one third on the first anniversary of the date of the grant, and one third on the second anniversary of the date of the grant. For the three months ended March 31, 2023 and 2022, the Company recorded a charge of approximately $0 and a reduction of expense of approximately $(65,000), respectively, related to these restricted stock unit awards.

On April 12, 2021, certain named executive officers and senior managers were granted 235,765 restricted stock units. These awards were valued at approximately $2,120,000 at the date of issuance, based upon the market price of the Company's common stock at the date of the grant, and vest one third on the date of the grant, one third on the first anniversary of the date of the grant, and one third on the second anniversary of the date of the grant. For the three months ended March 31, 2023 and 2022, the Company recorded a charge of approximately $177,000 and $177,000, 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 months ended March 31, 2023 and 2022, the Company recorded a charge of approximately $47,000 and $0, respectively, related to these restricted stock unit awards.

Additionally, in 2021 certain employees were offered 91,750 restricted stock units and in 2022 certain employees were offered 30,000 restricted stock units, as a condition of their employment. These awards were valued at approximately $778,068 at the date of issuance. 45,000 of the restricted stock units valued at $375,750 were forfeited in 2022. 46,750 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 months ended March 31, 2023 and 2022, the Company recorded a charge of approximately $27,000 and $47,000 respectively, related to these restricted stock unit awards.

The following table outlines the restricted stock unit activity for the three months ended March 31, 2023:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, December 31, 2022	312,092	$ 4.42
Granted	30,000	$ 2.14
Non-vested, March 31, 2023	342,092	$ 4.22

4. REVENUE

The following table disaggregates the Company's revenue by customer type and geographic area for the three months ended March 31, 2023:

	Direct	Distributors/ Strategic Partners	United States Government Agencies	Total
Product sales:				
United States	$ 3,770	$ —	$ —	$ 3,770
Germany	3,337,904	—	—	3,337,904
All other countries	1,502,599	3,065,766	—	4,568,365
Total product revenue	4,844,273	3,065,766	—	7,910,039
Grant and other income:				
United States	—	—	1,539,457	1,539,457
Total revenue	$ 4,844,273	$ 3,065,766	$ 1,539,457	$ 9,449,496

The following table disaggregates the Company's revenue by customer type and geographic area for the three months ended March 31, 2022:

	Direct	Distributors/ Strategic Partners	United States Government Agencies	Total
Product sales:				
United States	$ 57,592	$ 154,750	$ —	$ 212,342
Germany	3,783,526	—	—	3,783,526
All other countries	1,204,932	2,723,657	—	3,928,589
Total product revenue	5,046,050	2,878,407	—	7,924,457
Grant and other income:				
United States	—	—	766,967	766,967
Total revenue	$ 5,046,050	$ 2,878,407	$ 766,967	$ 8,691,424

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. Emergency Use Authorization ("EUA") of CytoSorb for use in critically-ill patients infected with COVID-19 with imminent or confirmed respiratory failure by the United States Food and Drug Administration (the "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. In addition, 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 CytoSorbents 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.

These government contracts have terms ranging from three months to four years. The Company may apply for an extension of the term of the contract in order to complete its research and development activities but would not receive additional funding during the extension period in excess of the original contract. See Note 2 regarding the accounting policies related to these contracts.

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:

	March 31, 2023	December 31, 2022
Contract receivables, which are included in grants and accounts receivable	$ 4,005,019	$ 3,822,452
Contract liabilities, which are included in accrued expenses and other current liabilities	$ 1,617,195	$ 1,682,837

Contract receivables represent balances due from product sales to distributors amounting to $3,329,854 and $2,944,031 at March 31, 2023 and December 31, 2022, respectively, and billed and unbilled amounts due on government contracts amounting to $675,165 and $878,421 at March 31, 2023 and December 31, 2022, respectively.

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 $176,647 and $166,065 at March 31, 2023 and December 31, 2022, respectively, and deferred grant revenue related to the billing on fixed price government contracts in excess of costs incurred, which amounted to $1,440,548 and $1,516,772 at March 31, 2023 and December 31, 2022, 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”). On December 28, 2022 (the "Fifth Amendment Date"), the Company entered into the Fifth Amendment of its Amended Loan and Security Agreement with Bridge Bank. The Fifth Amendment extends the draw period under the Fourth Amendment to the earlier of (i) March 1, 2023 and (ii) the occurrence of an Event of Default. On March 9, 2023, the Company entered into the Sixth Amendment of its Amended Loan and Security Agreement. The Sixth Amendment further extended the draw period to March 24, 2023. Therefore, no further draws are available as of the date of this filing.

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 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%. On December 27, 2022, the Company drew down the first $5 million tranche of the Term C loans available under the terms of the Fourth Amendment. Under the terms of the Fourth Amendment, commencing on February 1, 2023, the Company is required to make monthly payments of interest only through December 2023. The interest-only period will be further extended through June 2024 provided the Company has met both the required reserves test and the seventy-five percent test, as set forth in the Fourth Amendment, as of November 30, 2023. Commencing on January 1, 2024, if the Company does not meet both the required reserves test and the 75% test, the Company shall make equal monthly payments of principal of $208,333, together with accrued and unpaid interest. Commencing on July 1, 2024, if the Company meets both the required reserves test and the 75% test, the Company shall make equal monthly payments of principal of $277,778, together with accrued and unpaid interest. In either event, all unpaid principal and accrued and unpaid interest shall be due and payable in full on 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 was 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 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. This final fee is being accrued and charged to interest expense over the term of the loan. For the three months ended March 31, 2023, the Company recorded interest expense of approximately $10,714 related to the final fee. The Term Loans are evidenced by a secured promissory note issued to the Bank by the Company. If the Company elects to prepay the Term Loans pursuant to the terms of the Amended and Restated Loan and Security Agreement, it will owe a prepayment fee to the Bank, as follows: (1) for a prepayment made on or after the funding date of a Term Loan through and including the first anniversary of such funding date, an amount equal to 2.0% of the principal amount of such Term Loan prepaid; (2) for a prepayment made after the first anniversary of the funding date of a Term Loan through and including the second anniversary of such funding date, an amount equal to 1.5% of the principal amount of such Term Loan prepaid; and (3) for a prepayment made after the second anniversary of the funding date of a Term Loan, an amount equal to 1.0% of the principal amount of such Term Loan prepaid.

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 the 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.

Long-term debt consists of the following as of March 31, 2023:

Principal amount	$ 5,000,000
Accrued final fee	10,714
Subtotal	5,010,714
Less Current maturities	—
Long-term debt net of current maturities	$ 5,010,714

Principal payments of long-term debt are due as follows during the periods ending March 31:

2024	$ —
2025	2,500,000
2026	2,500,000
Total	$ 5,000,000

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 accrued approximately $598,000 as an estimate of this liability as of December 31, 2021. In January 2023, the Company received an assessment from the German tax authorities for the payroll tax audit of approximately $90,000. In addition, it was determined that the Company would owe additional social security and VAT taxes related to this matter of approximately $83,000. Accordingly, the Company has adjusted its accrual related to this payroll tax audit to approximately $173,000 as of December 31, 2022. As of March 31, 2023, approximately $83,000 remains accrued. This liability is included in accrued expenses and other current liabilities in the consolidated balance sheet as of December 31, 2022 and March 31, 2023. The expense related to this examination was included in selling, general and administrative expenses on the consolidated statements of operations and comprehensive loss.

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, the Company’s former 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 2023, these employment agreements automatically renewed for an additional one 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.

Effective March 31, 2023, Ms. Bloch retired from her role as Chief Financial Officer of the Company. Ms. Bloch's employment agreement expired on March 31, 2023, upon her retirement from the Company. In connection with Ms. Bloch's retirement, the Company and Ms. Bloch entered into a Consulting Agreement, dated as of March 31, 2023 (the "Consulting Agreement"), pursuant to which Ms. Bloch will serve as a consultant to the Company and as the Company's Interim Chief Financial Officer. In accordance with the terms of the Consulting Agreement, Ms. Bloch will continue to provide services to the Company which are customary in scope to those typically provided by a public company Chief Financial Officer. Unless terminated earlier by Ms. Bloch or by the Company upon fourteen days written notice, the Consulting Agreement will remain in effect until December 31, 2025, and thereafter as mutually agreed between the Company and Ms. Bloch.

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 March 31, 2023 and 2022, the Company recorded royalty expenses of approximately $234,000 and $232,000, 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, CytoSorbents has agreed to subsidize a portion of the marketing costs through a royalty payment to Fresenius Medical Care based on CytoSorb sales in the intensive care unit on Fresenius Medical Care platforms, excluding the United States. 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 months ended March 31, 2023, the Company did not record any expense related to this agreement as Fresenius did not commence any marketing activities as defined by the agreement.

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 March 31, 2023 and 2022 per the terms of the license agreement, the Company recorded licensing expenses of approximately $390,000 and $387,000, 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 $1,467,000 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 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 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, 2020, 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:

	March 31, 2023	December 31, 2022
Right-of-use asset	$ 12,469,905	$ 12,603,901
Total lease liability	$ 13,172,387	$ 13,250,944
Less current portion	(111,627)	(108,939)
Lease liability, net of current portion	$ 13,060,760	$ 13,142,005

The maturities of the lease liabilities are as follows as of March 31, 2023:

2024	$ 1,275,860
2025	1,666,361
2026	1,705,626
2027	1,745,970
2028	1,787,423
Thereafter	16,780,192
Total lease payments	24,961,432
Present value discount	(11,789,045)
Total	$ 13,172,387

For the three months ended March 31, 2023 and 2022, operating cash flows paid in connection with operating leases amounted to approximately $633,000 and $713,000, respectively.

As of March 31, 2023 and December 31, 2022, the weighted average remaining lease term was 13.4 years and 13.6 years, respectively.

8. NET LOSS PER SHARE

Basic loss per share and diluted loss per share for the three months ended March 31, 2023 and 2022 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 10,855,000 and 8,825,000 incremental shares as of March 31, 2023 and 2022, 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

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 Breakthrough Device Designation to CytoSorb for the removal of ticagrelor in a cardiopulmonary bypass circuit during emergent and urgent cardiothoracic surgery. 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 a pivotal randomized, controlled clinical trial in the U.S. and Canada, called the STAR-T trial, evaluating the use of DrugSorb-ATR during cardiothoracic surgery to remove ticagrelor to prevent or reduce perioperative bleeding complications in pursuit of U.S. FDA and Health Canada marketing approval.

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 203,000 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 COVID-19 patients todate. CytoSorb has also been granted FDA Breakthrough Designation for the removal of ticagrelor in a cardiopulmonary bypass circuit during emergent and urgent cardiothoracic surgery. CytoSorb was also granted a second FDA Breakthrough Device designation for 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.

We are focusing on three 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)
- Reduce cash burn and maintain tight control over expenses.

Our purification technologies are based on biocompatible, highly porous polymer beads that can actively remove toxic substances from blood and other bodily fluids by pore capture and surface adsorption. The technology is protected by 19 issued U.S. patents and multiple international patents, with applications pending both in the U.S. and internationally. We have numerous 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 future 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, 2022 as filed with the SEC on March 9, 2023. 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 in 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 U.S. sites. In November 2022, the first milestone was completed with the first one-third of patients enrolled, triggering the first Data Safety Monitoring Board (DSMB) meeting. The DSMB recommended to continue the study as planned without any modifications. In 2022, we also received FDA approval to expand the study to Canada and subsequently received Health Canada approval allowing inclusion of Canadian sites into the STAR-T trial in January 2023. In April 2023, the study reached the 2nd milestone of 67% enrollment or 80 patients. The study is expected to reach 100% enrollment sometime in the summer of 2023. Because of the brisk enrollment of the trial, we have elected to forego an interim analysis at this stage which would have otherwise taken several months to conclude, and instead focus on completing trial enrollment on schedule and initiate the final study analysis, while preserving the full statistical power of the study.

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. Study enrollment was paused in November of 2022 for business reasons and is scheduled to resume after completion of the STAR-T trial.

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 recruiting in the U.K., Germany, Austria and Sweden and is planned to expand to additional countries 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 with estimated first data readouts 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 U.S. **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 (73%) compared with the international benchmark Extracorporeal Life Support Organization (ELSO) Registry. The initial CTC results on the first 52 critically ill patients from five U.S. ECMO centers 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 registry completed enrollment with 100 patients from five centers, and the final results mirror the high survival (74%) seen in the previous analysis and have 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 actively enrolling. The speed of enrollment remains uncertain due to COVID-19 related institutional research staff shortages. We are evaluating options to improve enrollment, including a study protocol amendment for potential study design optimization.

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 is actively enrolling in Spain and Germany with plans to expand in more countries 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

- *Resume In-person Sales from a Strong Customer Base:* Our core customer base accounts for the majority of our direct sales and grew by 20-25% at the start of the pandemic and has remained stable since. 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, were the primary issue for volatility in ordering. We have begun to see an easing of these negative impacts of COVID-19 and we have experienced a return to in-person selling, which we believe 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:* We are now the preferred supplier of hemoadsorption technology to the three largest private hospital chains in Germany, including Asklepios Kliniken GmbH, and the former hospitals of RHÖN-KLINIKUM AG. Many of these hospitals are already current customers and our agreements facilitate access and sales of CytoSorb to these and all other relevant institutions within these hospital networks.

- *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 recent 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 *ex vivo* 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 hemoperfusion pump is adequate to implement our CytoSorb blood purification technology, without the complexity of a large dialysis or continuous renal replacement therapy (CRRT) machine, without the need for a dialysis technician, and where patients do not need to have failed kidneys. This would greatly simplify treatment with CytoSorb in the ICU - potentially enabling its *more* ubiquitous and earlier use on *more* patients while opening the door for *more* new applications in the emergency room, surgery suites, and elsewhere, in what we call the “hospital-wide” application. We have initially partnered with a major international dialysis company to distribute a high-quality hemoperfusion machine in Germany, Austria, and Luxembourg and are in the midst of a soft launch, to be followed by a broader rollout in these countries later this year, and in more countries in the not-to-distant future. The machine is only as good as the therapy that is being run on it, and CytoSorb is the market leading cytokine adsorbing technology that makes this an excellent combination treatment and a potentially game-changing new business model going forward.

- *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., Ireland and France, we now sell direct in three of the E.U.’s Big 5 Economies – Germany, France and the U.K. – and a total of 15 countries direct overall, while working with distributors or partners in the other two Big 5 Economies: Italy, and Spain.

- *Investment in important clinical studies in shock, liver failure, cardiac surgery, ATR, etc:* We are committed to funding Company-sponsored studies in key areas that we believe will drive international adoption and usage, with the goal of becoming a standard of care for those applications.

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. During the pandemic, CytoSorb has been used to treat dangerous inflammation and related life-threatening complications in more than 7,650 COVID-19 patients in more than 30 countries. 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.

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 was able to 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 U.S. 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*. The CTC Registry has completed enrollment and the final results confirming high survival (74%) 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, 2022, as filed with the SEC on March 9, 2023.

Research and Development Update

Our research and development work levels have returned back to pre-pandemic levels. The hiring of key technical staff remains a challenge in the current economic environment. Our recruiting process is ongoing, so that we can obtain the technical staff required to be able to timely execute on our various grant and non-grant related research and development projects. As of March 31, 2023, the revenue remaining to be earned on open grant contracts is $9.9 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:

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 March 31, 2023 and 2022:

Revenues:

Revenue from product sales was approximately $7,910,000 in the three months ended March 31, 2023, as compared to approximately $7,924,000 in the three months ended March 31, 2022, a decrease of approximately $14,000. As a result of the decrease in the average exchange rate of the Euro to the U.S. dollar, 2023 product sales were negatively impacted by approximately $349,000. For the three months ended March 31, 2023, the average exchange rate of the Euro to the U.S. dollar was $1.07 as compared to an average exchange rate of $1.12 for the three months ended March 31, 2022. Direct sales decreased approximately $202,000, or 4%. Distributor sales increased approximately $188,000, or 7%. There were no sales to hospitals in the United States under the EUA granted by the FDA for the three months ended March 31, 2023, as compared to sales of approximately $155,000 in the first quarter of 2022. There were no sales related to the demand for CytoSorb to treat COVID-19 patients during the three months ended March 31, 2023 as compared to approximately $300,000 in the first quarter of 2022.

Grant income was approximately $1,539,000 for the three months ended March 31, 2023 as compared to approximately $767,000 for the three months ended March 31, 2022, an increase of approximately $772,000, or 101%. This increase was a result of a strategic decision to deploy our research and development employees exclusively to grant related activities during the three months ended March 31, 2023. In addition, revenue earned on new grant awards was approximately $312,000 during the three months ended March 31, 2023.

Total revenues were approximately $9,449,000 for the three months ended March 31, 2023, as compared to total revenues of approximately $8,691,000 for the three months ended March 31, 2022, an increase of approximately $758,000, or 9%.

Cost of Revenues:

For the three months ended March 30, 2023 and 2022, cost of revenue was approximately $3,994,000 and $2,278,000, respectively, an increase of approximately $1,716,000. Product cost of revenues increased approximately $976,000 during the three months ended March 31, 2023 as compared to the three months ended March 31, 2022. This increase was due start-up activities related to our new manufacturing facility. Product gross margins were approximately 68% for the three months ended March 31, 2023, as compared to approximately 80% for the three months ended March 31, 2022, also due to start-up activities.

***Research and Development Expenses**:*

For the three months ended March 31, 2023, research and development expenses were approximately $4,214,000 as compared to research and development expenses of approximately $4,243,000 for the three months ended March 31, 2022, a decrease of approximately $29,000. This decrease was due to a decrease in clinical trial costs of approximately $807,000 related to the pause of our STAR-D trial in November 2022, and a decrease in non-grant related research and development activities of approximately $72,000. These decreases were offset by approximately $850,000 of costs incurred related to pre-production manufacturing activities required to bring the new manufacturing plant to a state of commercial readiness.

Legal, Financial and Other Consulting Expenses:

Legal, financial and other consulting expenses were approximately $669,000 for the three months ended March 31, 2023, as compared to approximately $801,000 for the three months ended March 31, 2022, a decrease of approximately $132,000. This decrease was due to a decrease in legal fees of approximately $174,000 related to the abandonment of certain patent applications in 2022 and a decrease in accounting and other consulting costs of approximately $33,000. These decreases were offset by an increase in employment agency fees of approximately $75,000.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were approximately $8,463,000 for the three months ended March 31, 2023, as compared to approximately $9,161,000 for the three months ending March 31, 2022, a decrease of approximately $698,000. This decrease was due to a decrease in salaries, commissions and related costs of approximately $641,000, a decrease in commercial insurance expenses of approximately $76,000, a decrease in travel and entertainment expenses of approximately $28,000, a decrease in public relations costs of approximately $23,000, a decrease in advertising costs of approximately $18,000 and a decrease in other general and administrative expenses of approximately $46,000. These decreases were offset by increases in non-cash stock compensation and non-cash restricted stock expense of approximately $134,000.

Gain (Loss) on Foreign Currency Transactions:

For the three months ended March 31, 2023, the gain on foreign currency transactions was approximately $661,000 as compared to a loss of approximately $1,213,000 for the three months ended March 31, 2022. The 2023 gain was directly related to the increase in the spot exchange rate of the Euro to the U.S. dollar as of March 31, 2023 as compared to December 31, 2022. The spot exchange rate of the Euro to the U.S. dollar was $1.09 per Euro as of March 31, 2023, as compared to $1.07 per Euro as of December 31, 2022.

Interest Expense, net:

For the three months ended March 31, 2023, interest expense was approximately $63,000, as compared to interest income of approximately $8,000 for the three months ended March 31, 2022. The change was the result of interest incurred related to the draw down of the $5,000,000 Term Loan with Bridge Bank in December 2022.

History of Operating Losses

We have experienced substantial operating losses since inception. As of March 31, 2023, we had an accumulated deficit of approximately $261,324,000, which included a loss of approximately $7,326,000 for the three-month periods ended March 31, 2023. 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 March 31, 2023, we had current assets of approximately $28,165,000 and current liabilities of approximately $10,436,000. As of March 31, 2023, $25 million of our total shelf amount was allocated to our ATM facility, of which approximately $24.3 million is still available. In April of 2023, we received approximately $1,000,000 in cash from the approved sale of our net operating losses and research and development credits from the State of New Jersey.

We are also managing our resources proactively, continuing to invest in key areas such as our U.S. pivotal STAR-T trial. We have instituted tighter cost controls which are expected to materially reduce our planned cash burn in 2023.

We believe that we have sufficient cash to fund the Company’s operations beyond twelve months from the issuance of the accompanying 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. 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 the third quarter of 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. 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, in 2022 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.

Additionally, COVID slowed our ability to generate clinical data to support our sales and marketing efforts. Currently, we are seeing an easing of the of the negative impacts of COVID-19. In 2023, we have regained access to hospitals and physicians which should positively impact our product sales in the future. The lessened impact of COVID-19 has also had a positive impact on patient enrollment of pivotal STAR-T clinical trial.

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 required 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. 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 also provided 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 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.

Critical Accounting Policies and Estimates

A discussion of our critical accounting policies and estimates is contained in our Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

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 Interim Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Interim 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 Interim 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 Interim 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 March 31, 2023 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, 2022, as filed with the SEC on March 9, 2023.

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	Sixth Amendment to the Amended and Restated Loan and Security Agreement, dated as of March 8, 2023, by and among CytoSorbents Corporation, CytoSorbents Medical, Inc. and Western Alliance Bank (incorporate by reference to Exhibit 10.30 of the Company's Annual Report on Form 10-K for the year ended December 31, 2022).
10.2	Consulting Agreement, dated March 31, 2023, by and between the Company and Ms. Kathleen P. Bloch (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 6, 2023).**
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 Interim 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 March 31, 2023, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at March 31, 2023 and December 31, 2022, (ii) Consolidated Statements of Operations for the three months ended March 31, 2023 and 2022, (iii) Consolidated Statement of Changes in Stockholders' Equity for the three months ended March 31, 2023 and 2022, (iv) Consolidated Statements of Cash Flows for the three months ended March 31, 2023 and 2022 and (v) Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* In accordance with SEC Release 33-8238, Exhibits 32.1 and 32.2 are being furnished and not filed.
** Portions of this exhibit identified by [***] have been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both not material and is private or confidential.

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: May 2, 2023

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

Dated: May 2, 2023

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

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: May 2, 2023
/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: May 2, 2023
/s/ Kathleen P. Bloch
Kathleen P. Bloch Interim 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 ending March 31, 2023 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in such Quarterly Report on Form 10-Q for the quarter ending March 31, 2023, fairly presents, in all material respects, the financial condition and results of operations of CytoSorbents Corporation.

Date: May 2, 2023

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 Interim Chief Financial Officer of CytoSorbents Corporation, hereby certify, that, to my knowledge:

1. The Quarterly Report on Form 10-Q for the quarter ending March 31, 2023, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in such Quarterly Report on Form 10-Q for the quarter ending March 31, 2023, fairly presents, in all material respects, the financial condition and results of operations of CytoSorbents Corporation.

Date: May 2, 2023

CYTOSORBENTS CORPORATION

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