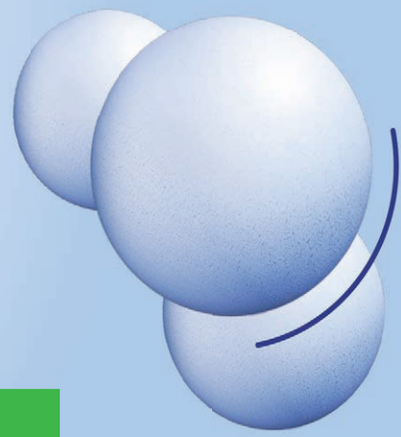
CytoSorbents™

Working to save lives
together.

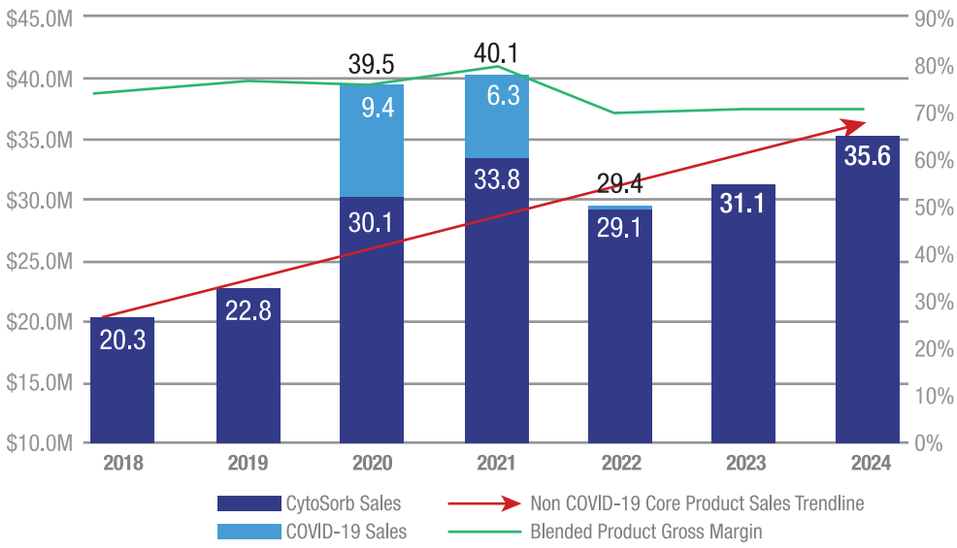


2024

Right Patient, Right Time, Right Dosing

NASDAQ: CTSO
www.cytosorb.com | www.cytosorbents.com

ANNUAL PRODUCT SALES



SELECTED FINANCIAL DATA

	For the Year Ended December 31,				
	2024	2023*	2022	2021	2020
Statement of Operations Data:					
Product Revenue	$35,594,520	$31,084,953	$29,359,910	$40,108,567	$39,452,502
Product Gross Profit	25,125,991	21,953,237	20,493,073	31,939,964	29,837,019
Operating Loss	(16,785,939)	(31,948,620)	(31,521,879)	(22,744,745)	(10,370,334)
Net Loss	(20,718,957)	(29,246,760)	(32,812,583)	(24,558,648)	(7,837,188)
Basic and Diluted Loss Per Common Share	$(0.38)	$(0.65)	$(0.75)	$(0.57)	$(0.20)
Weighted Average Common Shares	54,434,609	44,656,391	43,573,215	43,359,186	38,818,990
Balance Sheet Data:					
Cash, Restricted Cash & Short-Term Investments	$ 9,763,884	$15,615,095	$23,832,026	$53,825,166	$71,421,601
Working Capital	$11,778,999	$11,362,919	$24,045,139	$50,608,748	$72,299,881
Stockholders' Equity	$ 11,106,936	$23,481,214	$35,374,973	$62,578,197	$79,215,579

*As restated and reclassified

**Inactive

BOARD OF DIRECTORS

Michael G. Bator, MBA, Chairman
Founder and Partner of Quartz Advisory Group, LLC

Phillip P. Chan, MD, PhD
Chief Executive Officer of CytoSorbents Corporation

Edward R. Jones, MD, MBA
Past President and Managing Director of Delaware Valley Nephrology and Hypertension Associates

Jiny Kim, MBA
Vice President, Solta Medical at Bausch Health

Alan D. Sobel, CPA, CGMA
Managing Principal of New Jersey Offices CLA (CliftonLarsonAllen, LLP)

MANAGEMENT TEAM

Phillip P. Chan, MD, PhD
Chief Executive Officer

Vincent J. Capponi, MS
President and Chief Operating Officer

Peter J. Mariani, CPA**
Chief Financial Officer

Efthymios N. Deliargyris, MD, FACC, FESC, FSCAI, Chief Medical Officer

Christian Steiner, MD
Executive Vice President, Sales & Marketing, Managing Director – CytoSorbents Europe GmbH

Christopher M. Cramer, MS, MBA
Senior Vice President, Business Development

Corporate Address

CytoSorbents Corporation
305 College Road East
Princeton, NJ 08540
www.cytosorbents.com

Independent Registered Public Accounting Firm

Withum, Smith+Brown, PC
One Tower Center Boulevard, 14th Floor
East Brunswick, NJ 08816

General Counsel

Morgan, Lewis & Bockius
502 Carnegie Center, Princeton, NJ 08540

Transfer Agent

Equiniti Trust Company, LLC
6201 15th Avenue, Brooklyn, NY 11219

CytoSorbents 2025: Transforming Medicine

Dear Stockholders and Friends,

As we reflect on the past year and look ahead to what we believe will be a transformational 2025, I am pleased to share the significant progress we have made across our key initiatives. Our strong execution in the fourth quarter of 2024 drove robust performance, advanced critical regulatory milestones, and strengthened our financial position, setting the stage for future anticipated growth.

We closed 2024 on a high note, achieving total product sales for the year of $35.6 million, marking a 15% year-over-year increase with a healthy 71% product gross margin, and improved operating margins. These results reflect our disciplined approach to international market expansion with CytoSorb®, operational efficiency, and prudent cash management. Notably, direct sales outside of Germany grew by 28% and Distributor/Partner sales rose by 22%, though direct sales in Germany remained flat. We are pleased with the performance of our distributors and other direct sales teams and have taken proactive steps in early 2025 to return Germany to growth.

Regulatory momentum has also been a key driver of our progress. We have made significant strides in bringing our DrugSorb™-ATR therapy, designated as an FDA Breakthrough Device, to patients in need. Our FDA Novo application was submitted in September 2024 and is currently under interactive review. Additionally, after obtaining Medical Device Single Audit Program (MDSAP) certification, we also submitted our Medical Device License (MDL) application to Health Canada, which is now in advanced review. We remain on track and expect regulatory decisions from both agencies this year.

Financially, we took decisive steps to strengthen our balance sheet. First, we closed a $20 million debt facility in June 2024, Then in early 2025, thanks to the strong support of our shareholders, we successfully executed our Shareholder Rights Offering, raising net proceeds of $7.3 million, including the exercise of the Series A Right Warrant. This capital raise also facilitated the release of $5.0 million in restricted cash, increasing our total liquidity by $12.3 million.

Looking forward, we are focused on optimizing patient outcomes and accelerating adoption of CytoSorb. To that end, our central message of treating the "Right Patient at the Right Time with the Right Dose" of CytoSorb is resonating within the medical community. For example, recent studies in peer-reviewed journals continue to support the improvements in organ failure and mortality observed with the early and intensive use of CytoSorb in hyper-inflamed patients with septic shock. We believe this will yield better outcomes which will in turn drive greater usage and adoption.

Beyond our current markets, we are preparing for a potential significant growth opportunity in the U.S. and Canada with DrugSorb-ATR. Designed to address the serious perioperative bleeding risks posed by blood thinners like Brilinta® (ticagrelor, AstraZeneca) in coronary artery bypass graft (CABG) surgery, DrugSorb-ATR has the potential to transform clinical practice. Current guidelines recommend delaying CABG surgery for three to five days to allow Brilinta to wash out, increasing hospital stays, costs, and patient risks. DrugSorb-ATR offers a unique blood purification solution that could enable safe and immediate surgery without delay.

With FDA Breakthrough Device Designation and pending regulatory decisions, we estimate the total addressable market for DrugSorb-ATR in the U.S. and Canada could grow from $300 million today to over $1 billion as Brilinta becomes generic and DrugSorb-ATR expands into additional indications. If approved, we plan to execute a short-term controlled market release at key cardiac centers that participated in our START-T clinical trial, gathering real-world data and refining our commercialization strategy before a broader national rollout.

Our DrugSorb-ATR launch team is actively engaging with key opinion leaders, recruiting commercial talent, and developing a clear value proposition for patients, surgeons, and hospitals. Importantly, visibility and thought leadership remain integral to our launch strategy, with impactful new data being presented at major cardiovascular conferences highlighting the clinical benefits of antithrombotic drug removal in cardiac surgery. This growing body of clinical evidence strengthens our position in the market and reinforces the value of our technology.

With a solid foundation in commercial sales, regulatory progress, and financial stability, we are well-positioned to capitalize on the opportunities ahead. As we advance our global commercialization strategy and prepare for a potential launch of DrugSorb-ATR in the U.S. and Canada, we remain steadfast in our mission to deliver life-saving solutions that improve patient outcomes and create long-term value for our shareholders.

Thank you for your continued support and confidence in CytoSorbents.

Sincerely,

Dr. Phillip Chan
Chief Executive Officer
CytoSorbents Corporation

"CytoSorb is approved in the E.U. but neither CytoSorb nor DrugSorb-ATR are yet approved or cleared in the U.S."

2024 KEY ACCOMPLISHMENTS

More than 270,000 treatments to date globally

Achieved Key Regulatory Milestones

- U.S. FDA and Health Canada marketing applications for DrugSorb-ATR now in substantive review with regulatory decisions expected in 2025
- MDSAP certification
- Regulatory approval in Taiwan

Strengthened balance sheet with a $20M debt facility and our Q1 2025 Shareholder Rights Offering and Series A Right Warrant exercise

Launched the PuriFi hemoperfusion pump

Smoothly transitioned to new CFO Pete Mariani when former CFO Kathleen Bloch retired

Strong Financial Performance

- 2024 Product revenue was $35.6M,15% growth year-over-year, driven by 28% growth in Direct Sales outside of Germany and 22% growth in Distributor/Partner sales
- Healthy 71% product gross margins
- Operating loss for 2024 improved by 47% to $16.8M compared to $32M in 2023, reflecting higher revenue in 2024 and a 22% reduction in operating expenses

Launched our new corporate and product website, with rebranding across all properties including social media

Opened new Dubai subsidiary and added new international distributors

Significantly improved operational and financial performance and moved closer to our goal of bringing our core business to near cash flow breakeven by the end of 2025 through a combination of sales performance, product gross margins, effective cost controls, improved operating efficiencies, and focused cash management

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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

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 08540
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code **(732) 329-8885**

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

Title of each class:	Trading Symbol	Name of each exchange on which registered:
Common Stock, $0.001 par value	CTSO	**The Nasdaq Stock Market LLC (Nasdaq Capital Market)**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☑ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☑ No

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 and posted 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, or a smaller reporting company, or 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☑

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the common stock of the registrant held by non-affiliates as of June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $37.1 million based upon the closing price reported for such date on the Nasdaq Capital Market Exchange. As of March 31, 2025, there were approximately 62.5 million outstanding shares of the registrant's common stock.

Documents incorporated by reference:

Portions of the registrant's definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year are incorporated by reference into Part III of this Form 10-K and certain documents are incorporated by reference into Part IV of this Form 10-K.

EXPLANATORY NOTE

CytoSorbents Corporation ("Company," "we," "us," or "our") is filing this comprehensive Annual Report on Form 10-K for the year ended December 31, 2024 (this "Annual Report"). This Annual Report contains our audited consolidated financial statements for the year ended December 31, 2024, and restates certain sections of the 2023 consolidated financial statements to correct misstatements related to inventory and stock-based compensation expense for restricted stock units.

Restatement Background

As previously disclosed in our Current Report on Form 8-K filed with the Securities and Exchange Commission ("SEC") on March 31, 2025 (the "Current Report"), on March 25, 2025 the Company advised its independent registered public accounting firm, WithumSmith+Brown, PC ("Withum") that the following previously issued consolidated financial statements should no longer be relied upon, due to misstatements in inventory and stock-based compensation for restricted stock units contained in such financial statements, and that such consolidated financial statements should be restated:

a) the audited consolidated financial statements as of and for the year ended December 31, 2023, contained in the 2023 Annual Report,
b) the interim unaudited condensed consolidated financial statements as of and for the first three quarters of the year ended December 31, 2023, contained in our Quarterly Reports on Form 10-Q (the "2023 Quarterly Reports"), and
c) the interim unaudited condensed consolidated financial statements as of and for the first three quarters of the year ended December 31, 2024, contained in our Quarterly Reports on Form 10-Q (the "2024 Quarterly Reports").

Refer to Note 12 - Restatement of Previously Issued Financial Information, in the accompanying Consolidated Financial Statements included in Part II, Item 8 for additional information, including the impact on the specific financial statement line items.

Upon filing of this 2024 Annual Report, including the restated consolidated financial statements contained herein, the above referenced consolidated financial statements may be relied upon.

Impact on Internal Controls over Financial Reporting

See Item 9A, Controls and Procedures, for information related to identified material weaknesses in internal control over financial reporting and the related remedial measures.

CYTOSORBENTS CORPORATION
ANNUAL REPORT ON FORM 10-K
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Report, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Forward-looking statements discuss matters that are not historical facts. Because they discuss future events or conditions, forward-looking statements may include words such as "anticipate," "believe," "estimate," "intend," "could," "should," "would," "may," "seek," "plan," "might," "will," "expect," "predict," "project," "forecast," "potential," "continue," negatives thereof or similar expressions. These forward-looking statements are found at various places throughout this Report and include information concerning possible or assumed future results of our operations; business strategies; future cash flows; financing plans; plans and objectives of management; any other statements regarding future operations, future cash needs, business plans and future financial results, and any other statements that are not historical facts. Unless otherwise indicated, the terms "CytoSorbents," "Company," "we," "us" and "our" refer to CytoSorbents Corporation.

From time to time, forward-looking statements also are included in our other periodic reports on Forms 10-Q and 8-K, in our press releases, in our presentations, on our website and in other materials released to the public. Any or all of the forward-looking statements included in this Report and in any other reports or public statements made by us are not guarantees of future performance and may turn out to be inaccurate. These forward-looking statements represent our intentions, plans, expectations, assumptions and beliefs about future events and are subject to risks, uncertainties and other factors. Many of those factors are outside of our control and could cause actual results to differ materially from the results expressed or implied by those forward-looking statements. In light of these risks, uncertainties and assumptions, the events described in the forward-looking statements might not occur or might occur to a different extent or at a different time than we have described. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of the applicable Report or public statement. All subsequent written and oral forward-looking statements concerning other matters addressed in this Report or public statement and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this Report.

Except to the extent required by law, we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, a change in events, conditions, circumstances or assumptions underlying such statements, or otherwise. For discussion of factors that we believe could cause our actual results to differ materially from expected and historical results see "Item 1A — Risk Factors" below.

TRADEMARKS

This Report 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 its subsidiaries. This Report 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 Report 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

Item 1. Business.

Overview

We are a leader in the treatment of life-threatening conditions in the intensive care unit and cardiac surgery through blood purification. CytoSorbents' proprietary blood 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. Cartridges filled with these beads can be used with standard blood pumps already in the hospital (e.g. dialysis, continuous renal replacement therapy or CRRT, extracorporeal membrane oxygenation or ECMO, and heart-lung machines), where blood is repeatedly recirculated outside the body, through our cartridges where toxic substances are removed, and then back into the body. CytoSorbents' technologies are used in a number of broad applications. Specifically, two important applications are 1) the removal of blood thinners during and after cardiothoracic surgery to reduce the risk of severe bleeding, and 2) the removal of inflammatory agents and toxins in common critical illnesses that can lead to massive inflammation, organ failure and patient death. The breadth of these critical illnesses include, for example, sepsis, burn injury, trauma, lung injury, liver failure, cytokine release syndrome, and pancreatitis as well as the removal of liver toxins that accumulate in acute liver dysfunction or failure the removal of myoglobin in severe rhabdomyolysis that can otherwise lead to renal failure. In these diseases, the risk of death can be extremely high, and there are few, if any, effective treatments.

CytoSorbents' lead product, CytoSorb®, is approved in the European Union and distributed in dozens of countries worldwide, with more than 270,000 devices used cumulatively to date. CytoSorb was originally launched in the European Union under CE mark as the first cytokine adsorber. Additional CE mark extensions were granted for bilirubin and myoglobin removal in clinical conditions such as liver disease and trauma, respectively, and for ticagrelor and rivaroxaban removal in cardiothoracic surgery procedures. CytoSorb has also received FDA EUA in the United States for use in adult critically ill COVID-19 patients with impending or confirmed respiratory failure, to reduce pro-inflammatory cytokine levels. CytoSorb is not yet approved in the United States.

In the U.S. and Canada, CytoSorbents is developing the DrugSorb™-ATR antithrombotic removal system, an investigational device based on an equivalent polymer technology to CytoSorb, to reduce the severity of perioperative bleeding in high-risk surgery due to blood thinning drugs. It has received two U.S. Food and Drug Administration ("FDA") Breakthrough Device Designations: one for the removal of ticagrelor and another for the removal of the direct oral anticoagulants (DOAC) apixaban and rivaroxaban in a cardiopulmonary bypass circuit during urgent cardiothoracic procedures. In September 2024, the Company submitted a De Novo medical device application to the FDA requesting marketing approval to reduce the severity of perioperative bleeding in CABG patients on the antithrombotic drug ticagrelor, which was accepted for substantive review in October 2024. On November 1, 2024 we received Medical Device Single Audit Program (MDSAP) certification, a key regulatory milestone that certifies compliance of our quality management system with the standard regulatory requirements of Canada, the United States, Brazil, Japan and Australia; and then promptly submitted our Medical Device License (MDL) marketing application to Health Canada on November 1, 2024, with MDSAP certification – a requirement for the submission. Our applications with FDA and Health Canada continue to be in substantive and interactive review, and we continue to expect regulatory decisions from both agencies in 2025. DrugSorb-ATR is not yet granted or approved in the United States and Canada, respectively.

Upon approval, the Company expects to rapidly commercialize DrugSorb-ATR in the U.S. and Canada to address this large unmet medical need, with an initial estimated total addressable market of $300 million to $600 million that is anticipated to grow to $1-2 billion over time as we pursue additional indications for DrugSorb-ATR to remove additional classes of blood thinners and expansion of the antithrombotic removal application beyond cardiac surgery and across other surgical specialties. We believe that DrugSorb-ATR has the potential to become an "all-in-one" countermeasure for these agents.

Our executive offices are located at 305 College Road East, Princeton, New Jersey 08540, and our telephone number is (732) 329-8885. Our website address is http://www.cytosorbents.com. We have included our website address as an inactive textual reference only. We make available free of charge through our website our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material, or furnish it to the SEC. We also similarly make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. We are not including the information contained at http://www.cytosorbents.com, or at any other website address, as part of, or incorporating it by reference into, this Annual Report on Form 10-K.

Our Products and Applications

CytoSorbents' technology platform centers on hemocompatible, highly porous polymer beads that act like tiny sponges to remove harmful substances from blood by pore capture and concentration-dependent adsorption, without the need for ligands, antibodies, cells or biologics. CytoSorbents commercializes three different cartridges based on this bead technology. CytoSorb for critical care and cardiac surgery and ECOS-300CY for *ex vivo* organ perfusion in transplant are approved in the E.U., while VetResQ for emergency and critical care in animals is commercialized primarily in the U.S. CytoSorbents is currently seeking U.S. FDA and Health Canada marketing approval for DrugSorb-ATR to reduce the severity of perioperative bleeding in patients on the blood thinning drug, Brilinta, undergoing coronary artery bypass graft (CABG) surgery. The Company also commercializes the PuriFi hemoperfusion pump in select countries internationally.

CytoSorb is an extracorporeal blood purification cartridge that is approved in the European Union and distributed in more than 70 countries worldwide to reduce "cytokine storm" in common critical illnesses that can lead to massive inflammation, organ failure and patient death. In these diseases, the risk of death can be extremely high, and there are few, if any, effective treatments. CytoSorb removes the "fuel to the fire" of deadly inflammation that is often associated with organ failure and poor clinical outcomes. Given that an estimated 40-60% of patients in the ICU suffer from severe inflammation (e.g. sepsis, COVID, flu, trauma, burns, lung failure, complications of surgery, cytokine release syndrome, liver failure, pancreatitis, etc.) where the level of inflammation is directly correlated to severity of illness, CytoSorb is strategically positioned to help these patients. CytoSorb is also approved to reduce bilirubin (e.g. in liver failure) and myoglobin (e.g. in trauma and critical illness). CytoSorb is also used during and after cardiothoracic surgery to remove antithrombotic drugs and inflammatory mediators that can lead to postoperative complications, including severe bleeding, shock, failure to wean from mechanical ventilation, sepsis, and multiple organ failure. CytoSorb is also used in cardiac surgery applications to reduce inflammatory mediators and blood thinners, targeting a reduction in complications of cardiac surgery like sepsis, bleeding, and shock.

In contrast to dialysis which works like the kidney to remove metabolic waste products, small molecules, and water-soluble drugs in about 10-15% of patients in the intensive care unit who develop kidney failure, CytoSorb functions like the liver to remove a broad range of small to mid-molecular weight toxins that dialysis does not remove well – including cytokines, inflammatory mediators, bacterial toxins, liver toxins such as bilirubin and bile acids, proteins such as myoglobin, hemoglobin, and activated complement, peptides, fat-soluble drugs, and hydrophobic protein-bound substances. Because of this, CytoSorb is "Expanding the Dimension of Blood Purification™" in critical care and cardiac surgery, treating inflammation and also other conditions where toxic substances can cause harm, while restoring balance. Based on numerous published studies, we believe treating the right patient, at the right time, with the right therapy of CytoSorb is leading to improved clinical outcomes. In particular, when used early and aggressively on a hyperinflamed patient with worsening organ failure, CytoSorb treatment is associated with the reversal or prevention of many complications such as shock, acute respiratory distress syndrome (ARDS), and kidney failure. CytoSorb was granted U.S. FDA Emergency Use Authorization in April 2020 for use in adult critically ill COVID-19 patients with impending or confirmed respiratory failure. CytoSorb is not yet cleared or approved in the U.S.

DrugSorb-ATR is an investigational device that uses an equivalent polymer technology to CytoSorb to address a large unmet need for blood thinner reversal in cardiothoracic surgery. Millions of people worldwide are on anti-thrombotic drugs, also called blood thinners, to reduce the risk of heart attack and stroke. However, when one of those patients requires emergent cardiac surgery, guidelines recommend they wait 3-5 days for the blood thinners to "wash out" of their systems to avoid bleeding complications. Often the surgery cannot wait and patients are operated at a very high risk for major bleeding. The goals of DrugSorb-ATR are to allow patients to get the critical surgery they need without delay while also reducing the severity of bleeding complications. DrugSorb-ATR installs easily into a cardiopulmonary bypass (CPB) machine and as whole blood is pumped through the cartridge during an operation, it removes the free drug from blood to reverse its antithrombotic effect.

DrugSorb-ATR is initially focused on reducing the severity of perioperative bleeding in CABG patients on the anti-thrombotic drug Brilinta® (ticagrelor, AstraZeneca) in the U.S. and Canada, where approximately 60,000 patients on this medication will need urgent cardiovascular surgery annually in those two markets. Given current U.S. and Canadian prescribing trends that favor Brilinta over its competitors, Plavix (clopidogrel, BMS, Sanofi) and Effient (prasugrel, Daiichi Sankyo, Eli Lilly), and the recent availability of generic Brilinta, the number of eligible patients could increase substantially. Coronary Artery Bypass Grafting (CABG) is the most common type of cardiac surgery worldwide, and per the European Multicenter Study on CABG (E-CABG) Registry, the rate of severe bleeding is more than 3 times higher when patients undergo CABG within two days of the last dose of Brilinta, compared to those who underwent a 4-5 day washout. Data from our U.S. and Canada pivotal STAR-T (Safe and Timely Antithrombotic Removal of Ticagrelor) trial and European STAR Registry suggest the use of CytoSorbents' technology enables CABG patients to safely undergo surgery within 2 days of the last dose of Brilinta without the associated increased bleeding risk. CytoSorbents' technology was granted two FDA Breakthrough Device Designations, one for the removal of ticagrelor (2020) and another (2021) for the removal of the direct oral

anticoagulants (DOACs) Eliquis (apixaban, Pfizer, BMS) and Xarelto (rivaroxaban, Janssen, Bayer). In September 2024, the Company submitted a De Novo medical device application to the U.S. FDA requesting marketing approval to reduce the severity of perioperative bleeding in CABG patients on the antithrombotic drug ticagrelor, which was accepted for substantive review in October 2024. In November 2024, the Company received its Medical Device Single Audit Program (MDSAP) certification and submitted its Medical Device License (MDL) application to Health Canada. DrugSorb-ATR is not yet granted or approved in the United States and Canada, respectively.

If granted or approved, DrugSorb-ATR presents a potentially valuable value proposition to multiple stakeholders. For patients, they would be able to undergo their critical CABG surgery without significant delay and have reduced bleeding risk. For surgeons, it can potentially help get these patients into the operating room faster, while helping to avoid severe intra and postoperative bleeding complications that can be a nightmare scenario for surgeons while negatively impacting their surgical outcomes and the scheduling of new patient surgeries. For hospitals, decreased washout times in the hospital, fewer bleeding complications that require expensive ICU recovery, and faster throughput of revenue-generating cardiac surgeries means potentially better resource utilization, lower costs, and improved revenues while decreased adverse events helps preserve a hospital's quality rating.

Ahead of regulatory decisions for DrugSorb-ATR, we have been preparing our go-to-market strategy for the U.S. and Canada. This initially involves the building of a limited direct sales force and a controlled rollout of DrugSorb-ATR during the first three to six months following clearance or approval, starting with the original clinical sites from the STAR-T trial. This phased approach allows us to assess the commercial introduction process, particularly the value analysis committee (VAC) review and approval procedures for new hospital products. Additionally, it enables us to refine our messaging and establish a core group of sales representatives who will help train new hires as we scale nationally. The Company has identified key positions essential to building the commercial team and has initiated hiring while awaiting approvals from Health Canada and FDA. Given that DrugSorb-ATR is an FDA Breakthrough Device and that a large percentage of the target population fall under the U.S. Centers for Medicare and Medicaid Services (CMS), the Company is also pursuing additional reimbursement and coverage options through the New Technology Add on Payment (NTAP) and Transitional Coverage for Emerging Technologies (TCET) programs. Though we believe these additional programs are not necessary to sell DrugSorb, we believe they could enhance what we believe is an already strong value proposition based on expected clinical benefit and cost savings.

ECOS-300CY is approved in the E.U. to reduce cytokines and other inflammatory mediators when used in an *ex vivo* organ perfusion system, with the goal of helping to preserve or improve the health and quality of harvested solid organs to be transplanted. Due to the severe shortage of donor organs, the majority of transplanted solid organs come from brain dead donors ("BDD") and donation after cardiac death (DCD). However, cytokine storm and severe inflammation is common in these patients, which can degrade the functioning of solid organs like the heart, lungs, liver, and kidneys, resulting in substandard organs that often must be discarded. Although data demonstrate improved clinical outcomes when these organs undergo *ex vivo* organ perfusion, an increasing amount of published data in animal transplant models and real-world human clinical data highlight that the use of our technology with *ex vivo* organ perfusion is associated with better outcomes in terms of organ function and post-transplant outcomes, compared to *ex vivo* organ perfusion alone. Because of this, we believe the ECOS-300CY cartridge has the potential to significantly expand the solid organ donor pool and reduce the more than 150,000 patients on transplant waiting lists in the U.S. and E.U.

CytoSorbents announced a development partnership with Aferetica srl in 2017 to provide its ECOS-300CY technology under the exclusive trade name, PerSorb™, as part of Aferetica's program to develop the PerLife™ *ex vivo* organ perfusion system. In 2021, commercialization of PerSorb™ and Aferetica's PerLife™ *ex vivo* organ perfusion system commenced in Italy.

VetResQ is a broad-spectrum blood purification adsorber commercially available in the U.S. animal health market to help treat drug intoxication, deadly inflammation (via hemoadsorption of cytokines, bacterial toxins and other inflammatory mediators) and toxic injury in animals with critical illnesses such as septic shock, toxic shock syndrome, toxin-mediated diseases, pancreatitis, trauma, liver failure, heat stroke and lung injury. VetResQ is based upon an equivalent polymer technology to CytoSorb and is configured in three different sized cartridges (50, 150 and 300mL) to accommodate treatment of small, medium, and large animals such as cats, dogs, and high-value animals such as foals and horses. VetResQ is compatible with standard hemodialysis, continuous renal replacement therapy ("CRRT"), and hemoperfusion blood pumps. Based upon cumulative studies, VetResQ is capable of reducing a broad range of excessive inflammatory mediators and toxins that could otherwise cause direct tissue injury or serious systemic inflammation that can rapidly lead to instability, organ failure, and death. VetResQ is available in the U.S. only for veterinary animal usage and is not for human use.

PuriFi is an E.U. Medical Device Regulation (MDR) approved advanced hemoperfusion pump that we co-developed with our original equipment manufacturer (OEM) partner, and launched in June 2024 in the E.U. and other select countries that can replace standard hospital blood pumps to implement our various blood purification therapies. The PuriFi peristaltic blood pump features a number of differentiating innovations that separate it from other standard hemoperfusion pumps including a pre-assembled adult and

pediatric blood line kit, auto-priming, an auto-leveling bubble catcher, an intuitive touchscreen graphical user interface with a step-by-step user-friendly set-up guide, optional blood warming, and a rapid 10-minute set-up time. Together, these unique features enable an easy and rapid way to administer CytoSorbents' blood purification technologies like CytoSorb and VetResQ for critically ill and cardiac surgery patients.

Clinical Studies

We are focusing our company sponsored clinical research efforts on critical care and cardiac surgery applications of our technology, including the following:

Country	Trial Name	Indication	Status
United States	STAR-T	Ticagrelor Removal During Cardiac Surgery	Completed
United States	STAR-D	Direct Anticoagulants Removal During Cardiac Surgery	Terminated
United States	CTC Registry	CytoSorb in COVID-19 patients on ECMO under EUA	Completed
Germany	PROCYSS	Refractory Septic Shock Patients	Enrolling
International	STAR Registry	Real world outcomes in antithrombotic removal	Enrolling
International	COSMOS Registry	Real world outcomes in multiple critical care applications	Enrolling

Critical Care

In 2011, CytoSorb received EU regulatory approval under the CE Mark as an extracorporeal cytokine adsorber to be used in clinical situations where cytokines are elevated. As part of the CE Mark process, in 2011 we completed our randomized, controlled, European Sepsis Trial amongst 14 trial sites in Germany, with enrollment of 100 patients with sepsis and respiratory failure. The trial established that CytoSorb was well-tolerated and safe with no serious device related adverse events reported. The trial also demonstrated the ability of CytoSorb to reduce cytokines such as IL-6 from the blood of septic patients.

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 90-day survival rates (73%). This is in contrast to the approximately 50% 90-day survival rates when CytoSorb was not used, as reported from the North American cohort of the 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 published in the peer reviewed journal Critical Care. The data further demonstrate that earlier intervention with CytoSorb and ECMO was associated with shorter need for mechanical ventilation, ECMO support, and ICU length of stay. These results lend support to our concept of "enhanced lung rest," where ECMO helps the lungs rest by oxygenating blood extracorporeally and reducing the need for mechanical ventilation that can cause ventilator-induced lung injury, while CytoSorb reduces the circulating inflammatory mediators that cause continued capillary leak syndrome in the lungs. Together, the goal of this dual-therapy strategy is to give the lungs a chance to recover and heal, a pre-requisite for weaning off mechanical ventilation and ECMO.

The German **PROCYSS** multicenter, randomized controlled trial evaluating the ability of CytoSorb to restore hemodynamic stability in patients with refractory septic shock is enrolling, however, at significantly slower rate than expected. The Company in collaboration with Principal Investigator and scientific committee of the trial are critically reviewing options to modify the current study design with the intent of enabling better study progress and anticipate this process to be completed in 2025.

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, rhabdomyolysis, acute liver failure, and acute pancreatitis. The Registry is actively enrolling in Spain, Germany, Portugal, and Italy with plans to expand in more countries in 2025. The Registry is expected to contribute original analyses for presentations at international critical care conferences and publications in peer-reviewed journals on an ongoing basis starting in 2025.

Cardiac Surgery

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, Belgium and Sweden and is planned to expand to additional countries in 2025. Initial data outputs from the STAR Registry have already been presented at the EuroPCR and at the European Association of Cardiothoracic Surgery conferences in previous years with new analyses expected to be presented on an ongoing basis at international conferences and published in peer-reviewed journals in 2025 and beyond.

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 with multiple U.S. STAR-T study sites open. 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 early 2023, the study exceeded 50% enrollment and reached the 2nd milestone of 67% enrollment in the Spring of 2023, triggering another DSMB safety review, which found no safety concerns and recommended completion of the trial. The study completed enrollment in July of 2023 triggering the final DSMB safety review following database lock in December 2023, which reported no safety concerns thereby meeting the primary safety endpoint of the study. Based on the initial analysis of the STAR-T data, the study did not meet the primary effectiveness endpoint in the overall patient population that underwent different types of cardiac surgeries. However, the study did demonstrate evidence of reduced bleeding complications, including serious bleeding events, in patients in the pre-specified isolated coronary artery bypass graft ("CABG") surgery population. Patients undergoing CABG surgery represented more than 90% of the overall study population. The topline results of the U.S. and Canadian 140-patient, pivotal STAR-T randomized controlled trial were presented at the 104th Annual Meeting of the American Association for Thoracic Surgery ("AATS") held in Toronto, Canada on April 28, 2024. The Company submitted the DrugSorb-ATR medical device De Novo marketing application to the FDA on September 27, 2024. On November 1, 2024 we received Medical Device Single Audit Program (MDSAP) certification, a key regulatory milestone that certifies compliance of our quality management system with the standard regulatory requirements of Canada, the United States, Brazil, Japan and Australia; and promptly submitted our Medical Device License (MDL) marketing application to Health Canada on November 1, 2024.

In October 2021, we also received full FDA approval of an Investigational Device Exemption (IDE) application to conduct a double-blind, randomized, controlled clinical study for up to 120 patients entitled, "**S**afe and **T**imely **A**ntithrombotic **R**emoval – **D**irect Oral Anticoagulants (**STAR-D**)," in the United States to support FDA marketing approval. This was done under the previously announced 2nd FDA Breakthrough Device Designation granted for our DrugSorb-ATR Antithrombotic Removal System. This Breakthrough Device designation covers the removal of the Direct Oral Anticoagulants (DOACs) apixaban and rivaroxaban in a cardiopulmonary bypass circuit to reduce the likelihood of serious perioperative bleeding during urgent cardiac surgery. The STAR-D study was initiated, but the Company ultimately decided to place it on hold for business reasons, specifically related to prioritization and focused resource allocation to the completion of the STAR-T study and the subsequent regulatory submissions to FDA and Health Canada. Further discussions with the FDA to determine an appropriate label expansion strategy to include the removal of DOACs will ensue following the completion of the ongoing review of the current FDA application for DrugSorb-ATR for the removal of ticagrelor.

Research and Development

We have been engaged in research and development since inception. Since 2012, we have been awarded an aggregate of approximately $42.3 million in grants, contracts, and other non-dilutive funding from DARPA ($3.8M over 5 years), the U.S. Army ($100K Phase I SBIR; $50K Phase I option, $803K Phase II SBIR, $443K Phase II enhancement), the U.S. Air Force $3.1M Rapid Innovation Fund, the Congressionally Directed Medical Research Program Office, ("CDMRP", $718K), the National Heart, Lung and Blood Institute and USSOCOM ($203K Phase I SBIR; $1.5M Phase II SBIR; $3.0M Bridge SBIR), the Joint Program Executive Office – Chemical and Biological Defense, (JPEO-CBD), ($150K Phase I and Phase I option, $1.0M Phase II), the U.S. Army Peritoneal dialysis/mesh packing for hyperkalemia ($150K Phase I SBIR, $1.0M Phase II, $1.5M Sequential Phase II), Universal Plasma ($150K Phase I and 1.0M Phase II STTR; $2.9M US Army and CDMRP Rapid Innovation Fund; $4.4M CDMRP; $1.1M US Army Sequential Phase II; $2M DMRDP; and $4.3M JWMRP), Lipopolysaccharide Adsorption In Sepsis (National Institution of General Medical Sciences $282K), the U.S. Air Force program ($75K), New Jersey Technology Business Tax Certificate Program for research related

expenses ($8.6M), and others to further develop our technologies for sepsis, trauma and burn injury, and blood transfusions, respectively. Some payments are based on achieving certain technology milestones.

Commercial and Research Partners

Fresenius Medical Care AG

In December 2014, we established a multi-country partnership with Fresenius Medical Care to commercialize CytoSorb in France, Poland, Sweden, Denmark, Norway, and Finland. Fresenius received exclusive distribution rights and supported clinical development. A revised three-year agreement (effective January 2017) extended Fresenius' exclusive distribution for critical care applications through 2019 and included guaranteed minimum quarterly orders.

Additionally, we entered into a comprehensive co-marketing agreement with Fresenius. Under the terms of the co-marketing agreement, CytoSorbents and Fresenius agreed to jointly market CytoSorb to Fresenius' critical care customer base in all countries where CytoSorb was being actively commercialized. CytoSorb continued to be sold by our direct sales force or through our international network of distributors and partners, while Fresenius sold all ancillary products to their customers. Fresenius further provided written endorsements of CytoSorb for use with their multiFiltrate and multiFiltratePRO acute care dialysis machines that could be used by us and our distribution partners to promote CytoSorb worldwide.

In December 2018, the Company amended its 2014 Fresenius distribution agreement, granting exclusivity for certain applications in France, Czech Republic, and Finland. In 2019, several countries transitioned to co-marketing, and minimum purchase requirements were removed. The aforementioned exclusive agreements became non-exclusive in January 2022. In addition, also in December 2018 and in 2020, we entered into agreements to expand the partnership with Fresenius into South Korea, Mexico, Colombia and Ecuador.

In August 2022, CytoSorbents and Fresenius expanded their partnership with a new Marketing Agreement to promote CytoSorb globally (excluding the US) for critical care. Fresenius would promote CytoSorb as the featured solution for cytokine, bilirubin, and myoglobin on its critical care platforms worldwide with the exception of the U.S., in a comprehensive marketing campaign. The Marketing Agreement also included the certification of compatibility of CytoSorb for usage on Fresenius' current critical care platforms and provided for potential new collaborations on novel future innovations. The initial three-year agreement automatically renews for two years. Under the terms of this agreement, CytoSorbents would pay royalties on sales to offset program-specific marketing costs. Due to delays in the full implementation of this Marketing Agreement, no royalties were paid under this agreement in 2024 or 2023.

Aferetica s.r.l.

In 2015, we entered into a distribution agreement for CytoSorb with Aferetica s.r.l., a distributor based in Bologna, Italy that specializes in the sale of certain medical products and devices, specifically extracorporeal therapies, in the critical care, cardiac surgery and liver disease markets ("Aferetica"). The agreement was renewed and is ongoing.

In 2021, CytoSorbents and Aferetica announced the commercial launch in Italy of the PerSorb™ adsorber and the PerLife™ *ex vivo* organ perfusion system, respectively, to help restore and preserve harvested organs for transplant. The PerSorb adsorber is a private-label version of CytoSorbents' ECOS-300CY cartridge that is approved in the E.U. for this application.

Terumo Cardiovascular Group

On January 1, 2024, we entered into a second amended and restated agreement to the original distribution agreement from October 2016. Under the terms of this amended and restated agreement, Terumo received non-exclusive distribution rights in France to promote and sell the CytoSorb CPB procedure pack for intra-operative use during cardiac surgery at specifically named hospitals in France. This amended and restated agreement allowed the Company to sell directly to other hospital customers in France for the cardiac surgery application. Financial terms of this agreement have not been disclosed. The agreement terminated on December 31, 2023 and is currently under re-negotiation.

B. Braun Avitum AG

In March 2021, we announced announce the launch of a global co-marketing agreement with B. Braun Avitum AG, one of the world's leading manufacturers of medical devices and pharmaceutical products and services, to promote the use of CytoSorb® with B. Braun's latest OMNI® continuous blood purification platform and OMNIset® Plus bloodline set (set version 3.0 or higher). The

CytoSorb® adsorber is used in critical care for the extracorporeal removal of cytokines and inflammatory mediators from the bloodstream and can be operated with the B. Braun OMNI® acute dialysis machine. B. Braun will supply the market with the OMNI® and OMNIset® Plus while CytoSorbents and its network of direct sales, strategic partners, and distributors will continue to supply the market with CytoSorb®. This global co-marketing agreement applies to the countries where both products are registered (U.S. market is specifically excluded). Financial terms of this agreement have not been disclosed.

The Advisory Boards

From time to time our management meets with scientific advisors to obtain expert opinions on basic science, critical care medicine and cardiac surgery. We compensate all our SAB members according to fair market value and reimburse them for their travel expenses when attending meetings in person.

Royalty Agreement

In August 2003, in order to induce Guillermina Vega Montiel, a principal member of RenalTech International, LLC at the time, to make a $4 million investment in RenalTech International, LLC, Ms. Montiel was granted a perpetual royalty (the "Royalty") equal to three percent of all gross revenues, license fees, or sales of CytoSorb intellectual property received by us from sales or license of CytoSorb in the applications of sepsis, cardiopulmonary bypass surgery, organ donor, chemotherapy and inflammation control. In addition, for her investment, Ms. Montiel received 1,230,770 membership units of RenalTech International, LLC. Such membership units ultimately were converted into and became 7,420 shares of our common stock following our June 30, 2006 merger. In February 2017, all rights, title and interest to the Royalty were assigned to The Robert Shipley Living Trust. In November 2022, all rights, title and interest to the Royalty was assigned to ROKK, LLC. In August 2024, the Company and ROKK entered into the Amended and Restated Agreement to, among other items, clarify the scope of the term "gross revenue" from which the three percent royalty payment is calculated. Under the Amended and Restated Agreement, the term "Covered Product" means the Company's flagship product, CytoSorb, together with the currently commercialized versions of VetResQ and ECOS-300CY, as well as the versions of DrugSorb and DrugSorb-ATR that have been evaluated in human clinical trials, in each case as of the date of the Amended and Restated Agreement. For the year ended December 31, 2024 we have recorded royalty costs of approximately $1,060,000.

License Agreement

In 2003, Purolite filed a lawsuit against us asserting, among other things, co-ownership and co-inventorship of certain of our patents. On September 1, 2006, the United States District Court for the Eastern District of Pennsylvania approved a Stipulated Order and Settlement Agreement under which we and Purolite agreed to the settlement of the action. The Settlement Agreement provides us with the exclusive right to use our patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. In particular, the Settlement Agreement relates to several of our issued patents and several of our pending patent applications covering our biocompatible polymeric resins, our methods of producing these polymers, and the methods of using the polymers to remove impurities from physiological fluids, such as blood.

Under the terms of the Settlement Agreement, we have agreed to pay Purolite royalties of 2.5% to 5% on the sale of those of our products, if and when those products are sold commercially, that are used in direct contact with blood or, in certain cases, in direct contact with a physiological fluid other than blood. The royalty payments provided for under the Settlement Agreement would apply to our currently envisioned CytoSorb, VetResQ, and BetaSorb products. For the year ended December 31, 2024 per the terms of the license agreement we have recorded royalty costs of approximately $809,000. The 18-year term of this license agreement expired in August of 2024, and no further payments were made.

Product Payment & Reimbursement

CytoSorb

Germany

Effective January 1, 2024, the coding ("OPS") for plasmapheresis, adsorption (previously: immunoadsorption) and related treatments has been extensively restructured to enable a more precise and rational classification. Therefore, the coding for hemoadsorption therapy (including CytoSorb device) has been updated to the new procedure code "8-821.30 hemoperfusion [whole blood adsorption]: selective, removal of hydrophobic substances (low and/or middle-sized molecules)". This coding keeps on triggering the previous supplementary reimbursement that each hospital negotiates on an annual basis with the health insurers (valid in 2024: "ZE2023-09" as this code is being updated annually). A dedicated coding as well as reimbursement for hemoadsorption was effective

since January 1, 2017 (procedure code "8-821.2 adsorption of hydrophobic, small and middle-sized molecular substances"). According to the hospital's budget negotiations, the reimbursement rate not only covers the cost of the device, but the procedural costs as well.

Switzerland

Since 2020, the most specific procedure code ("CHOP") for any treatment with CytoSorb has been installed: "99.76.31 Adsorption of hydrophobic, small and middle-sized molecular substances". Before, in 2018 CytoSorb had to be coded via the pre-existing CHOP code 99.76.99 "Extracorporeal immunoadsorption, other" and in 2019 CytoSorb was assigned the first dedicated procedure code from the Swiss Federal Statistical Office, a division of the Federal Department of Home Affairs in Switzerland under the category "99.76.12 Adsorption of Cytokines and Interleukin". Use of these specific codes since 2019 gave Swiss hospitals the ability to collect cost data related to CytoSorb treatments. In 2021, SwissDRG performed the first cost analysis of all procedures coded with 99.76.31. This analysis showed that there were no additional treatment costs associated with use of CytoSorb against the relevant DRGs, suggesting CytoSorb may be cost neutral or even cost-saving across all indications.

Europe (excluding Germany and Switzerland)

Payment for our CytoSorb device in patients with life-threatening illnesses is country dependent in Europe. Most European markets issue reimbursement for standard therapies only, i.e. those recommended in relevant treatment guidelines. The Company is currently conducting randomized controlled trials (RCTs) to achieve this in all major indications. In the meantime, we are leveraging health economics, local data generation and KOL management in all major territories, with our partners and local sales teams, such as France, England, Italy, Spain, Russia, Belgium, Netherlands, Luxembourg, Poland, Sweden, Norway, Denmark and Finland.

In the United Kingdom, market access and reimbursement of drugs, medical devices and diagnostics is heavily dependent on the guidance published by the National Institute for Health and Care Excellence (NICE). In 2020, NICE published a Report on "Cytokine adsorption devices for treating respiratory failure in people with COVID-19". The report showed that cytokine adsorption devices reduce levels of cytokines in the blood in people with COVID-19. This may help improve lung function. In 2021, NICE published its report on CytoSorb for the removal of ticagrelor in urgent and emergent cardiac surgery patients in a MedTech Innovation Briefing (MIB) called "CytoSorb for reducing risk of bleeding during cardiac surgery". The MIB highlights the safety and efficacy of CytoSorb in this indication, as well its innovative nature and the substantial cost savings CytoSorb generates and has aided adoption in the UK.

Other Markets

CytoSorb is currently marketed and distributed in more than 76 countries around the world including Russia, Turkey and Israel. It is generally paid for through the standard DRG (diagnosis related group) payment, dedicated reimbursement codes, tender orders, private insurance, and/or self-pay. We are actively pursuing generation of new procedure codes in many countries we are currently serving. Across all countries, we are mitigating financial barriers though use of health economics, local data generation and targeted KOL management.

United States

CytoSorb is not yet approved in the U.S. but has received FDA Emergency Use Authorization in April 2020 for use in adult critically ill COVID-19 patients with imminent or confirmed respiratory failure. There is currently no specific reimbursement for CytoSorb in the U.S. Payment for our CytoSorb device in the U.S. for this application falls under the DRG prospective repayment system, which is currently the predominant inpatient hospital reimbursement methodology in the U.S., that was increased for COVID-19 applications as part of the CARES Act. Under this system, hospital reimbursement is generally based upon pre-determined amounts payable for specific diagnoses (e.g. septic shock with respiratory failure), regardless of the number of services provided during the patient's stay. If CytoSorb can improve outcomes and reduce the costs of ICU treatment and hospital length of stay, it could potentially save hospitals a significant amount of money.

In January 2021, the Centers for the Centers for Medicare & Medicaid Services (CMS) announced the Medicare Coverage of Innovative Technology (MCIT) pathway that will provide national Medicare coverage as early as the same day as FDA market authorization for Breakthrough Designated medical devices, where coverage would last 4 years. Although this program was rescinded by CMS in November 2021, a legislative version of the program is currently contained within the CARES 2.0 bill, though not yet approved. In June 2023, CMS announced a new initiative called "Transitional Coverage for Emerging Technologies" (TCET) as a potential replacement for MCIT, that would provide guaranteed coverage to FDA Breakthrough Devices for a certain period of time. In August 2024, CMS published a final notice detailing the TCET pathway. Eligibility requires a) FDA Breakthrough Device Designation, b) Determination that the device falls within a Medicare benefit category c) It is not also covered by a CMS National Coverage

Determination (NCD), and d) that no other law or regulation excludes participation. Manufacturers can voluntarily submit a formal self-nomination to be evaluated for the TCET program within 12 months of anticipated FDA marketing authorization. The FDA reviews applications on a quarterly basis with a strong focus on clinical evidence and will approve up to 5 devices a year for the program using existing NCD criteria. CMS anticipates that approved devices will have coverage under a TCET NCD for approximately 5 or more years as evidence is generated to address identified evidence gaps that can lead to a predictable, long-term Medicare coverage determination. CytoSorbents plans to pursue CMS TCET coverage given that it believes that DrugSorb-ATR, which was granted FDA Breakthrough Device Designation for the removal of ticagrelor (April 2020) and Direct Oral Anticoagulants (DOACs) apixaban and rivaroxaban (August 2021) during emergent or urgent cardiothoracic surgery, meets these criteria.

Competition

General

Our core adsorbent porous polymer bead technology is used in our marketed products, such as the CytoSorb, ECOS-300CY, and VetResQ cartridges, and other products under advanced development, such as CytoSorb XL and DrugSorb-ATR. We believe these products represent a unique approach to disease states and health complications associated with the presence of larger toxins (often referred to as middle molecular weight toxins) and poorly dialyzable drugs in the bloodstream, including sepsis, acute respiratory distress syndrome (ARDS), trauma, severe burn injury, pancreatitis, post-operative complications of cardiac surgery, damage to organs donated for transplant prior to organ harvest, renal disease, drug intoxication, and perioperative bleeding due to antithrombotic drugs. In many of these illnesses, with the exception of antibiotics and in some cases steroids, current standard of care therapy in the ICU is predominantly supportive care. Technologies such as mechanical ventilation, vasopressors and inotropes, and dialysis are often called “life support” and can keep critically ill patients alive, but do not actively reverse the underlying pathology, and in many cases can exacerbate illness. This is a major reason why critical illness remains a major unmet medical need and is associated with high morbidity and mortality, often exceeding 30%.

There are four common forms of blood purification, including hemodialysis, hemofiltration, hemoperfusion, and therapeutic plasma exchange (TPE). All modes are generally supported by standard hemodialysis machines. All take blood out of the body to remove toxins and unwanted substances from blood and utilize extracorporeal circuits and blood pumps. Dialysis and hemofiltration remove substances from blood by diffusion and ultrafiltration, respectively, through a semi-permeable membrane, allowing the passage of certain sized molecules across the membrane, but preventing the passage of other, larger molecules. Therapeutic plasma exchange can use either apheresis machines to centrifugally remove plasma or fluid from whole blood, or specialized plasma separator hemofilters that do the same, but requires replacement of plasma and/or fluid. Hemoperfusion utilizes solid or porous sorbents to remove substances based on pore capture and surface adsorption, not filtration. Of the four blood purification modalities, hemoperfusion is the easiest to implement.

CytoSorb: CytoSorb is a hemoperfusion cartridge, using an adsorbent of specified pore size, which controls the size of the molecules which can diffuse into the adsorbent and vastly increases the area available for surface adsorption. As whole blood flows over our polymer adsorbent, middle molecules such as cytokines diffuse into the polymer adsorbent and are adsorbed and removed from blood. For example, we have demonstrated the ability of CytoSorb to reduce key cytokines in the blood of human patients in a wide variety of settings, including for example, septic shock, ARDS, and endotoxemia. Our devices do not use semipermeable membranes or dialysate. In addition, our devices do not remove fluids from the blood like hemodialysis, hemofiltration, or TPE. Finally, our technology can be easily connected to a wide range of extracorporeal blood pumps and support high blood flow rates over the course of 24 hours, whereas other blood purification technologies require much more complexity and can only support relatively low flow rates. Accordingly, we believe that our technology has significant advantages as compared to other blood purification products, including ease of use. We believe we are the leader in acute care blood purification for most of our various clinical applications, which is highlighted by the significantly greater number of peer-reviewed publications than any of our competitors. Examples of E.U. approved blood purification competitors that claim to reduce cytokines include Oxiris and SepteX (Baxter/Vantiv), PMMA (Toray), HA330 and HA380 (Jafron), TPE (multiple manufacturers), Efferon-CT and Efferon-LPS (Efferon), and EMIC-2 (Fresenius Medical Care).

DrugSorb-ATR: To our knowledge, CytoSorb is the only therapy approved for the removal of ticagrelor and rivaroxaban (Xarelto®, Janssen, Bayer) in the E.U. during cardiac surgery in urgent or emergent cardiopulmonary bypass. The only recommended alternative is to wait for 3 to 5 days to allow natural drug elimination and washout prior to surgery. In the U.S., there are no approved or cleared therapies to reverse the effects of ticagrelor or DOAC anticoagulants during cardiac surgery. Besides DrugSorb-ATR, PhaseBio, a now defunct clinical-stage biopharmaceutical company, had licensed an intravenously administered monoclonal antibody fragment with high affinity for ticagrelor called bentracimab and conducted the U.S. REVERSE-IT (Rapid and SustainEd ReVERSal of TicagrElor – Intervention Trial) study, a Phase 3, prospective, multi-center, open-label, single-arm trial designed to study reversal of the antiplatelet effects of ticagrelor with bentracimab to treat patients who present with uncontrolled major or life-threatening bleeding

(n=8) or when used prophylactically in patients who require urgent surgery or an invasive procedure to prevent bleeding (n=142). Investigators reported a rapid reversal of anti-platelet activity in both subgroups. Among surgical patients, 66.4% had mild GUSTO (Global Use of Strategies to Open Occluded Coronary Arteries bleeding scale) bleeding, and 33.6% had moderate GUSTO bleeding perioperatively. Treatment-emergent adverse events (i.e. adverse events that were not present prior to treatment initiation or an event already present that worsens in either intensity or frequency following exposure to the treatment) were reported by 92.7% of enrolled patients. Four patients died (2.8%): two with septic shock, and two with cardiogenic shock. Of 150 patients, eight patients (5.3%) had thrombotic events, including two ischemic strokes, one transient ischemic attack, three myocardial infarctions, and two with arterial thromboembolisms in the right lower extremity. In November 2021, based on FDA feedback, PhaseBio announced that it continued to enroll more patients into the uncontrolled major or life-threatening bleeding arm of the study and intended to submit a BLA for both subgroups by Summer 2022. However, in October 2022, PhaseBio filed for Chapter 11 bankruptcy. The bentracimab asset was transferred to PhaseBio's creditor, SFJ Pharmaceuticals in December 2022, who filed an FDA Biologics License Application (BLA) for bentracimab in mid-2024 based on a second interim analysis of the REVERSE-IT trial, presumably including more patients with major and life-threatening bleeding related to ticagrelor, and announced that it expected a target action date in Q1 2025. The requested indications for use are not publicly available. SERB Pharmaceuticals has acquired exclusive U.S. commercial rights for the biologic. We believe DrugSorb-ATR has significant advantages, particularly safety, cost, and ease of use, over bentracimab in cardiac surgery.

ECOS-300CY: To our knowledge, there are no specifically approved therapies for cytokine removal other than ECOS-300CY for *ex vivo* organ perfusion.

VetResQ: Because VetResQ uses the equivalent polymer technology to CytoSorb, it benefits from the extensive human clinical experience in critical care, including diseases that also affect animals such as sepsis and infection, drug intoxication, pancreatitis, ARDS, and many other illnesses. Aimalojic competes with VetResQ in the U.S. animal health market primarily in the indication of drug overdose.

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 are continuing to develop HemoDefend-BGA for universal plasma based on funding, in part, by the U.S. Army Medical Research Acquisition Activity ("USAMRAA"), the NHLBI, and the USAF/AFMC.

The HemoDefend-BGA blood purification technology platform is designed to reduce anti-A and anti-B antibodies in plasma and whole blood. The goal is to either enable the production of freeze dried or frozen "universal plasma" that can administered to anyone, regardless of blood type, or enable fresh warm whole blood transfusions. If this technology is successfully developed and approved, it could have a number of important benefits, including: a) eliminating the need for blood-typed plasma, enabling its rapid use in trauma resuscitation and mass casualty events b) freeze-dried universal plasma would not require refrigeration, making it ideal for first responders, paramedics, medics, and stockpiling c) reducing the risk of transfusion reactions and improving patient outcome d) Enabling the use of low titer whole blood, ideal for trauma resuscitation; and e) reducing the risk of hemolytic transfusion reactions from blood-derived products.

In July 2020, the Company was awarded a three-year contract by the Assistant Secretary of Defense for Health Affairs, endorsed by the CDMRP, as part of a Peer Reviewed Medical Research Program Technology/ Therapeutic Development Award to complete preclinical development of the HemoDefend™-BGA plasma and whole blood adsorber (award number W81XWH2010712). This award provides for maximum funding of approximately $4,422,000 over a three-year period. As of December 31, 2024, we received approximately $4,422,000 funding under this contract and no further funding remaining under this contract.

On April 19, 2021, the Company received notification that it received a U.S. Army Medical Research Acquisition Activity Award (the "USAMRAAA") entitled "Investigation of a potassium adsorber for the treatment of hyperkalemia induced by traumatic injury and acute kidney injury in austere medicine." The USAMRAAA Phase II Sequential Award, for up to $1,499,987, was granted to the Company to continue development of two novel and distinct treatment options for life-threatening hyperkalemia. This award is being funded by the USAMRAAA under Contract No. W81XWH21C0045. As of December 31, 2024, we received $1,499,987 funding under the contract and no further funding remaining under the contract.

On May 9, 2022, the Company received a USAMRAA Award ("USAMRAAA") entitled "Demonstration of the Safety and Efficacy of Field-Ready Blood Group Antibody (BGA) Adsorber in the Porcine Universal Transfusion Model." The Department of Defense (DoD) Defense Medical Research and Development Program (DMRDP) Joint Program Committee 6 (JPC-6) Combat Casualty

Care Research Program (CCCRP) Battlefield Resuscitation for the Immediate Stabilization of Combat Casualties Award, for up to $1,977,024, was granted to the Company to validate the safety and efficacy of the BGA device in a preclinical study in pigs. This award is being funded by the USAMRAAA under Contract No. W81XWH-22-1-0235. As of December 31, 2024, we received $1,174,000 funding under the contract and have approximately $803,000 remaining under the contract, which is expected to be completed in 2025.

On August 22, 2022, the Company received a USAMRAAA entitled "Integrating Isoagglutinin Reduction for a Universal Dried Plasma Product for Battlefield and First Responder Use." This three-year Phase III contract, which is valued at $4,292,641, is to be used to customize the design of the HemoDefend-BGA™ filter for sterile integration into collections systems for freeze-dried plasma processing to generate freeze-dried universal plasma. Without the need for blood typing, widespread availability of universal plasma could help save lives via faster emergency treatment in both civilian and military settings. This award is being funded by the USAMRAAA under Contract No. W81XWH-22-C0046. As of December 31, 2024, we have received $2,922,000 funding under the contract and have approximately $1,371,000 remaining under the contract, which is expected to be completed in 2025.

These grants represent a substantial research cost savings to us and we believe demonstrate the strong interest of the medical and scientific communities in our technology. We are also exploring potential eligibility in several other government-sponsored grant programs which could, if approved, represent a future source of non-dilutive funds for our research programs.

Regulation

The medical devices that we manufacture are subject to regulation by numerous regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, the most comprehensive of which require that a clinical evaluation be conducted before a device receives approval for commercial distribution.

European Union Regulatory Process

In the EU, medical devices that we manufacture are required to comply with the Medical Devices Directive 93/42/EC ("MDD") and obtain CE Mark certification in order to market medical devices. The CE Mark certification, granted following approval from an independent notified body, is an EU-wide international symbol evidencing adherence to quality assurance standards and compliance with the MDD or other applicable European Medical Devices Directives. Distributors of medical devices may also be required to comply with other foreign regulations. The time required to obtain these foreign approvals to market our products may be longer or shorter than that required in the U.S., and requirements for those approvals may differ from those required by the FDA. In Europe, our devices are classified as Class IIb, and currently conform to the MDD. As of May 27, 2021, devices that have not received CE Mark renewal under the MDD or where existing device or processes are substantially amended, certification would be required in accordance with the new European Union Medical Device Regulation ("MDR"). However, devices already certified under the MDD can continue to use the CE Mark under the MDD until the expiry of those MDD CE certificates and in August of 2019, we announced that CytoSorb received renewal of its EU CE Mark through May 2024. In March 2023, the EU Parliament and Council extended the MDR transition period for CytoSorbents' CytoSorb device (Class IIb) to December 2028 and it will stay CE Marked under MDD until the end of transition period (subject to Notified Body surveillance) or until the full transition to MDR certification before the end of the transition period.

In March 2011, we successfully completed our technical file review with our notified body and received approval to apply the CE Mark to the CytoSorb device for multiple indications for use. We also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the EU. In June of 2024 we completed our MDSAP audit and received approval in November of 2024 extending the coverage of our ISO 13485 Certificate with the inclusion of Canadian Quality Systems requirements under MDSAP.

Since 2011, CytoSorbents has maintained a valid ISO13485 certificate. In July 2018, we successfully completed an audit upgrade from an ISO 13485:2003 certification to an ISO 13485:2016 certification, valid through 2019. Subsequent surveillance and recertification audits have been successfully completed to maintain the certification. In April 2022, we successfully completed an annual ISO 13485:2016 surveillance audit that encompassed both the Deer Park manufacturing site and the new manufacturing facility at 305 College Road East, Princeton, NJ. In September 2022, we received ISO 13485 Certification of this new facility, clearing the way for full manufacturing of CytoSorb, DrugSorb-ATR, and ECOS-300CY from this site. This certification is currently maintained.

In the EU, as in other geographies, there are limits to the claims we are allowed to make, associated with the use of our devices. Specifically, claims that are made are required to be in applicable CE Certificate and based on our Clinical Evaluation Report, which is

part of the conformity assessment process conducted by the Notified Body. If our claims exceed the assessed claims, either regarding performance or intended uses, we may be subject to regulatory actions, which could include customer notifications or even product recalls.

U.S. FDA Medical Device Regulatory Process: The FDA approval process for medical devices ensures that products entering the market meet safety and efficacy standards. Medical devices are classified into three categories—Class I, II, and III—based on risk. Class I devices pose the lowest risk and are often exempt from premarket review, while Class II and III devices require more rigorous regulatory oversight. There are three primary pathways for FDA approval: the 510(k) clearance, De Novo classification, and Premarket Approval (PMA).

The **510(k) clearance** pathway is the most common and applies primarily to Class II devices. It requires manufacturers to demonstrate that their device is "substantially equivalent" to a legally marketed predicate device. This means that the new device must have the same intended use and similar technological characteristics as the predicate. If the FDA determines substantial equivalence, the device can be marketed without undergoing extensive clinical testing. However, if no suitable predicate exists, the manufacturer must pursue an alternative pathway.

The **De Novo classification** pathway is intended for novel, low-to-moderate-risk devices that do not have a predicate but are not high-risk enough to require PMA. This process allows the FDA to classify new devices into Class I or II based on a risk assessment. Unlike the 510(k) pathway, De Novo requires more robust evidence of safety and effectiveness, but it does not demand the extensive clinical trial data needed for PMA.

The **Premarket Approval (PMA)** process is the most stringent pathway and typically reserved for high-risk Class III devices. It requires comprehensive scientific and clinical data to demonstrate reasonable assurance of safety and effectiveness. This pathway is typically reserved for life-sustaining or life-supporting devices, as well as those that pose significant risks. The PMA process includes rigorous clinical trials, manufacturing inspections, and post-market surveillance requirements. Because of the extensive data and regulatory scrutiny, the PMA process is the most time-consuming and expensive of the three pathways.

Each of these regulatory pathways is designed to balance patient safety with innovation, ensuring that medical devices entering the market are both effective and appropriately regulated based on their level of risk.

We seek FDA clearance of DrugSorb-ATR to reduce the severity of perioperative bleeding in patients on the blood thinning drug ticagrelor that require CABG surgery under the De Novo classification, which we believe is supported by the favorable benefit to risk profile established by the pivotal STAR-T trial data and STAR Registry data for this application. On September 27, 2024, the Company submitted a De Novo medical device application to the FDA requesting marketing approval of DrugSorb-ATR to reduce the severity of perioperative bleeding in patients on ticagrelor undergoing CABG surgery, which was accepted for substantive review in October 2024. Because DrugSorb-ATR has already received FDA Breakthrough Device Designation for this application, it is eligible for priority review. We are currently in the interactive review process with FDA and expect a regulatory decision in 2025.

With FDA clearance or approval, both before and after a device for the U.S. market is commercially released, we would have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, complaint handling, and manufacturers' required reports of adverse events and device malfunctions and other information to identify potential problems with marketed medical devices. We would also be subject to periodic inspection by the FDA for compliance with the FDA's QSR requirements, as mentioned above. In addition, the FDA and other U.S. regulatory bodies (including the Federal Trade Commission, the Office of the Inspector General of the Department of Health and Human Services, the Department of Justice (DOJ), and various state Attorneys General) monitor the manner in which we promote and advertise our products. Although physicians are permitted to use their medical judgment to employ medical devices for indications other than those cleared or approved by the FDA, we are prohibited from promoting products for such "off-label" uses and can only market our products for cleared or approved uses. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health; order a recall, repair, replacement, or refund of such devices, detain or seize adulterated or misbranded medical devices; or ban such medical devices. The FDA may also impose operating restrictions, enjoin and/or restrain certain conduct resulting in violations of applicable law pertaining to medical devices, including a hold on approving new devices until issues are resolved to its satisfaction, and work with the DOJ to assess civil or criminal penalties against our officers, employees, or us. Conduct giving rise to civil or criminal penalties may also form the basis for private civil litigation by third-party payers or other persons allegedly harmed by our conduct.

The placement of our devices in the U.S. market would be subject to regulation by the U.S. Department of Health and Human Services and comparable state agencies responsible for reimbursement and regulation of health care items and services. U.S. laws and regulations are imposed primarily in connection with the Medicare and Medicaid programs, as well as the government's interest in regulating the quality and cost of health care.

Federal health care laws apply when we or customers submit claims for items or services that are reimbursed under Medicare, Medicaid, or other federally funded health care programs. The principal federal laws include: (1) the False Claims Act which prohibits the submission of false or otherwise improper claims for payment to a federally-funded health care program; (2) the Anti-Kickback Statute which prohibits offers to pay or receive remuneration of any kind for the purpose of inducing or rewarding referrals of items or services reimbursable by a Federal health care program; (3) the Stark law which prohibits physicians from referring Medicare or Medicaid patients to a provider that bills these programs for the provision of certain designated health services if the physician (or a member of the physician's immediate family) has a financial relationship with that provider; and (4) health care fraud statutes that prohibit false statements and improper claims to any third-party payer. There are often similar state false claims, anti-kickback, and anti-self referral and insurance laws that apply to state-funded Medicaid and other health care programs and private third-party payers and some state laws apply regardless of payor (i.e., even in self-pay scenarios). These and other laws (including, for example, the Physician Payment Sunshine Act and state transparency and compliance laws) will become increasingly important as we progress toward commercialization in the U.S. In addition, the U.S. Foreign Corrupt Practices Act can be used to prosecute companies in the U.S. for arrangements with physicians, or other parties outside the U.S. if the physician or party is a government official of another country and the arrangement violates the law of that country.

The laws applicable to us are subject to change, and subject to evolving interpretations. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties including substantial fines and damages, and exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

The process of obtaining clearance or approval to market products is costly and time-consuming in virtually all of the major markets in which we expect to sell products and may delay the marketing and sale of our products. Countries around the world have recently adopted more stringent regulatory requirements, which are expected to add to the delays and uncertainties associated with new product releases, as well as the pre-clinical, clinical and regulatory costs of supporting those releases. No assurance can be given that any of our other medical devices will be approved on a timely basis, if at all, or that our CytoSorb® device will be approved for CE Mark labeling under the MDR in other potential medical applications or that it will be approved for cytokine adsorption in markets not covered by the CE Mark on a timely basis, or at all. In addition, regulations regarding the development, manufacture and sale of medical devices are subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition, and results of operations.

Health Canada Regulatory Process: In Canada, DrugSorb-ATR is classified as a Class III medical device (range Class I to IV). These devices require regulatory approval from Health Canada through the Medical Devices Bureau (MDB) within the Therapeutic Products Directorate. Manufacturers must submit a Medical Device License Application (MDLA) which includes detailed information on a device's safety, effectiveness, quality and risk mitigation measures. The application must comply with MDR and include a summary of clinical evidence, risk assessments, biocompatibility testing, and performance data. Health Canada conducts a scientific and regulatory review to ensure the device meets the Canadian Medical Device Conformity Assessment System (CMDCAS) requirements. In addition, Medical Device Single Audit Program (MDSAP) certification, that certifies medical device manufacturer compliance of its quality management system with the standard and regulatory requirements of Canada, the U.S., Brazil, Japan, and Australia, is a pre-requisite for filing an MDLA. If approved, the manufacturer receives a Medical Device License (MDL), allowing commercial distribution in Canada. Post-market surveillance, including mandatory incident reporting and compliance with MDSAP ensures continued safety and effectiveness. CytoSorbents received MDSAP certification and then submitted its MDLA for DrugSorb-ATR to Health Canada on November 1, 2024. We are currently in the review process with Health Canada and expect a regulatory decision in 2025.

Other Regulatory Matters:

FDA Emergency Use Authorization: On April 10, 2020 the FDA granted CytoSorbents Emergency Use Authorization of CytoSorb to treat patients 18 years of age or older, with confirmed COVID-19 admitted to the ICU with confirmed or imminent respiratory failure. Per the FDA, "The Emergency Use Authorization (EUA) authority allows the FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats by facilitating the availability and use of medical countermeasures needed during public health emergencies. Under Section 564 of the Federal Food, Drug, and Cosmetic Act (the "Act"), the FDA commissioner may allow unapproved medical products or unapproved uses of approved medical products to be

used in an emergency to diagnose, treat, or prevent serious or life-threatening disease or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives."

EUA is an authorization limited in scope and subject to FDA discretion regarding EUA duration. Devices with EUA are neither formally cleared nor approved for the indication to treat patients with COVID-19 infection. Such devices are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the device under Section 564(b)(l) of the Act, 21 U.S.C § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. The FDA can at its discretion cancel the EUA approval when there is no longer a threat to public health.

Hospital Reform in Germany: In July 2023, Germany's federal and state governments issued a consensus white paper that proposed hospital reform and a change in how hospitals are funded. In October 2024, the German Parliament fully passed the Hospital Care Improvement Act mandating hospital reform beginning in January 2025 through 2029. As part of the reform, government payments to hospitals would de-emphasize the DRG (diagnosis-related group) "lump sum" payment system that incentivizes revenue generation through more patients treated and procedures performed, and instead emphasize base payments focused on quality measures and appropriate patient care. This is expected to favor a shift of routine operations and procedures to outpatient centers, consolidation of smaller hospitals into larger ones, and importantly, an increased focus of remaining hospitals on sicker patients, more complex operations such as cardiothoracic surgery and organ transplant, and on therapies that help reduce the severity of illness and help patients recover faster. Hospitals must meet strict quality standards to receive money for operations. In addition, a 50 billion euro Hospital Transformation Fund is being established to make investments in modern infrastructure over 10 years to improve efficiency and reduce costs. Given that the goal of our therapies is to improve clinical outcomes while reducing the costs of critical care and cardiac surgery by controlling deadly inflammation and other life-threatening conditions, while reducing the need for expensive life support measures that keep patients in the hospital, we believe such reform may favor our business in the near and longer-term. Hospital administrators expect such change will take careful planning and time, potentially years, to implement.

VetResQ: In the U.S., the FDA does not require submission of a 510(k), PMA, or any other pre-market review application for devices used in veterinary medicine. Device manufacturers who exclusively manufacture or distribute veterinary devices are not required to register their establishments and list veterinary devices and are exempt from some post-marketing reporting. FDA does have regulatory oversight over veterinary devices and can take appropriate regulatory action. It is the responsibility of the manufacturer and/or distributor of these articles to assure that these animal devices are safe, effective, and properly labeled.

Other Country Requirements: Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries medical devices are regulated. Frequently, device companies may choose to seek and obtain regulatory approval of a device in a foreign country prior to application in the U.S., as we have done, given the differing regulatory requirements. However, this does not ensure approval of a device in the U.S.

Sales and Marketing

In 2012, we established our European subsidiary, CytoSorbents Europe GmbH, a wholly-owned subsidiary of CytoSorbents Corporation. Following the completion of a controlled market release in late June 2012, CytoSorb was formally launched in Germany with the fourth quarter of 2012 being the first full quarter of direct CytoSorb sales with our sales force in place. We began expansion into Austria and Switzerland. In March 2016, we established CytoSorbents Switzerland GmbH, a wholly-owned subsidiary of CytoSorbents Europe GmbH, to conduct marketing and direct sales in Switzerland. This subsidiary began operations during the second quarter of 2016. In 2017 we began direct sales in Belgium and Luxembourg. On March 5, 2019, the Company announced the expansion of direct sales of CytoSorb for all applications to Poland and the Netherlands, and critical care applications to Sweden, Denmark and Norway. In 2021, we expanded direct sales to include all applications in Sweden, Denmark and Norway. As part of this effort, the Company established CytoSorbents Poland Sp. z.o.o. 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. In May 2023, the Company formed CytoSorbents India Private Limited to provide marketing and direct sales services in India. In January 2025, we announced the opening of our new Regional Sales Subsidiary in Dubai, United Arab Emirates (UAE), providing a gateway into the Middle East and Africa. From the beginning of the controlled market release in the fourth quarter of 2011 through December 31, 2024, we achieved cumulative sales of CytoSorb of approximately $248.2 million. During this time period, the CytoSorb device represented substantially all of our product sales.

We are approved to sell CytoSorb in all 27 countries in the EU, including Germany, Italy, France and Spain as well as the United Kingdom, and currently have either direct sales or distributors or strategic partnerships in more than 76 countries worldwide.

Registration of CytoSorb is typically required in each of these countries prior to active commercialization, in a process that can take several months to more than a year to achieve. Variability in the timing of registration affects the initiation of active commercialization in these countries, which affects the timing of expected CytoSorb sales. We cannot generally predict the timing of these registrations, and there can be no guarantee that we will ultimately achieve registration in countries where we have established distribution. Outside of the EU, CytoSorb has distribution in Turkey, India, Sri Lanka, Australia, New Zealand, Russia, Serbia, Vietnam, Malaysia, Hong Kong, Chile, Panama, Costa Rica, Colombia, Brazil, Mexico, Argentina, Perú, Peru, Guatemala, Ecuador, Bolivia, the Dominican Republic, El Salvador, Iceland, Israel, UAE, Iran, Saudi Arabia and other Middle Eastern countries, and South Korea. We cannot guarantee that we will generate meaningful sales in the countries where we have established registration, due to other factors such as market adoption, reimbursement and/or geopolitical developments. We continuously evaluate other potential distributor and strategic partner networks in other countries that accept CE Mark approval.

In addition to our direct and distributor commercial channels, we have a number of strategic partners to market and distribute CytoSorb. These partners include Fresenius Medical Care AG, B. Braun Avitum AG, Aferetica s.r.l., and Terumo Cardiovascular Group. In August 2022, we expanded our partnership with Fresenius Medical Care to a global marketing collaboration. For detailed information regarding these partnerships, see the section entitled “Commercial and Research Partners” in item 1 of this report.

A significant portion of our revenues are from product sales in Germany. Substantially all of our grant receipts are from government agencies in the United States.

During the years ended December 31, 2024 and 2023, one distributor accounted for 11% and 10%, respectively, of the Company’s total revenue.

Orders received for product from both direct customers and distributors are fulfilled upon receipt. Accordingly, we have no significant sales backlog.

Intellectual Property and Patent Litigation

The medical device market in which we primarily participate is in large part technology driven. As a result, intellectual property rights, particularly patents and trade secrets, play a significant role in product development and differentiation. However, intellectual property litigation to defend or create market advantage is inherently complex, unpredictable and is expensive to pursue. Litigation often is not ultimately resolved until an appeal process is completed and appellate courts frequently overturn lower court patent decisions.

Moreover, competing parties frequently file multiple suits to leverage patent portfolios across product lines, technologies and geographies and to balance risk and exposure between the parties. In some cases, several competitors are parties in the same proceeding, or in a series of related proceedings, or litigate multiple features of a single class of devices. These forces frequently drive settlement not only of individual cases, but also of a series of pending and potentially related and unrelated cases. In addition, although monetary and injunctive relief is typically sought, remedies are generally not determined until the conclusion of the proceedings and are frequently modified on appeal. Accordingly, the outcomes of individual cases are difficult to time, predict or quantify and are often dependent upon the outcomes of other cases in other forums, both domestic and international.

We rely on a combination of patents, trademarks, trade secrets and non-disclosure agreements to protect our intellectual property. As of the issuance date of this Annual Report on Form 10-K, our patent portfolio includes 22 issued United States patents as well as multiple issued foreign patents and pending patent applications both in the U.S. and internationally, directed to various compositions and methods of use related to our blood purification technologies, which are expected to expire between 2026 and 2044 absent any patent term extensions. Management believes that any near-term expiring patents will not have a significant impact on our ongoing business. The following table provides a brief description of our patents that have been issued in the U.S.:

Product Group	Description/Indications	Patent Term	Patent Expiration	Patent Type
CytoSorb	Size-Selective Hemoperfusion Polymeric Adsorbents	20 Years	11/20/2026	Standard
CytoSorb	Size-Selective Hemoperfusion Polymeric Adsorbents	20 Years	11/20/2026	Standard
CytoSorb	Size-Selective Hemoperfusion Polymeric Adsorbents	20 Years	11/20/2026	Standard
CytoSorb	Method of Treating Inflammation	20 Years	3/31/2031	Standard
CytoSorb	Method of Treating Inflammation	20 Years	4/1/2031	Standard
CytoSorb	Method of Treating Inflammation	20 Years	4/1/2031	Standard
CytoSorb	Method of Treating Inflammation	20 Years	4/1/2031	Standard
CytoSorb	Method of Treating Inflammation	20 Years	4/30/2031	Standard
CytoSorb	Polymer Modification	20 Years	12/31/2031	Standard
CytoSorb	Method of Removal of Impurities from Whole Blood	20 Years	1/6/2032	Standard
CytoSorb	Use of Polymeric Sorbent Polymers	20 Years	8/10/2032	Standard
CytoSorb	Hemocompatible Modifiers	20 Years	3/31/2034	Standard
CytoSorb	Methods of Reducing Contamination in a Biological Substance	20 Years	6/3/2034	Standard
CytoSorb	Removing Protein Based Toxins and Potassium from Biological Fluids	20 Years	10/22/2035	Standard
CytoSorb	Method of Treating Acute Radiation Syndrome	20 Years	10/22/2035	Standard
CytoSorb	Use of Gastrointestinally Administered Porous Sorbent Polymers	20 Years	10/22/2035	Standard
CytoSorb	Hemocompatible Porous Beads	20 Years	10/21/2036	Standard
CytoSorb	Removal of Endotoxemia	20 Years	5/17/2037	Standard
CytoSorb	Method of Removing Toxins From Blood	20 Years	7/30/2038	Standard
CytoSorb	Connector Assembly and Methods of Use	20 Years	10/16/2040	Standard
CytoSorb	Method of Treating Traumatic Brain Injury	20 Years	9/2/2044	Standard
CytoSorb	Absorbents for Removal of Antibodies from Human Plasma and Whole Blood	20 Years	12/6/2041	Standard

There can be no assurance that pending patent applications will result in issued patents, that patents issued to us will not be challenged or circumvented by competitors, or that such patents will be found to be valid or sufficiently broad to protect our technology or to provide us with a competitive advantage. Certain of these patents also have foreign counterparts.

We also rely on non-disclosure and non-competition agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how and to determine the scope and validity of the proprietary rights of others. Patent litigation can be costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that the outcome of litigation will be favorable to us. Accordingly, we may seek to settle some or all of our pending litigation described below. Settlement may include cross-licensing of the patents which are the subject of the litigation as well as our other intellectual property and may involve monetary payments to or from third parties.

We currently hold multiple trademarks including CytoSorb®, ECOS-300CY®, VetResQ®, HemoDefend™, BetaSorb™, DrugSorb™, and K^{+}ontrol™. We have spent considerable resources registering the trademark and building brand awareness and equity of the CytoSorb® tradename, which has been used in commerce since 2006. We expect to maintain and defend our various trademarks to the fullest extent possible.

Environmental Matters

We believe that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on us or our business. We incur waste removal costs in connection with both our solid and liquid wastes which

are byproducts of our manufacturing process. We utilize the services of various qualified contractors to dispose of these waste products. These waste removal costs amounted to approximately $322,000 for the year ended December 31, 2024.

Employees

As of the issuance date of this Annual Report on Form 10-K, we had 149 employees. We also utilize consultants and temporary service providers who are not our employees, as necessary. None of our employees are represented by a labor union or are subject to collective-bargaining agreements and we believe we have good relationships with our employees.

Item 1A. Risk Factors

Risks Related to our Business and our Industry

We have a history of losses and expect to incur substantial future losses.

We have experienced substantial operating losses since inception. As of December 31, 2024, we had an accumulated deficit of approximately $304.0M, which included net losses of approximately $20.7M and $29.2M for the years ended December 31, 2024 and 2023, respectively. Our losses have resulted principally from costs incurred in the research and development of our polymer technology, clinical studies and general and administrative expenses. We intend to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for the establishment of manufacturing arrangements and a marketing and distribution presence and other general and administrative expenses, are expected to result in continuing net losses for the foreseeable future. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to achieve profitability will depend, among other things, on continued adoption and usage of our products in the market, obtaining additional regulatory approvals in markets not covered by the CE mark, establishing sales and marketing arrangements with third parties, satisfactory reimbursement in key territories, and raising sufficient funds to finance our activities. No assurance can be given that our product development efforts will be successful, that our current CE Mark will enable us to achieve profitability, that additional regulatory approvals in other countries will be obtained, that any of our products will be manufactured at a competitive cost and will be of acceptable quality, that reimbursement will be available or satisfactory, that we will be able to achieve profitability or that profitability, if achieved, can be sustained, or our ability to raise additional capital when needed or on terms acceptable to us. Our failure with respect to any or all of these matters would have a material adverse effect on our business, operating results, financial condition and prospects.

We will require additional capital in the future to fund our operations.

As of December 31, 2024, we had current assets of approximately $21.9 million, including cash and cash equivalents of $3.3 million and current liabilities of approximately $9.8 million. For the year ended December 31, 2024, our cash burn, which we define as the total of cash used in operating and investing activities from our statement of cash flows, was approximately $15.1 million. Our current and historical cash burn is not necessarily indicative of our future use of cash and cash equivalents.

The Company will require additional financing in the future to support the commercialization of its products and proposed products, to initiate and complete new additional clinical studies, and for general working capital purposes. If the Company were to obtain such additional financing through equity financing, the current ownership interest of its stockholders would be diluted and there can be no assurance that the Company will be successful in its capital raising efforts. Should the financing the Company requires be unavailable to the Company, or on terms unacceptable to the Company when the Company requires it, the consequences could have a material adverse effect on the Company's business, operating results, financial condition and prospects. The amount of long-term capital needed is expected to depend on many factors, including:

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

We have an effective shelf registration statement dated September 30, 2024 with the SEC which enables us to raise up to $150 million in one or more offerings, through the issuance and sale of any combination of equity securities, debt securities, warrants and units. Approximately $149.7 million of this amount was available as of December 31, 2024. We have also allocated $25 million of our total shelf amount to our ATM facility. A December 31, 2024, approximately $19.4 million was available for use under the ATM facility.

On December 30, 2021, we entered into an Open Market Sale Agreement with Jefferies LLC (the "Sale Agreement"). Pursuant to the Sale Agreement we may offer to sell, from time to time, shares of our common stock, up to a maximum of $25,000,000. During the year ended December 31, 2023, the Company sold 2,656,464 shares pursuant to the Sale Agreement, at an average selling price of $1.76 per share, generating net proceeds of approximately $4,532,000. During the year ended December 31, 2024, the Company sold 382,823 shares pursuant to the Sale Agreement, at an average selling price of $1.04 per share, generating net proceeds of approximately $388,000.

In June 2024, we closed on a $20 million term-loan facility with Avenue Capital Group which provided an initial tranche of $15 million at the closing, of which $10 million was immediately available at closing and $5 million that remained classified as restricted cash through January 10, 2025, when it was released from its restriction. Another tranche of $5 million may be disbursed at the Company's request between July 1, 2025 and December 31, 2025, provided that the Company receives FDA marketing approval of its DrugSorb-ATR application. Concurrently with the closing of the first tranche, the Company paid off our existing debt with Bridge Bank.

On January 10, 2025, we closed the subscription period of its previously announced shareholder Rights Offering (the "Rights Offering"), raising aggregate gross proceeds of $6.25 million from the sale of all 6.25 million Units reserved for the Rights Offering. Participants in the Rights Offering received Units, each Unit comprising of one share of common stock of the Company, one Series A Right Warrant to purchase one share of common stock, and one Series B Right Warrant to purchase one share of common stock. The Right Warrants, as discussed below, will provide additional opportunity to purchase up to an additional 6,250,000 shares of common stock.

Proceeds from the Rights Offering satisfied the second condition of a debt covenant which now allows for the $5.0 million of restricted cash on our consolidated balance sheet to become unrestricted, and available for use.

The Right Warrants are exercisable commencing on their date of issuance and the exercise price shall be equal to (i) in the case of the Series A Right Warrants, 90% of the 5-day volume weighted average price of our Common Stock over the last 5-trading days prior to the expiration date of the Series A Right Warrants on February 24, 2025, rounded down to the nearest whole cent but (x) not lower than $1.00 and (y) not higher than $2.00, and (ii) in the case of the Series B Right Warrants, 90% of the 5-day volume weighted average price of our common stock over the last 5-trading days prior to the expiration date of the Series B Right Warrants on April 10, 2025, rounded down to the nearest whole cent but (x) not lower than $2.00 and (y) not higher than $4.00.

On February 24, 2025, approximately 1.4 million Series A Right Warrants were exercised by holders, including members of management and the Board of Directors, at an exercise price of $1.13 per warrant, providing an additional $1.6 Million in aggregate gross proceeds.

As of the issuance date of this Annual Report on Form 10-K, we have raised a total of $7.3 million, net of offering fees, through the Rights Offering, and the exercise of the Series A Right Warrants. The equity raises also provided for $5 million of restricted cash to become unrestricted. As a result, our proforma unrestricted cash and cash equivalents, a non-GAAP measure, on December 31, 2024, assuming the net proceeds from the Rights Offering and the Series A Right Warrant exercise had occurred at that date, has increased by $12.3 million to $15.6 million, compared to the reported amount of $3.3 million

The Company will continue evaluating various financing alternatives, including debt financing, strategic partnerships and other non-equity financing arrangements, including royalty financing. While there can be no assurance that the Company will be successful in obtaining alternative non-equity financing, if such financing is obtained through arrangements with collaborative partners or other non-dilutive sources, such as royalty financing, the Company may have to relinquish economic and/or proprietary rights to some of its technologies or products under development that it would otherwise seek to develop or commercialize itself. Such events may have a material adverse effect on the Company's business, operating results, financial condition and prospects.

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

A pandemic, epidemic or outbreak of an infectious disease may materially and adversely affect our business and operations. As an example, an outbreak of an infectious disease could originate and spread rapidly, affecting global economies. Such an event could

cause disruptions in our global supply chain, our ability to obtain raw materials, the manufacturing of and demand for our lead product, CytoSorb, the commercialization of CytoSorb, our research and development activities, and the conduct of current and future clinical trials. It could also affect the operations of the U.S. Food and Drug Administration and other health authorities, which could result in delays of reviews and approvals, including with respect to DrugSorb-ATR and our product candidates. Such an event may impact and may continue to directly or indirectly impact our clinical trials, including but not limited to, the anticipated completion date of these trials and the pace of enrollment, as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices, and clinical trial staff may experience disruptions. Such facilities and offices may be required to focus limited resources on other matters, and may not be available, in whole or in part, for clinical trial services. There may be delays in patient enrollment in our clinical trials. In addition, employee disruptions and remote working environments related to such an event and the federal, state and local responses to it, could materially impact the efficiency and pace with which we work and develop our product candidates, our ability to execute and invoice upon government grants and contracts, and the manufacturing of CytoSorb. We may experience challenges in hiring necessary staff members to conduct our research and development activities, including technical staff. Further, the potential economic impact brought on by, and the duration of, such an event is difficult to assess or predict, but could impact the global financial markets and reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. Additionally, the stock market may experience volatility, and macro factors may impact our critical care and cardiac surgery markets, including in certain geographies. For example, widespread staffing shortages, decreased availability of hospital beds, fewer patients, increased hospital restrictions resulting in decreased access of our sales representatives to hospitals and fewer sales meetings with physicians could result in lower-than-expected sales of CytoSorb. The ultimate impact of such an event is highly uncertain and subject to change.

Our operating results are subject to seasonal fluctuation.

Our total revenue is subject to seasonal fluctuation. Our sales seasonality is affected by a number of factors, including but not limited to, hospital budgets and buying patterns, customer, employee and healthcare worker vacation schedules, religious, national, and state holidays, scientific and medical conference schedules, seasonal illnesses such as influenza, seasonal or weather-related differences in hospital admissions and the timing of insurance benefits, among others. See "A pandemic, epidemic or outbreak of an infectious disease may materially and adversely affect our business and operations." As a result, seasonality has had, and we expect it to continue to have, an impact on our results of operations.

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

We have historically been engaged primarily in research and development activities and have generated limited revenues to date. With the launch of our CytoSorb product in the EU and elsewhere, there can be no assurance that we will be able to successfully manage the balance of our research and development operations with our planned commercial enterprise. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by an enterprise in balancing development, which include unanticipated problems relating to testing, product registration, product labeling, regulatory compliance and manufacturing, with commercialization, which includes problems with market adoption, reimbursement, marketing problems and additional costs. Our products and product candidates will require significant additional research and testing, and we will need to overcome significant regulatory burdens prior to commercialization in other countries, such as the U.S., and for ongoing compliance for our CE Mark. Although we believe we are currently adequately capitalized, we will need to raise additional funds to complete additional clinical studies and obtain regulatory approvals in other countries before we can begin selling our products in markets not covered by our CE Mark. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any products, generate any significant revenues or ever achieve and maintain a substantial level of sales of our products.

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

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

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

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

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

As of the issuance date of this Annual Report on Form 10-K, we had 149 full-time and part-time employees as well as several consultants and temporary employees. Our success will depend to a significant degree upon the continued services of our key management team and advisors, including, Dr. Phillip Chan, our Chief Executive Officer; Peter J. Mariani, our Chief Financial Officer; Vincent Capponi, our President and Chief Operating Officer and Dr. Efthymios Deliargyris, our Chief Medical Officer. On July 30, 2019, we entered into amended and restated executive employment agreements with its principal executives, Dr. Phillip P. Chan, Chief Executive Officer, Vincent Capponi, President and Chief Operating Officer, and Kathleen P. Bloch, Chief Financial Officer. Each agreement had an initial term of three years and were retroactively effective as of January 1, 2019. On April 12, 2020, CytoSorbents Corporation entered into an executive employment agreement with Dr. Efthymios Deliargyris, who began employment as Chief Medical Officer on May 1, 2020, with an initial term that expires on December 31, 2021. On August 14, 2024, CytoSorbents Corporation entered into an executive employment agreement with Peter J. Mariani, who began employment as Chief Financial Officer on August 14, 2024 following the retirement of former CFO Kathy Bloch, with an initial term that expires on December 31, 2025. After the expiration of the initial terms, the employment agreements automatically renew for additional terms of one year unless either party provides written notice of non-renewal at least 60 days prior to a renewal. The employment agreements for the Named Executive Officers above have automatically renewed for another one-year term. There can be no assurance that key management personnel or other members of our management team and advisors will continue to provide services to us. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Management and other

employees may voluntarily terminate their employment with us at any time. Additionally, the increasing demand for qualified personnel may make it more difficult for us to attract and retain qualified employees. Changing demographics and labor work force trends may make it difficult for us to replace departing employees at our manufacturing and other facilities and we may experience increased turnover rates. U.S. labor market conditions are currently challenging and labor shortages have been exacerbated during and following the COVID-19 pandemic. These conditions are expected to persist into 2025 and may lead to higher labor costs. If we fail to attract and retain qualified personnel, or if we experience labor shortages, we may experience higher costs and other difficulties. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources.

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

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

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

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

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

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

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

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued, and even if issued, the patents may not meaningfully protect our products or product candidates, effectively prevent competitors and third parties

from commercializing competitive products or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

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

We cannot be certain that our patents and patent rights will be effective in protecting our products, product candidates and technologies. In addition, our existing patents are scheduled to expire between 2026 and 2044. Failure to protect such assets may have a material adverse effect on our business, operations, financial condition and prospects.

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

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

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

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

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

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

Our existing patents are scheduled to expire between 2026 and 2044. While we are seeking additional patent coverage which may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products and product candidates, we may be open to competition from generic versions of such methods and devices.

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

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

Our products are subject to international regulation as medical devices under the Medical Devices Directive and, once our CE Mark under MDD expires in December 2028 will be subject to the new European Union Medical Device Regulation ("MDR"). In Europe, which we expect to provide the initial market for our products, the notified body and Competent Authority govern, where applicable, development, clinical studies, labeling, manufacturing, registration, notification, clearance or approval, marketing, distribution, record keeping, and reporting requirements for medical devices. Different regulatory requirements may apply to our products depending on how they are categorized by the notified body under these laws. Current international regulations classify our CytoSorb device as a Class IIb device. Even though we have received CE mark certification of the CytoSorb device, there can be no assurance that we will be able to continue to comply with the required annual auditing requirements or other international regulatory requirements that may be applicable. In addition, there can be no assurance that government regulations applicable to our products or the interpretation of those regulations will not change. The extent of potentially adverse government regulation that might arise from future legislation or administrative action cannot be predicted. There can be no assurances that reimbursement will be granted or that additional clinical data will be required to establish reimbursement.

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

In March 2011, CytoSorb, was "CE marked" in the EU as an extracorporeal cytokine adsorber indicated for use in clinical situations where cytokines are elevated, allowing for commercial marketing. The CE Mark demonstrates that a conformity assessment has been carried out and the product complies with the Medical Devices Directive. A re-certification audit was conducted in April 2019. The successful completion of this audit CE-certifies CytoSorb under the current Medical Device Directive (93/42/EEC) until December 2028. Prior to the expiration of such certificate, we will apply for certification under the new Medical Devices Regulation (MDR). Failure to certify CytoSorb under the Medical Devices Regulation will prevent us from using the CE mark for commercial distribution of CytoSorb in the European Union. Any new product that we submit for the CE Mark after August 2019 must be approved under the new Medical Devices Regulation.

Furthermore, if:

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

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

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

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

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

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

Our business could be negatively impacted by changes in the domestic and global political environment.

We ship our products internationally and as a result are subject to negative impacts in the global political environment. For example, specific legislative and regulatory proposals can be introduced to change international trade law, regulations or interpretations thereof (possibly with retroactive effect) of various jurisdictions or limit treaty benefits that, if enacted, could materially increase the cost of our goods to export internationally, increase our effective tax rate, or have a material adverse impact on our financial condition and results of operation. We cannot predict whether industry initiatives to seek tariff carve-outs for devices or other life sciences goods and products will be successful. We also cannot predict the effect on our tax and tariff burden, if any, of the imposition of new or increased tariffs by one country and the response of other countries that retaliate in response. It is possible that these changes could adversely affect our business.

Additionally, we could be negatively impacted by political policy changes domestically. For example, federal and state budgetary cuts at state and federal agencies, the withholding of federal grant funds, staffing shortages and the reallocation of regulatory priorities by key federal agencies that oversee our products, services, and associated reimbursement, including FDA and the U.S. Department of Health and Human Services more broadly could adversely affect our business. Such political developments may require us to allocate significant time, resources, and expense to modifying our policies and procedures, processes, systems, and practices to ensure compliance or adapt to the new regulatory climate, particularly to the extent such actions are subject to protracted and uncertain legal challenges. To the extent changes in the political environment have a negative impact on us or on our markets, our business, results of operation, and financial condition could be materially and adversely affected in the future.

Clinical study results for our CytoSorb and/or DrugSorb-ATR device may not be indicative of our future clinical study results, and we cannot assure you that any clinical study results will lead to results sufficient for necessary regulatory clearances or product sales. Additionally, clinical and pre-clinical data is susceptible to varying interpretations, which could delay, limit, reduce, or prevent additional regulatory clearances or product sales.

To date, we have conducted limited clinical studies on our CytoSorb and DrugSorb-ATR product. There can be no assurance that we will successfully complete additional clinical studies or that our current or future clinical studies will lead to results necessary to receive additional regulatory approvals in markets not covered by the CE Mark. While clinical studies conducted by us and others

have produced results we believe to be encouraging, data already obtained, or in the future obtained, from pre-clinical studies and clinical studies do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical studies. CytoSorb, DrugSorb-ATR and our other products and product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in previous studies, which could result in decreased sales of our products and product candidates and have an adverse effect on our business and results of operations. Moreover, pre-clinical and clinical data are susceptible to varying interpretations, which could delay, limit or prevent additional regulatory approvals in markets not covered by the CE Mark. A number of companies in the medical device and pharmaceutical industries have suffered significant setbacks in advanced clinical studies, even after promising results in earlier studies. The failure to adequately demonstrate the safety and effectiveness of CytoSorb, DrugSorb-ATR or another product under development could delay or prevent regulatory clearance of the device, resulting in delays to commercialization, and could materially harm our business and results of operations. Even though we have received approval to apply the CE Mark to our CytoSorb device as a cytokine adsorber, there can be no assurance that we will be able to receive approval under the MDR for other potential applications of CytoSorb, or that we will receive regulatory clearance or marketing approval from authorities in other targeted regions or countries.

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

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

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

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

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

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

We work with many medical and clinical advisors in critical care, cardiac surgery, trauma, and other areas who are associated with healthcare institutions. Their association with these institutions may currently or in the future involve conflicting interests in the event they or these institutions enter into consulting or other arrangements with competitors of ours.

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

In March 2011, we received approval from our notified body to apply the CE Mark to our CytoSorb device for commercial sale as a cytokine adsorber. We also achieved ISO 13485:2003 Full Quality Systems certification, and have since upgraded to ISO 13485:2016 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the EU. We also achieved the Medical Device Single Audit Program (MDSAP) certification that is necessary for product approval in certain countries such as Canada. We manufacture CytoSorb at our manufacturing facilities in New Jersey for sale in the EU and around the world, as well as for additional clinical studies. Manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices ("cGMP") for medical devices, as set forth in the QSR. As such, we are subject to continual review and periodic inspections to assess compliance with cGMP/QSR requirements as required by our International notified body. Accordingly, we must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and

quality control. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we or the third-party manufacturers of our products fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products on a timely basis, or at all.

We depend on a limited number of suppliers for chemicals, other raw materials, and molded parts used in the development and manufacture of our products. Although we typically second source and validate the quality of chemicals, raw materials, and molded parts any change in the availability of these components, or availability of single sourced materials, without an alternative source may result in lengthy delays or disruptions in manufacturing if we need to change or cannot identify a supplier for any reason which could have a material impact on our business and results of operations.

Our ability to manufacture and distribute products is dependent, in part, upon availability and quality of chemicals, raw materials, molded parts and other components supplied by third parties. Any disruption in the supply of these ingredients or components or any problems in their standard of quality could materially affect our ability to manufacture and distribute our products, maintain sufficient inventory levels or otherwise meet customer demand, and could result in legal liabilities that could materially affect our ability to realize profits or otherwise harm our business, financial, and operating results. We primarily source the raw materials for our products from domestic suppliers but may be required to source from international suppliers if our domestic suppliers are unable to meet our supply requirements. Generally, we qualify only a single source of reagents and molded parts for use in each product due to the cost and time required to validate and qualify a second source of supply. If we were to change the supplier of a raw material for a product, the cost for the material could be greater than the amount we paid with the previous supplier. Changes in suppliers are rare but could occur as a result of a supplier's business failing, an issue arising from an FDA inspection, failure to maintain our required standards of quality, or a *force majeure* event. As a result, we carefully select suppliers, based on various factors including quality, reliability of supply, and long-term financial stability. From time to time, we may experience temporary or long-term disruptions in the supply of certain of our raw materials that could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

Weakness in the global economy, and in particular in the United States and Europe, could negatively impact our revenue and operating results.

The United States and Europe and other economies may suffer from uncertainty, volatility, disruption, and other adverse conditions, such as inflation or the rising cost of energy, and these conditions have adversely impacted and may continue to adversely impact the business community and the financial markets. Adverse economic and financial market conditions may negatively affect our markets, thereby negatively impacting our revenue and operating results. As a result, if economic and financial market conditions weaken or deteriorate, then our revenue and operating results, including our ability to grow and expand our business and operations, could be materially and adversely affected.

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

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

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

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

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

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

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

For the year ended December 31, 2024, we derived approximately 37% of our net product sales from sales in Germany. Despite modest European and global growth, there are many economic and political issues that could negatively impact the health of Germany's economy, the broader EU economy, and the world economy overall. Examples include the uncertainty over the implications of the United Kingdom's exit from the EU, also known as "Brexit," economic instability in a number of EU member countries, and changes in the political leadership in the EU and United States. Germany and other European countries face additional risks to their local economies, some of which include the impact of foreign exchange fluctuations, unemployment, tightening of monetary policy, the economic burden of immigration, diminished liquidity and reliance on debt, the rising cost of healthcare, and other factors. In addition, the German government, insurance companies, health maintenance organizations and other payers of healthcare costs continue to focus on healthcare reform and containment of healthcare costs. For example, in October 2024, the German Parliament fully passed the Hospital Care Improvement Act mandating hospital reform beginning in January 2025 through 2029. As part of the reform, government payments to hospitals would de-emphasize the DRG (diagnosis-related group) "lump sum" payment system that incentivizes revenue generation through more patients treated and procedures performed, and instead emphasize base payments focused on quality measures and appropriate patient care. This is expected to favor a shift of routine operations and procedures to outpatient centers, consolidation of smaller hospitals into larger ones, and importantly, an increased focus of remaining hospitals on sicker patients, more complex operations such as cardiothoracic surgery and organ transplant, and on therapies that help reduce the severity of illness and help patients recover faster. Hospitals must also meet strict quality standards to receive money for operations. Although we believe our products are aligned with the goals of Germany healthcare reform, the ultimate scope, implementation and timing of these reforms remains uncertain and we cannot accurately predict the impact that such reforms may have on our business, our customers, our existing reimbursement and such policies and procedures for seeking reimbursement, or our results of operations. Furthermore, we cannot predict whether Germany's economy will continue to grow or decline consistent with the overall global economy, which decline would negatively impact the demand for medical devices and healthcare technologies generally and lead to reduced spending on the products we provide. In addition, continued healthcare cost containment efforts may result in lower prices and a reduction or elimination of reimbursement for our products. Due to the concentration of our product sales in this country, any of the foregoing may have a negative impact on our revenues, business operations and financial condition.

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

Significant portions of our business are conducted in Europe, including the U.K.; Asia; and other international geographies. Interruptions in international relationships such as the exit by the U.K. from the EU, the war between Russia and Ukraine, the conflict in the Middle East, and trade disputes such as the current trade negotiations between the U.S. and China, or the threatened tariffs with China, Canada, and Mexico, could result in changes to regulations governing our products and our intellectual property, disruption of our manufacturing or commercial operations, our inability to timely engage with and collect payment from customers in Russia and

other affected regions, or otherwise affect our ability to do business. Additionally, global events such as the current COVID-19 coronavirus pandemic, war between Russia and Ukraine, and the conflict in the Middle East, that have or could, slow worldwide economies, disrupt travel and trade, and destabilize financial markets, may interfere with our ability to raise capital, sell and market our products, obtain reimbursement and payment of our products, or reduce the ability of our customers to pay for our product. Although these global problems transcend our company and afflict companies across industries and borders, these and similar events could adversely affect us, or our business partners or customers.

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

Involvement in a war or other military action or international acts of terrorism may cause significant disruption to commerce throughout the world. To the extent that such disruptions result in (i) delays or cancellations of customer orders, (ii) a general decrease in consumer spending on healthcare technology, (iii) our inability to effectively market and distribute our products globally (iv) our inability to timely engage with and collect payment from our customers or (v) our inability to access capital markets, our business and results of operations could be materially and adversely affected. For example, in response to the conflict between Russia and Ukraine, the United States has imposed and may further impose, and other countries may additionally impose, broad sanctions or other restrictive actions against governmental and other entities in Russia. CytoSorb is currently distributed in Russia. While the existing sanctions do not currently prohibit the distribution of CytoSorb in Russia, additional sanctions may be imposed in the future that could prevent us from selling CytoSorb in this or other affected regions. Additionally, further escalation of geopolitical tensions or new conflicts, such as the evolving conflict between Israel and Gaza and the surrounding areas, could have a broader impact that extends into other markets where we do business. We are unable to predict whether acts of international terrorism or the involvement in a war or other military actions by the United States and/or the countries in which we sell or distribute our products, including Russia, will result in any long-term commercial disruptions or if such involvement or responses will have any long-term material adverse effect on our business, results of operations, or financial condition.

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

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

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

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

In addition, changes in our products or changes in applicable export or import laws, tariffs, and regulations may create delays in the introduction and sale of our products in international markets or, in some cases, prevent the export or import of our products to certain countries, governments or persons altogether. Any change in export or import laws and regulations, shift in the enforcement or scope of existing laws, tariffs, and regulations, or change in the countries, governments, persons, products, or technologies targeted by such laws, tariffs, and regulations, could also result in decreased use of our products, or in our decreased ability to export or sell our

products to existing or potential customers. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business, financial condition and results of operations.

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

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

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

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

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

personal information depending on the context. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted.

Risks Connected to Our Securities

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

Our common stock closed as high as $1.55 and as low as $0.70 per share between January 1, 2024 and December 31, 2024 on Nasdaq. On March 28, 2025, the closing price of our common stock, as reported on Nasdaq, was $1.00. Historically, medical device company securities such as our common stock have experienced extreme price fluctuations. Some of the factors leading to this volatility include, but are not limited to:

- fluctuations in our operating results;
- announcements of product releases by us or our competitors;
- announcements of clinical data, analyst or media reports;
- financial status:
- announcements of acquisitions and/or partnerships by us and our competitors; and
- general market conditions.

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

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

Our directors, executive officers and principal stockholders together beneficially own a significant percentage of the voting control of the common stock on a fully diluted basis. Accordingly, these stockholders could have a significant influence over the outcome of any corporate transaction or other matter submitted to stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets and also could prevent or cause a change in control. The interests of these stockholders may differ from the interests of our other stockholders. Third parties may be discouraged from making a tender offer or bid to acquire us because of this concentration of ownership. As of December 31, 2024, three shareholders hold 17.2% of our shares and our directors and officers hold 5.6% of our shares on a fully diluted basis.

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

On December 3, 2014, we effected a twenty-five-for-one (25:1) reverse split of our common stock. Immediately after the reverse stock split, we changed our state of incorporation from the State of Nevada to the State of Delaware pursuant to an Agreement and Plan of Merger, dated December 3, 2014, whereby we merged with and into our recently formed, wholly-owned Delaware subsidiary. Pursuant to the Agreement and Plan of Merger effecting the merger, we adopted the certificate of incorporation, as amended and restated, and bylaws of our Delaware subsidiary as our certificate of incorporation and bylaws at effective time of the merger. As a result, our certificate of incorporation, as amended and restated, authorizes the issuance of up to 5,000,000 shares of “blank check” preferred stock, with such designation rights and preferences as may be determined from time to time by the Board of Directors. Currently, our certificate of incorporation, as amended and restated, which was effective June 12, 2019, authorizes the issuance of up to 100,000,000 shares of common stock, of which approximately 45,170,000 shares remain available for issuance as of December 31, 2024 and may be issued by us without stockholder approval.

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

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

- authorize the issuance of “blank check” preferred stock without any need for action by stockholders;
- eliminate the ability of stockholders to call special meetings of stockholders;

- prohibit stockholder action by written consent; and
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations will require an increased amount of management attention and external resources. We intend to continue to invest all reasonably necessary resources to comply with evolving standards, which may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to compliance activities.

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

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

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

On September 30, 2024 we entered into a new Open Market Sale Agreement with Jefferies LLC (the "Sale Agreement"). Pursuant to the Sale Agreement we may offer to sell, from time-to-time shares of our common stock through "at-the-market" offerings, up to a maximum of $20,000,000. We are not obligated to make or continue to make any sale of shares of our common stock under the "at-the-market" offerings. Although any sale of securities pursuant to the "at-the-market" offerings will result in a concomitant increase in cash for each share sold, it may result in shareholder dilution and may cause our share price to fall.

The evaluation of potential financial misstatements and determination of the materiality and need to restate certain sections of our previously issued consolidated financial statements has been time consuming, resulted in additional expense and may subject us to additional risks and uncertainties, including loss of investor confidence, and the increased possibility of litigation and regulatory inquiries.

As discussed in Item 8's Note 12 – Restatement of Previously Issued Financial Information, to correct misstatements in inventory and stock-based compensation for restricted stock units, we have restated certain sections of our audited consolidated financial statements as of and for the year ended December 31, 2023 and our interim unaudited consolidated financial statements contained in the Quarterly Reports on Form 10-Q as of and for the first three quarters of the years ended December 31, 2023 and December 31, 2024. The process to identify and evaluate the materiality and impact of potential financial misstatements has been time consuming and resulted in additional expense. The restatement may result in a loss of investor confidence in the accuracy of our financial disclosures and cause reputational risks for our business. In addition, we have incurred, and may continue to incur, additional costs for accounting, audit and legal fees in connection with or related to the restatement. For example, we have recently expended unanticipated fees for multiple accounting and legal advisors to assist with the application of technical accounting requirements. Finally, the restatement could subject us to additional risks and uncertainties, including the increased possibility of litigation, regulatory inquiries, or other matters.

We have identified a material weakness in our internal control over financial reporting, which could, if not effectively remediated, result in additional restatements of our financial statements, and a failure to meet our reporting and financial obligations, each of which could adversely affect our results of operations and financial condition.

As discussed above, our management has concluded that we did not maintain effective internal control over financial reporting as of December 31, 2024, due to a material weakness relating to the accounting for stock-based compensation corresponding to grants of restricted stock units. Specifically, our controls were not effectively designed or operating to ensure that restricted stock unit expense was properly accounted for. We are actively engaged in remediating the identified material weakness. Management has begun implementing measures to strengthen our internal control over financial reporting, including redesigning internal control procedures and enhancing documentation processes related to the accounting for restricted stock unit grant and vesting events. These efforts are intended

to ensure accurate and timely reporting in accordance with U.S. GAAP for both interim and annual periods. Because of the inherent limitations in all control systems, no evaluation or strengthening of controls can provide absolute assurance that all control failures within the Company have been or will be detected. Accounting standards are complex and are subject to changing guidance and differing interpretations. Notwithstanding the exertion of significant effort and resources to interpret and apply accounting standards (and any related guidance), it is possible that they may be misinterpreted or misapplied, or that prior interpretations may be reconsidered and changed, which may result in technical accounting errors. Any such accounting error could result in additional restatements of our previously issued consolidated financial statements. Accordingly, we cannot be certain that our efforts to remediate the identified material weakness will ensure effective internal control over financial reporting going forward. We also face risks associated with the cost of establishing, maintaining and enhancing effective internal control over financial reporting. We have invested and expect to continue to invest significant resources in future years, to develop and maintain the necessary documentation and testing procedures required by Section 404(a) of the Sarbanes-Oxley Act. Ensuring we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis is a costly and time-consuming effort.

Item 1B. Unresolved Staff Comments.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

Item 1C. Cybersecurity.

Risk Management and Strategy

We recognize the importance of managing the material risks of cybersecurity threats, and we have implemented processes for identifying and assessing cybersecurity risks and incidents. We have also integrated these processes into our overall risk management system, including senior management's periodic reviews of cybersecurity risks or threats. Senior management oversees and works closely with our IT department to continuously review and evaluate cybersecurity risks in alignment with our business goals and needs.

With respect to cybersecurity risks and threats, we utilize various third-party consultants and advisors to assist us with regular reviews, internal audits and best practices, including threat prevention and detection, security reviews and enhancements, penetration testing and full scope IT audits. CytoSorbents also has strict processes in place for the review of third-party service providers engaged, including thorough security assessments before engagement and annual monitoring of their IT environments and controls.

Governance

Our Chief Executive Officer and Chief Financial Officer are primarily responsible for timely updating the Board of Directors and the Audit Committee of the Board of Directors (the "Audit Committee") about any material cybersecurity incidents or threats or any cybersecurity related issues worthy of their attention.

Our Board of Directors has designated the Audit Committee as the primary committee responsible for reviewing and managing cybersecurity risks and threats at CytoSorbents. The Audit Committee is comprised of members of the Board of Directors with diverse experience in healthcare, finance and information technology, enabling them to effectively oversee cybersecurity risks and threats. Our management team, with assistance from third-party consultants or advisors as appropriate, provides quarterly updates regarding cybersecurity risks and threats to the Audit Committee and ad hoc updates or communications are provided to the entire Board of Directors as needed.

The IT Operations team is primarily responsible for the timely identification, review, severity assessment and management of cybersecurity incidents. In the event of a cybersecurity incident, the IT Department leadership follows the procedures outlined in our Cybersecurity Incident Response Policy and works closely with management to form a Security Incident Response Team comprised of members from the appropriate functional teams. In accordance with this policy, senior management will also communicate the occurrence of any significant cybersecurity incidents to our Board of Directors, Audit Committee and auditors on a timely basis and will keep them informed of the remediation plans and progress.

Item 2. Properties.

We currently operate one facility in Princeton, New Jersey and two facilities in Berlin, Germany as follows:

1. In March 2021, we entered into a lease agreement for a new 48,511 square foot operating facility at 305 College Road East, Princeton, New Jersey, which contains office, laboratory, manufacturing and warehouse space. The lease commenced in April 2021 and expires in March 2037. As of December 31, 2024, our monthly base rent is approximately $121,000.

2. Our office facility leases in Berlin, Germany requires 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.

3. Our warehouse facility lease in Berlin, Germany commenced on April 1, 2021 and requires monthly payments of base rent of approximately $7,800 through its expiration on March 31, 2026.

In the opinion of management, the leased properties are adequately insured, are in good condition and suitable for the conduct of our business. We also collaborate with numerous institutions, universities and commercial entities who conduct research and testing of our products at their facilities.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings arising in the ordinary course of business. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact because of defense and settlement costs, diversion of management resources and other factors.

On March 5, 2024, a former employee, filed a complaint against us in the Superior Court of New Jersey, Law Division, Mercer County, alleging breach of the New Jersey Conscientious Employee Protection Act (“CEPA”). The complaint specifically alleges that we violated the provisions of the CEPA by allegedly terminating the former employee in retaliation for complaining about certain business practices. We dispute these allegations and intend to vigorously defend against them, but there can be no assurance as to the outcome of the litigation.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Beginning on December 23, 2014, our common stock began trading on Nasdaq under the symbol "CTSO." Previously, the Company's common stock traded in the over-the counter-market on the OTC Bulletin Board.

Approximate Number of Equity Security Holders

As of March 31, 2025, there were approximately 11,100 stockholders of record. Because shares of our common stock are held by depositaries, brokers and other nominees, the number of beneficial holders of our shares is larger than the number of stockholders of record.

Issuer Purchases of Securities

There were no repurchases of the Company's securities during the year ended December 31, 2024.

We have an effective shelf registration statement that was declared effective on September 30, 2024 with the SEC which enables us to raise up to $150 million in one or more offerings, through the issuance and sale of any combination of equity securities, debt securities, warrants and units. Approximately $149.7 million of this amount was available as of December 31, 2024. We have also allocated $19.7 million of our total shelf amount to our ATM facility. As of December 31, 2024, approximately $19.4 million was available for use under the ATM facility.

Recent Sales of Unregistered Securities

We had no sales of unregistered securities in 2024 that have not been previously disclosed in a Current Report on Form 8-K or Quarterly Report on Form 10-Q.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of the results of operations and financial condition for the fiscal years ended December 31, 2024 and 2023 should be read in conjunction with our consolidated financial statements, and the notes to those consolidated financial statements that are included elsewhere in this Report.

Overview

We are a leader in the treatment of life-threatening conditions in the intensive care unit and cardiac surgery through blood purification. CytoSorbents' proprietary blood 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. Cartridges filled with these beads can be used with standard blood pumps already in the hospital (e.g. dialysis, ECMO, heart-lung machines). CytoSorbents' technologies are used in a number of broad applications. Specifically, four important applications are 1) the removal of blood thinners during and after cardiothoracic surgery to reduce the risk of severe bleeding 2) the removal of inflammatory agents in common critical illnesses such as sepsis, burn injury, trauma, lung injury, liver failure, cytokine release syndrome, and pancreatitis that can lead to massive inflammation, organ failure and patient death 3) the removal of liver toxins that accumulate in acute liver dysfunction or failure and 4) the removal of myoglobin in severe rhabdomyolysis that can otherwise lead to renal failure. In these diseases, the risk of death can be extremely high, and there are few, if any, effective treatments.

CytoSorbents' lead product, CytoSorb®, is approved in the European Union and distributed in more than 70 countries worldwide, with more than 270,000 devices used cumulatively to date. CytoSorb was originally launched in the European Union under CE mark as the first cytokine adsorber. Additional CE mark extensions were granted for bilirubin and myoglobin removal in clinical conditions such as liver disease and trauma, respectively, and for ticagrelor and rivaroxaban removal in cardiothoracic surgery procedures. CytoSorb has also received FDA EUA in the United States for use in adult critically ill COVID-19 patients with impending or confirmed respiratory failure, to reduce pro-inflammatory cytokine levels. CytoSorb is not yet approved in the United States.

In the U.S. and Canada, CytoSorbents is developing the DrugSorb™-ATR antithrombotic removal system, an investigational device based on an equivalent polymer technology to CytoSorb, to reduce the severity of perioperative bleeding in high-risk surgery due to blood thinning drugs. It has received two FDA Breakthrough Device Designations: one for the removal of ticagrelor and another for the removal of the direct oral anticoagulants (DOAC) apixaban and rivaroxaban in a cardiopulmonary bypass circuit during urgent cardiothoracic procedures.

In September 2024, the Company submitted a De Novo medical device application to the FDA requesting marketing approval to reduce the severity of perioperative bleeding in CABG patients on the antithrombotic drug ticagrelor, which was accepted for substantive review in October 2024. On November 1, 2024 we received Medical Device Single Audit Program (MDSAP) certification, a key regulatory milestone that certifies compliance of our quality management system with the standard regulatory requirements of Canada, the United States, Brazil, Japan and Australia; and then promptly submitted our Medical Device License (MDL) marketing application to Health Canada on November 1, 2024, with MDSAP certification – a requirement for the submission. Our applications with FDA and Health Canada continue to be in substantive and interactive review, and we continue to expect regulatory decisions from both agencies in 2025. DrugSorb-ATR is not yet granted or approved in the United States and Canada, respectively.

The Company has numerous marketed products and products under development based upon this unique blood purification technology protected by many issued U.S. and international patents and registered trademarks, and multiple patent applications pending, including ECOS-300CY®, CytoSorb-XL™, HemoDefend-RBC™, HemoDefend-BGA™, VetResQ®, K+ontrol™, DrugSorb™, ContrastSorb, and others. For more information, please visit the Company's website at www.cytosorbents.com or follow us on Facebook and X.

Summary of Operational and Business Highlights

- Total product revenue (excluding grant income) was $35.6 million for the year ended December 31, 2024, an increase of $4.5 million, or 15%, compared to the year ended December 31, 2023
- Gross profit was 25.1 million for the year ended December 31, 2024, an increase of $3.2 million, or 14%, compared to the year ended December 31, 2023
- Our loss from operations was improved by 47% to approximately $16.8 million, from $31.9 million for the years ended December 31, 2024 and 2023 respectively. This improvement was the result of revenue growth, and a 22% reduction in total operating expense.
- Secured a $20 million credit facility
- Launched the PuriFi Pump, and standalone hemoperfusion pump designed to support early treatment with CytoSorb without standard dialysis machines
- We submitted our DrugSorb-ATR DeNovo marketing application to the FDA on September 27, 2024, and announced FDA acceptance and initiation of substantive review of our application on October 22, 2024. This filing included the results of our STAR-T pivotal trial, and was supported with real world evidence from our STAR Registry
- We received Medical Device Single Audit Program (MDSAP) certification on November 1, 2024, a key regulatory milestone that certifies compliance of our quality management system with the standard regulatory requirements of Cananda, the United States, Brazil, Japan and Australia
- Submitted our Medical Device License (MDL) marketing application to Health Canada on November 1, 2024, concurrent with MDSAP certification – a requirement for submission, with data from both the STAR-T trial and the STAR Registry
- Surpassed 270,000 CytoSorb treatments delivered cumulatively to date
- In the first quarter of 2025 we strengthened our balance sheet with the completion of a shareholder Rights Offering in January 2025 that provided $5.8 million net proceeds, and then added another $1.5 million, net proceeds with the exercise of the Series A Right Warrant in February. This equity raise satisfied a debt covenant to release $5 million in restricted cash already on our balance sheet. As a result, this raise increased our unrestricted cash liquidity by a total of $12.3 million.

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. Inflationary pressures may continue to impact our product gross margins in the future.

Results of Operations

Comparison of the year ended December 31, 2024 and 2023

	For the Year Ended December 31,			
	2024		2023 As Restated	
	Amount	% of Revenue	Amount	% of Revenue
Product revenue	$ 35,594,520	100 %	$ 31,084,953	100.0 %
Cost of goods sold	10,468,529	29 %	9,131,716	29 %
Gross profit	25,125,991	71 %	21,953,237	71 %
Operating expenses:				
Research and development	6,916,181	19 %	15,594,442	50 %
Selling, general and administrative	34,995,749	98 %	38,307,415	123 %
Total operating expenses	41,911,930	118 %	53,901,857	173 %
Loss from operations	(16,785,939)	(47)%	(31,948,620)	(103)%
Other income (expense):				
Interest expense, net	(1,399,092)	(4)%	(157,891)	(1)%
Gain (loss) on foreign currency transactions	(4,224,721)	(12)%	1,949,257	6 %
Miscellaneous income (expense)	(30)	0 %	96,755	0 %
Total other income (expense), net	(5,623,843)	(16)%	1,888,121	6 %
Loss before benefit from income taxes	$ (22,409,782)	(63)%	$ (30,060,499)	(97)%

Product Revenue

For the year ended December 31, 2024, we generated total revenue of approximately $35.6 million as compared to revenues of approximately $31.1 million for the year ended December 31, 2023, an increase of approximately $4.5 million, or 15%. The increase in revenues related to increases in direct sales and distributor sales of $1.7 million or 9%, and $2.7 million or 22%, respectively, during the year ended December 31, 2024, as compared to the year ended December 31, 2023.

Gross Profit

Gross profit was approximately $25.1 million for the year ended December 31, 2024, an increase of approximately $3.2 million or 14%, as compared to gross profit of $22.0 million for the year ended December 31, 2023. Product gross margins were 71% and 71% for the years ended December 31, 2024 and 2023, respectively.

Research and Development Expenses

Our research and development costs were approximately $6.9 million and $15.6 million for the years ended December 31, 2024 and 2023, respectively, a decrease of approximately $8.7 million, or 56%. This decrease was driven by a decrease in our clinical trial costs due to the completion of the STAR-T clinical trial in December 2023. Clinical expenses excluding compensation were approximately $2.8 million and $9.2 million for the years ended December 31, 2024 and 2023, respectively, a decrease of approximately $6.4 million. In addition, research and development compensation expenses decreased by $1.2 million from $3.6 million for the year ended December 31, 2023 to $2.4 million for the year ended December 31, 2024, due to reductions in headcount.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses were approximately $35.0 million and $38.3 million for the years ended December 31, 2024 and 2023, respectively, a decrease of approximately $3.3 million, or 9%. This decrease was mainly due to a decrease in salaries of approximately $2.3 million related to headcount reductions, and a decrease in net legal, consulting and professional expenses of approximately $1.4 million.

Loss From Operations

Our loss from operations decreased by 47% to approximately $16.8 million, from $31.9 million for the years ended December 31, 2024 and 2023 respectively. This improvement was the result of revenue growth, and a 22% reduction in total operating expense.

Interest Expense, Net

For the year ended December 31, 2024, Interest expense, net, was approximately $1.4 million, as compared to $0.2 million for the year ended December 31, 2023. The increase was due to interest incurred on the Avenue Capital Group debt that was closed during the second quarter of 2024. This financing increased the principal amount of our debt to $15 million from $5 million and the interest rate increased to 13.5% from 8%.

Gain (Loss) on Foreign Currency Transactions

For the year ended December 31, 2024, the loss on foreign currency transactions was approximately $4.2 million, as compared to a gain on foreign currency transactions of approximately $1.9 million for the year ended December 31, 2023. The loss was directly related to the decrease in the spot exchange rate of the Euro to the U.S. dollar as of December 31, 2024, as compared to December 31, 2023. The exchange rate of the Euro to the U.S. dollar was $1.03 per Euro as of December 31, 2024, as compared to $1.11 per Euro at December 31, 2023. The 2023 gain is directly related to the increase of the exchange rate of the Euro as of December 31, 2023, as compared to December 31, 2022. The exchange rate of the Euro to the U.S. dollar was $1.11 per Euro as of December 31, 2023, as compared to $1.07 per Euro as of December 31, 2022.

Benefit from Income Taxes

Our benefit from income taxes was approximately $1.7 million and $0.8 million for the years ended December 31, 2024, and 2023, respectively. This benefit was realized by utilizing the New Jersey Technology Business Tax Certificate Transfer Program whereby the State of New Jersey allows us to sell a portion of our state net operating losses to a third party.

Liquidity and Capital Resources

Since inception, our operations have been primarily financed through the issuance of debt and equity securities. As of December 31, 2024, we had current assets of approximately $21.6 million and current liabilities of approximately $9.9 million. As of December 31, 2024, $19.7 million of our total shelf amount was allocated to our at-the-market facility (“ATM facility”), of which approximately $19.4 million remained available.

During the year ended December 31, 2024, the Company sold 382,823 shares pursuant to the Sale Agreement, at an average selling price of $1.01 per share, generating proceeds of approximately $179,000, net of fees.

In June of 2024, we closed on a $20 million term-loan facility with Avenue Capital Group which provided an initial tranche of $15 million at the closing of which $10 million was immediately available at closing and $5 million constitutes restricted cash subject to release to the Company prior to March 31, 2025, provided certain conditions are met. Another tranche of $5 million may be disbursed at the Company’s request between July 1, 2025 and December 31, 2025, provided that the Company receives FDA marketing approval of its DrugSorb-ATR application. Concurrently with the closing of the first tranche, the Company paid off our existing debt with Bridge Bank.

In March of 2024, we received approximately $880,000 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 proactively managing our resources with a focus on driving commercial success, investing in key areas such as our regulatory submissions of DrugSorb-ATR to U.S. FDA and Health Canada and the development of clinical data. We have also instituted and continue to maintain tight control over expenditures and have lowered our spending significantly over the past year.

As of December 31, 2024, we have approximately $9.8 million in cash (a non-GAAP measure), including approximately $3.3 million in unrestricted cash and cash equivalents, $5 million in restricted cash classified as a current asset, and $1.5 million of non-current restricted cash which is not expected to fund Company's operations beyond the next twelve months from the issuance of these consolidated financial statements This matter raise substantial doubt about the Company's ability to continue as a going concern. However, as of the issuance date of this Annual Report on Form 10-K, the Company continues to be in the process of an equity raise through a Rights Offering that has included the following:

- On January 10, 2025, we closed the subscription period of its previously announced shareholder Rights Offering (the "Rights Offering"), raising aggregate gross proceeds of $6.25 million from the sale of all 6.25 million Units reserved for the Rights Offering. Participants in the Rights Offering received Units, each Unit comprising of one share of common stock of the Company, one Series A Right Warrant to purchase one share of common stock, and one Series B Right Warrant to purchase one share of common stock. The Right Warrants, as discussed below, will provide additional opportunity to purchase up to an additional 6,250,000 shares of common stock.

- Proceeds from the Rights Offering satisfied the second condition of a debt covenant which now allows for the $5.0 million of restricted cash on our consolidated balance sheet to become unrestricted, and available for use.

- The Right Warrants are exercisable commencing on their date of issuance and the exercise price shall be equal to (i) in the case of the Series A Right Warrants, 90% of the 5-day volume weighted average price of our Common Stock over the last 5-trading days prior to the expiration date of the Series A Right Warrants on February 24, 2025, rounded down to the nearest whole cent but (x) not lower than $1.00 and (y) not higher than $2.00, and (ii) in the case of the Series B Right Warrants, 90% of the 5-day volume weighted average price of our common stock over the last 5-trading days prior to the expiration date of the Series B Right Warrants on April 10, 2025, rounded down to the nearest whole cent but (x) not lower than $2.00 and (y) not higher than $4.00.

- Exercise of the Right Warrants require additional investment separate from the purchase of the Units. We reserved 6.25 million shares of common stock for exercise of the Right Warrants, after which any remaining unexercised Right Warrants will immediately expire worthless. The Right Warrants are transferable until they have expired.

- On February 24, 2025, approximately 1.4 million Series A Right Warrants were exercised by holders, including members of management and the Board of Directors, at an exercise price of $1.13 per warrant, providing an additional $1.6 Million in aggregate gross proceeds.

As of the issuance date of this Annual Report on Form 10-K, we have raised a total of $7.3 million, net of offering fees, through the Rights Offering, and the exercise of the Series A Right Warrants. The equity raises also provided for $5 million of restricted cash to become unrestricted. As a result, our proforma unrestricted cash and cash equivalents, a non-GAAP measure, on December 31, 2024, assuming the net proceeds from the Rights Offering and the Series A Right Warrant exercise had occurred at that date, has increased by $12.3 million to $15.6 million, compared to the as reported amount of $3.3 million

Our expected future capital requirements may depend on many factors including expanding our customer base and sales force, the timing and extent of spending in obtaining regulatory approval and introduction of new products, including the regulatory approval and introduction of DrugSorb-ATR in the U.S. and Canada which is expected in 2025, and the related opportunity to receive Tranche 2 of Avenue Capital Commitment by December 31, 2025 and extend the principle re-payment terms of the facility beginning in the third quarter of 2026. Additional sources of liquidity available to us include issuance of additional equity securities through the Series B Right Warrant, or other public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to our shareholders. There is no assurance that we will be able to secure funding on terms acceptable to us, or at all. The increasing need for capital could also make it more difficult to obtain funding through either equity or debt. Should additional capital not become available to us as needed, we may be required to take certain actions, such as slowing sales and marketing expansion, delaying further regulatory approvals, or reducing headcount. As a result of these additional uncertainties, the accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is actively pursuing financing sources, including less or non-dilutive debt financing, additional grant funding, royalty financing, strategic or direct investments, equity financing, and/or combinations thereof. There can be no assurance that management will be successful in these endeavors.

Loan and Security Agreement

On June 28, 2024 (the "Closing Date"), the Company entered into a Loan and Security Agreement with the Avenue Capital Group. Avenue Capital Group agreed to loan the Company up to an aggregate of $20 million, to be disbursed in two tranches: (1) one tranche of $15 million ("Tranche 1"), of which $10 million is available to the Company on the Closing Date and $5 million which remained classified as restricted cash through January 10, 2025, when it was released from its restriction as the following conditions were met: (i) the FDA has accepted Company's application for review with respect to DrugSorb-ATR De Novo 510(k) and (ii) the Company has received a minimum of $3 million in net proceeds from the sale of its equity securities after the Closing Date. A second tranche of up to $5 million, may be disbursed at the Company's request between July 1, 2025 and December 31, 2025, provided that the Company receives FDA marketing approval of its DrugSorb-ATR application ("Tranche 2" and together with Tranche 1, the "Avenue Capital Commitment"). All unpaid principal and accrued and unpaid interest shall be due and payable in full by the maturity date. If the 2nd tranche is fully funded by December 2025, the maturity date is January 1, 2028; otherwise, the maturity date is July 1, 2027. Commencing on August 1, 2024, the Company shall make monthly interest only payments during the initial 25-month period following the Closing Date, followed by equal monthly installments through the maturity date consisting of principal plus accrued and unpaid interest.

On October 22, 2024, the Company announced that the FDA had accepted its application of for DrugSorb-ATR, which was one of the two conditions required by the restricted cash debt covenant. Proceeds from the Rights Offering on January 10, 2025 satisfied the second condition of the debt covenant which now allows for the $5,000,000 of restricted cash on the Company's consolidated balance sheets to become unrestricted, and available for use.

The proceeds from the Avenue Capital Commitment were used to pay off the existing outstanding debt with Bridge Bank and will additionally be used for working capital purposes and to fund general business requirements. Amounts borrowed under the Avenue Capital Commitment shall bear interest at a variable rate per annum equal to the greater of (A) the Prime Rate plus five percent (5.00%) or (B) thirteen and one-half percent (13.50)%.

For further discussion regarding the Loan Agreement please see Long Term Debt note to our Consolidated Financial Statements, included elsewhere in this Annual Report on Form 10-K.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. We believe the following critical accounting policies and estimates have significant effect in the preparation of our consolidated financial statements.

Revenue Recognition

Revenue is recognized when the Company ships its products to its direct customers and distributors/strategic partners. The amount of revenue recognized reflects the consideration the Company expects to be entitled to receive in exchange for the products shipped or the services provided under their grant contracts. To achieve this core principle, the Company applies the following five steps:

1. Identify Contracts with Customers - The Company's contracts with its direct customers are generally in the form of a purchase order. The Company has formal written contracts with each of its distributors/strategic partners that define their respective territories and minimum purchase commitments which must be met in order to maintain exclusivity in their territory. Distributors/strategic partner customers also submit purchase orders with each order that define the terms of shipment and transaction price.

2. Identify Performance Obligations - The performance obligations in contracts with direct customers and distributors/strategic partners are for the shipment of the CytoSorb device and related accessory parts.

3. Determine Transaction Price - The price charged is based on the Company's price list for the CytoSorb device and related accessory parts for both direct customers and distributor/strategic partners. The Company does not permit returns for product sales. The Company also provides for certain rebates and discounts to direct customers for sales of its product that are earned based upon sales volume. These amounts, which are earned based on calendar year sales volume, are recorded as a reduction of sales as earned.

4. Allocate Transaction Price to Performance Obligations - The transaction price for the performance obligation is based on the purchase orders received for both direct customers and on the type of contract and are outlined in each contract.

5. Recognize Revenue as Performance Obligations are Satisfied - The Company satisfies its performance obligation to direct customers and distributors/strategic partners generally upon shipment of the products.

Research and Development, Net of Grant Income

All research and development costs, payments to laboratories, research consultants and costs related to clinical trials and studies are expensed when incurred.

Currently, accounting for grants does not fall under ASC 606, as the grantor will not benefit directly from the Company's expansion or product development, and no products or services are transferred to the grantor. As there is no authoritative guidance under U.S. GAAP on accounting for grants to for profit business entities from government entities, the Company has adjusted its accounting policy for recording grants to analogize the guidance provided by IAS 20. Accordingly, the Company has retroactively, as of January 1, 2023, reclassified grant income, net of expenses, as a reduction of research and development expenses.

Stock Based-Compensation

As discussed in Notes 2 and 11 to the consolidated financial statements, the Company grants stock-based awards including stock options, restricted stock units and performance-based stock awards to their employees as compensation for their service. The Company recorded approximately $3,759,534 of stock-based compensation expense during the year ended December 31, 2024. In 2024, the Company granted 1,214,400 performance awards, and recorded stock-based compensation expense of approximately $208,000 related to these awards. The number of shares awarded are contingent on certain performance metrics, and the quantity of awards received can range based on the level of performance achieved.

Lease Commitments

We currently operate our leased facility in Princeton, New Jersey and two leased facilities in Berlin, Germany as follows:

- In March 2021, we entered into a lease agreement for a new 48,511 square foot operating facility at 305 College Road East, Princeton, New Jersey, which contains office, laboratory, manufacturing and warehouse space. The lease commenced in April 2021 and expires in March 2037. As of December 31, 2024, our monthly base rent is approximately $121,000.

- Our office facility leases in Berlin, Germany requires combined base rent payments for a total of 11,495 square feet 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.
- Our warehouse facility lease in Berlin, Germany commenced on April 1, 2021 and requires monthly payments of base rent of approximately $7,800 through its expiration on March 31, 2026.

Patents

Legal costs incurred to establish 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

Our Consolidated Financial Statements and notes thereto are included elsewhere in this Annual Report on Form 10-K and incorporated herein by reference. See Item 15 of Part IV.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, mean controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company on the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including, our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures are not designed at a reasonable assurance level and are not effective due to a material weakness, as further described below.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) of the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed to provide reasonable assurance to our management and board of directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, errors or fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. Also, projections of any evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2024.

Changes in Internal Control Over Financial Reporting

Discussion of Material Weakness

A material weakness (as defined in Rule 12b-2 under the Exchange Act) is a deficiency, or combination of deficiencies, in our internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements would not be prevented or detected on a timely basis.

In connection with our preparation and the audit of our consolidated financial statements as of and for the year ended December 31, 2024, we identified a material weakness in our internal control over financial reporting related to the accounting for inventory and stock-based compensation corresponding to grants of Restricted Stock Units. Specifically, our controls were not effectively designed or operating to ensure that inventory and restricted stock unit grants or vesting activities were recorded within the proper accounts and at the proper amounts.

Remediation Activities

We are actively engaged in remediating the identified material weakness. Management has begun implementing measures to strengthen our internal control over financial reporting, including redesigning internal control procedures and enhancing documentation processes related to the accounting for restricted stock unit grant and vesting events. These efforts are intended to ensure accurate and timely reporting in accordance with U.S. GAAP for both interim and annual periods. Key steps in our remediation plan include:

- Developing and implementing more robust control procedures to validate that the inputs and assumptions used in stock-based compensation expense calculation models are accurate and reflect proper application of generally accepted accounting principles.

- Increasing oversight and review by executive management to ensure the completeness and accuracy of restricted stock unit expense calculations and their corresponding Journal Entries.

We are committed to completing the remediation of this material weakness as expeditiously as possible and expect these enhancements to be fully implemented during the fiscal year ending December 31, 2025. However, the material weakness will not be considered fully remediated until the new controls have been operational for a sufficient period of time and tested to demonstrate their effectiveness.

Notwithstanding the material weaknesses, management has concluded that the consolidated financial statements included elsewhere in this Annual Report present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with GAAP.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection.

None.

PART III

Item 10. Directors, Executive Officers and Control Persons.

Information required by this Item regarding our executive officers, Board of Directors, Section 16(a) compliance, Audit Committee, Audit Committee financial expert, Code of Business Conduct and Ethics, and other corporate governance matters is incorporated by reference from our definitive proxy statement for our 2025 annual meeting of stockholders, scheduled for June 12, 2025. This proxy statement, containing the sections "Officers and Key Employees," "Nomination and Election of Directors," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Board of Directors and Corporate Governance 1 Matters," will be filed within 120 days of our fiscal year end

The text of our Code of Business Conduct and Ethics, which applies to our directors and employees (including our principal executive officer, principal financial officer, and principal accounting officer or controller, and persons performing similar functions), is posted in the "Corporate Governance" section of our website, www.cytosorbents.com. A copy of the Code of Business Conduct and Ethics can be obtained free of charge on our website. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission and The Nasdaq Stock Market.

The information presented on our website is not a part of this Annual Report on Form 10-K and the reference to our website is intended to be an inactive textual reference only.

Item 11. Executive Compensation.

Information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the sections entitled "Executive Compensation," "Director Compensation" and "Board of Directors and Corporate Governance Matters" contained in our definitive proxy statement for our 2025 annual meeting of stockholders scheduled to be held on June 12, 2025, which we intend to file within 120 days of the end of our fiscal year.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the sections entitled "Principal Stockholders," "Stock Ownership of Directors, Nominees for Director, and Executive Officers" and "Equity Compensation Plan Information" contained in our definitive proxy statement for our 2025 annual meeting of stockholders scheduled to be held on June 12, 2025, which we intend to file within 120 days of the end of our fiscal year.

Item 13. Certain Relationships and Related Transactions and Director Independence.

Information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the section(s) entitled "Certain Relationships and Related Party Transactions" and "Board of Directors and Corporate Governance Matters," "Compensation for Executive Officers and Directors, "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" contained in our definitive proxy statement for our 2025 annual meeting of stockholders scheduled to be held on June 12, 2025, which we intend to file within 120 days of the end of our fiscal year.

Item 14. Principal Accounting Fees and Services.

This information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the section entitled "Audit and Other Fees" contained in our definitive proxy statement for our 2025 annual meeting of stockholders scheduled to be held on June 12, 2025, which we intend to file within 120 days of the end of our fiscal year.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Financial Statements and Schedules:

1. Financial Statements

The following consolidated financial statements and reports of independent registered public accounting firm are included herein:

2. Financial Statement Schedules

Not applicable.

3. List of Exhibits

Exhibit No.	Description
3.1	Second Amended and Restated Certificate of Incorporation, dated June 12, 2019 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8
3.2	Second Amended and Restated Bylaws of CytoSorbents Corporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8
4.1	Description of Capital Stock of CytoSorbents Corporation (incorporated by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 10, 2022).
4.2	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 11, 2023).
4.3	Form of Subscription Right Warrant Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 9, 2024).
4.4	Form of Series A Right Warrant Certificate (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 9, 2024).
4.5	Form of Series B Right Warrant Certificate (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed with the SEC on December 9, 2024).
10.1+	Amended and Restated Employment Agreement, dated as of July 30, 2019, by and between CytoSorbents Medical, Inc. and Phillip P. Chan (incorporated by reference to Exhibit 10.1
10.2+	Amended and Restated Employment Agreement, dated as of July 30
10.3+	Amended and Restated Employment Agreement, dated as of July 30, 2019, by and between CytoSorbents Medical, Inc. and Kathleen P. Bloch (incorporated by reference to Exhibit 10.3
10.4+	Employment Agreement by and between the Company and Efthymios Deliargyris, M.D., dated April 12, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 27, 2020).
10.5+†	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 Registrant's Current Report on Form 8-K filed with the SEC on April 6, 2023).
10.6+	Employment Agreement, dated September 18, 2023, by and between the Company and Ms. Kathleen Bloch (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 19, 2023).
10.7	Consulting Agreement, dated August 13, 2024, by and between the Company and Kathleen P. Bloch (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed with the SEC on August 16, 2024).
10.8+	Employment Agreement, dated August 14, 2024, by and between the Company and Mr. Peter J. Mariani (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 16, 2024).
10.9+	Form of Payment Reduction Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 3, 2024).
10.10+	Form of Nonqualified Stock Option Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on April 3, 2024).

10.11	Restricted Stock Unit Award Agreement (Inducement Award), dated as of August 14, 2024, by and between the Registrant and Peter Mariani (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on August 16, 2024).
10.12	Nonstatutory Option Award Agreement (Inducement Award), dated as of August 14, 2024, by and between the Registrant and Peter Mariani (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on August 16, 2024).
10.13	Nonstatutory Option Award Agreement (Inducement Award), dated as of August 14, 2024, by and between the Registrant and Peter Mariani (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed with the SEC on August 16, 2024).
10.14	Royalty Agreement between Guillermina Vega Montiel and the Registrant dated as of August 11, 2003 (incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 31, 2015).
10.15	Assignment and Assumption of Certain Royalty Rights, dated as of November 22, 2022, by and among Robert Shipley Living Trust, ROKK, LLC, and CytoSorbents Medical, Inc (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 9,2023).
10.16	Stipulated Order and Settlement Agreement between Bro-Tech Corporation,
10.17†	Distribution Agreement between Biocon Biologics Limited and the Registrant dated as of September 20, 2013 (incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 31, 2015).
10.18†	First Amendment to the Distribution Agreement between Biocon Biologics Limited and the Registrant, dated October 30, 2014 (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 31, 2015).
10.19+	CytoSorbents Corporation 2006 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form
10.20+	Amendment No. 1 to the CytoSorbents Corporation 2006 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's registration statement on Form S-8 filed with the SEC on November 4, 2014).
10.21	Amended and Restated CytoSorbents Corporation 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-8 filed with the SEC on August 26, 2019).
10.22	Amended and Restated Loan and Security Agreement, dated as of March 29, 2018, by and among CytoSorbents Corporation, CytoSorbents Medical, Inc. and Western Alliance Bank (incorporated by reference to Exhibit 10.1
10.23	First Amendment to Amended and Restated Loan and Security Agreement, dated as of July 30, 2019, by and among CytoSorbents Corporation, CytoSorbents Medical, Inc. and Western Alliance Bank (incorporated by reference to Exhibit 10.1
10.24	Third Amendment to Amended and Restated Loan and Security Agreement, dated as of December 4, 2020, by and among CytoSorbents Corporation, CytoSorbents Medical, Inc. and Western Alliance Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 10, 2020).
10.25	Fourth Amendment to the Amended and Restated Loan and Security Agreement, dated as of January 19, 2022, by and among CytoSorbents Corporation, CytoSorbents Medical, Inc. and Western Alliance Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 20, 2022).
10.26	Fifth Amendment to the Amended and Restated Loan and Security Agreement, dated as of December 28, 2022, by and among CytoSorbents Corporation, CytoSorbents Medical, Inc. and Western Alliance Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 29, 2022).

10.27	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 (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 9, 2023).
10.28	Seventh Amendment to the Amended and Restated Loan and Security Agreement, dated as of May 16, 2023, by and among CytoSorbents Corporation, CytoSorbents Medical, Inc. and Western Alliance Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 1, 2023).
10.29†	Loan and Security Agreement, dated as of June 28, 2024, by and among CytoSorbents Corporation, the lenders, and the administrative and collateral agent party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 5, 2024).
10.30†	Supplement to the Loan and Security Agreement, dated as of June 28, 2024, by and among CytoSorbents Corporation, the lenders, and the administrative and collateral agent party thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on July 5, 2024).
10.31	Form of Warrant, by and between CytoSorbents Corporation and Avenue Venture Opportunities Fund, LP (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on July 5, 2024).
10.32	Success Fee Letter, dated as of March 29, 2018, by and among CytoSorbents Corporation, CytoSorbents Medical, Inc. and Western Alliance Bank (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on April 4, 2018).
10.33	Success Fee Letter, dated as of January 19, 2022, by and among CytoSorbents Corporation, CytoSorbents Medical, Inc. and Western Alliance Bank (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on January 20, 2022).
10.34†	Exclusive Distribution Agreement, dated as of September 26, 2014, by and between CytoSorbents Europe GmbH and Aferetica s.r.l. (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 7, 2019).
10.35†	Amendment to Exclusive Distribution Agreement, dated December 15, 2014, by and between CytoSorbents Europe GmbH and Aferetica s.r.l (incorporated by reference to Exhibit 10.24 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 7, 2019).
10.36	Open Market Sale AgreementSM, dated as of December 30, 2021, by and between CytoSorbents Corporation and Jefferies LLC (incorporated by reference from Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 30, 2021).
10.37	Marketing Agreement, dated as of August 1, 2022, by and between CytoSorbents Corporation and Fresenius Medical Care Deutschland GmbH (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 3, 2022).
10.38	Lease, dated as of March 26, 2021, by and between 300 CR LLC and CytoSorbents Medical, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 31, 2021).
10.39†	Securities Purchase Agreement, dated as of December 11, 2023, by and among CytoSorbents Corporation and the investors party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 11, 2023).
19.1*	Insider Trading Policy.
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 15, 2024).
23.1*	Consent of WithumSmith+Brown, PC.

31.1*	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of the Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97	Compensation Recoupment Policy (incorporated by reference to Exhibit 97 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 15, 2024).
101	The following materials from CytoSorbents Form 10-K for the fiscal year ended December 31, 2023, formatted in Extensible Business Reporting Language (XBRL): (1) Consolidated Balance Sheets at December 31, 2023 and December 31, 2022, (iii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2023, 2022 and 2021, (iii) Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity/(Deficit) for the years ended December 31, 2023, 2022 and 2021, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2023, 2022 and 2021, and (v) Notes to the Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed or furnished herewith.

\+ Management contract or compensatory plan or arrangement of the Registrant required to be filed as an exhibit to this Annual Report.

† Confidential treatment has been requested for certain portions of this exhibit. The confidential portions of this exhibit have been omitted and filed separately with Securities and Exchange Commission.

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

Item 16. Form 10-K Summary.

None.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, CytoSorbents Corporation has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 31st day of March, 2025.

CYTOSORBENTS CORPORATION

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Dr. Phillip P. Chan Dr. Phillip P. Chan	Chief Executive Officer (Principal Executive Officer) and Director	March 31, 2025
/s/ Peter J. Mariani Peter J. Mariani	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2025
/s/ Michael G. Bator Michael G. Bator	Chairman of the Board	March 31, 2025
/s/ Alan D. Sobel Alan D. Sobel	Director	March 31, 2025
/s/ Edward R. Jones Edward R. Jones	Director	March 31, 2025
/s/Jiny Kim Jiny Kim	Director	March 31, 2025

FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
CytoSorbents Corporation:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of CytoSorbents Corporation (the 'Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, changes in stockholder's equity, cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years ended December 31, 2024 and 2023, in conformity with accounting principles generally accepted in the United States of America.

Restatement of the Previously Issued Consolidated Financial Statements

As discussed in Note 12 to the consolidated financial statements, the 2023 consolidated financial statements have been restated to correct material misstatements related to stock-based compensation expense for restricted stock units and inventory.

Emphasis of the Matter – Restatement of Unaudited Interim Condensed Consolidated Financial Statements

As discussed in Note 12 to the consolidated financial statements, the unaudited interim condensed consolidated financial statements as of and for the three months ended March 30, 2024 and 2023, as of and for the three and six months ended June 30, 2024 and 2023, and as of and for the three and nine months ended September 30, 2024 and 2023, have been restated to correct material misstatements related to stock-based compensation expense for restricted stock units and inventory.

Substantial Doubt Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the entity has suffered recurring losses from operations, has experienced cash used in operations, and has an accumulated deficit, which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which they relate.

Evaluation of warrants

Description of the Matter

As described in Note 5 to the consolidated financial statements, the Company entered into a Loan and Security Agreement in June 2024. As additional consideration for the commitment, the Company also issued the lender warrants with a fair value of $690,709 to purchase an aggregate of 1,645,569 shares of the Company's common stock for cash at the exercise price of $0.79, which expire on June 28, 2029. The Company determined that the warrants met all the criteria for equity classification and recorded them as a component of additional paid-in capital upon the closing of the transaction in July 2024.

The principal considerations for our determination of the financial statement classification of the warrants as a critical audit matter are the existence of complexities in applying the accounting standards related to certain warrant agreement provisions, including settlement provisions and derivative elements. Auditing these elements involved especially complex auditor judgment, specialized knowledge and skills due to the terms of the applicable agreement

How We Addressed the Matter in Our Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, obtaining an understanding of and evaluating the design and implementation of controls over management's process for the accounting treatment, reading the agreements, and evaluating the accounting for the warrant issuance. Testing management's process included (i) evaluating the internal controls and application of the accounting framework used by management; (ii) testing the mathematical accuracy of management's calculations; (iii) testing the inputs and assumptions used and (iv) testing the completeness and accuracy of the underlying data used in the calculations. Professionals with specialized skill and knowledge were used to assist in (i) evaluating management's application of the accounting framework and (ii) testing the mathematical accuracy of management's calculation and evaluating the conclusion related to the accounting classification of the warrant issuance.

/s/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2004.

East Brunswick, New Jersey
March 31, 2025
PCAOB ID Number 100

CYTOSORBENTS CORPORATION
CONSOLIDATED BALANCE SHEETS

	At December 31, 2024	At December 31, 2023 As restated
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 3,279,926	$ 14,131,137
Restricted cash, current	5,000,000	—
Grants and accounts receivable, net of allowances of $157,701 and $49,663 at December 31, 2024 and 2023, respectively	7,319,597	6,057,072
Inventories	2,732,907	3,375,817
Prepaid expenses and other current assets	3,270,812	1,834,485
Total current assets	**21,603,242**	**25,398,511**
Property and equipment - net	9,002,383	10,056,354
Restricted cash	1,483,958	1,483,958
Right-of-use asset	11,511,236	12,058,896
Other assets	3,770,681	3,958,603
Total Assets	**$ 47,371,500**	**$ 52,956,322**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,339,885	$ 3,802,170
Accrued expenses and other current liabilities	6,031,670	7,359,786
Lease liability – current portion	452,688	373,636
Current maturities of long-term debt	—	2,500,000
Total current liabilities	**9,824,243**	**14,035,592**
Lease liability, net of current portion	12,443,971	12,896,659
Long-term debt, net of current maturities	13,996,350	2,542,857
Total Liabilities	**36,264,564**	**29,475,108**
Commitments and Contingencies		
Stockholders' Equity:		
Preferred Stock, Par Value $0.001, 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2024 and 2023	—	—
Common Stock, Par Value $0.001, 100,000,000 shares authorized at December 31, 2024 and 2023; and 54,830,146 and 54,240,265 shares issued and outstanding at December 31, 2024 and 2023, respectively	54,830	54,240
Additional paid-in capital	310,808,711	306,187,314
Accumulated other comprehensive income	4,252,013	529,321
Accumulated deficit	(304,008,618)	(283,289,661)
Total stockholders' equity	**11,106,936**	**23,481,214**
Total Liabilities and Stockholders' Equity	**$ 47,371,500**	**$ 52,956,322**

The Notes to Consolidated Financial Statements are an integral part of these statements.

CYTOSORBENTS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year ended December 31, 2024	Year ended December 31, 2023 As restated
Product revenue	$ 35,594,520	$ 31,084,953
Cost of goods sold	10,468,529	9,131,716
Gross profit	25,125,991	21,953,237
Operating expenses:		
Research and development, net of grant income	6,916,181	15,594,442
Selling, general and administrative	34,995,749	38,307,415
Total operating expenses	41,911,930	53,901,857
Loss from operations	(16,785,939)	(31,948,620)
Other income (expense):		
Interest expense, net	(1,399,092)	(157,891)
Gain (loss) on foreign currency transactions	(4,224,721)	1,949,257
Miscellaneous income (expense)	(30)	96,755
Total other income (expense), net	(5,623,843)	1,888,121
Loss before benefit from income taxes	(22,409,782)	(30,060,499)
Benefit from income taxes	1,690,825	813,739
Net loss attributable to common stockholders	$ (20,718,957)	$ (29,246,760)
Basic and diluted net loss per common share	$ (0.38)	$ (0.65)
Weighted average number of shares of common stock outstanding	54,434,609	44,656,391
Comprehensive loss:		
Net loss	$ (20,718,957)	$ (29,246,760)
Other comprehensive income (loss):		
Foreign currency translation adjustment	4,027,003	(1,799,874)
Comprehensive loss	$ (16,691,953)	$ (31,046,634)

The Notes to Consolidated Financial Statements are an integral part of these statements.

CYTOSORBENTS CORPORATION
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	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
Cumulative effect of adjustments to beginning balance	—	—	777,310	—	(45,023)	732,287
Stock-based compensation (as restated)	—	—	4,155,342	—	—	4,155,342
Proceeds from the exercise of stock options for cash, net of fees incurred	84,905	85	218,193	—	—	218,278
Issuance of common stock offerings, net of fees incurred	10,389,554	10,390	14,245,542	—	—	14,255,932
Common stock issued upon vesting of restricted stock units, less shares withheld to cover taxes	130,091	130	(209,094)	—	—	(208,964)
Other comprehensive loss, foreign currency translation adjustment	—	—	—	(1,799,874)	—	(1,799,874)
Net loss (as restated)	—	—	—	—	(29,246,760)	(29,246,760)
Balance at December 31, 2023 (as restated)	54,240,265	$ 54,240	$ 306,187,314	$ 529,321	$ (283,289,661)	$ 23,481,214
Stock-based compensation	—	—	3,759,534	—	—	3,759,534
Issuance of common stock offerings, net of fees incurred	382,823	385	178,269	—	—	178,654
Common stock issued upon vesting of restricted stock units, less shares withheld to cover taxes	207,058	205	(7,115)	—	—	(6,910)
Issuance of warrants	—	—	690,709	—	—	690,709
Other comprehensive loss, foreign currency translation adjustment	—	—	—	3,722,692	—	3,722,692
Net loss	—	—	—	—	(20,718,957)	(20,718,957)
Balance at December 31, 2024	54,830,146	$ 54,830	$ 310,808,711	$ 4,252,013	$ (304,008,618)	$ 11,106,936

The Notes to Consolidated Financial Statements are an integral part of these statements.

CYTOSORBENTS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31, 2024	Year ended December 31, 2023 As restated
Cash flows from operating activities:		
Net loss	$ (20,718,957)	$ (29,246,760)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued final fee	111,422	42,857
Amortization of debt discount	264,702	—
Amortization of loan costs	116,028	—
Depreciation and amortization	1,570,104	1,459,066
Amortization of right-of-use asset	174,024	564,356
Bad debt expense	115,161	14,434
Impairment of patents	333,735	655,685
Foreign currency transaction (gains) losses	4,224,721	(1,949,257)
Stock-based compensation	3,759,534	4,155,342
Changes in operating assets and liabilities:		
Grants and accounts receivable	(1,720,419)	(245,616)
Inventories	500,466	183,273
Prepaid expenses and other current assets	(1,351,805)	1,104,167
Other assets	1,050	(49)
Accounts payable and accrued expenses	(1,807,575)	1,607,366
Net cash used in operating activities	(14,427,809)	(21,655,136)
Cash flows from investing activities:		
Purchases of property and equipment	(284,343)	(538,115)
Patent costs	(385,087)	(398,121)
Net cash used in investing activities	(669,430)	(936,236)
Cash flows from financing activities:		
Proceeds from long-term debt	15,000,000	—
Repayment of long-term debt	(5,000,000)	—
Payment of final fee	(150,000)	—
Payment of loan costs	(697,950)	—
Equity contributions - net of fees incurred	178,654	14,255,932
Proceeds from exercise of stock options	—	218,278
Net cash provided by financing activities	9,330,704	14,474,210
Effect of exchange rates on cash	(84,676)	(99,769)
Net change in cash, cash equivalents, and restricted cash	(5,851,211)	(8,216,931)
Cash, cash equivalents, and restricted cash at beginning of year	15,615,095	23,832,026
Cash, cash equivalents, and restricted cash at end of year	$ 9,763,884	$ 15,615,095
Supplemental disclosure of cash flow information:		
Cash paid during the year for interest	$ 1,290,396	$ 376,668
Supplemental disclosure of non-cash financing activities:		
Warrants issued in connection with long-term debt	$ 690,709	$ —
Capital expenditures included in accounts payable	$ 7,968	$ —
Settlement of accrued bonuses with restricted stock units	$ 197,892	$ 403,939

The Notes to Consolidated Financial Statements are an integral part of these statements.

CYTOSORBENTS CORPORATION
Notes to Consolidated Financial Statements
December 31, 2024

1. BASIS OF PRESENTATION

The accompanying consolidated financial statements include the results of CytoSorbents Corporation (the "Parent"), CytoSorbents Medical Inc., its wholly owned operating subsidiary (the "Subsidiary"), and CytoSorbents Europe GmbH, its wholly owned European subsidiary (the "European Subsidiary"). In addition, the consolidated financial statements include CytoSorbents Switzerland, CytoSorbents Poland Sp. z.o.o., CytoSorbents Medical UK Limited, and CytoSorbents France SAS, the wholly owned subsidiaries of CytoSorbents Europe GmbH, and CytoSorbents UK Limited and CytoSorbents India Private Limited, wholly-owned subsidiaries of CytoSorbents Medical, Inc. These entities are collectively referred to as the "Company".

As of December 31, 2024, the Company's total cash and cash equivalents and restricted cash was approximately $9.8 million, with $6.5 million classified as restricted, and $3.3 million as unrestricted and available to fund operations. This matter raises substantial doubt about the Company's ability to continue as a going concern.

As of the issuance date of this Annual Report on Form 10-K, the Company has raised a total of $7.3 million, net of offering fees, through the Rights Offering (see Note 13 – Subsequent Event), and the exercise of the Series A Right Warrants (see Note 13 – Subsequent Event). The equity raises also provided for $5 million of restricted cash to become unrestricted. As a result, our proforma unrestricted cash and cash equivalents, a non-GAAP measure, on December 31, 2024, assuming the net proceeds from the Rights Offering and the Series A Right Warrant exercise had occurred at that date, has increased by $12.3 million to $15.6 million, compared to the as reported amount of $3.3 million.

Our expected future capital requirements may depend on many factors including expanding our customer base and sales force, the timing and extent of spending in obtaining regulatory approval and introduction of new products, including the regulatory approval and introduction of DrugSorb-ATR in the U.S. and Canada which is expected in 2025, and the related opportunity to receive Tranche 2 of Avenue Capital Commitment (See Note 5. Long-Term Debt) by December 31, 2025 and extend the principal re-payment terms of the facility beginning in the third quarter of 2026. Additional sources of liquidity available to us include issuance of additional equity securities through the Series B Right Warrant, or other public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to our shareholders. There is no assurance that we will be able to secure funding on terms acceptable to us, or at all. The increasing need for capital could also make it more difficult to obtain funding through either equity or debt. Should additional capital not become available to us as needed, we may be required to take certain actions, such as slowing sales and marketing expansion, delaying further regulatory approvals, or reducing headcount. As a result of these additional uncertainties, the accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is actively pursuing financing sources, including less or non-dilutive debt financing, additional grant funding, royalty financing, strategic or direct investments, equity financing, and/or combinations thereof. There can be no assurance that management will be successful in these endeavors.

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 and based in New Jersey, 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, based in Berlin, Germany conducts sales and marketing related operations for the CytoSorb device outside of the United States.

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 and CytoSorbents India Private Limited, wholly-owned subsidiaries of CytoSorbents Medical, Inc. All significant intercompany transactions and balances have been eliminated in consolidation.

Sales and expenses denominated in foreign currencies are translated at average exchange rates in effect throughout the year. Assets and liabilities of foreign operations are translated at period-end exchange rates with the impacts of foreign currency translation recorded in cumulative translation adjustment, a component of accumulated other comprehensive income. Foreign currency transactions gains and losses are included in other income (loss), net in the consolidated statements of operations and other comprehensive loss.

Segment Information

The Company manages its operations and allocates resources as a single operating segment. The Company's chief operating decision-maker ("CODM") is its Chief Executive Officer ("CEO") who makes operating decisions, assesses financial performance and allocates resources based on consolidated financial information. As such, the Company has determined that it operates in one reportable segment.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. The Company's restricted includes amounts held as collateral for a letter of credit with Bridge Bank, securing the College Road facility lease.

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

	December 31,	
	2024	2023
Cash and cash equivalents	$ 3,279,926	$ 14,131,137
Restricted cash, current	5,000,000	—
Restricted cash	1,483,958	1,483,958
Total cash, cash equivalents and restricted cash*	$ 9,763,884	$ 15,615,095

* See Note 1 – Basis of Presentation for further discussion regarding restricted cash.

Grants and Accounts Receivable (Net of Allowance for Credit Losses)

Trade accounts receivable consist of amounts due from direct customers, distributors and agencies of the U.S. government and are presented at net realizable value. At each balance sheet date, the Company estimates an expected allowance for credit losses inherent in the Company's accounts receivable portfolio based on historical experience, specific allowances for known troubled accounts, and other available evidence. In addition, also at each reporting date, this estimate is updated to reflect any changes in credit risk since the receivable was initially recorded. This estimate is calculated on a pooled basis where similar risk characteristics exist. The Company has identified the following portfolio segments: direct customers, distributors/strategic partners and the U.S. government.

A fixed reserve percentage for each pool is derived from a review of the Company's historical losses in relation to the total pool. This estimate is adjusted quarterly for management's assessment of current conditions, reasonable and supportable forecasts regarding future events, and any other factors deemed relevant by the Company. The Company believes historical loss information is a reasonable starting point in which to calculate the expected allowance for credit losses as the Company's portfolio segments have remained constant over the Company's historical evaluation period.

The Company writes off receivables when there is information that indicates the debtor is facing significant financial difficulty and there is no possibility of recovery. If any recoveries are made from any accounts previously written off, they are recognized as an offset to credit loss expense in the year of recovery. The total amount of write-offs was immaterial to the financial statements as a whole for the year ended December 31, 2024.

The allowance for credit losses reflects accounts receivable balances that are written off when management determines they are uncollectible.

The allowance for credit losses is measured on a collective (pool) basis when similar risk characteristics exist, and measures the allowance for credit losses using the following methods:

Direct Customers—The Company measures expected credit losses on direct customer receivables using an aging methodology. The risk of loss for direct customer receivables is low based on the Company's historical experience. The estimate of expected credit losses considers historical credit loss information that is adjusted for current conditions and supportable forecasts.

Distributors/Strategic Partners—The Company measures expected credit losses on distributor receivables using an individual reserve methodology. The risk of loss in this portfolio is low based on the Company's historical experience. The estimate of expected credit losses considers the past payment history of each distributor.

U.S. Government- These receivables are related to the Company's government grants. The Company measures expected credit losses on these receivables using an individual reserve methodology. The risk of loss in this portfolio is very low based on the Company's historical experience, as these receivables are supported by approved grant award contracts.

Inventories

Inventories are valued at the lower of cost or net realizable value. Cost is determined using a first-in first-out ("FIFO") basis. 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 statements of operations in the year of disposal. Repairs and maintenance expenditures are expensed as incurred.

Patents

Legal costs incurred to establish 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. During the years ended December 31, 2024 and 2023, the Company wrote-off patent costs of approximately $333,735 and $655,685, respectively, related to the impairment of certain issued patents and pending patent applications in certain specific jurisdictions and the

abandonment of certain pending patent application costs in the ordinary course of business. This charge is included in legal, financial and other consulting in the consolidated statements of operations and comprehensive loss.

Leases

The Company accounts for leases in accordance with FASB Accounting Standards Update ("ASU") 2016-02, Leases, Topic 842 ("ASC 842"). Operating lease ROU assets and operating lease liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term. The Company determines if a contract contains a lease at the inception date and determines the lease classification, recognition, and measurement at commencement date. ROU assets also include adjustments related to prepaid or deferred lease payments. As the Company's leases do not provide an implicit rate, the Company uses the incremental borrowing rate based on the information available at lease commencement date in determining the present value of lease payments. Options to extend a lease are included in the lease term when it is reasonably certain that the Company will exercise such options. Certain of the Company's lease agreements include provisions for the Company to pay the lessor for common area maintenance, real estate taxes, and insurance, which the Company accounts for as variable lease costs.

Revenue Recognition

Revenue is recognized when the Company ships its products to its direct customers and distributors/strategic partners. The amount of revenue recognized reflects the consideration the Company expects to be entitled to receive in exchange for the products shipped or the services provided under their grant contracts. To achieve this core principle, the Company applies the following five steps:

1. Identify Contracts with Customers - The Company's contracts with its direct customers are generally in the form of a purchase order. The Company has formal written contracts with each of its distributors/strategic partners that define their respective territories and minimum purchase commitments which must be met in order to maintain exclusivity in their territory. Distributors/strategic partner customers also submit purchase orders with each order that define the terms of shipment and transaction price.

2. Identify Performance Obligations - The performance obligations in contracts with direct customers and distributors/strategic partners are for the shipment of the CytoSorb device and related accessory parts.

3. Determine Transaction Price - The price charged is based on the Company's price list for the CytoSorb device and related accessory parts for both direct customers and distributor/strategic partners. The Company does not permit returns for product sales. The Company also provides for certain rebates and discounts to direct customers for sales of its product that are earned based upon sales volume. These amounts, which are earned based on calendar year sales volume, are recorded as a reduction of sales as earned.

4. Allocate Transaction Price to Performance Obligations - The transaction price for the performance obligation is based on the purchase orders received for both direct customers and on the type of contract and are outlined in each contract.

5. Recognize Revenue as Performance Obligations are Satisfied - The Company satisfies its performance obligation to direct customers and distributors/strategic partners generally upon shipment of the products.

Research and Development, Net of Grant Income

All research and development costs, payments to laboratories, research consultants and costs related to clinical trials and studies are expensed when incurred.

Currently, accounting for grants does not fall under ASC 606, as the grantor will not benefit directly from the Company's expansion or product development, and no products or services are transferred to the grantor. As there is no authoritative guidance under U.S. GAAP on accounting for grants to for profit business entities from government entities, the Company has adjusted its accounting policy for recording grants to analogize the guidance provided by International Accounting Standard 20 ("IAS 20"). Accordingly, the Company has retroactively, as of January 1, 2023, reclassified grant income, net of expenses, as a reduction of research and development expenses.

Research and Development

All research and development costs, payments to laboratories, research consultants and costs related to clinical trials and studies are expensed when incurred. Grant income, net of expenses, is presented as a reduction of research and development expenses.

Advertising Expenses

Advertising costs are charged to activities when incurred. Advertising expense amounted to approximately $335,284 and $252,686, in 2024 and 2023, respectively, and is included in selling, general, and administrative expenses in 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. 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 the accounting standards associated with uncertain tax provisions. The Company is accounting for an uncertain tax position of approximate $2.2 and $2.1 million for the years ended December 31, 2024 and 2023, respectively. The Company had no unrecognized tax benefits as of December 31, 2024 and 2023. 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 tax carryforwards and Research and Development credits 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 SAS 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 credit losses 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. Beginning in April of 2023, the Company joined the IntraFi network, and established an Insured CashSweep (“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. (See Note 3 for further information relating to the Company’s revenue.)

As of December 31, 2024, and 2023 one distributor accounted for approximately 19% of outstanding grants and accounts receivables. For the years ended December 31, 2024 and 2023, one distributor accounted for 11% and 10%, respectively, 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.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480 and ASC 815 "Derivatives and Hedging" ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own ordinary shares and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of equity at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as liabilities at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations.

The warrants issued upon the closing of the Company's December 13, 2023, offering and the closing of the Company's June 2024 debt financing both met the criteria for equity classification under ASC 815. Accordingly, these warrants have been classified as equity as of December 31, 2024 and December 31, 2023.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock-based payment awards made to employees, including stock options, restricted shares ("RSUs"), based on estimated fair values at the award grant date. The fair value of stock-based awards is amortized over the vesting period of the award using a straight-line method.

Stock-based compensation expense for awards with performance conditions is recognized when it is probable that the performance condition will be achieved and is then recognized over the requisite service period. Any changes in the probability assessment are accounted for as a cumulative true up to the current period compensation cost.

To estimate the fair value of an award, the Company uses the Black-Scholes option pricing model. This model requires inputs such as expected life, expected volatility, expected dividend yield of stock and risk-free interest rate. These inputs are subjective and generally require significant analysis and judgment to develop. While estimates of expected life and volatility are derived primarily from the Company's historical data, the risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The Company accounts for forfeitures in the period they occur.

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

Net Loss per Common Share

Basic net loss per share is computed by dividing loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net 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 warrants, stock options and restricted shares. The computation of diluted net loss per share does not assume conversion, exercise or contingent exercise of securities that would have an anti-dilutive effect on earnings.

The following table presents the calculation of net loss per share:

Basic and Diluted:	Years Ended December 31, 2024	2023 As Restated*
Numerator:		
Net loss attributable to common stockholders per consolidated statements of operations	$ (20,718,957)	$ (29,246,760)
Denominator:		
Weighted average common shares outstanding used to compute basic and diluted loss per share	54,434,609	44,656,391
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.38)	$ (0.65)

* See Note 12 – Restatement of Previously Issued financial information for details.

The following table presents the potentially dilutive shares that were excluded from the computation of diluted net loss per share of common stock attributable to common stockholders, because their effect was anti-dilutive, as adjusted to give effect to the Stock Split:

	As of December 31, 2024	2023
Stock options outstanding	12,341,914	10,548,174
Warrants for common stock	4,352,130	2,706,561
RSUs*	3,450,836	3,254,005

*Total number of RSUs include 2,809,500 units with a Change in Control-Based performance condition.

Shipping and Handling Costs

The cost of shipping products to customers and distributors is typically borne by the customer or distributor. The Company records shipping and handling costs in cost of goods sold. Total freight costs amounted to approximately $409,273 and $464,324 for the years ended December 31, 2024 and 2023, respectively.

Effect of Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, “Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40)” (“ASU 2020-06”). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity’s own equity. The ASU is part of the FASB’s simplification initiative, which aims to reduce unnecessary complexity in U.S. GAAP. The ASU’s amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company implemented the updated guidance as of January 1, 2024, and this did not have an impact on its consolidated financial statements.

In November 2023, the FASB issued Accounting Standards Update (“ASU”) 2023-07, Segment Reporting—Improvements to Reportable Segment Disclosures (Topic 280), which will require public companies to provide more transparency in both quarterly and annual reports about the expenses they incur from revenue generating reportable business segments. In addition, the ASU requires that a public entity disclose significant segment expenses that are regularly provided to the chief operating decision maker, an amount for other segment items by reportable business segment, including a description of its composition, and the primary measures of a business segment’s profit or loss in assessing segment performance. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company implemented the updated guidance as of December 31, 2024, which resulted in the addition of new segments disclosures (see Note 11). Also, the implementation of ASU 2023-07, did not have an impact on other disclosures to the consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09 entitled “Income Taxes (Topic 740): Improvements to Income Tax Disclosures”. This ASU provides guidance related to additional disclosures that will be required related to income taxes. The updated guidance is effective for public entities for fiscal years beginning after December 15, 2024. This ASU will result in additional disclosures in the Company’s consolidated financial statements related to income taxes in 2025.

On November 19, 2024, the Financial Accounting Standards Board (the "FASB") issued a proposed Accounting Standards Update to establish authoritative guidance for the accounting and reporting of government grants received by business entities. The FASB has decided to pursue an International Accounting Standards 20 ("IAS 20") accounting model. Under IAS 20, a grant relating to income may be reported separately as 'other income' or deducted from the related expense. The Company has evaluated its accounting and reporting policy for government grants relative to this project and the requirements of IAS 20. Currently, accounting for grants does not fall under ASC 606, as the grantor will not benefit directly from the Company's expansion or product development, and no products or services are transferred to the grantor. As there is no authoritative guidance under U.S. GAAP on accounting for grants to for profit business entities from government entities, the Company has adjusted its accounting policy for recording grants to analogize the guidance provided by IAS 20. Accordingly, the Company has retroactively, as of January 1, 2023, reclassified grant income, net of expenses, as a reduction of research and development expenses.

Reclassification of Grant Income and Operating Expenses

As noted above on Effect of Recent Accounting Pronouncements the Company has retroactively, as of January 1, 2023, reclassified grant income, net of expenses, as a reduction of research and development expenses. For the years ended December 31, 2024 and 2023, Grant Income and the related expenses were as follows:

	2024	2023
Grant income	$ 3,610,759	$ 5,264,426
Grant income-related expenses	$ (3,583,233)	$ (5,129,952)

In addition, the Company changed its accounting policy to report legal, financial and other consulting costs, which was previously its own separate line item within the Operating Expenses section of the Consolidated Statements of Operations and Comprehensive Loss to now being merged into the Selling, General and Administrative Expenses line item. These expenses previously presented within legal, financial and other consulting costs are general and administrative in nature; accordingly, the updated presentation would provide the user of the Consolidated Financial Statements a better picture of the purpose of those expenses. For the years ended December 31, 2024 and 2023, the total amount of expenses that would have been reported as Legal, financial and other consulting costs under the previous accounting policy amounted to $3,199,357 and $4,272,296, respectively.

For comparative purposes, the Company has recorded the following reclassification adjustments to the previously reported Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2023:

	As Previously Reported	Adjustments	As Reclassified*
Grant income	$ 5,264,426	$ (5,264,426)	$ —
Total revenue	$ 36,349,379	$ (5,264,426)	$ 31,084,953
Cost of revenues	$ (13,957,356)	$ 5,129,952	$ (8,827,404)*
Gross profit	$ 22,392,023	$ (134,474)	$ 22,257,549 *
Research and development	$ (15,728,915)	$ 134,473	$ (15,594,442)
Legal, financial and other consulting	$ (4,272,296)	$ 4,272,296	$ —
Selling, general and administrative	$ (33,600,065)	$ (4,272,296)	$ (37,872,361)*
Total operating expenses	$ (53,601,276)	$ 134,474	$ (53,466,803)

* See Note 12 – Restatement to Previously Issued Financial Information for further adjustments to these line items.

For comparative purposes, the Company has recorded the following reclassification adjustments to the previously reported Consolidated Statements of Cash Flows:

	As Previously Reported	Adjustments	As Reclassified*
Non-cash compensation	$ 371,397	$ (371,397)	$ —
Stock-based compensation	$ 3,329,307	$ 371,397	$ 3,700,704

* See Note 12 – Restatement to Previously Issued Financial Information for further adjustments to these line items. * These reclassification adjustments reflected in these consolidated cash flows statements line items also reflect the restatement adjustments applicable to the statements of changes to stockholders' equity.

3. REVENUE

The following table disaggregates the Company's revenue by customer type and geographic area for the year ended December 31, 2024:

	Direct	Distributors/ Strategic Partners	Total
Product revenue:			
United States	$ 114,611	$ 36,000	$ 150,611
Germany	13,049,729	—	13,049,729
All other countries	7,616,123	14,778,057	22,394,180
Product revenue	$ 20,780,463	$ 14,814,057	$ 35,594,520

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

	Direct	Distributors/ Strategic Partners	Total
Product revenue:			
United States	$ 66,773	$ —	$ 66,773
Germany	12,964,806	—	12,964,806
All other countries	5,956,042	12,097,332	18,053,374
Product revenue	$ 18,987,621	$ 12,097,332	$ 31,084,953

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 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.

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. The Company does not currently incur any outside/third-party incremental costs to obtain any of these contracts.

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

	December 31, 2024	December 31, 2023
Contract receivables, which are included in grants and accounts receivable	$ 4,426,890	$ 3,846,271
Contract liabilities, which are included in accrued expenses and other current liabilities	$ 596,042	$ 1,577,141

Contract receivables represent balances due from product sales to distributors amounting to $4,233,888 and $3,270,724 at December 31, 2024 and 2023, respectively, and billed and unbilled amounts due on government contracts amounting to $193,002 and $575,547 at December 31, 2024 and 2023, respectively. Contract receivable amounted to $3,822,452 as of January 1, 2023.

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 $176,714 and $196,322 at December 31, 2024 and 2023, respectively, and deferred grant liability related to the billing on fixed price government contracts in excess of costs incurred, which amounted to $419,328 and $1,376,819 at December 31, 2024 and 2023, respectively.

4. BALANCE SHEET COMPONENTS

Inventories

The Company had the following major classes of inventory:

	December 31, 2024	December 31, 2023 As Restated*
Raw Materials	$ 569,824	$ 685,801
Work in Process	502,525	838,871
Finished Goods	1,964,870	1,851,145
Inventories	**$ 3,037,219**	**$ 3,375,817**

* See Note 12 – Restatement of Previously Issued financial information for details.

Property and equipment - net

The Company's Property and equipment - net, consist of the following:

	December 31 2024	December 31 2023	Depreciation/ Amortization Period
Furniture and fixtures	$ 1,453,623	$ 1,462,778	7 years
Equipment and computers	5,491,048	5,404,743	3 to 7 years
Leasehold improvements	6,282,710	6,224,863	Lesser of term of lease or estimated useful life
	13,227,381	13,092,384	
Less accumulated depreciation and amortization	4,224,998	3,036,030	
Property and Equipment, Net	**$ 9,002,383**	**$ 10,056,354**	

Depreciation expense for the years ended December 31, 2024 and 2023, amounted to $1,341,262 and $1,239,600, respectively.

Other assets

Other assets consist of the following:

	December 31, 2024	December 31, 2023
Patent applications pending	$ 1,612,118	$ 1,945,532
Patents issued	3,390,768	2,982,253
Less accumulated amortization of patents issued	(1,254,850)	(1,021,233)
Patents, net	3,748,036	3,906,552
Other	22,644	52,051
Other Assets	**$ 3,770,680**	**$ 3,958,603**

Patent amortization expense amounted to $235,146, and $222,836 for the years ended December 31, 2024 and 2023, respectively.

Patent amortization expense for the next five years and thereafter is scheduled as follows:

2025	$ 253,622
2026	252,481
2027	246,956
2028	234,087
2029	234,087
Thereafter	914,685
Scheduled amortization of patents issued	$ 2,135,918

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31, 2024	December 31, 2023 As Restated
Accrued salaries and commissions	$ 3,387,675	$ 3,344,080
Professional fees	769,577	956,432
Clinical studies	589,577	686,908
Deferred revenue	419,331	1,380,821
Other	865,510	991,545
Accrued expenses and other current liabilities	**$ 6,031,670**	**$ 7,359,786**

* See Note 12 – Restatement of Previously Issued financial information for details.

5. LONG-TERM DEBT

Avenue Capital Group:

On June 28, 2024 (the "Closing Date"), the Company entered into a Loan and Security Agreement with the Avenue Capital Group ("Loan"). Avenue Capital Group agreed to loan the Company up to an aggregate of $20 million, to be disbursed in two tranches: (1) one tranche of $15 million ("Tranche 1"), of which $10 million was available to the Company on the Closing Date and $5 million constitutes restricted cash, which was released from its restriction on January 10, 2025, as the following conditions were achieved: (i) the FDA has accepted Company's application for review with respect to DrugSorb-ATR De Novo 510(k) and (ii) the Company has received a minimum of $3 million in net proceeds from the sale of its equity securities after the Closing Date. The restriction will be released on a dollar for dollar basis for equity raised between $3 million and $5 million and (2) a second tranche of up to $5 million, which may be disbursed at the Company's request between July 1, 2025 and December 31, 2025, provided that the Company receives FDA marketing approval of its DrugSorb-ATR application ("Tranche 2" and together with Tranche 1, the "Avenue Capital Commitment"). The proceeds from the Avenue Capital Commitment were used to pay off the existing outstanding debt with Bridge

Bank and will additionally be used for working capital purposes and to fund general business requirements. Amounts borrowed under the Avenue Capital Commitment shall bear interest at a variable rate per annum equal to the greater of (A) the Prime Rate plus five percent (5.00%) or (B) thirteen and one-half percent (13.50)%.

On October 22, 2024 the Company announced that the FDA had accepted its application of DrugSorb-ATR, which was one of the two conditions required by the restricted cash debt covenant. Proceeds from the Rights Offering on January 10, 2025 (See note 13 – Subsequent Event) satisfied the second condition of the debt covenant which now allows for the $5 million of restricted cash on the Company's consolidated balance sheets to become unrestricted, and available for use.

The loan requires interest-only payments for the first 25 months, followed by equal monthly installments of principal plus accrued and unpaid interest until maturity. All unpaid principal and accrued and unpaid interest shall be due and payable in full on July 1, 2027; provided, however that if the Company draws the full amount of Tranche 2 by December 2025, all unpaid principal and accrued and unpaid interest shall be due and payable in full by January 1, 2028.

As of the Closing Date, the Company recorded the following discounts:

Fair value of warrants issued to Avenue Capital Group	$	690,000
Debt issuance cost		640,000
Commitment fee paid on the Closing Date (1% of the Avenue Capital Group commitment)		200,000
Total discounts recorded at inception against Avenue Capital Group Long Term Debt	$	1,530,000

The Company amortizes debt discounts as interest expense using the interest method through the maturity date. The loan and security agreement included a final payment upon maturity of $900,000. The Company accretes the final payment as interest expense using the interest method through the maturity date.

Upon a prepayment, the Company would incur a fee ranging from 1% to 3% of the outstanding principal, depending of the time of payment in relation to the maturity date.

The Loan and Security Agreement includes customary loan conditions, company representations and warranties, company affirmative covenants and company negative covenants for secured transactions of this type. As of December 31, 2024, the Company was in compliance with these covenants.

As additional consideration for the Commitment, on June 28, 2024, the Company also issued Avenue Capital Group with warrants with a fair value of $690,709 to purchase an aggregate of 1,645,569 shares of the Company's common stock for cash at the exercise price of $0.79, which expire on June 28, 2029. The number of warrants is fixed, however, the exercise price may be adjusted down if the Company raises equity (excluding sales of equity utilizing the Company's at-the-market equity facility) at a share price that is lower than $0.79. These warrants meet the criteria for equity classification under ASC 815.

The Lenders were also granted the right while the Commitment is outstanding to convert up to an aggregate amount of $2 million of the principal amount of the outstanding Growth Capital Loans into the Company's common stock at a fixed conversion price of 120% of the Closing Price (as defined in the warrant) or $0.95 per share (the "Conversion Option").

The Company's obligations under the Loan and Security Agreement are joint and several. The obligations under the Loan and Security Agreement are secured by a first priority security interest in favor of the Lenders with respect to the Company's Shares (as defined in the Loan and Security Agreement) and the Company's Collateral (as defined in the Loan and Security Agreement), which includes the Company's intellectual property, pursuant to that certain Intellectual Property Security Agreement, dated as of June 28, 2024, by and between the Company and the Administrative and Collateral Agent.

As of December 31, 2024, long-term debt consists of the following:

Principal amount	$	15,000,000
Less unamortized debt discount		(1,003,650)
Subtotal		13,996,350
Less current maturities		—
Long-term debt net of current maturities	$	13,996,350

As of December 31, 2024, principal payments of long-term debt are due as follows:

2026	$ 6,250,000
2027	8,750,000
Total	**$ 15,000,000**

Bridge Bank

On June 28, 2024, concurrent with the closing of the Avenue Capital Group financing discussed above, the Company paid off its existing outstanding debt with Bridge Bank.

As of December 31, 2023, long-term debt consists of the following amounts due to Bridge Bank:

Principal amount	$ 5,000,000
Accrued final fee	42,857
Subtotal	5,042,857
Less current maturities	2,500,000
Long-term debt net of current maturities	$ 2,542,857

As of December 31, 2024, the following commitments survive after the termination of the Bridge Bank Amended and Restated Loan and Security Agreement and related amendments:

2022 Success Fee Letter

Pursuant to the 2022 Success Fee Letter, the Borrower will pay to the Bank a success fee equal to (i) 1% of $5 million if the Company draws down the first tranche of the Term C Loan and is payable only if the Company's stock price equals or exceeds $8 for five consecutive trading days; (ii) 1.5% of $5 million if the Company draws down the second tranche of the Term C Loan and is payable only if the Company's stock price equals or exceeds $10 for five consecutive trading days; and (iii) 2% of $5,000,000 if the Company draws down the third tranche of the Term C Loan and is payable only if the Company's stock price equals or exceeds $12 for five consecutive trading days (together, the "Success Fee"). Borrower may pay the Success Fee in cash or in shares of common stock, at Borrower's sole discretion. The right of Bank to receive the Success Fees and the obligation of the Borrower to pay the Success Fees hereunder shall terminate on the date that is fifth anniversary of the funding date of the last Term C Loans made but shall survive the termination of the Loan Agreement and any prepayment of the Term C Loans. The termination date of the 2022 Success Fee Letter is December 27, 2027.

6. LEASES

The Company has operating leases that primarily relate to operating facilities in both the United States and Germany. The Company leases its operating facilities under operating lease arrangements with varying expiration dates through March 2037. As of December 31, 2024, the remaining lease term of the Company's operating leases ranges from six to twelve years.

Supplemental statement of operations and cash flows related to operating leases is as follows:

	For the year ended December 31,	
	2024	2023
Cash paid in connection with operating leases	$ 1,683,461	$ 2,403,025
Operating lease expense	$ 2,234,616	$ 1,802,490

Supplemental balance sheet information related to operating leases is as follows:

	December 31,	
	2024	2023
Right-of-use asset	$ 11,511,236	$ 12,058,896
Lease liability – current portion	$ 452,688	373,636
Lease liability – net of current portion	12,443,971	12,896,659
Total lease liability	$ 12,896,659	$ 13,270,295
Weighted average discount rate	9.8 %	9.8 %
Weighted average remaining lease term	11.7 years	12.7 years

As of December 31, 2024, the maturities of the lease liabilities are as follows:

2025	$ 1,695,676
2026	1,735,747
2027	1,776,920
2028	1,819,224
2029	1,862,893
Thereafter	13,550,383
Future operating lease payments	22,440,843
Imputed interest	(9,544,184)
Total lease liability	$ 12,896,659

7. INCOME TAXES

The Company accounts for income taxes under ASC 740. Deferred income tax assets and liabilities are determined based upon differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

The Company's consolidated loss before income taxes for the years ended December 31, 2023, 2022 and 2021 is as follows:

	Year Ended December 31,	
	2024	2023
Domestic	$ (11,722,734)	$ (21,913,297)
Foreign	(10,687,048)	(8,147,202)
Total	$ (22,409,782)	$ (30,060,499)

The provision for income taxes consists of the following:

	December 31,	
	2024	2023
State Tax, including sale of New Jersey losses & credits	$ (1,690,825)	$ (813,739)
Foreign tax provision	—	—
Total	$ (1,690,825)	$ (813,739)

The Company has deemed any foreign earnings will be indefinitely reinvested. Currently, foreign operations have resulted in an accumulated deficit. The Company will continue to analyze their stance if their circumstances change in the future.

As of December 31, 2024, the Company had federal net operating loss ("NOL") carry forwards of $103,299,951, state NOL carry forwards of $6,449,176, and foreign NOL carry forwards of $59,061,197 which are available to reduce future taxable income. Any unutilized NOL carry forwards will begin to expire at various dates starting in 2025 and some may be carried indefinitely. As of December 31, 2024 and 2023, the Company had Federal and state research and development tax credit carryforwards of $2,224,012 and $0 (net of uncertain tax benefits), respectively, available to reduce future tax liabilities which will begin to expire at various dates starting in 2026.

The federal NOL carryforwards of $47.7 million, if not utilized, will expire between 2025 and 2038. The federal NOL carryforwards of $55.7 million generated since 2018 are subject to an 80% limitation on taxable income, do not expire and will carry forward indefinitely.

The NOL carry forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. The NOLs may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state tax provisions. In addition to the new provisions enacted under the Tax Cuts and Jobs Act, This could limit the amount of NOLs that the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will generally be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not determined whether such a change has occurred and accordingly, the utilization of the net operating loss carryforwards may be subject to certain limitations.

Sale of NOLs

The Company may be eligible, from time to time, to receive cash from the sale of its Net Operating Losses and R&D tax credits under the State of New Jersey Technology Business Tax Certificate Transfer Program.

As of December 31, 2024, the Company has accrued a receivable $1,690,825 from the approved sale of the 2023 state NOL and research and development credits. The Company expects to collect this receivable in the first half of 2025.

The principal components of the Company's deferred tax assets and liabilities are as follows:

	Year Ended December 31,	
	2024	2023 As Restated
Current and long term deferred tax assets:		
Federal NOL	$ 21,692,990	$ 20,409,328
Foreign NOL	17,164,274	15,172,966
NJ NOL	458,536	1,253,713
Net operating loss carryforward	39,315,800	36,836,007
Stock Options	482,824	418,776
Federal R&D Credit	2,224,012	2,113,233
NJ R&D Credit	—	197,406
Research and development credit carryforward	2,224,012	2,310,639
Other	458,013	242,841
Charitable Contributions	5,832	5,832
Accruals and others	463,845	248,673
§174(b) research & experimental	5,485,885	5,495,850
§163(j) business interest expense	255,450	—
Lease Liability	3,625,251	3,730,280
Gross deferred tax assets	51,853,067	49,040,225
Less valuation allowance	(48,267,681)	(45,334,554)
	3,585,386	3,705,671
Deferred tax liability:		
Fixed Assets	(349,578)	(315,915)
Right of Use Asset	(3,235,808)	(3,389,756)
Net deferred tax assets	$ —	$ —

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Based on this assessment, management has established a full valuation allowance against all of the deferred tax assets for each period because it is more likely than not that all of the deferred tax assets will not be realized.

The changes in valuation allowance for the years ended December 31, 2024 and 2023 were $2,933,127 and $6,031,103, respectively.

A reconciliation of income tax (expense) benefit at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

	Year Ended December 31,	
	2024	2023
Federal statutory rate	21.0 %	21.0 %
State taxes, net of federal benefit	2.6	5.1
Foreign rate differential	3.1	2.2
Permanent items	(3.6)	(1.9)
Other rate change and true-up	0.3	(0.7)
NJ NOL and R&D credit write-off	(8.4)	—
True up of foreign NOLs	(4.2)	—
NJ Amended NOL	1.8	—
Uncertain tax positions	(0.6)	(7.0)
Change in valuation allowance	(13.1)	(20.1)
R&D credit	1.1	1.8
Sale of 2023 NJ R&D & NOL	7.6	2.7
Other	—	(0.4)
Effective income tax rate	7.6 %	2.7 %

A reconciliation of the unrecognized tax benefit balances is as follows:

	Year Ended December 31,	
	2024	2023
Balance at beginning of the year	$ 2,113,233	$ —
Increase for tax positions of prior years	(9,276)	1,571,431
Increase for tax positions in current year	120,056	541,802
Balance at end of the year	$ 2,224,013	$ 2,113,233

The total amount of unrecognized tax benefits that could affect our effective tax rate, if recognized, was $2.2 million and $2.1 as of December 31, 2024 and 2023, respectively. The Company and its subsidiaries file income tax returns in the U.S. federal jurisdiction and New Jersey. With few exceptions, we are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for years before 2019, although NOL carryforwards and tax credit carryforwards from any year are subject to examination and adjustment for at least three years following the year in which they are fully utilized. As of December 31, 2024, no significant adjustments have been proposed relative to our tax positions.

For year ended December 31, 2024, there are no interest and penalties relating to our uncertain tax positions.

8. COMMITMENTS AND CONTINGENCIES

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.

On March 5, 2024, a former employee, filed a complaint against us in the Superior Court of New Jersey, Law Division, Mercer County, alleging breach of the New Jersey Conscientious Employee Protection Act (“CEPA”). The complaint specifically alleges that we violated the provisions of the CEPA by allegedly terminating the employee in retaliation for complaining about certain business practices. We dispute these allegations and intend to vigorously defend against them, but there can be no assurance as to the outcome of the litigation.

Royalty Agreement

The Company is party to various royalty and license agreements that require the payment of royalty fees. Royalty expense amounted to approximately $1.9 million and $2.2 million for the years ended December 31, 2024 and 2023, respectively. Royalty expense is included in selling, general and administrative expenses in the consolidated statements of operations and comprehensive loss. The decrease in royalty fees in 2024 was the result of the expiration of a 4% royalty in August of 2024, net of increases in revenue applicable to royalty agreements.

401 (k) Plan

In June 2014, the Company formed the CytoSorbents 401(k) Plan. The plan is a defined contribution plan as described in section 401(k) of the Internal Revenue Code ("IRC") covering substantially all full-time employees. Employees are eligible to participate in the plan on the first day of the calendar quarter following three full months of employment. Participants may defer up to 100% of their eligible compensation subject to certain IRC limitations. Effective January 1, 2021, the Company changed its matching contribution to 100% of the participants contribution up to three percent of compensation plus 50% of the participants contribution over three percent of compensation up to a maximum of five percent of compensation. Matching contributions amounted to $472,022 and $405,408 for the years ended December 31, 2024 and 2023, respectively.

9. 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

For the years ended December 31, 2024 and 2023, issuance of common stock offerings, net of fees incurred were as follows:

	For the year ended December 31, 2024		For the year ended December 31, 2023	
	Shares Issued	Proceeds, Net of Fees	Shares Issued	Proceeds, Net of Fees
December 13, 2023 Offering	—	$ —	7,733,090	$ 9,785,000
Open Market Sale Agreement with Jefferies LLC	382,823	178,654	2,656,464	4,470,932
	382,823	$ 178,654	10,389,554	$ 14,255,932

December 13, 2023 Offering

On December 13, 2023, the Company closed on a registered direct offering for the sale of common stock, directly to investors, which included warrants to purchase up to 2,706,561 shares of common stock (the "Offering"). Each share of common stock and accompanying warrant to purchase up to 0.35 shares of common stock, were sold together for a combined purchase price of $1.33 (before issuance costs). Each warrant is immediately cash exercisable at an exercise price of $2.00 per share and will expire on the fifth anniversary of the issue date. The Company's executive officers, directors, and certain non-executive officer employees of the Company also participated in the Offering with a combined investment of $435,000.

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 and expires after three years. On July 26, 2024, the Company filed a registration statement on Form S-3 with the SEC (the "2024 Shelf"), which 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. On September 26, 2024, the Company filed Amendment No. 1 to the Form S-3 with the SEC. The 2024 Shelf was declared effective by the SEC on September 30, 2024. Because the Company's market capitalization is less than $75 million, it will be subject to baby shelf rules which limit the amount of securities sales the Company can make to one-third of its public market float over a 12-month period.

Open Market Sale Agreement with Jefferies LLC

On December 30, 2021, the Company entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC (the "Agent"), pursuant to which the Company may sell, from time to time, at its option, shares of the Company's common stock having an aggregate offering price of up to $25 million through the Agent, as the Company's sales agent. However, as a result of limitations related to our market capitalization discussed above, the Company may offer and sell shares of the Company's common stock having an aggregate offering price of up to approximately $19.7 million from time to time through the Agent. If the Company's public float increases above $75 million, the Company may sell additional amounts under the Sales Agreement. All shares of the Company's common stock offered and sold, or to be offered and sold under the Sale Agreement will be issued and sold pursuant to the Company's 2024 Shelf by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, in block transactions or if specified by the Company, in privately negotiated transactions.

Subject to the terms of the Sales Agreement, the Agent is required to use its commercially reasonable efforts consistent with their normal sales and trading practices to sell the shares of the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company is required to pay the Agent a commission of up to 3.0% of the gross proceeds from the sale of the shares of the Company's common stock sold thereunder, if any.

10. STOCK-BASED COMPENSATION

Stock Option Plans

As of December 31, 2024, the Company had two Long Term Incentive Plans (the "2014 Plan" and the "2006 Plan") to attract, retain, and provide incentives to employees, officers, directors, and consultants. The Plans generally provide for the granting of stock, stock options, stock appreciation rights, restricted shares, or any combination of the foregoing to eligible participants.

In June 2024, the Company amended and restated CytoSorbents Corporation 2014 Long-term Incentive Plan (the "Plan"). The amended and restated CytoSorbents Corporation 2014 Long-term Incentive Plan (the "Plan") increased the number of shares to be reserved and authorized for issuance under the Plan by 7,500,000 shares to 20,900,000 shares of our Common Stock.

A total of 20,900,000 and 2,400,000 shares of common stock are reserved for issuance under the 2014 Plan and the 2006 Plan, respectively. As of December 31, 2023, there were approximately 647,000 and 654,000 shares of common stock remaining for issuance under the 2014 Plan and the 2006 Plan, respectively. As of December 31, 2024, there were approximately 3,700,000 and 654,000 shares of common stock remaining for issuance under the 2014 Plan and the 2006 Plan, respectively.

Total stock-based compensation expense for the year ended December 31, 2024 amounted to $3.8 million, of which $3.2 million and $0.6 million were for stock options and restricted stock units, respectively. Total stock-based compensation expense for the year ended December 31, 2023 amounted to $4.2 million, of which $3.3 million and $0.9 million were for stock options and restricted stock units, respectively. These amounts are included in selling, general, and administrative expenses on the consolidated statements of operations and comprehensive loss.

The summary of the stock option activity for the years ended December 31, 2024 and 2023 is as follows:

	Shares	Weighted Average Exercise per Share	Weighted Average Remaining Contractual Life (Years)
Outstanding, December 31, 2022	9,474,824	$ 4.66	7.36
Granted	2,601,880	$ 3.43	9.52
Forfeited	(974,555)	$ 2.96	—
Expired	(467,332)	$ 5.61	—
Exercised	(86,643)	$ 2.59	—
Outstanding, December 31, 2023	10,548,174	$ 4.49	7.01
Granted	3,982,846	$ 0.97	9.32
Forfeited	(1,391,897)	$ 2.24	—
Expired	(797,209)	$ 5.34	—
Outstanding, December 31, 2024	12,341,914	$ 3.55	6.81

The fair value of each stock option was estimated using the Black-Scholes pricing model which takes the following inputs into account.

Year - Ended	Grant Date Exercise Price Range	Expected Life of the Stock Option*	Expected Volatility Range	Expected Dividends	Risk Free Interest Rate Range
December 31, 2023	$ 1.17 - $3.71 per share	6 years	70.4% to 75.6 %	— %	3.50% to 4.76 %
December 31, 2024	$ 0.84 - $1.19 per share	6 years	75.6% to 80.1 %	— %	3.60% to 4.65 %

*The expected term of the options granted is derived using the “simplified method” which computes expected term as the average of the sum of the vesting term plus the contract term.

In addition, the Company recognizes forfeitures as they occur.

The intrinsic value is calculated at the difference between the market value as of December 31, 2024 of $0.91 and the exercise price of the shares.

Options Outstanding

Range of Exercise Price	Number Outstanding at December 31, 2024	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
$0.84 - $13.20	12,341,914	$ 3.55	6.81	$ 1,000

Options Exercisable

Number Exercisable at December 31, 2024	Weighted Average Exercise Price	Aggregate Intrinsic Value
6,107,366	$ 5.46	$ —

The summary of the status of the Company's non-vested options for the year ended December 31, 2024, is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2024	5,205,736	$ 1.89
Granted	3,982,846	0.68
Forfeited	(1,391,897)	1.52
Vested	(1,562,137)	2.26
Non-vested, December 31, 2024	6,234,550	$ 1.09

As of December 31, 2024, the Company had approximately $3,035,000 of total unrecognized compensation cost related to stock options which will, on average, be amortized over 32 months.

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

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2023	4,851,739	$ 1.84
Granted	2,601,880	2.35
Forfeited	(974,555)	1.95
Vested	(1,273,328)	2.59
Non-vested, December 31, 2023	5,205,736	$ 1.89

As of December 31, 2023, the Company had approximately $4,868,000 of total unrecognized compensation cost related to stock options which will, on average, be amortized over 42 months.

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 Company's 2014 Long-Term Incentive Plan.

The following table is a summary the outstanding balance of these restricted stock units at the end of each of the past two calendar years:

	Total	Intrinsic Value
December 31, 2022	2,890,500	$ 4,480,275
Granted 2023	394,000	—
Forfeited 2023	(461,000)	—
December 31, 2023	2,823,500	$ 3,134,085
Granted 2024	331,250	—
Forfeited 2024	(345,250)	—
December 31, 2024	2,809,500	$ 2,556,645

Due to the uncertainty over whether these restricted stock units will vest, which will only happen upon a Change in Control, no charge for these restricted stock units has been recorded in the consolidated statements of operations and comprehensive loss through the year ended December 31, 2024.

Other Restricted Stock Units:

The following table outlines the restricted stock unit activity (not related to change in control-based awards) for the year ended December 31, 2024:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2024	430,505	$ 3.31
Granted	548,000	$ 0.96
Forfeited	(40,000)	$ 3.73
Vested	(297,169)	$ 3.23
Non-vested, December 31, 2024	641,336	$ 1.31

The following table outlines the restricted stock unit activity for the year ended December 31, 2023:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2023	312,092	$ 4.42
Granted	385,000	$ 3.23
Forfeited	(62,500)	$ 3.57
Vested	(204,087)	$ 4.79
Non-vested, December 31, 2023	430,505	$ 3.31

At December 31, 2024 and December 31, 2023, the remaining weighted average vesting period for restricted stock awards subject to vesting was 43 months and 37 months, respectively and the remaining unrecognized restricted stock unit compensation expense was $538,000 and $842,000, respectively.

Warrants

As of December 31, 2024, the Company had 2,706,561 warrants outstanding related to the Company's December 13, 2023 Offering. These warrants are immediately cash exercisable at an exercise price of $2.00 per share and expire on December 13, 2028. Another 1,645,569 warrants were issued on June 28, 2024 in connection with the Company's Loan and Security Agreement with Avenue and these warrants have an exercise price of $0.79 and expire on June 28, 2029. The number of warrants is fixed, however, the exercise price may be adjusted down if the Company raises equity (excluding sales of equity utilizing the Company's at-the-market equity facility) at a share price that is lower than $0.79. These warrants are exercisable into the Company's common stock.

11. SEGMENT INFORMATION

The Company operates and manages its business as one reportable segment and one operating segment, which is the business of developing, testing and selling blood purification medical devices. The Company's chief operating decision maker, or CODM, is the Company's Chief Executive Officer. The CODM assesses performance of the segment and decides how to allocate resources based on Revenue growth, Gross Margin, Operating Expenses, adjusted net loss, adjusted EBITDA and cash burn (cash used in operating and investing activities) derived from the Company's consolidated results of operations and cash flows and total assets of the segment.

The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets. All material long-lived assets are located in New Jersey, and Berlin Germany. Long-lived assets consist of property and equipment, net and operating lease right-of-use assets.

Factors used in determining the reportable segment include the nature of the Company's operations, the organizational and reporting structure and the type of information reviewed by the CODM to allocate resources and evaluate financial performance. The accounting policies of the segment are the same as those described in Note 2 to the consolidated financial statements of the Company included in this Annual Report on Form 10-K.

The Company operates as one reportable operating segment. Consisting of one reportable operating segment, the components presented in the consolidated statements of operations also present the components of the Company's single operating segment.

The CODM uses financial metrics to evaluate the Company's spending and monitor budget versus actual results. The monitoring of budgeted versus actual results is used in assessing performance of the segment and in establishing resource allocation across the organization. The financial metrics used by the CODM in evaluating the Company's spending and monitoring budget versus actual results are as follows:

	Years ended December 31,	
	2024	2023 As Restated*
Product revenue	$ 35,594,520	$ 31,084,953
Gross Profit	$ 25,125,991	$ 21,953,237
Gross Margin	71 %	71 %
Total Operating Expenses	$ 41,911,930	$ 53,901,857
EBITDA and Adjusted EBITDA (both non-GAAP measures):		
Net loss	$ (20,718,957)	$ (29,246,760)
Interest expense	1,399,092	(157,891)
Benefits from income taxes	(1,690,825)	813,739
Depreciation and amortization expense	1,570,104	1,459,066
Loss before interest expense, income taxes, depreciation and amortization ("EBITDA"), a non-GAAP measure	(19,440,586)	(28,443,541)
Stock-based compensation	3,759,534	4,155,342
Gain (loss) on foreign currency transactions	4,224,721	(1,949,257)
Adjusted EBITDA, a non-GAAP measure	$ (11,456,331)	$ (26,237,456)
Adjusted net loss, a non-GAAP measure:		
Net loss	$ (20,718,957)	$ (29,246,760)
Stock-based compensation	3,759,534	4,155,342
Gain (loss) on foreign currency transactions	4,224,721	(1,949,257)
Adjusted net loss, a non-GAAP measure	$ 12,734,702	$ 27,040,675
Total cash used in operating and investing activities	$ (15,097,239)	$ (22,591,372)
Total Assets	$ 47,675,811	$ 52,956,322

* See Note 12 – Restatement of Previously Issued financial information for details.

Significant expense categories regularly provided to the CODM consist of the following:

	Years ended December 31,	
	2024	2023 As Restated*
Research and development:		
Clinical expenses	$ 4,482,691	$ 11,329,684
Other research and development expenses	2,433,490	4,264,758
Total research and development	$ 6,916,181	$ 15,594,442
Selling, general and administrative		
Commission expense	$ 2,903,705	$ 2,289,773
Royalty expense	1,869,016	2,156,323
Stock-based compensation	3,759,534	4,155,341
Legal, financial and consulting	3,178,787	4,272,296
Other general and administrative	23,244,707	25,433,682
Total selling, general and administrative	$ 34,995,749	$ 38,307,415

* See Note 12 – Restatement of Previously Issued financial information for details.

Capital expenditures of the segment totaled $669,430 and $936,236 for the years ended December 31, 2024 and 2023, respectively.

12. RESTATEMENT OF PREVIOUSLY ISSUED FINANCIAL INFORMATION

Restatement of Previously Issued Financial Information

During the year ended December 31, 2024, the Company identified and corrected the following errors, which were recorded incorrectly in previously issued financial statements included in our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q:

– Overstatement of Inventory due to a clerical error.

– Understatement of stock-based compensation expense and related corrections of accrued liabilities, additional paid in capital, and accumulated deficit related to errors in the application of the Company's accounting policy for RSUs. Based on the Company's accounting policy for stock-based compensation, expense for RSUs is measured and recorded against additional paid-in-capital based on estimated fair values at the award's grant date. The Company incorrectly adjusted compensation expense based on the fair value of the award at its vesting date. In addition, the Company recorded part of the compensation expense against accrued liabilities.

The following periods were impacted by the restatement:

- the audited consolidated financial statements as of and for the year ended December 31, 2023,
- the interim unaudited condensed consolidated financial statements as of and for the first three quarters of the year ended December 31, 2023, and
- the interim unaudited condensed consolidated financial statements as of and for the first three quarters of the year ended December 31, 2024.

Summary of Effect of Restatement of Previously Issued Financial Information

The tables below summarize the impact of the restated amounts on the previously reported consolidated balance sheets for the impacted periods. The Consolidated Balance Sheet adjustments in the tables below that impact the line items of additional paid-in

capital, accumulated deficit, and total stockholders' equity also reflecting the same amounts that those line items were impacted in the Consolidated Statements of Changes in Stockholders' Equity.

	Inventories	Total Current Assets	Total Assets	Accrued expenses and other current liabilities	Total Current Liabilities	Total Liabilities	Additional paid-in capital*	Accumulated deficit*	Total Stockholders' Equity*	Total Liabilities and Stockholders' Equity
As of March 31, 2023, as previously reported (Unaudited)	$ 1,725,673	$ 28,164,991	$ 57,462,835	$ 7,329,386	$ 10,435,916	$ 28,507,390	$ 288,514,368	$ (261,323,761)	$ 28,955,445	$ 57,462,835
Effect of restatement	—	—	—	(982,492)	(982,492)	(982,492)	1,023,458	(40,966)	982,492	—
As of March 31, 2023, as restated (Unaudited)	$ 1,725,673	$ 28,164,991	$ 57,462,835	$ 6,346,894	$ 9,453,424	$ 27,524,898	$ 289,537,826	$ (261,364,727)	$ 29,937,937	$ 57,462,835

* The restatement adjustment reflected in these balance sheet line items also reflect the restatement adjustments applicable to the statements of stockholders' equity.

	Inventories	Total Current Assets	Total Assets	Accrued expenses and other current liabilities	Total Current Liabilities	Total Liabilities	Additional paid-in capital*	Accumulated deficit*	Total Stockholders' Equity*	Total Liabilities and Stockholders' Equity
As of June 30, 2023, as previously reported (Unaudited)	$ 2,045,985	$ 23,643,953	$ 52,444,767	$ 7,400,735	$ 10,351,130	$ 28,350,071	$ 290,199,035	$ (267,476,845)	$ 24,094,696	$ 52,444,767
Effect of restatement	—	—	—	(365,876)	(365,876)	(365,876)	854,971	(489,095)	365,876	—
As of June 30, 2023, as restated (Unaudited)	$ 2,045,985	$ 23,643,953	$ 52,444,767	$ 7,034,859	$ 9,985,254	$ 27,984,195	$ 291,054,006	$ (267,965,940)	$ 24,460,572	$ 52,444,767

* The restatement adjustment reflected in these balance sheet line items also reflect the restatement adjustments applicable to the statements of stockholders' equity.

	Inventories	Total Current Assets	Total Assets	Accrued expenses and other current liabilities	Total Current Liabilities	Total Liabilities	Additional paid-in capital*	Accumulated deficit*	Total Stockholders' Equity*	Total Liabilities and Stockholders' Equity
As of September 30, 2023, as previously reported (Unaudited)	$ 2,977,146	$ 19,260,643	$ 47,575,037	$ 7,580,287	$ 11,972,396	$ 29,063,415	$ 292,153,561	$ (276,670,365)	$ 18,511,622	$ 47,575,037
Effect of restatement	—	—	—	(299,965)	(299,965)	(299,965)	764,826	(464,861)	299,965	—
As of September 30, 2023, as restated (Unaudited)	$ 2,977,146	$ 19,260,643	$ 47,575,037	$ 7,280,322	$ 11,672,431	$ 28,763,450	$ 292,918,387	$ (277,135,226)	$ 18,811,587	$ 47,575,037

* The restatement adjustment reflected in these balance sheet line items also reflect the restatement adjustments applicable to the statements of stockholders' equity.

	Inventories	Total Current Assets	Total Assets	Accrued expenses and other current liabilities	Total Current Liabilities	Total Liabilities	Additional paid-in capital*	Accumulated deficit*	Total Stockholders' Equity*	Total Liabilities and Stockholders' Equity
As of December 31, 2023, as previously reported	$ 3,680,129	$ 25,702,823	$ 53,260,634	$ 7,870,149	$ 14,545,955	$ 29,985,471	$ 305,196,874	$ (282,505,272)	$ 23,275,163	$ 53,260,634
Effect of restatement	(304,312)	(304,312)	(304,312)	(510,363)	(510,363)	(510,363)	990,440	(784,389)	206,051	(304,312)
As of December 31, 2023, as restated	$ 3,375,817	$ 25,398,511	$ 52,956,322	$ 7,359,786	$ 14,035,592	$ 29,475,108	$ 306,187,314	$ (283,289,661)	$ 23,481,214	$ 52,956,322

* The restatement adjustment reflected in these balance sheet line items also reflect the restatement adjustments applicable to the statements of stockholders' equity.

	Inventories	Total Current Assets	Total Assets	Accrued expenses and other current liabilities	Total Current Liabilities	Total Liabilities	Additional paid-in capital*	Accumulated deficit*	Total Stockholders' Equity*	Total Liabilities and Stockholders' Equity
As of March 31, 2024, as previously reported (Unaudited)	$ 3,738,767	$ 19,992,800	$ 47,070,605	$ 8,132,063	$ 13,424,101	$ 28,142,680	$ 305,984,268	$ (288,863,133)	$ 18,927,925	$ 47,070,605
Effect of restatement	—	—	—	(700,457)	(700,457)	(700,457)	1,215,696	(515,239)	700,457	—
As of March 31, 2024, as restated (Unaudited)	$ 3,738,767	$ 19,992,800	$ 47,070,605	$ 7,431,606	$ 12,723,644	$ 27,442,223	$ 307,199,964	$ (289,378,372)	$ 19,628,382	$ 47,070,605

* The restatement adjustment reflected in these balance sheet line items also reflect the restatement adjustments applicable to the statements of stockholders' equity.

	Inventories	Total Current Assets	Total Assets	Accrued expenses and other current liabilities	Total Current Liabilities	Total Liabilities	Additional paid-in capital*	Accumulated deficit*	Total Stockholders' Equity*	Total Liabilities and Stockholders' Equity
As of June 30, 2024, as previously reported (Unaudited)	$ 4,316,752	$ 21,955,300	$ 53,426,791	$ 6,877,163	$ 10,336,268	$ 36,690,188	$ 307,514,758	$ (293,006,279)	$ 16,736,603	$ 53,426,791
Effect of restatement	—	—	—	(692,020)	(692,020)	(692,020)	1,359,220	(667,201)	692,019	(1)
As of June 30, 2024, as restated (Unaudited)	$ 4,316,752	$ 21,955,300	$ 53,426,791	$ 6,185,143	$ 9,644,248	$ 35,998,168	$ 308,873,978	$ (293,673,480)	$ 17,428,622	$ 53,426,790

* The restatement adjustment reflected in these balance sheet line items also reflect the restatement adjustments applicable to the statements of stockholders' equity.

	Inventories	Total Current Assets	Total Assets	Accrued expenses and other current liabilities	Total Current Liabilities	Total Liabilities	Additional paid-in capital*	Accumulated deficit*	Total Stockholders' Equity*	Total Liabilities and Stockholders' Equity
As of September 30, 2024, as previously reported (Unaudited)	$ 3,247,756	$ 16,597,368	$ 47,804,011	$ 5,660,051	$ 8,430,191	$ 34,804,921	$ 308,441,887	$ (295,340,370)	$ 12,999,090	$ 47,804,011
Effect of restatement	—	—	—	(145,782)	(145,782)	(145,782)	1,245,114	(1,099,333)	145,782	(1)
As of September 30, 2024, as restated (Unaudited)	$ 3,247,756	$ 16,597,368	$ 47,804,011	$ 5,514,269	$ 8,284,409	$ 34,659,139	$ 309,687,001	$ (296,439,703)	$ 13,144,872	$ 47,804,010

* The restatement adjustment reflected in these balance sheet line items also reflect the restatement adjustments applicable to the statements of stockholders' equity.

The tables below summarize the impact of the restated and reclassified amounts on the previously reported consolidated statements of operations and comprehensive loss:

	Three Months Ended (Unaudited)			Six Months Ended (Unaudited)	Nine Months Ended (Unaudited)	Year Ended
	March 31, 2023	June 30, 2023	September 30, 2023	June 30, 2023	September 30, 2023	December 31, 2023
Cost of goods sold:						
As previously reported (incl. reclassification)	$ 2,531,198	$ 2,092,856	$ 2,161,044	$ 4,624,054	$ 6,785,231	$ 8,827,404
Effect of restatement	—	—	—	—	—	304,312
As restated and reclassified	$ 2,531,198	$ 2,092,856	$ 2,161,044	$ 4,624,054	$ 6,785,231	$ 9,131,716
Gross Profit:						
As previously reported (incl. reclassification)	$ 5,378,841	$ 5,979,556	$ 5,592,972	$ 11,358,396	$ 16,951,369	$ 22,257,549
Effect of restatement	—	—	—	—	—	(304,312)
As restated and reclassified	$ 5,378,841	$ 5,979,556	$ 5,592,972	$ 11,358,396	$ 16,951,369	$ 21,953,237
Selling, general and administrative:						
As previously reported (incl. reclassification)	$ 9,132,508	$ 8,908,983	$ 9,207,867	$ 18,041,490	$ 27,316,155	$ 37,872,361
Effect of restatement	(3,453)	448,136	(5,261)	444,683	439,422	435,054
As restated and reclassified	$ 9,129,055	$ 9,357,119	$ 9,202,606	$ 18,486,173	$ 27,755,577	$ 38,307,415
Total Operating Expenses:						
As previously reported (incl. reclassification)	$ 13,270,437	$ 12,538,793	$ 12,943,170	$ 25,809,228	$ 38,819,197	$ 53,466,803
Effect of restatement	(3,453)	448,136	(5,261)	444,683	439,422	435,054
As restated and reclassified	$ 13,266,984	$ 12,986,929	$ 12,937,909	$ 26,253,911	$ 39,258,619	$ 53,901,857
Loss From Operations						
As previously reported	$ (7,891,596)	$ (6,559,237)	$ (7,350,198)	$ (14,450,832)	$ (21,867,828)	$ (31,209,254)
Effect of restatement	3,453	(448,136)	5,261	(444,683)	(439,422)	(739,366)
As restated	$ (7,888,143)	$ (7,007,373)	$ (7,344,937)	$ (14,895,515)	$ (22,307,250)	$ (31,948,620)
Loss Before Benefit From Income Taxes						
As previously reported	$ (7,325,883)	$ (6,153,084)	$ (9,193,520)	$ (13,478,967)	$ (22,672,487)	$ (29,321,134)
Effect of restatement	3,453	(448,136)	5,261	(444,683)	(439,422)	(739,365)
As restated	$ (7,322,430)	$ (6,601,220)	$ (9,188,259)	$ (13,923,650)	$ (23,111,909)	$ (30,060,499)
Net Loss Attributable To Common Stockholders						
As previously reported	$ (7,325,883)	$ (6,153,084)	$ (9,193,520)	$ (13,478,967)	$ (22,672,487)	$ (28,507,395)
Effect of restatement	3,453	(448,136)	5,261	(444,683)	(439,422)	(739,365)
As restated	$ (7,322,430)	$ (6,601,220)	$ (9,188,259)	$ (13,923,650)	$ (23,111,909)	$ (29,246,760)
Basic And Diluted Net Loss Per Common Share						
As previously reported	$ (0.17)	$ (0.14)	$ (0.21)	$ (0.31)	$ (0.52)	$ (0.64)
Effect of restatement	$ 0.00	$ (0.01)	$ 0.00	$ (0.01)	$ (0.00)	$ (0.01)
As restated	$ (0.17)	$ (0.15)	$ (0.21)	$ (0.32)	$ (0.52)	$ (0.65)
Comprehensive Loss						
As previously reported	$ (7,934,091)	$ (6,545,758)	$ (7,537,846)	$ (14,479,849)	$ (22,017,695)	$ (30,307,269)
Effect of restatement	3,453	(448,136)	5,261	(444,683)	(439,422)	(739,365)
As restated	$ (7,930,638)	$ (6,993,894)	$ (7,532,585)	$ (14,924,532)	$ (22,457,117)	$ (31,046,634)

	Three Months Ended (Unaudited)			Six Months Ended (Unaudited)	Nine Months Ended (Unaudited)
	March 31, 2024	June 30, 2024	September 30, 2024	June 30, 2024	September 30, 2024
Cost of goods sold :					
As previously reported (Incl. reclassification)	$ 2,420,222	$ 2,339,206	$ 3,356,965	$ 4,759,429	$ 8,116,394
Effect of restatement	(304,312)	—	—	(304,312)	(304,312)
As restated and reclassified	$ 2,115,910	$ 2,339,206	$ 3,356,965	$ 4,455,117	$ 7,812,082
Gross Profit:					
As previously reported (Incl. reclassification)	$ 6,569,298	$ 6,502,583	$ 5,255,830	$ 13,071,880	$ 18,327,710
Effect of restatement	304,312	—	—	304,312	304,312
As restated and reclassified	$ 6,873,610	$ 6,502,583	$ 5,255,830	$ 13,376,192	$ 18,632,022
Selling, general and administrative:					
As previously reported (Incl. reclassification)	$ 9,247,906	$ 8,401,933	$ 7,826,632	$ 17,649,838	$ 25,476,470
Effect of restatement	35,161	151,963	433,432	187,125	620,557
As restated and reclassified	$ 9,283,067	$ 8,553,896	$ 8,260,064	$ 17,836,963	$ 26,097,027
Total Operating Expenses:					
As previously reported (Incl. reclassification)	$ 11,494,816	$ 9,921,405	$ 9,652,077	$ 21,416,221	$ 31,068,297
Effect of restatement	35,161	151,963	433,432	(187,125)	620,557
As restated and reclassified	$ 11,529,977	$ 10,073,368	$ 10,085,509	$ 21,603,346	$ 31,688,854
Loss From Operations					
As previously reported	$ (4,925,518)	$ (3,418,822)	$ (4,396,247)	$ (8,344,341)	$ (12,740,587)
Effect of restatement	269,150	(151,963)	(433,432)	117,187	(316,245)
As restated	$ (4,656,368)	$ (3,570,785)	$ (4,829,679)	$ (8,227,154)	$ (13,056,832)
Loss Before Benefit From Income Taxes					
As previously reported	$ (6,357,861)	$ (4,143,146)	$ (2,334,091)	$ (10,501,007)	$ (12,835,098)
Effect of restatement	269,150	(151,963)	(433,432)	117,187	(316,245)
As restated	$ (6,088,711)	$ (4,295,109)	$ (2,767,523)	$ (10,383,820)	$ (13,151,343)
Net Loss Attributable To Common Stockholders					
As previously reported	$ (6,357,861)	$ (4,143,146)	$ (2,334,091)	$ (10,501,007)	$ (12,835,098)
Effect of restatement	269,150	(151,963)	(433,432)	117,187	(316,245)
As restated	$ (6,088,711)	$ (4,295,109)	$ (2,767,523)	$ (10,383,820)	$ (13,151,343)
Basic And Diluted Net Loss Per Common Share					
As previously reported	$ (0.12)	$ (0.08)	$ (0.04)	$ (0.19)	$ (0.24)
Effect of restatement	$ 0.01	$ 0.00	$ (0.01)	$ (0.00)	$ (0.00)
As restated	$ (0.11)	$ (0.08)	$ (0.05)	$ (0.19)	$ (0.24)
Comprehensive Loss					
As previously reported	$ (5,134,686)	$ (3,721,824)	$ (4,664,834)	$ (8,856,510)	$ (13,521,344)
Effect of restatement	$ 269,150	$ (151,963)	$ (433,432)	$ 117,187	$ (316,245)
As restated	$ (4,865,536)	$ (3,873,787)	$ (5,098,266)	$ (8,739,323)	$ (13,837,589)

The table below summarizes the impact of the restated amounts on the previously reported consolidated statements of cash flows. The consolidated statements of cash flows adjustments in the tables below that impact the line items of stock-based compensation

also reflect the same amounts that the stock-based compensation line items was impacted by in the consolidated statements of changes in stockholders' equity.

	Three Months Ended (Unaudited) March 31, 2023	Six Months Ended (Unaudited) June 30, 2023	Nine Months Ended (Unaudited) September 30, 2023	Year Ended December 31, 2023
Cash Flows From Operating Activities:				
Net Loss Attributable To Common Stockholders:				
As previously reported	$ (7,325,883)	$ (13,478,967)	$ (22,672,487)	$ (28,507,394)
Effect of restatement	3,453	(444,683)	(439,422)	(739,366)
As restated	$ (7,322,430)	$ (13,923,650)	$ (23,111,909)	$ (29,246,760)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:				
Stock-Based Compensation*				
As previously reported	$ 1,080,486	$ 1,295,028	$ 2,647,678	$ 3,700,704
Effect of restatement	(3,453)	444,683	439,422	454,638
As restated	$ 1,077,033	$ 1,739,711	$ 3,087,100	$ 4,155,342
Inventories				
As previously reported	$ 1,747,144	$ 1,449,881	$ 471,822	$ (121,039)
Effect of restatement	—	—	—	304,312
As restated	$ 1,747,144	$ 1,449,881	$ 471,822	$ 183,273
Accounts Payable and accrued expenses				
As previously reported	$ 629,833	$ 291,068	$ 1,047,700	$ 1,623,580
Cumulative effect of restatement adjustments on balance sheet (year-to-date)	(250,206)	366,410	432,320	221,923
Non-cash reclassification to additional paid-in-capital	250,206	(366,410)	(432,320)	(238,137)
As restated	$ 629,833	$ 291,068	$ 1,047,700	$ 1,607,366

* The restatement adjustment reflected in this statements of cash flows line items also reflect the restatement adjustments applicable to the statements of stockholders' equity.

	Three Months Ended (Unaudited) March 31, 2024	Six Months Ended (Unaudited) June 30, 2024	Nine Months Ended (Unaudited) September 30, 2024
Cash Flows From Operating Activities:			
Net Loss Attributable To Common Stockholders:			
As previously reported	$ (6,357,861)	$ (10,501,007)	$ (12,835,098)
Effect of restatement	269,150	117,187	(316,245)
As restated	$ (6,088,711)	$ (10,383,820)	$ (13,151,343)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:			
Stock-Based Compensation*			
As previously reported	$ 924,304	$ 1,761,888	$ 2,248,403
Effect of restatement	35,161	187,125	620,557
As restated	$ 959,465	$ 1,949,013	$ 2,868,960
Accounts Payable and accrued expenses			
As previously reported	$ (1,281,724)	$ (2,032,014)	$ (3,165,684)
Cumulative effect of restatement adjustments on balance sheet (year-to-date)	190,094	181,657	(364,581)
Non-cash reclassification to additional paid-in-capital	(190,094)	(181,657)	364,581
As restated	$ (1,281,724)	$ (2,032,014)	$ (3,165,684)

* The restatement adjustment reflected in this statements of cash flows line items also reflect the restatement adjustments applicable to the statements of stockholders' equity.

The table below summarizes the impact of the restated and reclassified amounts on the previously reported consolidated statements of changes in stockholders' equity:

	Three Months Ended (Unaudited)			Six Months Ended (Unaudited)	Nine Months Ended (Unaudited)	Year Ended
	March 31, 2023	June 30, 2023	September 30, 2023	June 30, 2023	September 30, 2023	December 31, 2023
Net loss (row), Accumulated deficit (column), Stockholders' equity (column)						
As previously reported (incl. reclassification)	$ (7,325,883)	$ (6,153,084)	$ (9,193,520)	$ (13,478,967)	$ (22,672,487)	$ (28,507,394)
Effect of restatement	3,453	(448,136)	5,261	(444,683)	(439,422)	(739,366)
As restated and reclassified	$ (7,322,430)	$ (6,601,220)	$ (9,188,259)	$ (13,923,650)	$ (23,111,909)	$ (29,246,760)
Stock-based compensation (row), Additional paid-in capital (column), Stockholders' equity (column)						
As previously reported (incl. reclassification)	$ 1,080,486	$ 214,542	$ 1,352,650	$ 1,295,028	$ 2,647,678	$ 3,700,704
Effect of restatement	(3,453)	448,136	(5,261)	444,683	439,422	454,638
As restated and reclassified	$ 1,077,033	$ 662,678	$ 1,347,389	$ 1,739,711	$ 3,087,100	$ 4,155,342
Common stock issued upon vesting of restricted stock units, less shares withheld to cover taxes (row), Additional paid-in capital (column), Stockholders' equity (column)						
As previously reported (incl. reclassification)	$ —	$ 183,600	$ 220,211	$ 260,151	$ 403,811	$ 403,809
Effect of restatement	—	(260,873)	(351,293)	(612,166)	(612,775)	(612,773)
As restated and reclassified	$ —	$ (77,273)	$ (131,082)	$ (352,015)	$ (208,964)	$ (208,964)

	Three Months Ended (Unaudited)			Six Months Ended (Unaudited)	Nine Months Ended (Unaudited)
	March 31, 2024	June 30, 2024	September 30, 2024	June 30, 2024	September 30, 2024
Net loss (row), Accumulated deficit (column), Stockholders' equity (column)					
As previously reported (incl. reclassification)	$ (6,357,861)	$ (4,143,146)	$ (2,334,091)	$ (10,501,007)	$ (12,835,099)
Effect of restatement	269,150	(151,963)	(433,432)	117,187	(316,245)
As restated and reclassified	$ (6,088,711)	$ (4,295,109)	$ (2,767,523)	$ (10,383,820)	$ (13,151,344)
Stock-based compensation (row), Additional paid-in capital (column), Stockholders' equity (column)					
As previously reported (incl. reclassification)	$ 924,304	$ 837,584	$ 486,515	$ 1,761,888	$ 2,248,403
Effect of restatement	35,161	151,963	433,432	187,125	620,557
As restated and reclassified	$ 959,465	$ 989,547	$ 919,947	$ 1,949,013	$ 2,868,960
Common stock issued upon vesting of restricted stock units, less shares withheld to cover taxes (row), Additional paid-in capital (column), Stockholders' equity (column)					
As previously reported (incl. reclassification)	$ —	$ 11,201	$ 186,692	$ 11,201	$ 197,892
Effect of restatement	—	(17,428)	(285,796)	(17,428)	(204,802)
As restated and reclassified	$ —	$ (6,227)	$ (99,104)	$ (6,227)	$ (6,910)

In relation to the errors discussed above, the consolidated statements of changes in stockholders' equity includes a cumulative effect of adjustments to the beginning balances as of January 1, 2023 of additional paid-in-capital (increase of $777,310), accumulated deficit (decrease of $45,023) and stockholders' equity (increase of $732,287).

13. SUBSEQUENT EVENTS

Management has evaluated subsequent events through the date of issuance of these consolidated financial statements and has determined that there are no subsequent events outside the ordinary scope of business that require adjustment to, or disclosure in, the financial statements other than those described below.

Rights Offering

On January 10, 2025, the Company closed the subscription period of its previously announced rights offering (the "Rights Offering"), raising aggregate gross proceeds of $6.25 million ($5.8 million net of fees) from the sale of all 6.25 million Units reserved for the Rights Offering. Participants in the Rights Offering received Units, each Unit comprising of one share of common stock of the Company, one Series A Right Warrant to purchase one share of common stock, and one Series B Right Warrant to purchase one share of common stock. Up to an additional 6.25 million shares of common stock may be issued upon exercise of the Right Warrants.

Proceeds from the closing of the subscription period satisfy a debt covenant which allows for $5,000,000 of restricted cash on the Company's consolidated balance sheets to now become unrestricted, and available for use.

The Right Warrants are exercisable commencing on their date of issuance and the exercise price shall be equal to (i) in the case of the Series A Right Warrants, 90% of the 5-day volume weighted average price of our Common Stock over the last 5-trading days prior to the expiration date of the Series A Right Warrants on February 24, 2025, rounded down to the nearest whole cent but (x) not lower than $1.00 and (y) not higher than $2.00, and (ii) in the case of the Series B Right Warrants, 90% of the 5-day volume weighted average price of our Common Stock over the last 5-trading days prior to the expiration date of the Series B Right Warrants on April 10, 2025, rounded down to the nearest whole cent but (x) not lower than $2.00 and (y) not higher than $4.00.

Exercise of the Right Warrants require additional investment separate from the purchase of the Units. 6.25 million shares of common stock have been reserved for exercise of the Right Warrants, after which any remaining unexercised Right Warrants will immediately expire worthless. The Right Warrants are transferable until they have expired.

On February 24, 2025, approximately 1.4 million Series A Right Warrants were exercised by holders, including members of management and the Board of Directors, at an exercise price of $1.13 per warrant, providing an additional $1.6 million in aggregate gross proceeds ($1.5 million net of fees).

Exhibit 19.1

CYTOSORBENTS CORPORATION
AMENDED AND RESTATED
INSIDER TRADING POLICY

Adopted December 9, 2024

I. Purpose

This Insider Trading Policy (this "Policy") provides the standards of CytoSorbents Corporation (the "Company") with respect to transactions in Company securities, or securities of other publicly-traded companies, while in possession of material, non-public information. In addition, this Policy is intended to assure compliance with laws and regulations regarding material non-public information and the trading of securities, to prevent even inadvertent violations of these laws or the appearance of impropriety, and to protect our employees, our board of directors, and our business from legal liability.

II. Applicability

A. Covered Persons. This Policy applies to (i) all directors, officers, employees and consultants of the Company and its subsidiaries ("***Employees***"); (ii) family members of all Employees of the Company and its subsidiaries; (iii) entities (such as trusts, limited partnerships and corporations) over which such individuals have or share voting or investment control; (iv) any other persons whom the Compliance Officer may designate because they have access to material nonpublic information concerning the Company; and (v) any person who receives material nonpublic information from any Company insider (each, a "***Covered Person***").

Employees of the Company are responsible for ensuring compliance by family members and members of their households and by entities over which they exercise voting or investment control.

B. Applicable Transactions.

1. General Rule. This Policy applies to all transactions in the Company's securities, including common stock and any other securities the Company may issue from time to time, such as preferred stock, warrants and convertible debentures, as well as to derivative securities relating to the Company's stock, whether or not issued by the Company, such as exchange-traded options. For purposes of this Policy, the term "trade" includes any transaction in the Company's securities, including gifts and pledges.

2. Employee Benefit Plans.

Equity Incentive Plans. The trading prohibitions and restrictions set forth in this Policy do not apply to the exercise of stock options or other equity awards, including any exercise for cash or net exercise pursuant to which the grantee has elected to have the Company withhold shares of stock to satisfy tax withholding requirements or the exercise price of the option, but do apply to

broker-assisted cashless exercises and all market sales of securities acquired through the exercise of stock options or other equity awards.

Employee Stock Purchase Plans. The trading prohibitions and restrictions set forth in this Policy do not apply to periodic contributions by the Company or employees to employee stock purchase plans or employee benefit plans (e.g., a pension or 401(k) plan) which are used to purchase Company securities pursuant to the employee's advance instructions. However, no officers or employees may alter their instructions regarding the level of withholding or the purchase of Company securities in such plans while in the possession of material nonpublic information. Any sale of securities acquired under such plans is subject to the prohibitions and restrictions of this Policy.

III. Trading in Company Securities While in Possession of Material Non-Public Information is Prohibited

Any Covered Person who is aware of material nonpublic information relating to the Company may not, either directly or through family members or other persons or entities:

(i) buy or sell securities of the Company, other than pursuant to a trading plan that complies with Rule 10b5-1 promulgated by the Securities and Exchange Commission ("***SEC***"),

(ii) engage in any other action to take personal advantage of that information,

(iii) disclose that information to others outside the Company, including friends and family members, where such information may be used by such person to his or her advantage in the trading of securities of companies to which such information relates (a practice referred to as "***tipping***"), or

(iv) make recommendations or express opinions as to trading in the Company's securities, except such Covered Person may advise others not to trade in the Company's securities if doing so might violate the law or this Policy.

In addition, it is the policy of the Company that any officer, director, employee or consultant who, in the course of working for the Company, learns of material nonpublic information of another company with which the Company does business, such as a customer or supplier, may not trade in that company's securities until that information becomes public or is no longer material.

IV. Additional Restrictions

In addition, certain individuals, including executive officers, directors and other named employees are subject to further restrictions on trading under this Policy.

A. Section 16 Insiders. The Company has designated those persons listed on Exhibit A attached hereto as the directors and executive officers who are subject to the reporting provisions and trading restrictions of Section 16 of the Securities Exchange Act of 1934 (the "***Exchange Act***") and the underlying rules and regulations promulgated by the SEC. Each person listed on Exhibit A is referred to herein as a "***Section 16 Insider***." The Company will amend Exhibit A from time to time as necessary to reflect the addition and the resignation or departure of Section 16 Insiders.

B. Insider Employees. The Company has designated those persons listed on Exhibit B attached hereto as employees who have frequent access to material nonpublic information concerning the

Company ("***Insider Employees***"). The Company will amend Exhibit B from time to time as necessary to reflect the addition and departure of Inside Employees.

C. Additional Restrictions. Because Section 16 Insiders and Insider Employees are more likely than other employees to possess material nonpublic information about the Company, and in light of the reporting requirements to which Section 16 Insiders are subject under Section 16 of the Exchange Act, Section 16 Insiders and Insider Employees are subject to the additional restrictions set forth in Appendix I hereto. For purposes of this Policy, Section 16 Insiders and Insider Employees are each referred to as "***Insiders***."

V. Insider Trading Compliance Officer

The Company has designated an Insider Trading Compliance Officer on Exhibit C (the "***Compliance Officer***"). The Company will amend Exhibit C from time to time as necessary to reflect the addition and departure of one or more Compliance Officers.

The duties of the Compliance Officer will include the following:

(i) Administering this Policy and monitoring and enforcing compliance with all policy provisions and procedures.

(ii) Responding to all inquiries relating to this policy and its procedures.

(iii) Designating and announcing trading blackout periods.

(iv) Providing copies of this Policy and other appropriate materials to (i) all current Covered Persons (ii) new employees, directors, officers and consultants, and (iii) such other persons as the Compliance Officer determines have access to material nonpublic information concerning the Company.

(v) Administering, monitoring and enforcing compliance with federal and state insider trading laws and regulations; and assisting in the preparation and filing of all required SEC reports relating to trading in Company securities, including without limitation Forms 3, 4, 5 and 144 and Schedules 13D and 13G.

(vi) Revising the Policy as necessary to reflect changes in federal or state insider trading laws and regulations.

(vii) Maintaining as Company records originals or copies of all documents required by the provisions of this Policy or the procedures set forth herein, and copies of all required SEC reports relating to insider trading, including without limitation Forms 3, 4, 5 and 144 and Schedules 13D and 13G.

(viii) Maintaining the accuracy of the list of Section 16 Individuals as set forth on Exhibit A and the list of Insider Employees as set forth on Exhibit B, and updating such lists periodically as necessary to reflect additions or deletions.

The Company may designate one or more individuals who may perform the Compliance Officer's duties in the event that the Compliance Officer is unable or unavailable to perform such duties.

In fulfilling his or her duties under this Policy, the Compliance Officer shall be authorized to consult with the Company's outside counsel.

VI. Definition of "Material Non-Public Information"

A. "*Material*". Information about the Company is "material" if it would be expected to affect the investment or voting decisions of a reasonable shareholder or investor, or if the disclosure of the information would be expected to significantly alter the total mix of the information in the marketplace about the Company. In simple terms, material information is any type of information which could reasonably be expected to affect the market price of the Company's securities. Both positive and negative information may be material. While it is not possible to identify all information that would be deemed material, the following types of information ordinarily would be considered material:

(i) Financial performance, especially quarterly and year-end operating results, and significant changes in financial performance or liquidity.

(ii) Company projections and strategic plans.

(iii) Potential mergers or acquisitions, the sale of Company assets or subsidiaries or major partnering agreements.

(iv) New major contracts, orders, suppliers, customers or finance sources or the loss thereof which have a financial, operational or strategic impact on the Company.

(v) Discoveries, results of or significant changes or developments in products or product lines, research or technologies, data, studies or tests.

(vi) Significant changes or developments in supplies or inventory, including significant product defects, recalls or product returns.

(vii) Significant pricing changes.

(viii) Stock splits, public or private securities/debt offerings, or changes in Company dividend policies or amounts.

(ix) Changes in senior management or membership of the Board of Directors.

(x) Labor disputes or negotiations.

(xi) Actual or threatened major litigation, or the resolution of such litigation.

(xii) Receipt or denial of regulatory approval for products.

B. "*Nonpublic*". Material information is "nonpublic" if it has not been widely disseminated to the general public through a report filed with the SEC or through major newswire services, national news services or financial news services. For the purpose of this Policy, information will be considered public after the close of trading on the second full trading day following the Company's widespread public release of the information.

C. Consult the Compliance Officer When in Doubt. Any employees who are unsure whether the information that they possess is material or nonpublic must consult the Compliance Officer for guidance before trading in any Company securities.

I. VII. Blackout Periods and Trading Windows

A. Generally. In order to avoid any questions and to protect both employees and the Company from any potential liability, from time to time the Company may impose a "***blackout***" period during which some or all of the Company's employees may not buy or sell the Company's securities. The Compliance Officer will impose such a blackout period if, in his or her judgment, there exists nonpublic information that would make trades by the Company's employees (or certain of the Company's employees) inappropriate in light of the risk that such trades could be viewed as violating applicable securities laws. When the Company imposes a blackout period, it will notify the Covered Persons affected.

B. Exception. These trading restrictions do not apply to transactions under a pre-existing written plan, contract, instruction, or arrangement under Rule 10b5-1 (an "***Approved 10b5-1 Plan***") that meets the qualifications listed in Section XII of Appendix I to this Policy.

Covered Persons are generally permitted to trade in the Company's securities when no blackout period is in effect. Generally this means that Covered Persons can trade during the period beginning on the day on which a blackout period ends pursuant, and ending on the day on which a blackout period begins. However, even during this trading window, a Covered Person who is in possession of any material non-public information should not trade in the Company's securities until the information has been made publicly available or is no longer material.

VIII. Other Prohibited Actions

A. Employee Participation in Blogs. Employees are prohibited from participating in blog discussions, message board discussions or other Internet forums regarding the Company's securities or business.

B. Disclosing Material Non-Public Information. The Company is required under the federal securities laws to avoid the selective disclosure of material nonpublic information. The Company has established procedures for releasing material information in a manner that is designed to achieve broad dissemination of the information immediately upon its release. Only designated Company spokespersons are authorized to disclose material non-public information. Employees may not, therefore, disclose material information to anyone outside the Company, including family members and friends, other than in accordance with those established procedures. Any inquiries from outsiders regarding material nonpublic information about the Company should be forwarded to the Compliance Officer or the Chief Executive Officer.

C. Prohibited Transactions.

1. *Short Sales*. Short sales of the Company's securities evidence an expectation on the part of the seller that the securities will decline in value, and therefore signal to the market that the seller has no confidence in the Company or its short-term prospects. In addition, short sales may reduce the seller's incentive to improve the Company's performance. For these reasons, short sales of the

Company's securities are prohibited by this Policy. In addition, Section 16(c) of the Exchange Act expressly prohibits executive officers and directors from engaging in short sales.

2. *Publicly Traded Options*. A transaction in options is, in effect, a bet on the short-term movement of the Company's stock and therefore creates the appearance that the director or employee is trading based on inside information. Transactions in options also may focus the director's or employee's attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in puts, calls or other derivative securities involving the Company's stock, on an exchange or in any other organized market, are prohibited by this Policy. (Option positions arising from certain types of hedging transactions are governed by the section below captioned "Hedging Transactions.")

3. *Hedging Transactions*. Certain forms of hedging or monetization transactions, such as zero-cost collars and forward sale contracts, allow an employee to lock in much of the value of his or her stock holdings, often in exchange for all or part of the potential for upside appreciation in the stock. These transactions allow the employee to continue to own the covered securities, but without the full risks and rewards of ownership. When that occurs, the employee may no longer have the same objectives as the Company's other shareholders. Therefore, such transactions involving the Company's securities are prohibited by this Policy.

4. *Margin Accounts and Pledges*. Securities held in a margin account may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Company securities, directors, officers and other employees are prohibited from holding Company securities in a margin account or pledging Company securities as collateral for a loan.

IX. Violations of Laws or this Policy, Reporting and Responsibility

Violations of Insider Trading Laws, Securities Regulations or this Policy can result in severe consequences.

A. Civil and Criminal Penalties. The consequences of prohibited insider trading or tipping can be severe. Persons violating insider trading or tipping rules may be required to disgorge the profit made or the loss avoided by the trading, pay civil penalties up to three times the profit made or loss avoided, face private action for damages, as well as being subject to criminal penalties, including up to 20 years in prison and fines of up to $5 million. The Company and/or the supervisors of the person violating the rules may also be required to pay major civil or criminal penalties.

B. Company Discipline. Violation of this Policy or federal or state insider trading laws by any director, officer or employee may subject the director to removal proceedings and the officer or employee to disciplinary action by the Company, including termination for cause.

C. Reporting Violations. Any person who violates this Policy or any federal or state laws governing insider trading, or knows of any such violation by any other person, must report the violation immediately to the Compliance Officer or the Audit Committee of the Company's Board of Directors, or if no Audit Committee exists, to the Board of Directors. Upon learning of any such violation, the Compliance Officer or Audit Committee, in consultation with the Company's legal counsel, will determine whether the Company should release any material nonpublic information or whether the Company should report the violation to the SEC or other appropriate governmental authority.

D. Responsibility. Every employee has the individual responsibility to comply with this Policy against illegal insider trading. An employee may, from time to time, have to forego a proposed transaction in the Company's securities even if he or she planned to make the transaction before learning of the material nonpublic information and even though the employee believes that he or she may suffer an economic loss or forego anticipated profit by waiting.

X. This Policy Continues to Apply Following Termination Relationship

The Policy continues to apply to transactions in the Company's securities even after termination of employment or other relationship with the Company (including, for the avoidance of doubt, a Director's termination of service on the Company's Board of Directors). If a Covered Person is in possession of material nonpublic information when his or her relationship with the Company terminates, he or she may not trade in the Company's securities until that information has become public or is no longer material.

XI. This Policy is Subject to Revision

The Company may change the terms of this Policy from time to time to respond to developments in law and practice. The Company will take steps to inform all affected persons of any material change to this Policy.

XII. Employee Acknowledgment

The Policy will be made available on the Company's website and delivered to all Employees upon its adoption by the Company, and to all new other Employees at the start of their employment or relationship with the Company. Upon first receiving a copy of the Policy or any revised versions, each Employee must sign an acknowledgment that he or she has received a copy and agrees to comply with the Policy's terms. This acknowledgment and agreement will constitute consent for the Company to impose sanctions for violation of this Policy and to issue any necessary stop-transfer orders to the Company's transfer agent to enforce compliance with this Policy.

CYTOSORBENTS CORPORATION

Re: Insider Trading Policy

Ladies and Gentlemen:

Enclosed is a copy of the Insider Trading Policy as adopted by CytoSorbents Corporation (the "***Company***") on December 9, 2024. **PLEASE READ IT VERY CAREFULLY.** As it indicates, the consequences of insider trading can be drastic to both you and the Company.

To show that you have read the policy and agree to be bound by it, please sign and return the attached copy of this letter to Peter J. Mariani or James Cason, the Company's Compliance Officers, as soon as possible.

Very truly yours,

_____

_____

Compliance Officer

CERTIFICATION

The undersigned certifies that the undersigned has read, understands and agrees to comply with the Insider Trading Policy of CytoSorbents Corporation (the "***Company***"). The undersigned agrees that the undersigned will be subject to sanctions, including, as to employees of the Company, termination of employment, that may be imposed by the Company, in its discretion, for violation of the Company's policy, and that the Company may give stop-transfer and other instructions to the Company's transfer agent against the transfer of Company securities by the undersigned in a transaction that the Company considers to be in contravention of its policy.

Employee or Insider:

Signature

Printed

Name Date

APPENDIX I
Special Restrictions on Transactions in Company Securities by
Executive Officers, Directors and Insider Employees

I. Overview

To minimize the risk of apparent or actual violations of the rules governing insider trading, we have adopted these special restrictions relating to transactions in Company securities by Insiders. As with the other provisions of this Policy, Insiders are responsible for ensuring compliance with this Appendix I, including restrictions on all trading during certain periods, by family members and members of their households and by entities over which they exercise voting or investment control. Insiders should provide each of these persons or entities with a copy of this Policy.

II. Quarterly Blackout Periods and Quarterly Trading Window

In addition to the restrictions that are applicable to all Employees, specifically the blackout periods and trading windows pursuant to Section VII of the Policy, no Insider may trade during a "quarterly blackout period".

A. Quarterly Blackout Periods. Trading by Insiders in the Company's securities is prohibited during the period beginning on the 16th day of the month prior to the end of a fiscal quarter and ending following the close of trading on the second full trading day following the public issuance of the Company's earnings release for the most recent fiscal quarter. During these periods, Insiders generally possess or are presumed to possess material non-public information about the Company's financial results.

B. Quarterly Trading Windows. The trading window generally opens following the close of trading on the second full trading day following the public issuance of the Company's earnings release for the most recent fiscal quarter, and closes at the close of trading three weeks prior to the end of a fiscal quarter.

Even when the window is open, Insiders and other Employees are prohibited from trading in the Company's securities while in possession of material nonpublic information. The Company's Compliance Officer will advise Insiders when the trading window opens and closes.

III. Hardship Exemptions

The Compliance Officer may, on a case by case basis, authorize a transaction in the Company's securities outside of the trading window (but in no event during a special blackout period) due to financial or other hardship. Any request for a hardship exemption must be in writing and must describe the amount and nature of the proposed transaction and the circumstances of the hardship. (The request may be made as part of a pre-clearance request, so long as it is in writing.) The Insider requesting the hardship exemption must also certify to the Compliance Officer within two business days prior to the date of the proposed trade that he or she is not in possession of material nonpublic information concerning the Company.

The existence of the foregoing procedure does not in any way obligate the Compliance Officer to approve any hardship exemption requested by an Insider.

IV. Individual Account Blackout Periods

Certain trading restrictions apply during a blackout period applicable to any Company individual account plan in which participants may hold Company stock (such as the Company's 401(k) Plan). For the purpose of such restrictions, a "blackout period" is a period in which the plan participants are temporarily restricted from making trades in Company stock. During any blackout period, directors and executive officers are prohibited from trading in shares of the Company's stock that were acquired in connection with such director's or officer's service or employment with the Company. Such trading restriction is required by law, and no hardship exemptions are available. The Company will notify directors and executive officers in the event of any blackout period.

V. Pre-Clearance of Trades

As part of the Company's Insider Trading Policy, all purchases and sales of equity securities of the Company by Section 16 Insiders or Insider Employees, other than transactions that are not subject to the Policy or transactions pursuant to a Rule 10b5-1 trading plan approved by the Board of Directors or its Audit Committee, must be pre-cleared by one of the Compliance Officers. The intent of this requirement is to prevent inadvertent violations of the Policy, avoid trades involving the appearance of improper insider trading, facilitate timely Form 4 reporting and avoid transactions that are subject to disgorgement under Section 16(b) of the Exchange Act.

Requests for pre-clearance must be submitted in writing to the Compliance Officers at least **two** business days in advance of each proposed transaction. If the Insider leaves a voicemail message or submits the request by email and does not receive a response from the Compliance Officers within **24** hours, the Insider will be responsible for following up to ensure that the message was received.

A request for pre-clearance should provide the following information:

(i) The nature of the proposed transaction and the expected date of the transaction.

(ii) Number of shares involved.

(iii) If the transaction involves a stock option exercise, the specific option to be exercised.

(iv) Contact information for the broker who will execute the transaction.

Once the proposed transaction is pre-cleared, the Section 16 Insider or Insider Employee may proceed with it on the approved terms, provided that he or she complies with all other securities law requirements, such as Rule 144 and prohibitions regarding trading on the basis of inside information, and with any special trading blackout imposed by the Company prior to the completion of the trade. The Section 16 Insider or Insider Employee and his or her broker will be responsible for immediately reporting the results of the transaction as further described below.

In addition, pre-clearance is required for the establishment of a Rule 10b5-1 trading plan. However, pre-clearance will not be required for individual transactions effected pursuant to a pre-cleared Rule 10b5-1 trading plan that specifies or establishes a formula for determining the dates, prices and amounts of planned trades. Of course, the results of transactions effected under a trading plan must be

reported immediately to the Company since they will be reportable on Form 4 within two business days following the execution of the trade, subject to an extension of not more than two additional business days where the Section 16 Insider is not immediately aware of the execution of the trade.

Notwithstanding the foregoing, any transactions by the Compliance Officers shall be subject to pre-clearance by the Chief Executive Officer, or if he/she is not available, the Chief Operating Officer.

VII. Reporting of Transactions

To facilitate timely reporting under Section 16 of the Exchange Act of Insider transactions in Company stock, Section 16 Insiders are required to (a) report the details of each transaction immediately after it is executed and (b) arrange with persons whose trades must be reported by the Insider under Section 16 (such as immediate family members living in the Insider's household) to immediately report directly to the Company and to the Insider the details of any transactions they have in the Company's stock.

Transaction details to be reported include:

(i) Transaction date (trade date).

(ii) Number of shares involved.

(iii) Price per share at which the transaction was executed (before addition or deduction of brokerage commission and other transaction fees).

(iv) If the transaction was a stock option exercise, the specific option exercised.

(v) Contact information for the broker who executed the transaction.

The transaction details must be reported to the Compliance Officer, with copies to the Company personnel who will assist the Section 16 Insider in preparing his or her Form 4.

VIII. Policy Committee

This Policy will be monitored by a committee, which shall be the Nominating and Corporate Governance Committee of the Board of Directors of the Company, or if no such committee exists, the Board of Directors (the "Committee"). In addition to monitoring this Policy, the Committee (or the Board of Directors) will be responsible for recommending any modification to this Policy, if necessary or advisable, to the Company.

IX. Persons Subject to Section 16

Most purchases and sales of Company securities by its directors, executive officers and greater-than-10% stockholders are subject to Section 16 of the Exchange Act. The Committee will review, at least annually, those individuals who are deemed to be executive officers for purposes of Section 16 and will recommend any changes regarding such status to the Board of Directors. An executive officer is generally defined as the president, principal financial officer, principal accounting officer or controller, any vice president in charge of a principal business unit, division or function or any other officer or person who performs a policy making function.

X. Form 4 Reporting

Under Section 16, most trades by Insiders are subject to reporting on Form 4 within two business days following the trade date (which in the case of an open market trade is the date when the broker places the buy or sell order, not the date when the trade is settled). To facilitate timely reporting, all transactions that are subject to Section 16 must be reported to the Company ***on the same day as the trade date***, or, with respect to transactions effected pursuant to a Rule 10b5-1 plan, on the day the Insider is advised of the terms of the transaction.

XI. Named Employees Considered Insiders

The Committee will review, at least annually, those individuals deemed to be Insiders for purposes of this Appendix I. Insiders shall include persons subject to Section 16 and such other persons as the Committee deems to be Insiders. Generally, Insiders shall be any person who by function of their employment is *consistently* in possession of material nonpublic information *or* performs an operational role, such as head of a division or business unit, that is material to the Company as a whole.

XII. Special Guidelines for 10b5-1 Trading Plans

Notwithstanding the foregoing, an Insider will not be deemed to have violated the Insider Trading Policy if he or she effects a transaction that meets all of the enumerated criteria below.

A. The transaction must be made pursuant to a documented plan (the "*Plan*") entered into in good faith that complies with all provisions of Rule 10b5-1 (the "*Rule*"), including, without limitation:

1. Each Plan must:

(a) specify the amount of securities to be purchased or sold and the price at which and the date on which the securities are to be purchased or sold, or

(b) include a written formula or algorithm, or computer program, for determining the amount of securities to be purchased or sold and the price at which and the date on which the securities were to be purchased or sold.

2. In any case, then such Plan must prohibit the Insider and any other person who possesses material nonpublic information from exercising any subsequent influence over how, when, or whether to effect purchases or sales.

B. Each Plan must be approved prior to the effective time of any transactions under such Plan by the Company. The Company reserves the right to withhold approval of any Plan that it determines, in its sole discretion,

(i) fails to comply with the Rule,

(ii) exposes the Company or the Insider to liability under any other applicable state or federal rule, regulation or law,

(iii) creates any appearance of impropriety,

(iv) fails to meet the guidelines established by the Company, or

(v) otherwise fails to satisfy review by the Committee for any reason, such failure to be determined in the sole discretion of the Committee.

C. Any modifications to the Plan or deviations from the Plan without prior approval of the Company will result in a failure to comply with this Policy. Any such modifications or deviations are subject to the approval of the Company in accordance with Section B above.

D. Each Plan must be established at a time when the trading window is open.

E. Each Plan must provide appropriate mechanisms to ensure that the Insider complies with all rules and regulations, including Rule 144, Rule 701 and Section 16(b), applicable to securities transactions under the Plan by the Insider.

F. Each Plan must provide for the suspension of all transactions under such Plan in the event that the Company, in its sole discretion, deems such suspension necessary and advisable, including suspensions necessary to comply with trading restrictions imposed in connection with any lock-up agreement required in connection with a securities issuance transaction or other similar events.

G. None of the Company nor any of the Company's officers, employees or other representatives shall be deemed, solely by their approval of an Insider's Plan, to have represented that any Plan complies with the Rule or to have assumed any liability or responsibility to the Insider or any other party if such Plan fails to comply with the Rule.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S3 Nos. (333-226372, 333-194394, 333-193053, 333-205806, 333-257910, and 333-281062) and Form S8 Nos. (333-233459, 333-220630, 333-199852, 333-203244, and 333-281624) of CytoSorbents Corporation of our report dated March 31, 2025 (which includes an explanatory paragraph relating to the CytoSorbents Corporation ability to continue as a going concern), relating to the consolidated financial statements as of and for the years ended December 31, 2024 and 2023, which appear in this Form 10-K.

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey
March 31, 2025

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to pursuant to Rule 13a-14(a) or Rule 15d-14(a)
of the Securities Exchange Act of 1934, as amended

I, Phillip P. Chan, Chief Executive Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 consolidated 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(s) 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 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) 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(s) 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.

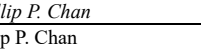
Signature	**Title**	**Date**
*  * Dr. Phillip P. Chan	Chief Executive Officer (Principal Executive Officer) and Director	March 31, 2025

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to pursuant to Rule 13a-14(a) or Rule 15d-14(a)
of the Securities Exchange Act of 1934, as amended

I, Peter J. Mariani, Chief Financial Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 consolidated 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(s) 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 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) 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(s) 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.

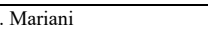
Signature	**Title**	**Date**
*  * Peter J. Mariani	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2025

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. Section 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of CytoSorbents Corporation (the "Company") for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission (the "Report"), I, Phillip P. Chan, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge and belief: (1) the Report 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 the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Signature	Title	Date
/s/ Dr. Phillip P. Chan Dr. Phillip P. Chan	Chief Executive Officer (Principal Executive Officer) and Director	March 31, 2025

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. Section 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of CytoSorbents Corporation (the "Company") for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission (the "Report"), I, Peter J. Mariani, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge and belief: (1) the Report 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 the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Signature	Title	Date
<u>/s/ Peter J. Mariani</u> Peter J. Mariani	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2025

CORPORATE INFORMATION

About CytoSorbents Corporation (NASDAQ: CTSO)

CytoSorbents Corporation is a leader in the treatment of life-threatening conditions in the intensive care unit and cardiac surgery through blood purification. CytoSorbents' proprietary blood 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. Cartridges filled with these beads can be used with standard blood pumps already in the hospital (e.g. dialysis, continuous renal replacement therapy or CRRT, extracorporeal membrane oxygenation or ECMO, and heart-lung machines), where blood is repeatedly recirculated outside the body, through our cartridges where toxic substances are removed, and then back into the body. CytoSorbents' technologies are used in a number of broad applications. Specifically, two important applications are 1) the removal of blood thinners during and after cardiothoracic surgery to reduce the risk of severe bleeding, and 2) the removal of inflammatory agents and toxins in common critical illnesses that can lead to massive inflammation, organ failure and patient death. The breadth of these critical illnesses includes, for example, sepsis, burn injury, trauma, lung injury, liver failure, cytokine release syndrome, and pancreatitis as well as the removal of liver toxins that accumulate in acute liver dysfunction or failure, and the removal of myoglobin in severe rhabdomyolysis that can otherwise lead to renal failure. In these diseases, the risk of death can be extremely high and there are few, if any, effective treatments.

CytoSorbents' lead product, CytoSorb®, is approved in the European Union and distributed in over 70 countries worldwide, with more than a 270,000 devices used cumulatively to date. CytoSorb was originally launched in the European Union under CE mark as the first cytokine adsorber. Additional CE mark extensions were granted for bilirubin and myoglobin removal in clinical conditions such as liver disease and trauma, respectively, and for ticagrelor and rivaroxaban removal in cardiothoracic surgery procedures. CytoSorb has also received FDA Emergency Use Authorization in the United States for use in adult critically ill COVID-19 patients with impending or confirmed respiratory failure. CytoSorb is not yet approved or cleared in the United States.

In the U.S. and Canada, CytoSorbents is developing the DrugSorb™-ATR antithrombotic removal system, an investigational device based on an equivalent polymer technology to CytoSorb, to reduce the severity of perioperative bleeding in high-risk surgery due to blood thinning drugs. It has received two FDA Breakthrough Device Designations: one for the removal of ticagrelor and another for the removal of the direct oral anticoagulants (DOAC) apixaban and rivaroxaban in a cardiopulmonary bypass circuit during urgent cardiothoracic procedures. In September 2024, the Company submitted a De Novo medical device application to the U.S. FDA requesting marketing approval to reduce the severity of perioperative bleeding in CABG patients on the antithrombotic drug ticagrelor, which was accepted for substantive review in October 2024. In November 2024, the Company received its MDSAP certification and submitted its Medical Device License (MDL) application to Health Canada. DrugSorb-ATR is not yet granted or approved in the United States and Canada, respectively.

The Company has numerous marketed products and products under development based upon this unique blood purification technology protected by many issued U.S. and international patents and registered trademarks, and multiple patent applications pending, including ECOS-300CY®, CytoSorb-XL™, HemoDefend-RBC™, HemoDefend-BGA™, VetResQ®, K+ontrol™, DrugSorb™, ContrastSorb, and others. For more information, please visit the Company's website at https://ir.cytosorbents.com/ or follow us on Facebook and X.

Annual Meeting of Stockholders

The Annual Meeting of Stockholders of CytoSorbents Corporation will be held virtually on Thursday, June 12, 2025, at 10:00 a.m. Eastern Time.

Stock Profile

Our common stock began trading on NASDAQ beginning on December 23, 2014. Prior to December 23, 2014, our common stock traded on the OTC Bulletin Board ("OTCBB") and OTCQB under the symbol "CTSO." Prior to May 2010, our common stock traded on the OTCBB under the symbol "MSBT," but was changed to "CTSO" as part of our name change to CytoSorbents Corporation. Our common stock began trading on the OTCBB on August 9, 2006.

Investor Relations

To obtain copies of this annual report or other financial information please write or call:

Effie Perdikis
305 College Road East
Princeton, 08540
ZPerdikis@cytosorbents.com
732.329.8885

ICR Healthcare
ir@cytosorbents.com

Forward-Looking Statements

This press release includes forward-looking statements intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, future targets and outlooks for our business, representations and contentions, and the outcome of our regulatory submissions, the anticipated benefits of the Rights Offering, and are not historical facts and typically are identified by use of terms such as "may," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements in this press release represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. Factors which could cause or contribute to such differences include, but are not limited to, the risks discussed in our Annual Report on Form 10-K, filed with the SEC on March 31, 2025, as updated by the risks reported in our Quarterly Reports on Form 10-Q, and in the press releases and other communications to shareholders issued by us from time to time which attempt to advise interested parties of the risks and factors which may affect our business. We caution you not to place undue reliance upon any such forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, other than as required under the Federal securities laws.

CytoSorbents™

Working to save lives
together.

305 College Road East, Princeton, New Jersey 08540
732.329.8885